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Psychosocial, Legal, and Ethical Dimensions of Ultrasound Imaging in Pregnancy

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V. <u>PSYCHOSOCIAL, LEGAL, AND ETHICAL DIMENSIONS OF ULTRASOUND</u> IMAGING IN PREGNANCY

This chapter addresses psychosocial, legal, and ethical dimensions of ultrasound imaging in preganacy. The panel recognizes the importance of these areas and, while these concerns are not covered by the questions assigned, their significance is reflected in the constituency of the panel, in the literature on ultrasound, and in testimony before the panel. Several presentations to the panel directly involved concerns about personal, emotional, legal, and psychological aspects of application of ultrasound technology. For example, the International Childbirth Education Association (ICEA) distributed a comprehensive position paper (28) that addresses many aspects of the subject. The statement stressed that pregnant women have responsibility to be directly involved in decisions regarding their individual medical care and that all use of ultrasound should have medical indication.

Interestingly, much of the concern expressed has focused on real or potential dehumanization of obstetrical health care through technology. This concern has been expressed directly or indirectly to the panel. In the following discussion, one of the observations that can be made is that ultrasonography may, in fact, humanize by increasing the perception and value of the fetus for parents. There may be, however, attendant psychological risk and benefits.

An improved data base and resolution of some of the issues and questions identified in earlier sections will help to clarify, but not resolve, the issues identified in this section. Evaluation and treatment of the fetus have become increasingly possible in the last decade, with ultrasonography providing much of the technologic impetus. Psychosocial, legal, and ethical

dimensions will probably become increasingly important as experience with ultrasound broadens in scope and lengthens in timeframe.

PSYCHOSOCIAL DIMENSIONS

Recent literature indicates that psychosocial as well as physical prenatal factors may be etiologic determinants of pregnancy outcome (2,4,5, 6,12,15,18,23). There is a paucity of literature defining normal prenatal behavior and maternal attitude or anxiety patterns in a concise and clinically useful way. Nevertheless, in reviews by McFarlane (15), Sherashefsky (23), Daly (6), and Cohen (2), and in papers by Crandon (4,5), Newton (18), and Laukaran (12), maternal psychological variables are related to the incidence of habitual spontaneous abortion, hyperemesis gravidarum, pre-eclampsia, prolonged labor, prematurity, prenatal accidents, a decrease in 5-minute Apgar scores, and neonatal hyperactivity. Although some of the evidence may appear speculative or suggestive, Laukaran (12) summarizes current thought when she states that there is justification for considering maternal attitude as a clinically significant risk factor with regard to fetal outcome.

A growing emphasis on maternal-infant bonding includes consideration of physiological and psychological interactions between the gravida and her unborn child (21). The process of maternal-fetal attachment has been investigated by authors (3,10,15,22,23,25) who theorize that negative maternal attitudes during pregnancy may portend negative attitudes toward the baby postpartum with concomitant risk of psychological or physical child abuse. Prenatal variables cited include maternal narcissism, maternal ability to visualize the mothering experience, and ability to fantasize and individualize fetal features and activities. Prenatal maternal activities and emotions, such as cigarette smoking (14), eating (7), and anxiety states (1, 4, 5, 12, 18, 23), are known to produce measurable effects on the fetus.

There is limited research concerning the psychological aspects of the ultrasound examination. To date, interest has focused primarily on positive implications of ultrasound imagery in basically normal pregnancies. Milne and Rich (16) have observed the process of ultrasound-image recognition by mothers and have divided this process into "stages of awareness." Sonography personnel have been observed to influence these stages through verbal descriptions of images. These authors also observed "pleasurable anticipation" and "mild anxiety" in patients prior to the scan. Janus and Janus (9) attributed mild anxiety prior to the scan to inadequate patient preparation and lack of education of patients and physicians. Milne and Rich (16) observed anecdotally that several women, when interviewed postscan, indicated that ultrasound images of the fetus influenced their perceptions of the fetus as they continued to visualize perceived fetal activity with images similar to those seen on the ultrasound screen. Kohn et al. (11) observed a greater sense of attachment to the fetus in patients receiving high-feedback during ultrasound imagery.

Reading and Cox in England completed a study to assess the psychological effects of ultrasound on the pregnant woman's attitudes and anxiety (19). The "at risk" woman was excluded from the study in order to ensure homogeneous and comparable groups. Women were assigned at random to one of two scan groups or a no-scan control group. Scans were performed on women in the experimental groups between 10 and 14 weeks gestation (menstrual dating). In a "high-feedback" group, women who had ultrasound were shown

the monitor screen and received verbal explanations of the screen and images. A "low-feedback" group was not allowed to view the monitor screen at the time of the ultrasound scan, and there was no specific verbal feedback. Women in all groups were comparable in terms of social class, and staff interaction was the same with all groups. Assessment of attitude toward pregnancy performed by adjective analysis revealed pre- versus post-ultrasound differences, with more positive attitudes present in the high-feedback group. There was no detected change in baseline anxiety levels in either of the experimental groups which could be attributed to ultrasound imaging. The study groups were very small.

The papers cited above are initial attempts to study the potential effects of ultrasound technology on emotional and psychological aspects of pregnancy. It is important to investigate the possibility that positive or negative psychological effects might result from ultrasound examination in those pregnancies in which the mother has a high level of concern. Enhancement of parental, especially maternal, awareness might be very useful in some situations such as a family history of poor infant attachment or child abuse. Reading (20) has suggested that ultrasound imaging feedback may improve compliance with suggested prenatal behavioral changes such as cessation of smoking.

On the other hand, there may be negative psychological effects from ultrasound imaging feedback in cases such as abnormal pregnancies or prior to elective termination. The present state of knowledge in these areas is today largely anecdotal or speculative.

Research Directions

As discussed, early studies of the psychological impact of ultrasound imaging support the possibility that ultrasound feedback may result in behavioral and psychological changes of significance. Research methodology and interpretation of results in studies to date are controversial. Many questions remain to be answered:

- Are there incidences of deleterious effects of ultrasound imagery on maternal perception of the fetus?
- Can ultrasound imaging produce a positive effect on patients who are highly anxious prenatally?
- Would a positive effect on anxiety have clinical significance as measured by pregnancy outcome and child development?
- How many women are receiving prenatal gender information through ultrasound imagery?
- Does prenatal knowledge of fetal gender affect prenatal attachment or anxiety?
- What is the appropriate role of sonography personnel in relation to patients' image perceptions?
- Is attachment of the mother to the fetus enhanced by ultrasound imagery?
- If enhancement occurs, should it be encouraged in special situations such as high-risk pregnancies, terminations, or adoption?

Further investigation of these and other questions may lead to the development of ultrasound use patterns designed to enhance maternal attachment, decrease maternal anxiety, and/or minimize psychological impact of negative occurrences during an ultrasound examination. The psychosocial dimension of ultrasound scanning seems obvious to patients and personnel in the field. Further attention to this aspect, development of knowledge, and refinement of techniques to optimal benefit of all patients receiving ultrasound scan are appropriate.

LEGAL-ETHICAL DIMENSIONS

Consideration of the legal and ethical aspects regarding the use of diagnostic ultrasound in pregnancy is not the main focus of this conference. Nevertheless, liability and legal-ethical concerns will have an impact on the utilization of ultrasound during pregnancy and are outlined below. The complexity of these issues suggests further evaluation.

Liability for Negligence

To date, court decisions have not been officially reported to establish precedent on liability for negligence in regard to diagnostic ultrasound in pregnancy. However, based on surveys performed by the AIUM and ACOG, numerous cases have been filed which are at various stages of litigation (26).

The majority relate to misdiagnoses, including failure to diagnose ectopic pregnancy or abdominal pregnancy, to diagnose twins, and to detect fetal anomalies. A number of other cases concern failure to perform ultrasound when deemed appropriate. The remaining cases relate to alleged negligence for misinterpretation of results, artifacts mistaken for lesions, delay in communicating information to the clinician, and ultrasonographer-related problems.

Because ultrasound is a new and evolving field, questions such as the following remain to be addressed:

- What is the appropriate standard of skill, care, and training for physicians and sonographers with regard to performance and interpretation of ultrasound?
- Is ultrasound a "routine" procedure widely available and accepted, or does the practice vary by location?
- How does extent of practice vary (i.e., use and frequency of routine screening and high-risk implications)?

- Does the standard of care differ for obstetricians, radiologists, other physicians, and sonographers?
- What are the implications for lack of licensing and uniform standards for physicians and sonographers?
- Is there a duty to inform all pregnant women as to the availability and benefit/risks of ultrasound?
- What are the implications for lack of standards for the manufacturer?
- Does a manufacturer have a duty to obtain and disclose information about ultrasound intensity, field, and calibration?

Informed Consent and Related Issues

The current standard of practice is not to obtain <u>written</u> informed consent prior to performance of an ultrasound examination. The only exception appears to be when it is utilized for strictly educational or experimental purposes.

Prior to an ultrasound examination, the patient should be informed of the clinical indication, specific benefits, potential risks, and alternatives, if any. In addition, if the patient requests information about the exposure time and intensity, it should be provided. A written form may expedite this process in some cases. Patient access to educational materials regarding ultrasound is strongly encouraged to supplement the information communicated directly to the patient.

Furthermore, these examinations should be conducted in a manner and take place in a setting which assure patient dignity and privacy. This approach should ideally include, but not necessarily be limited to:

- Prior material knowledge and approval of the presence of nonessential personnel with the number of such personnel kept to a minimum.
- An intent to share with the parents, either during the examination or shortly thereafter, the information derived.

- An offer of choice about viewing the fetus; and
- An offer of choice about learning the sex of the fetus, if such information becomes available.

Ultrasound examinations performed <u>solely</u> to satisfy the family's desire to know the fetal sex, to view the fetus, or to obtain a picture of the fetus should be discouraged. In addition, visualization of the fetus <u>solely</u> for educational or commercial demonstration without medical benefit to the patient should not be performed.

Conflicts of Maternal and Fetal Interests

Significant legal-ethical problems are posed when:

- The mother does not desire the pregnancy or is ambivalent about the prospect;
- Prior indications exist for a possible positive diagnosis of an abnormality; or
- The ultrasound examination reveals an abnormality.

Some legal-ethical issues such as the following may thus arise (27):

- More opportunities for in utero detection and treatment of congenital malformations will be presented to parents. Although fetal therapy carries potential benefits, it is not without significant ethical problems such as selection of fetal patients, informed consent, and conflicts of maternal and fetal interests.
- More false-negative and false-positive diagnoses will accompany increased use of fetal ultrasound examinations. Issues of responsibility and liability will accompany both.
- The physician may deem that an ultrasound would be appropriate for the health of the baby but the mother refuses. When, if at all, do the interests of the fetus become paramount if the ultrasound could predict conditions conducive to fetal therapy?

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