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● *Safety of Nonmedical Use of Ultrasound*

WFUMB SYMPOSIUM ON SAFETY OF NONMEDICAL USE OF ULTRASOUND

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INTRODUCTION AND PREFACE

The World Federation for Ultrasound in Medicine and Biology (WFUMB) has embarked on a project to arrive at international guidelines and consensus statements on the safe and appropriate use of ultrasound in nonmedical applications. The project was initiated in response to concerns about the growing number of commercial enterprises that offer prospective parents nondiagnostic keepsake or souvenir images and videos of the fetus during pregnancy. Several professional ultrasound organisations have formed and published guidelines relevant to their particular requirements and circumstances. The American Institute of Ultrasound in Medicine (AIUM) has taken a strong position against the practice of the so-called ''shopping mall entertainment ultrasound'' phenomenon in the USA, with published support by the US Food and Drug Administration (FDA). As the WFUMB comprises global membership, it is appropriate that it obtains input into the preparation of guidelines for standards of practice from a wide international audience. It is also important to establish whether there is evidence based on safety issues, besides the more obvious ethical considerations.

This document provides some background information and a consensus on the safety of diagnostic ultrasound established as the end product of a WFUMB Safety Symposium. The primary objective is to establish Guidelines for the Safe Use of Ultrasound in Nonmedical Applications, such as keepsake or souvenir videos. The process is the result of workshop-style interactive meetings of invited internationally renowned scientists, clinical end-users and government regulators who were chosen for their expertise in acoustical physics, interactions of ultrasound with biologic tissue and clinical knowledge.

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The WFUMB Safety Symposium on Nonmedical Use of Ultrasound established an international working group that has received input from other organisations including the American Institute of Ultrasound in Medicine (AIUM), the Australasian Society of Ultrasound in Medicine (ASUM), the European Federation of Societies of Ultrasound in Medicine and Biology (EFSUMB), the European Committee for Medical Ultrasound Safety (ECMUS), the British Medical Ultrasound Society (BMUS), the FDA Centre for Devices and Radiological Health (FDA), the Federation of Latin American Ultrasound Societies (FLAUS), the Asian Federation of Societies for Ultrasound in Medicine and Biology (AFSUMB), the International Society for Ultrasound in Obstetrics and Gynecology (ISUOG) and Health Canada. Following assessment of the current published data and scientific opinion, this working group drafted guidelines for the nonmedical use of ultrasound.

The Organising Committee for this WFUMB Safety Symposium comprised members of the WFUMB Safety Committee. Key topics were identified and authors assigned to prepare documented material. As part of a proactive strategy, the WFUMB Safety Committee formed a collaborative working alliance with the Safety Committee of the International Society for Ultrasound in Obstetrics and Gynaecology (ISUOG) to pursue a joint effort for establishing a consensus of expert opinion for the development of international guidelines on nonmedical use of ultrasound. To achieve that end, the committees worked together on the assessment of bioeffects material. To maximise publicity and to enhance the internal review process, these topics were presented in a dedicated session in the program of the 2007 Congress of the International Society of Ultrasound in Obstetrics and Gynaecology. The ISUOG Board agreed to include a joint WFUMB/ISUOG workshop within the scientific program of the

17th ISUOG Congress, held in Florence during October 7 to 11, 2007. In the spirit of true collaboration between the two major ultrasound societies, the program sessions were co-chaired by Drs. S. B. Barnett and J. S. Abramowicz; Chairs of the WFUMB Safety Committee and ISUOG Safety Committee, respectively. The workshop program comprised an introductory debate on the provocative motion, that ''The Nonmedical Use of Ultrasound is Safe and Beneficial''. The protagonists, Dr. Beryl Benacerraf and Dr. Lawrence Platt, provoked a lively and entertaining debate. The prevailing opinion was that the nonmedical use of ultrasound is not appropriate and should be avoided. During the public discussion that followed, there was clear consensus that there was little, or no, support for the nonmedical use of ultrasound outside the clinical setting. This session was immediately followed by invited presentations on the selected topics, including; Bioeffects and Safety Risk, Epidemiology and Relevance of Neural Migration Studies, Ethical Issues, patient's rights and potential misuse, Regulatory Considerations, and Live Scanning of Pregnant Models for Equipment Exhibitions.

This safety/standards workshop, within the ISUOG scientific program, was remarkably well attended and may prove to be a successful formula for future meetings. The conclusions of the workshop and the subject, in general, were reviewed and considered in subsequent meetings of a select working group of safety committee representatives of the WFUMB and ISUOG.

As co-chairs of this collaborative scientific venture, Drs. S. Barnett and J. Abramowicz wish to record their gratitude to all participants and contributors to this project. The successful outcome was achieved through the continued professional support of the Boards of the WFUMB and ISUOG.

CONCLUSIONS OF WFUMB/ISUOG SAFETY SYMPOSIUM

- Ultrasonic imaging is considered to be safe when carried out in the clinical diagnostic setting by trained personnel following appropriate professional guidelines. However, since it cannot be unequivocally proven to be without risk from undetected bioeffects, it is important to be more concerned about safety where expected benefit of the procedure is low.
- Ultrasound imaging necessitates the introduction of energy into the body. As with any such technique, there is a finite probability that this may cause biological change. For medically indicated diagnostic ultrasound scans this probability is considered to be sufficiently low, and the benefit sufficiently great that there is no concern as to its safety when used in the clinical setting. However, when ultrasound is used for nonmedical purposes for which there is no clear diagnostic benefit, the relative risk/benefit ratio is altered and greater margins of safety are necessary.
- Evidence from human studies is inconclusive. There are no scientific epidemiologic data from exposure to outputs and scanning procedures of modern ultrasound equipment on which to base the direct assessment of safety.
- Besides having no obvious clinical benefit, the use of ultrasound in, nonaccredited, scanning for keepsake or souvenir purposes outside the clinical setting carries a potential for adverse effects from misinterpretation of fetal scans that appear superficially normal and may give false reassurance.
- When clinical benefit is low, or uncertain, the use of ultrasound in fetal examinations may be unwarranted.

WFUMB RECOMMENDATIONS ON NONMEDICAL USE

- The WFUMB disapproves of the use of ultrasound for the sole purpose of providing keepsake or souvenir images of the fetus.
- Ultrasonography is a medical procedure that should only be carried out in the clinical setting where there is a medical indication and when carried out under the supervision of a physician or an expert.
- The use of ultrasound to provide keepsake images or videos of the fetus may be acceptable if it is undertaken as part of the normal clinical diagnostic ultrasound examination, provided that it does not increase exposure to the fetus.
- In the absence of supporting evidence of safety, caution should be used to minimize ultrasound exposure to the fetus.
- When using ultrasound for nonmedical reasons the ultrasound equipment display should be used to ensure that $TI < 0.5$ and $MI < 0.3$.
- Ultrasound imaging for nonmedical reasons is not recommended unless carried out for education, training or demonstration purposes.
- Live scanning of pregnant models for equipment exhibition at ultrasound congresses is considered a nonmedical practice that should be prohibited since it provides no medical benefit and affords potential risk to the fetus.

WFUMB POLICY STATEMENT ON NONMEDICAL USE OF ULTRASOUND (APPROVED BY WFUMB COUNCIL, JUNE 2008)

- The WFUMB disapproves of the use of ultrasound for the sole purpose of providing souvenir images of the fetus. Because the safety of an ultrasound examination cannot be assured, the use of ultrasound without medical benefit should be avoided. Furthermore, ultrasound should be

employed only by health professionals who are well trained and updated in ultrasound clinical usage and bioeffects.

EXECUTIVE SUMMARY

The conclusions and recommendations for safe use of nonmedical ultrasound were drawn from information provided by individual contributions during this project and from published position statements and guidelines of major imaging and health organizations.

Diagnostic ultrasound imaging is considered to be safe when carried out in the clinical setting by trained personnel following appropriate professional guidelines. However, it should be recognized that there are no scientific epidemiologic data from exposure to outputs and scanning procedures of modern ultrasound equipment on which to base a direct assessment of safety.

The prudent use of medical ultrasound refers to ''medically indicated'' procedures, *i.e.*, those where an improved diagnostic outcome is expected. The use of ultrasound imaging simply to view the fetus for demonstration purposes, to verify fetal gender, or to obtain a personal photograph or keepsake video does not constitute a referred medical use.

The market for ultrasound entertainment scans has been driven in part by reluctance of some medical practitioners to provide still or video images to patients, due partly to concerns that images provided to patients could be used as evidence in claims of failure to diagnose a congenital abnormality. If a congenital abnormality is, in fact, present and has been missed, having given the patient an image with or without the abnormality is probably minimally, if at all, additionally incriminating. On the other hand, by providing patients having medically indicated scans with multiple still images or video clips creates good relations with patients, and a potential deterrent to future professional liability claims.

Public health experts, clinicians and industry agree that exposure of the fetus to ultrasound for solely for nonmedical purposes should be avoided. Various ultrasound organizations around the world support the position against the use of ultrasound for nonmedical purposes. For example, the American Institute of Ultrasound in Medicine (AIUM) is firm in its opposition to nonmedical use of obstetric ultrasonography, and the commercialization of fetal sonograms by nonprofessionals. The AIUM also encourages ultrasound equipment manufacturers to agree not to sell imaging systems to nonmedical imaging facilities. The U.S. Food and Drug Administration Centre for Devices and Radiological Health (FDA) takes the position that persons who promote, sell or lease ultrasound equipment for making fetal keepsake or souvenir videos are performing unapproved use of a medical device. In addition, those who subject individuals to ultrasound exposure using a diagnostic ultrasound device (a prescription device) without a physician's order may be in violation of State or local laws or regulations regarding the use of a prescription medical device. It should be recognized that while the FDA has regulatory authority regarding the marketing of safe and effective medical devices, its jurisdiction does not encompass their use. It also has regulatory power over the manufacture and sale of ultrasound systems.

Health Canada regulates diagnostic ultrasound devices under the Food and Drugs Act, the Radiation Emitting Devices Act and the Medical Devices Regulations. This ensures the safety and effectiveness of the devices when they are used for their licensed diagnostic purposes. Health Canada has established Guidelines for the Safe Use of Diagnostic Ultrasound that state that ultrasound should not be used for any of the following activities: To have a picture of the fetus, solely for nonmedical reasons; to learn the sex of the fetus, solely for nonmedical reasons; or for commercial purposes, such as trade shows or producing pictures or videos of the fetus.

Health Canada recommends that parents do not expose their unborn babies to fetal ultrasound for the purpose of making ''keepsake'' or souvenir videos. Diagnostic fetal ultrasound imaging should be undertaken only on referral from a licensed health care provider within a clinical setting by highly qualified professionals.

The British Medical Ultrasound Society has issued users safety guidelines for nondiagnostic uses of ultrasound imaging where upper limits of ultrasound exposure are set at $TI < 0.5$ and $MI < 0.3$. These restrictive levels of exposure were installed to provide a lower risk for procedures where there is no obvious clinical benefit.

Whilst the use of ultrasound solely for nonmedical purposes outside of the clinical setting (*e.g.*, for commercial, nondiagnostic purposes) is not recommended, inclusion of some time for ''entertainment ultrasound'' during a referred medical examination may provide a solution to satisfy patients, providers and regulators. However, whilst this might address potential issues of patients (mothers) rights, there is no consideration for the rights of the fetus, as a patient. There are significant ethical and potential medico-legal issues at stake.

There are a number of important safety issues that require consideration before undertaking any nonmedical ultrasound imaging during a clinical diagnostic examination:

- The ultrasound exposure time applied to the fetus should not significantly increase.
- Qualified and trained personnel should always operate the ultrasound equipment.
- The ultrasound machine should be properly maintained and accurately calibrated.
- The patient must have a complete anatomic survey of her fetus prior to any additional nonmedical/bonding ultrasound scan. With the anatomy scan performed first,

it is unlikely that additional abnormalities would be detected during the bonding part of the process.

- It is important that the attending ultrasound specialist is familiar with the risk of ultrasound bioeffects and understands the purpose of the equipment output display.

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APPENDIX

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