



JOINT CAR/SOGC POSITION STATEMENT ON NON-MEDICAL USE OF FETAL ULTRASOUND

Approved: February 2014

This Joint Policy Statement has been prepared by the Diagnostic Imaging Committee of the Society of Obstetricians and Gynaecologists of Canada and Point of Care Ultrasound Working Group of the Canadian Association of Radiologists and approved by the Executive and Council of the Society of Obstetricians and Gynaecologists of Canada and the Board of Directors of the Canadian Association of Radiologists.

PRINCIPAL AUTHOR(S)

Shia Salem, MD, Toronto, ON
Kenneth Lim (Chair), MD, Vancouver, BC
Michiel C. Van den Hof, MD, FRCSC, Halifax NS

CAR POINT OF CARE ULTRASOUND WORKING GROUP MEMBERS

David Vickar (Chair), MD, Edmonton, AB
Shia Salem, MD, Toronto, ON
Alison Harris, MD, Vancouver, BC
David Lautner, MD, Calgary, AB
Joseph O'Sullivan, MD, Ottawa, ON
Yves Patenaude, MD, Montreal, QC
Valerie Keough, MD, Halifax, NS

DIAGNOSTIC IMAGING COMMITTEE MEMBERS

Kenneth Lim (Chair), MD, Vancouver, BC
Stephen Bly, PhD, Ottawa, ON
Kimberly Butt, MD, Fredericton, NB
Yvonne Cargill, MD, Ottawa, ON
Gregory Davies, MD, Kingston, ON
Nanette Denis, RDMS, CRGS, Saskatoon, SK
Gail Hazlitt, RN, RDMS, Winnipeg, MB
Lucie Morin, MD, Outremont, QC
Kentia Naud, MD, Halifax, NS
Annie Ouellet, MD, Sherbrooke, QC

DISCLOSURE STATEMENT

Disclosure statements have been received from all members of the committee(s).

DISCLAIMER

This document reflects emerging clinical and scientific advances on the date issued and is subject to change. The information should not be construed as dictating an exclusive course of treatment or procedure to be followed. Local institutions can dictate amendments to these opinions. They should be well documented if modified at the local level. None of these contents may be reproduced in any form without prior written permission of the CAR and SOGC.

BOARD OF DIRECTORS / CONSEIL D'ADMINISTRATION

Dr. Jacques Lévesque President / Président Dr. James Fraser Past President / Président sortant Dr. William Miller President Elect / Président élu Dr. Emil Lee Vice-President / Vice-président
Dr. Robert Abraham Dr. Bruce Berscheid Dr. Nimu Ganguli Dr. Scott Harris Dr. Daniel Lindsay Dr. Andrew Mason Dr. Neety Panu Dr. Laurence Pélouquin Dr. Michael Rivers-Bowerman Dr. Robert Sevick Dr. Jana Taylor

Fetal ultrasound is a valuable tool in modern obstetrical care. This imaging technique is useful in assessing a fetus for anomalies, for ensuring fetal health, and assessing fetal growth and development if performed by properly trained individuals in a carefully monitored and medically supervised environment. It is also an important technology in education and research. This imaging technology uses high-frequency low-energy sound waves; it does not use ionizing radiation. The availability of ultrasound machines for purchase and use for non-clinical purposes has led to the proliferation of “entertainment” ultrasound units throughout Canada. With recent media coverage of non-medical clinics performing gender determination in the first trimester, the CAR and SOGC find it necessary to update their previous policy statements on this issue and to issue a new joint policy statement.

Although there is no definitive evidence of fetal abnormalities or harmful biological effects linked to diagnostic ultrasound in humans, the procedure involves targeted energy exposure to the fetus and therefore a theoretical risk for effects on fetal development, as suggested by studies of biological effects of ultrasound reported at or near diagnostic intensities in both human studies and animal models.^(1–3) Of particular concern are recent studies in animal models that report subtle effects on the physiology and development of the fetal brain.^(4–7)

With the non-medical use of fetal ultrasound, the maintenance of technical safeguards, operator training, qualifications, expertise, standards for infection control, and governing competency are no longer ensured. As a result, fetal energy exposure may not be appropriately monitored, and operators of the equipment may not be adequately trained to recognize fetal and placental abnormalities that may adversely affect fetal and maternal outcomes.

Other potential harms include false-positive diagnoses leading to unnecessary investigations and anxiety; false reassurance to the patient that everything is “normal”; and physical harm if unsafe levels of abdominal pressure and fetal maneuvering are used to obtain a suitable commercial product. The fetus should not be exposed to ultrasound for commercial and entertainment purposes, and it could be considered unethical to perform these scans.⁽⁸⁾

Both Health Canada ⁽⁹⁾ and the Food and Drug Administration (FDA) in the United States ⁽¹⁰⁾ have recommended against commercial and entertainment ultrasound. Health Canada recommends that ultrasound should not be used to take a picture of the fetus solely for non-medical reasons, to learn the sex of the fetus solely for non-medical reasons, or for commercial purposes, such as the display of pictures or videos of a fetus at trade shows.

The FDA states that people who promote, sell, or lease ultrasound equipment for making “keepsake” fetal videos should know that the FDA views this as an unapproved use of a medical device. In addition, the FDA cautions that 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 use of a prescription medical device. These recommendations have been endorsed nationally and internationally by reputable professional medical and sonographic organizations, many of which have recently updated their policies. ^(11–20)

The CAR and SOGC support the Health Canada recommendations and recommend that ultrasound be used prudently and only by qualified health professionals and that energy exposure be limited to the minimum that is medically necessary.

This technology should not be used for the sole purpose of determining fetal gender without a medical indication for that scan.

The CAR and SOGC strongly oppose the non-medical use of fetal ultrasound and encourage governments to join with our organizations to find appropriate means to deal with this public health issue.

REFERENCES

1. Kieler H, Axelsson O, Haglind B, Nilsson S, Salvesen KA. Routine ultrasound screening in pregnancy and the children's subsequent handedness. *Early Hum Dev* 1998; 50(2):233–45.
2. Salvesen KA, Eik-Nes SH. Ultrasound during pregnancy and birth weight, childhood malignancies and neurological development. *Ultrasound Med Biol* 1999 Sept; 25(7):1025–31.
3. Kieler H, Chattingius S, Haglind B, Palmgren J, Axelsson O. Sinistrality. A side effect of prenatal sonography: a comparative study of young men. *Epidemiology* 2001 Nov; 12(6):618–23.
4. Yang FY. Prenatal exposure to diagnostic ultrasound impacts blood-brain barrier permeability in rats. *Ultrasound Med Biol* 2012 Jun;38(6):1051-714.Schneider-Kolsky ME: Ultrasound exposure of the foetal chick brain: effects on learning and memory. *Int J Dev Neurosci* 2009 Nov; 27(7):677–83
5. Schneider-Kolsky ME. Ultrasound exposure of the foetal chick brain: effects on learning and memory. *Int J Dev Neurosci* 2009 Nov; 27(7):677–83
6. Suresh R. Effect of diagnostic ultrasound during the fetal period on learning and memory in mice. *Ann Anat* 2008; 190(1):37–45
7. Ang ES Jr. Prenatal exposure to ultrasound waves impacts neuronal migration in mice. *SO - Proc Natl Acad Sci U S A* 2006 Aug 22; 103(34):12903–10
8. Leung JL. Ethical analysis of non-medical fetal ultrasound. *SO – Nurse Ethics* 2009 Sep; 16(5):637–46
9. Health Canada (HC), Public Health Agency of Canada (PHAC). It's your health. Fetal ultrasound for keepsake videos. November 2003. Available at: http://www.hc-sc.gc.ca/iyh-vsv/med/ultrasound-echographie_e.html.
10. U.S. Food and Drug Administration (FDA). Fetal keepsake videos. August 2005. Updated May, 2011. Available at: <http://www.fda.gov/cdrh/consumer/fetalvideos.html>.
11. NCRP Report No. 140. Exposure criteria for medical diagnostic ultrasound. Criteria based on all known mechanisms. Recommendations of the National Council on Radiation Protection and Measurements. Issued December 31, 2002.
12. Bly S, Van den Hof MC; Diagnostic Imaging Committee, Society of Obstetricians and Gynaecologists of Canada. Obstetric ultrasound biological effects and safety. *J Obstet Gynaecol Can* 2005; 27(6):572–575.
13. American Institute of Ultrasound in Medicine (AIUM). Keepsake Fetal Imaging. AIUM Official Statement, April 2012.
14. American Institute of Ultrasound in Medicine (AIUM). Prudent use in pregnancy. AIUM Official Statement, April 2012.

15. ISUOG-WFUMB Statement on the non-medical use of ultrasound, 2011. *Ultrasound Obstet Gynecol* 2011;38:688
16. American College of Obstetricians and Gynecologists (ACOG) Committee Opinion No 359. *Obstet Gynecol* 2007;109:243–245.
17. American College of Radiology (ACR). ACR Statement on fetal keepsake videos for entertainment only. Available at: http://www.acr.org/s_acr/doc.asp?CID=2192&DID=16912.
18. The College of Physicians and Surgeons of Ontario. Ultrasound for non-medical reasons. May 2010. Available at: <http://www.cpso.on.ca/Policies/ultrasound.htm>.
19. Society of Diagnostic Medical Sonographers (SDMS). Non-Diagnostic Use of Ultrasound for Entertainment Purposes in the Obstetrical Setting. May 28, 2008 Available at: <http://www.sdms.org/positions/>.
20. Canadian Society of Diagnostic Medical Sonographers (CSDMS). Statement on ultrasound for entertainment. CSDMS Standards, March 1994. Available at: <http://www.csdms.com/docs/01.pdf>.