 GUIDELINES ON THE USE OF DOPPLER ULTRASOUND IN EARLY PREGNANCY

NIFLA last addressed the issue Pregnancy Resource Medical Clinics (PRMCs) using Doppler ultrasound in the Clinic Tips of July 2005. This issue of Clinic Tips will review this issue in light of more recent information, guidelines and research related to Doppler use.

Recent legislative attacks on PRMCs in Washington, Oregon, New Mexico, Baltimore and New York make it clear that there are those who want to stop the work of PRMCs. Therefore, the highest standards of care for patient safety must be carefully considered when offering medical services.

Review of Principles Relating to Doppler – NIFLA Recommendations:

1. The utilization of ultrasound constitutes the practice of medicine. Therefore, a sonogram should be provided only when there is a valid medical indication justifying its use. One medical indication for OB sonograms is to determine a viable intrauterine pregnancy evidenced by fetal cardiac activity. Fetal cardiac activity is typically visualized with Brightness (B-Mode) and documented in Motion Mode (M-mode) sonography. Audible Doppler is not used to hear the heartbeat.

2. Ultrasound employs high frequency sound waves that provide images of the unborn. It has not been found to have harmful effects in over forty years of clinical use and is generally considered safe. The use of obstetrical ultrasound is guided by the ALARA principle – As Low As Reasonably Achievable. Thus, the lowest amount of ultrasonic exposure should be used to obtain the necessary diagnostic information. ALARA defines the standard of practice in regard to the amount of exposure to ultrasound energy that an unborn should receive.

3. Doppler is used to measure blood flow in vessels. It is primarily used during prenatal care in the 2nd or 3rd trimesters of pregnancy to determine if there is lack of blood flow to the fetal heart and brain. The output of ultrasound energy is greatly increased when Doppler is used – over seven times that of standard B-mode scanning.

4. The ALARA principle dictates that the unborn be exposed to the lowest amount of ultrasound energy to obtain the needed information. Thus, when cardiac activity is visualized, there is no medical indication for Doppler. If Doppler is utilized only to “hear” the heartbeat, then the unborn is exposed for far more acoustic energy than necessary and ALARA is violated. Such use of sonography is considered for “entertainment” purposes by the medical community and the FDA and is prohibited. The American Institute in Ultrasound Medicine (AIUM) says: “Although the general use of ultrasound for medical diagnosis is considered safe, ultrasound energy has the potential to produce biological effects. Ultrasound bioeffects may result from scanning for a prolonged period, inappropriate use of color or pulsed Doppler ultrasound without a medical indication, or excessive thermal or mechanical index settings.”

5. PRMCs must operate under the best practice standards of care recognized by the medical community lest they be perceived as lacking credibility, labeled as “fake clinics” and invite legislative regulation.

6. Hand held Doppler units (without sonographic images) are routinely used in prenatal care after 10-11 weeks to confirm cardiac activity. These devices produce audible fetal heart sounds, yet emit much lower power levels than sonography equipment. If cardiac activity cannot be confirmed by hand held Doppler, a sonogram is performed for visualization of the beating heart. PRMCs often desire to use Doppler as a powerful life-affirming tool allowing a pregnant woman, uncertain about her plans, to allow a pregnant woman, uncertain about her plans, to hear the amplified sound of her unborn’s beating heart. Yet, when cardiac activity is visualized by an ultrasound exam there is no medical indication for Doppler use.

7. Ultrasound energy is converted to heat at the tissue level and is capable of raising it above physiologic norms. This is expressed by the term “thermal index” (TI). The

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recommended range of safety TI should be is (≤1.0) for prenatal scanning. The FDA requires the TI index be displayed on the screen in the upper right hand corner if an ultrasound machine has capabilities of raising the TI to greater than 1.0, as would a machine with pulsed and color Doppler. The output potential with Doppler is significantly higher than B-mode imaging because of the intensity it produces and the small focus of tissue examined. Though ultrasound use is widespread, using Doppler in early pregnancy is not.

Hopefully, every medical professional performing sonograms at your PRMC is knowledgeable about the above information, since it is presented during the physics session of NIFLA’s Institute in Limited Obstetrical Ultrasound.

**UPDATES ON USE OF DOPPLER:**

NIFLA continues to monitor medical literature and guidelines to determine whether Doppler is a tool that should be utilized by medical professionals in PRMCs. Statements released by the World Federation for Ultrasound in Medicine and Biology (WFUMB) in 2011 on the safe use of Doppler ultrasound during 11- to 14-week scans (or earlier in pregnancy) have further confirmed our earlier position. WFUMB states: “Pulsed Doppler (spectral, power and color flow imaging) ultrasound should not be used routinely.” An article on safety of OB ultrasound states: “Currently, the responsibility for monitoring the safety of an ultrasound exam rests with the user. Interestingly, recent surveys of ultrasound practitioners have found that most end users have poor knowledge regarding safety in pregnancy. Given the potential temperature elevations with Doppler and the teratogenicity of hyperthermia, first trimester Doppler exams should be discouraged.”

The following is taken from AIUM statements, approved April 6, 2009: “Acoustic output from diagnostic ultrasound devices is sufficient to cause temperature elevations in fetal tissue... In general, temperature elevations become progressively greater from B-mode to color Doppler to spectral Doppler applications.” AIUM further states, “Although, in general, an adverse fetal outcome is possible at any time during gestation, most severe and detectable effects of thermal exposure in animals have been observed during the period of organogenesis. For this reason, exposures during the first trimester should be restricted to the lowest outputs consistent with obtaining the necessary diagnostic information.” Further, a sonographer shared concerns for the PRMCs as a result of a legal workshop on issues relating to sonography at the 2010 AIUM Conference in San Diego. Participants were told that litigation has been pursued in cases where a baby born with anomalies had received a first trimester ultrasound with Doppler.

The question that any PRMC must ask in providing diagnostic ultrasound services is what is the medical indication for this exam? Doppler without a medical indication has been criticized in the medical community as inappropriate and contrary to responsible medical practice. During the stage of organogenesis (from conception through the 10th week LMP), the heart, brain, eyes, and ears are very sensitive organs that focused and intense ultrasound energy from Doppler could possibly affect. We, who are in the business of protecting life, should be very concerned that we do not utilize technology that could later be found to have harmful effects on the very one whose life we value so highly.

NIFLA has pioneered the movement to provide limited OB sonograms within medical/legal standards of care for pregnant women and to provide them the information necessary to ensure a fully informed consent. NIFLA recognizes that PRMCs desire to use Doppler, however, there exists the responsibility to follow guidelines for patient safety put forth by experts who study and develop ultrasound technology. Thus, in light medical standards and the possibility of harmful effects to the unborn, NIFLA continues to strongly discourage utilizing Doppler.

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