

Joint SOGC/CAR Policy Statement on Non-medical Use of Fetal Ultrasound

This joint policy statement has been prepared by the Diagnostic Imaging Committee of the Society of Obstetricians and Gynaecologists of Canada and the Point of Care Ultrasound Working Group of the Canadian Association of Radiologists and approved by the Executive and Council of the Society of Obstetrics and Gynaecology of Canada and the Board of Directors of the Canadian Association of Radiologists.

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Fetal ultrasound is a valuable tool in modern obstetrical care. This imaging technique is useful in assessing a fetus for anomalies, 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 a proliferation of “entertainment” ultrasound units throughout Canada. With recent media coverage of non-medical clinics performing gender determination in the first trimester, the SOGC and CAR 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.

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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 Canada⁹ and the Food and Drug Administration (FDA) in the United States¹⁰ 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}

SOGC and CAR 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.

SOGC and CAR 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

- 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;50:233–45.
- Salvesen KA, Eik-Nes SH. Ultrasound during pregnancy and birth weight, childhood malignancies and neurological development. *Ultrasound Med Biol* 1999;25:1025–31.
- 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;12:618–23.
- Yang FY, Lin GL, Horng SC, Chen RC. Prenatal exposure to diagnostic ultrasound impacts blood-brain barrier permeability in rats. *Ultrasound Med Biol* 2012;38:1051–714.
- Schneider-Kolsky ME. Ultrasound exposure of the foetal chick brain: effects on learning and memory. *Int J Dev Neurosci* 2009;27:677–83.
- Suresh R, Ramesh Rao T, Davis EM, Ovchinnikov N, McRae A. Effect of diagnostic ultrasound during the fetal period on learning and memory in mice. *Ann Anat* 2008;190:37–45.
- Ang ES Jr, Gluncic V, Duque A, Schafer ME, Rakic P. Prenatal exposure to ultrasound waves impacts neuronal migration in mice. *Proc Natl Acad Sci U S A* 2006;103:12903–10.
- Leung JL. Ethical analysis of non-medical fetal ultrasound. *Nurse Ethics* 2009;16:637–46.
- Health Canada; Public Health Agency of Canada. It’s your health. Fetal ultrasound for keepsake videos. November 2003. Available at: <http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/med/ultrasound-echographie-eng.php>. Accessed on November 1, 2013.
- U.S. Food and Drug Administration. Fetal keepsake videos. August 2005. Updated May, 2011. Available at: <http://www.fda.gov/medicaldevices/safety/alertsandnotices/patientalerts/ucm064756.htm>. Accessed on November 1, 2013.
- National Council on Radiation Protection and Measurements. 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. Available at: http://www.ncrponline.org/Publications/Press_Releases/140press.html. Accessed on November 1, 2013.
- Bly S, Van den Hof MC; Diagnostic Imaging Committee, Society of Obstetricians and Gynaecologists of Canada. Obstetric ultrasound biological effects and safety. SOGC Clinical Practice Guidelines, No. 160, June 2005. *J Obstet Gynaecol Can* 2005;27:572–5.
- American Institute of Ultrasound in Medicine. Keepsake fetal imaging. AIUM official statement, April, 2012. Available at: <http://www.aium.org/officialStatements/31>. Accessed on November 1, 2005.
- American Institute of Ultrasound in Medicine. Prudent use in pregnancy. AIUM official statement, April, 2012. Available at: <http://www.aium.org/officialStatements/31>. Accessed on November 1, 2005.
- Salvesen K, Lees C, Abramowicz J, Brezinka C, Ter Haar G, Maršál K; Bioeffects and Safety Committee; Board of the International Society of Ultrasound in Obstetrics and Gynecology (ISUOG). ISUOG-WFUMB Statement on the non-medical use of ultrasound, 2011. *Ultrasound Obstet Gynecol* 2011;38:688–94.
- ACOG Committee on Ethics. American College of Obstetricians and Gynecologists Committee Opinion No. 359: Commercial enterprises in medical practice. *Obstet Gynecol* 2007;109:243–5.
- American College of Radiology. ACR Statement on fetal keepsake videos for entertainment only. Available at: <http://www.acr.org/About-US/Media-Center/Position-Statements/Position-Statements-Folder/ACR-Statement-on-Fetal-Keepsake-Videos-for-Entertainment-Only>. Accessed on November 1, 2013.
- College of Physicians and Surgeons of Ontario. Fetal ultrasound for non-medical reasons. Policy Statement No. 4–10. May 2010. Available at: <http://www.cpso.on.ca/Policies/ultrasound.htm>. Accessed on November 1, 2013.
- Society of Diagnostic Medical Sonographers. Non-diagnostic use of ultrasound for entertainment purposes in the obstetrical setting. May 28, 2008. Available at: <http://www.sdms.org/positions/nondiagnostic.asp>. Accessed on November 1, 2013.
- Canadian Society of Diagnostic Medical Sonographers. Statement on ultrasound for entertainment. CSDMS Standards, March 1994. Available at: <http://www.csdms.com/docs/ppgpdf>. Accessed on November 1, 2013.