Risky business: Applying Risk/Benefit Analysis consistently in entertainment ultrasound

Short title: Ultrasound risk/benefit

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Introduction
Fetal nonmedical entertainment ultrasound (NEU) using 3D and 4D fetal images is widely available. Couples are offered real-time scans, souvenir images, DVDs and sex determination. This is sometimes referred to as entertainment, boutique, shopping mall, elective, or fetal keepsake imaging. It appears to be most prevalent in the USA where, in one study, 9% of pregnant women admitted having had nonmedical scans.\(^1\)

There is controversy regarding the use of fetal ultrasound for entertainment; professional bodies strongly oppose it. The principal reason cited is the risk of harmful bioeffects. For example, when actor Tom Cruise purchased an ultrasound system with plans to personally scan his fiancée Katie Holmes, doctors warned: ‘if it is not medically necessary, the use of ultrasound raises unnecessary physical risk to the fetus’\(^2\).

Concern that ultrasound could cause bioeffects in the fetus should be of immense importance to people in all countries. Virtually everyone under 25 years of age in western nations was exposed to ultrasound in utero, commonly multiple scans. The impact of any bioeffects could be devastating.

In this paper we will argue that professional organizations’ concerns about bioeffects in NEU are hypocritical. We advocate a relook at our approach; the important factors are gestational age and power of ultrasound, not the indication for the scan or where it is performed. Current arguments using risk-benefit balance to oppose NEU fail.

Entertainment Ultrasound and Bioeffects

Entertainment ultrasound comes in two forms. NEU is performed outside medical settings where there is no therapeutic or diagnostic aim. Alternatively, non-medically-indicated scans may be performed by sonographers in medical clinics within the context of a professional relationship – for example as a supplement to diagnostic scans. We will refer to this as medical entertainment ultrasound (MEU). Virtually all medically indicated scans will include demonstration of fetal images to the couple and there is no sharp dividing line clearly differentiating this from diagnostic segments of the scan.

There is no support for NEU among professional bodies. Exposing the fetus to ultrasound with no anticipation of medical benefit is said to be unjustifiable.\(^3\) Others have similar statements.\(^4,5,6,7\) The underlying principle is ALARA (as low as reasonably achievable) acoustic output and dwell time.\(^8\) Concern is so great that the American Food and Drug Administration can seize machines used without a prescription for entertainment purposes; and it encourages states to take action against technicians who perform nonmedical ultrasounds.\(^9\) Others have argued, however, that there should be minimal ethical objection to boutique fetal imaging on the basis of bioeffects if the time and intensity of the ultrasound examination are reasonable.\(^10\)
There is also concern about MEU. It is claimed that use of 2D or 3D only to view the fetus, obtain a picture of the fetus, or determine the fetal sex without a medical indication is inappropriate and contrary to responsible medical practice\(^{11}\). This implies we are dealing with a dangerous technique. But statements are contradictory; the British Medical Ultrasound Society states that research and "bonding" scans endorsed by a clinician or midwife comply\(^5\). Yet it opposes NEU. It is unclear how non-diagnostic scans can carry differing risks depending who requests them.

**Is entertainment ultrasound higher risk than diagnostic ultrasound?**

It is claimed that NEU is particularly risky since untrained commercial operators have no concerns that there might be some hidden danger of ultrasound\(^{12}\). But trained medical scanners may be guilty of the same failing. Since 1992 it has been the responsibility of the operator of the machine to monitor the output displays to ensure the safe use of ultrasound. But in one report, only 28% of regular ultrasound users knew where to find the safety indices on the screen of their own machine\(^{13}\). Only 22% knew how to adjust the energy output. Machine power displays have ‘failed to provide a basis for safe scanning\(^{14}\). Furthermore there are no recommended limits on the number of, or indications for, ‘diagnostic’ ultrasound examinations. Doctors often perform numerous scans each pregnancy. Some obstetricians scan low risk women at every antenatal visit; guidelines do not discourage this practice.

The suggestion that NEU is riskier than diagnostic ultrasound is flawed because, given appropriate power levels, there is little likelihood that it is quantitatively or qualitatively more dangerous than diagnostic ultrasound. Imagine that in 40 years an individual is found to have suffered harm from ultrasound performed while he was a fetus. His mother had diagnostic ultrasound scans, including Doppler, at 8, 12 and 19 weeks, a scan researching aortic flow at 13 weeks then a NEU at 26 weeks. It is not relevant to him that one of the scans was for entertainment. None of them was likely to offer him medical benefit - they were unlikely to show problems that would allow him health enhancing treatments. Importantly, ultrasound bioeffects would almost certainly be due to the diagnostic scans. Similar thoughts apply to MEU. Focusing on the scan’s indication or where it is performed is a distraction.

Nevertheless, many professional statements are cautionary regarding the risks of NEU, and sometimes also MEU, but reassuring about the risks of diagnostic or teaching scans\(^8, 15\).

**How much risk is too much?**

It is not known if diagnostic ultrasound causes bioeffects particularly using post 1992 power levels\(^{16}\). We need to know. But there is a separate question about how we should respond to small or theoretical risks. The approach that is sometimes taken is to draw on a principle of non-maleficence\(^{17}\) or a precautionary principle\(^{18, 19}\) to justify avoiding such risks. However, the problem is that possible risks apply to almost any new treatment or medical intervention (e.g. gene therapies), and these principles might prevent the
development of major medical advances. A more rational approach is to attempt to balance possible risks with potential benefits.

Professional bodies have shown a willingness to balance potential risks and benefits of ultrasound. Many professional statements imply that the risks of ultrasound to the fetus are sufficiently high, or sufficiently uncertain, that scans should only be performed when they convey significant benefits to the woman. They claim that diagnostic ultrasound conveys such benefits, whereas NEU does not.

This line of argument faces two problems. First, it seems quite possible that many women receive benefits from NEU that are comparable to those that they receive from diagnostic ultrasound. Consider the case of women who undergo midtrimester medical ultrasound even though they would not consider abortion in the presence of an abnormality. Since it is primarily a test for fetal abnormality, the benefits that such women derive from the scans are likely to be small, indeed little greater than those from NEU. Indeed, in some diagnostic scans, such as those intended to detect threatened miscarriages, there are likely to be few, if any, medical benefits. The benefits may take the form of psychological reassurance – not dissimilar to the benefits of entertainment ultrasound.

Second, and most important, it is not at all clear that the ‘significant benefits to the woman’ test is an appropriate one. Is it ethical to impose risks on a fetus so that the woman can derive some significant (but not enormous) benefit? For example, we might find it unethical for a woman to drink alcohol or take recreational drugs if this may harm the fetus, even though the woman may consider that the benefits to her are significant. One of the authors has argued elsewhere that a pregnant woman has strong moral reasons to refrain from behaviours that potentially cause a child to be born in a harmed state and have little prospect of benefiting it. This reason does not presuppose that the fetus is a person. It is grounded on principles of respect for the interests of sentient beings and prevention of harm to future individuals. Debate needs to focus on when, if ever, it is reasonable to perform a test that is in the interests of the woman but has a risk, however low, of causing significant morbidity to the future child.

Perhaps a more defensible position for professional organizations would be one holding that the risks of ultrasound to the fetus are sufficiently high, or sufficiently uncertain, that ultrasound scans should only be performed where they convey significant benefits to the fetus. Again it might be argued that diagnostic ultrasound would typically pass this test, whereas EU would not. But while some diagnostic ultrasound scans potentially benefit the fetus, such as those to identify third trimester fetal compromise, the majority convey no such benefits. Scans commonly pose a net risk to the fetus, quite apart from any bioeffects. Many are performed to provide information that could result in termination of a fetus – hardly in the fetus’ interests! Nuchal translucency scans, for example, are performed primarily for risk assessment of chromosome abnormality; the fetus faces a significant risk of abortion if a problem is found. They primarily offer women choice if an anomaly is detected. Teaching and research scans typically convey no benefit to the fetus, and expose the fetus to risk of any bioeffects.
The second problem is that NEU may in a few circumstances pass the ‘significant benefit to the fetus’ test. These scans may increase bonding, and may therefore reduce a fetus’ risk of therapeutic abortion. That is, they may be more in the fetus’ interests than medical scans, when the only possible alternative outcome in most cases is abortion. Indeed, several states in the USA require that women have a compulsory pre-abortion ultrasound to try to discourage abortion.

The ‘significant benefit to the woman’ test may be inappropriate. In any case, it fails to distinguish between medical and non-medical scans since benefits to the woman may be comparable. The ‘significant benefit to the fetus’ test, though perhaps more defensible, can favour entertainment rather than diagnostic ultrasound: NEU may convey a net benefit to the fetus, and diagnostic ultrasound may present a net harm.

NEU may often be unethical because the risk of bioeffects is larger than any potential health benefit to the fetus, and because there is no sufficiently great benefit to the woman to outweigh the net risk imposed on the fetus. But the same is also true of many diagnostic, teaching and research ultrasound scans.

Criticism of NEU by professional organizations reflects their concern about potential bioeffects. There have been other objections but these also are not persuasive. Consistency demands that training, research, frequently repeated scans in low risk women, plus scans using higher power Doppler should also be either firmly discouraged or clear guidelines introduced. This has not happened. On the contrary, research and "bonding" scans endorsed by a clinician or midwife may be considered to comply, apparently even for frivolous indications.

**Conclusion**

Current widespread use of diagnostic ultrasound is not discouraged by professional bodies. It makes no sense to oppose NEU in this environment where the timing of ultrasound exposure and likely power levels is low risk compared to many diagnostic scans.

Since fetal ultrasound is believed to have non-negligible risks, a position needs developing that balances maternal and fetal interests. Consistent policies should then follow indicating when it is reasonable to perform or prolong scans for entertainment. Quality statements, however, are predicated on having improved research into the potential adverse effects of current generation ultrasound equipment.

Statements by professional bodies seem to imply that the purpose of a scan can impact on the risk of bioeffects. But whether a scan is medically necessary cannot be relevant to its physical risk to the fetus. Risk of bioeffects varies with gestation and ultrasound power, not the indication. Professional organisations misuse the risk/benefit concept and are hypocritical in its application.
If ultrasound produces adverse bioeffects then it will not be a single late B-mode entertainment ultrasound that results in most harm. It will be diagnostic ultrasound. It will be the multiple medical scans, often including Doppler, often in the first trimester and often for small clinical benefit. Doctors would be called to account, not businessmen. Our focus must be on reducing all fetal exposure, especially in the embryonic period. We should first face the major issue of documenting and reducing fetal diagnostic ultrasound exposure before confronting the more minor issue of entertainment ultrasound.

Given current clinical practice, on the basis of bioeffects there are no good reasons for opposing entertainment ultrasound.
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