

# Ultrasound for entertainment

## *Double standards or simple medical self-interest?*



**Dr Lachlan de Crespigny**  
FRANZCOG

**Businesses offering non-medical fetal ultrasound provide real-time and souvenir 3D and 4D fetal images with DVDs, including sex determination. They are also known as entertainment, boutique, 'shopping mall', elective, or fetal keepsake imaging. These businesses have opened up around Australia and New Zealand, including in private homes.**

In the United States, one group found that 9.3 per cent of pregnant women take up entertainment ultrasound.<sup>1</sup>

However, there is controversy regarding the use of fetal ultrasound for entertainment: medical ultrasound is said to be acceptable and non-medical ultrasound is said to be unacceptable. I will argue that this approach is unjustifiable and wrong.

### Bioeffects

When American actor Tom Cruise purchased an ultrasound system with plans to do scans on fiancée Katie Holmes himself, doctors warned that that if not medically necessary, ultrasound risks physical harm to the fetus.<sup>2</sup> However, whether a scan is medically necessary or not cannot be relevant to its physical risk to the fetus. Bioeffects vary with gestation and ultrasound power, not the indication. If we believe that ultrasound presents physical risks to the fetus, then we should also be warning patients who have clinical scans. Patients must be warned of significant risks. We should also do more to minimise medical exposure.

The Food and Drug Administration (FDA) also suggests that the purpose of the scan can impact on the risk of bioeffects. It offers unlimited support to medical ultrasound but a blanket ban on entertainment ultrasound: 'Ultrasonic fetal scanning is generally considered safe and is properly used when medical information on a pregnancy is needed', however, 'exposing the fetus to ultrasound with no anticipation of medical benefit is not justified.'<sup>3</sup> But why not, if it is generally considered safe?

The American Institute of Ultrasound in Medicine (AIUM) argues for an extreme view that few clinicians would follow: it 'encourage(s) sharing images with patients'<sup>4</sup> but asserts that 'to obtain a picture of the fetus or determine fetal gender without a medical indication is inappropriate and contrary to responsible medical practice.'<sup>5</sup>

*'The pivotal role that the ultrasound examination can have in women developing a more positive attitude towards their fetus has long been recognised.'*<sup>10'</sup>

The International Society of Ultrasound in Obstetrics and Gynaecology (ISUOG) states that: 'B-mode acoustic outputs are generally not high enough to produce deleterious effects. Their use, therefore, appears to be safe for all stages of pregnancy.'<sup>6</sup> However, it also states that examinations should not be for entertainment purposes. Again, this is contradictory. If ultrasound is safe, it can be used for entertainment, if it is not safe, then careful consideration is needed before doing clinical scans.

ISUOG advises that: 'Spectral and colour Doppler may produce high intensities and routine examination by this modality during the embryonic period is rarely indicated.'<sup>6</sup> It is troubling that clinicians ignore ISUOG and frequently use Doppler in the first trimester for research, a perceived indication or merely for interest. Yet, if a patient asks about ultrasound for entertainment purposes later in pregnancy when the risks are far lower, they are likely to be given a lecture on the dangers of unnecessary ultrasound.

*Ultrasound in Obstetrics and Gynecology* accepts papers in which colour and pulsed Doppler are used in the first trimester on continuing pregnancies only if five conditions are satisfied, including that maximum, minimum and mean exposure times used for the patient cohort must be given.<sup>7</sup> It is surprising that in this environment, doctors are not more enquiring about, or even set limits to, ultrasound power to be used when they refer or perform an ultrasound scan.

Ultrasound use in pregnancy includes:

- Multiple scans: There are no recommended limits on a number of examinations. Indeed, in many countries such as Germany, multiple ultrasound examinations are recommended – sometimes at every antenatal visit.
- Ultrasound examinations are commonly prolonged extensively for research and teaching, often using higher power Doppler, more prolonged ultrasound exposure and early in pregnancy.

The confidence that diagnostic ultrasound doesn't produce harmful bioeffects is high. The widespread use of medical ultrasound is not discouraged. It seems ridiculous to oppose one non-medical ultrasound examination in this environment. Non-medical 3D ultrasound examinations are carried relatively late in pregnancy using B-mode. The power levels and timing of ultrasound exposure is low-risk compared to many medical uses.

In August 2005, in the Australian Society for Ultrasound in Medicine's (ASUM) *Ultrasound Bulletin*, much of the opposition to the non-medical use of ultrasound was because of potential bioeffects.<sup>8</sup> However, opposition on the basis of bioeffects fails. If limiting ultrasound exposure was of great importance, professional organisations should have policies that highlight the dangers of ultrasound in clinical practice. They don't. Even Chervenak and

McCullough, who oppose non-medical ultrasound, state that if biologic risk were the whole of the ethical story, there would be minimal objection to boutique fetal imaging if the time and intensity of the ultrasound examination were reasonable.<sup>9</sup> Credible opposition must be based on other criteria.

We are left with lean pickings mounting a case against non-medical fetal ultrasound on criteria other than bioeffects.

*'If limiting ultrasound exposure was of great importance, professional organisations should have policies that highlight the dangers of ultrasound in clinical practice. They don't.'*

## Entertainment

Patient satisfaction and consumerism is a fundamental part of obstetric care. This should not be different for the ultrasound examination, which is one of the most exciting experiences in pregnancy. It would be inappropriate not to show women images of their fetus. The pivotal role that the ultrasound examination can have in women developing a more positive attitude towards their fetus has long been recognised.<sup>10</sup>

Couples love high quality 3D and 4D ultrasound. The images can be extraordinarily life-like. For all categories of maternal-fetal bonding, 3D ultrasound examinations are reported by some to consistently score higher than 2D alone<sup>11</sup>, although not by all.<sup>12</sup> The difference may be related to image quality. Maternal weight and fetal position are fundamental determinants of image quality for 3D and 4D ultrasounds.

While non-medical 3D ultrasound examinations may be said to trivialise ultrasound, so do we all in our daily practices when we attempt to satisfy patient needs by demonstrating fetal images.

If women have a customer-focused scan and keepsakes, then there should be little need for an 'entertainment ultrasound' industry. Devoting extra time to the ultrasound session for the sake of entertainment, including 3D and 4D imaging and providing keepsake images, generates some costs. Part of the skill is to incorporate patient focus into the medical examination taking limited extra time. Inevitably, there is some increased ultrasound exposure, but using B-mode this should be small.

## Consistent policies are needed

Some bioeffect statements are inconsistent. ASUM's 'Consent To Ultrasound Scanning For Teaching Purposes'<sup>12</sup> reads: 'I understand that medical studies to date have not demonstrated any adverse biological affect at the low power intensities used for imaging.' On the other hand, ASUM's statement on 'Non-Medical Entertainment Ultrasound'<sup>13</sup> emphasises long-term effects and the possibility of subtle effects being not completely known: 'Recommended power output levels have been significantly increased in recent years and much of the safety data relating to the use of diagnostic ultrasound precedes the increased permitted power outputs.' It is difficult to take statements seriously when they are biased and contradictory.

ASUM's statements include other contradictions. 'Non-medical Entertainment Ultrasound' states that equipment must be used by trained individuals and to seek relevant diagnostic information with the minimum of exposure. These apparently important recommendations are not revealed to those kindly signing the 'Scanning for Teaching Purposes' form, who consent to a scan for teaching only (by inference untrained individuals), that is not intended to provide diagnostic information and, far from a minimum of exposure, must consent to one or multiple examinations. Which group is hearing the truth?

## Other purported concerns

The 'baby picture' might promote the view among pregnant women that they are obligated subsequently to take any and every risk to protect their 'babies'; or the picture may look odd and provoke fear and concern.<sup>9</sup> However, medical scans share these risks.

A suggested ethical concern in boutique fetal imaging is that the physician's economic self-interest becomes primary.<sup>9</sup> However, as with plastic surgeons, the goal of providing a high quality service and satisfying a customer's needs comes before economic self-interest.

Chervenak and McCullough<sup>9</sup> argue that non-medical imaging with no physician present is ethically deficient because counselling is unavailable. If so, it is even more ethically unacceptable in a diagnostic obstetric ultrasound practice in which, as is common in Australia, there is either no doctor on site or the doctor does not counsel.

Concerns about missing abnormalities and potential communication problems are satisfied if there is appropriate information for customers in advance. Providers are unlikely to pretend that they offer a diagnostic service. Legal disclaimers for non-medical ultrasound are much better documented than those for limited medical ultrasound. For such scans, including biophysical profiles and dating, women are not routinely given legal disclaimers. Many women must not understand the limits.

We would all agree that pregnant women could use their financial resources more wisely. However, we do not try to dictate how women should spend their money in other situations.

*'Women describe their non-medical ultrasound experience as more positive than their medical ultrasound examination, citing that the staff were friendlier, took time to point out fetal features and spent a longer amount of time with them.'*<sup>14</sup>

## Discussion

Our specialty faces many divisive ethical and political debates. Some such issues have a profound effect on the health of the people for whom we advocate: Australian and New Zealand women. Whether or not a group of women choose to waste their money on apparently low-risk fetal ultrasound for entertainment is a relatively trivial issue. The issue we should address is: How did we fail to satisfy their needs?

We need to be careful before encouraging legislation against non-medical ultrasound. Legislation would need to define the fine line between medical and non-medical services.

The major providers of 3D and 4D ultrasound equipment, General Electric (GE) and Philips, have global policies that they will not sell equipment to non-medical providers. However, they are sellers of a product, not custodians of good practice. Why would they refuse to sell? Where would they draw the line? Would they refuse to sell to a medical provider who also provided non-medical entertainment ultrasound?

Women describe their non-medical ultrasound experience as more positive than their medical ultrasound examination, citing that the staff were friendlier, took time to point out fetal features and spent a longer amount of time with them.<sup>1</sup> The lesson is clear.

The development of entertainment fetal ultrasound is a sign that we need to do more to satisfy the needs of our patients. To take a stand against it reeks of self-interest.

### Proposals:

1. That we learn lessons from entertainment fetal ultrasound rather than opposing it; and
2. Statements on limits to ultrasound exposure must be consistent, whatever the indication for the scan.

### References

1. Simonsen S, Branch D, Rose N. The Complexity of Fetal Imaging: Reconciling Clinical Care With Patient Entertainment. *Obstet Gynecol.* 2008; 112(6): 1351-1354.
2. Tom Cruise's Reported Unsupervised Use of Fetal Keepsake Ultrasound Raises Risk for Baby and Is Potentially Unlawful: <http://ocmb.xenu.net/ocmb/viewtopic.php?p=141369&sid=9f494fcfedc1574c5c1ae7fa9686459>.
3. Fetal Keepsake Videos: [www.fda.gov/cdrh/consumer/fetalvideos.html](http://www.fda.gov/cdrh/consumer/fetalvideos.html)
4. American Institute of Ultrasound in Medicine. Keepsake Fetal imaging 2005: [www.aium.org/publications/viewStatement.aspx?id=31](http://www.aium.org/publications/viewStatement.aspx?id=31) .
5. Laurel. Medical ultrasound safety: prudent use. American Institute of Ultrasound in Medicine; 1999.
6. Abramowicz J, Kossoff G, Marsal K, Ter Haar G. Safety Statement, 2000 (reconfirmed 2003). ISUOG Bioeffects and Safety Committee. *Ultrasound Obstet Gynecol.* 2003; 21, 100.
7. Campbell S, Platt L. The publishing of papers on first-trimester Doppler. *Ultrasound Obstet Gynecol.* 1999; 14: 159-160.
8. August 2005 ASUM *Ultrasound Bulletin*: [www.asum.com.au/open/bulletin/bull\\_v8n3.htm](http://www.asum.com.au/open/bulletin/bull_v8n3.htm) .
9. Chervenak F, McCullough L. An ethical critique of boutique fetal imaging: A case for the medicalization of fetal imaging. *Am J Obstet Gynecol.* 2005; 192: 31-33.
10. Reading AE, Cox DN, Sledmore CM, Campbell S. Psychological changes over the course of the pregnancy: a study of attitudes towards the foetus/neonate. *Health Psychol.* 1984; 3: 211-21.
11. Ji E, Pretorius D, Newton R, Uyan K, Hull A, Hollenbach K, Nelson T. Effects of ultrasound on maternal-fetal bonding: a comparison of two- and three-dimensional imaging. *Ultrasound Obstet Gynecol.* 2005; 25(5):473-7.
12. Rustico M, Mastromatteo C, Grigio M, Maggioni C, Gregori D, Nicolini U. Two-dimensional vs. two- plus four-dimensional ultrasound in pregnancy and the effect on maternal emotional status: a randomized study. *Ultrasound Obstet Gynecol.* 2005; 25(5):468-72.
13. ASUM's Consent To Ultrasound Scanning For Teaching: [www.asum.com.au/site/files/P&S/B6\\_policy.pdf](http://www.asum.com.au/site/files/P&S/B6_policy.pdf) .
14. ASUM's statement on Non-Medical Entertainment Ultrasound: [www.asum.com.au/site/files/P&S/F1\\_policy.pdf](http://www.asum.com.au/site/files/P&S/F1_policy.pdf) .



**The Nuchal Translucency Ultrasound, Education and Monitoring Program is an education and credentialing Program initially funded by the Government's Department of Health and Ageing for all practitioners performing Nuchal Translucency screening for pregnant women.**

**The primary objective of the program is patient care. The RANZCOG, in conjunction with the Fetal Medicine Foundation (FMF) in the United Kingdom, has set up a process for certification in the 11-14 week scan to ensure that all those performing this ultrasound examination have been adequately trained to do so and that high standards of performance are maintained by continuous education and audit.**

**Over 1500 delegates have participated in the program since it began in October 2001 and the twice yearly face-to-face theoretical courses continue to reach maximum capacity. We are about to launch our online education facility which will address the needs of learners who are embarking on becoming certified in the performance of the first trimester NT ultrasound scan.**

**Once accreditation in the 11-14 week scan has been obtained, candidates are entitled to receive the FMF software for the calculation of risk for Down syndrome using maternal age, Nuchal Translucency measurement and maternal serum free  $\beta$ -hCG and PAPP-A.**

**For further information, please contact the Nuchal Translucency Coordinator:  
(t) +61 3 9412 2938 (e) [nuchaltrans@ranzocg.edu.au](mailto:nuchaltrans@ranzocg.edu.au) (w) [www.nuchaltrans.edu.au/certification.shtml](http://www.nuchaltrans.edu.au/certification.shtml)**