Sponsored by Perinatal Quality Foundation

Perinatal QUALITY .org

The Examiner

Winter 2019

As Low As Reasonably Achievable (ALARA)

Bryann Bromley, MD and Jean Lea Spitz, MPH, CAE, RDMS

The Perinatal Quality Foundation (PQF) strongly supports the worldwide consensus that users of ultrasound equipment have the responsibility to adhere to ALARA principles minimizing fetal exposure to ultrasound energy.

The bioeffects of ultrasound fall into two broad categories: mechanical effects, which are most noticeable when there is gas present, and thermal effects. During obstetric ultrasounds, power should be monitored through the TI (thermal index) and MI (mechanical index) and the total and dwell time of the examination should be limited. Because there is very little gas in the fetus, thermal effects are of more concern in obstetric ultrasound than mechanical effects. Adherence to ALARA principles provides reasonable assurance that an obstetrical ultrasound examination does not produce an adverse thermal effect.

Literature shows that many users of obstetric ultrasound do not understand the importance of ALARA, do not understand the rationale for specific requirements, and do not know what or where the output display indices are.[1,2,3] Despite providing feedback on image submissions that display a TIB greater than 0.7, PQF image reviewers have found that participants often resubmit images with the same ALARA concerns. In an effort to reinforce ALARA principles, the bullets below outline the components of and rationale for ALARA principles in prenatal scanning.

- **Dwell time:** Dwell time is the time the ultrasound beam is targeted on one location. Moving the ultrasound beam frequently during examinations and not dwelling in one area allows time for deposited heat to dissipate and minimizes the potential for thermal effects.
- **Avoid dwelling on areas with bone:** Heat from ultrasound is preferentially absorbed by bone and then radiated to surrounding structures. It is therefore important to avoid dwelling on calcified areas such as the fetal head and spine. When imaging these areas, move frequently coming back to targeted areas to obtain needed images but do not “dwell” unnecessarily.
- **Set the machine power control to zero when the exam is over:** Every patient deserves the least amount of energy required to image her pregnancy. Resetting power to zero at the end of an exam and adjusting it as needed during the next examination will ensure that high energy outputs are not unnecessarily used.
- **Know where MI and TI are displayed:** The output display standards are unitless values displayed on every screen, and all users of obstetric ultrasound should know where the MI and TI are located and monitor them carefully. The mechanical index (MI) should be as low as possible and always under 1.0. Before the 9th week of pregnancy when only soft tissue is present in the imaging field, TI should be reported as the thermal index of soft tissue (TIS). Beginning at 10 weeks of pregnancy, however, the presence of bone in the imaging field requires use of the thermal index of bone (TIB) since TIS will underestimate the power applied.
- **Use TIB setting equal to or less than 0.7 after 9 weeks gestation:** Animal studies have shown that a temperature rise of less than 1.5 degrees centigrade may be used clinically without reservation. TI is an estimate of temperature increase but is known to underestimate the actual in some applications. In fetal examinations in which the ultrasound beam passes through non-attenuating fluid the TI may underestimate the true temperature increase by a factor of up to 2. Therefore, recent consensus recommendations endorse 0.7 as the upper limit of TIB in obstetric ultrasound. [4]
- **Use Doppler only when necessary:** Doppler may be used for specific benefit in pregnancy if the TIB is kept equal to or under 0.7. Color Doppler has less power than spectral Doppler. The use of spectral Doppler to document or listen to the fetal heart beat is contrary to ALARA principles. M-mode or video of the heart beat may be used for documentation.

1. Sheiner E, et al. What do clinical users know regarding safety of ultrasound during pregnancy? J Ultrasound Med 2007;26:319-325.
2. Marsal K. The output display standard: has it missed its target? Ultrasound in Obstet Gynecol 2005;25:211-214.
3. Bagley J, et al. Safety Practices of Sonographers and Their Knowledge of the Biologic Effects of Sonography. J Diag Med Sono 2011; 27(6):252-61.
4. Harris GR, et al. Comparison of Thermal Safety Practice Guidelines for Diagnostic Ultrasound Exposures. Ultrasound in Medicine & Biology 2016; 42(2):345-357.

Prenatal exome sequencing in the setting of fetal structural abnormalities

Lorraine Dugoff, MD

Fetal structural abnormalities are detected in approximately 2-3% of pregnancies. Approximately 32% of fetuses with a structural abnormality detected on ultrasound have an abnormal karyotype.[1] Chromosomal microarray increases the diagnostic yield by approximately 6% in fetuses with structural anomalies and a normal fetal karyotype.[2,3] Despite genetic abnormalities detected through karyotype and microarray, approximately 60% of fetuses with a structural abnormality will not have a genetic cause identified with those tests alone.

Exome sequencing (ES) is a genetic test that uses high-throughput technology to sequence exons, which are the protein-coding region of genes. The goal of ES is to identify genetic variants (mutations) that alter protein sequences and lead to single gene disorders. There is a growing body of literature demonstrating that ES may help to identify genetic abnormalities in fetuses with structural anomalies with uninformative karyotype and microarray testing.[1,4] Look out for our next issue with a full article summarizing the potential benefits of prenatal ES and recommendations regarding its use in clinical practice!

1. Petrovski S, Aggarwal V, Giordano JL et al. Whole-exome sequencing in the evaluation of fetal structural anomalies: a prospective cohort study. Lancet Jan 31, 2019
2. Wapner RJ, Martin CL, Levy B, Ballif BC, Eng CM, Zachary JM, et al. Chromosomal microarray versus karyotyping for prenatal diagnosis. N Engl J Med. 2012;367:2175-84.
3. Hillman SC, McMullan DJ, Hall G et al. Use of prenatal chromosomal microarray: prospective cohort study and systematic review and meta-analysis. Ultrasound Obstet. Gynecol.2013, 41, 610–620.
4. Lord J, McMullan DJ, Eberhardt RY et al. Prenatal exome sequencing analysis in fetal structural anomalies detected by ultrasonography (PAGE): a cohort study. Lancet Jan 31, 2019

CLEAR Program Updates for 2019

Jennifer McIntosh, MD

The Perinatal Quality Foundation CLEAR (Cervical Length Image Review) Program has some exciting updates for 2019! Many of these changes are in response to feedback from those who have used our educational program. We are excited to announce that while CLEAR has served as an educational initiative since its inception in 2012, we have re-designed it as a credentialing program. This is an important change that will require re-credentialing every 3 years, as evidence suggests that re-credentialing is imperative in order to maintain high quality standards. This information will be sent to currently credentialed providers and those who have begun the education process via email and will also be clearly posted on our website. The following changes are in effect as of January 2019:

- All new CLEAR providers will be credentialed for a 3-year time period that will be subject to review/re-credentialing at 3 year intervals.
- All previously credentialed providers will be strongly encouraged to participate in this voluntary re-credentialing process between January 2019 and December 2019.
- The re-credentialing process will cost $50 to cover administrative expenses.
- Re-credentialing will proved CME credits towards the
- American Board of Obstetrics and Gynecology Maintenance of Certification and the American Institute of Ultrasound Medicine.
- Certificates suitable for posting in your office will specify your start and end dates of your credentialing.
- A database of credentialed providers will be maintained and available to the public.

Additionally, we are pleased to announce that we have revised our course materials to address real-world issues including where to optimally measure the internal os, tips and tricks for good technique, and an expanded image review. These changes will be on our website in Spring 2019. Please check out the new materials!

Happy Birthday FMC

Mark Tomlinson, MD

The Fetal Monitoring Credentialing (FMC) exam is 5 years old this month. It was introduced to fill a gap in assessing competency fetal heart rate interpretation and management for those providing front line obstetric care. Of the 4000 individuals have taken the exam since 2014, just over 50% are physicians, 5% are certified nurse midwives, and nearly 45% are nurses. Nearly 70% of examinees take the exam as part of quality initiatives from 66 participating institutions. With this number of participants, individual questions have been statistically validated and test reliability can now be demonstrated.

Electronic fetal monitoring is a foundational skill for physician and nursing providers alike as it continues to be used in the majority of labors in the US. It requires not only an understanding of basic electronic fetal monitoring (EFM) principles but also an ability to apply them clinically. To this end, the FMC exam adds a novel judgment component to traditional questions testing knowledge. We are excited to explore the relationship between the knowledge and judgment components of the exam. These analyses may also identify potential opportunities to focus educational efforts to specific individual or institutional needs and thereby support the Perinatal Quality Foundation's mission to improve the quality of obstetrical care.

The Examiner is published quarterly by the Perinatal Quality Foundation.