AIMS For a better birth...

Ultrasound

By Beverley Beech

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In the last issue, AIMS Chair Beverley Beech reported on ultrasound advertising. We report back on the response of the Advertising Standards Authority.

Women are urged to have a series of ultrasound examinations during their pregnancies to 'check' that their babies are okay. They are not told that ultrasound can only detect some abnormalities, or that there can be false alarms which can turn a happy pregnancy into a rollercoaster of anxiety, or that ultrasound is not risk free. The attractive idea of seeing the baby in the uterus has led commercial companies to advertise 3D and 4D ultrasound pictures that really do show realistic close-ups. AIMS wrote to the Advertising Standards Authority (ASA) to complain about the false and misleading claims in: the Babybond's advertisements in the National Childbirth Trust's magazine; the Baby Beats advert in Tatler magazine, and quotes from Professor Stuart Campbell in The Times (see AIMS Journal Vol 16, No4). AIMS complained about the false and misleading claims for 3D and 4D ultrasound. In our letter to the ASA we said that the advertisements contravened the ASA standards. To our surprise, we were told that the ASA could do nothing about advertisements on the web. The magazine ads cleverly refer the reader to the web where their claims are made and thereby avoid ASA sanctions. '[The] ASA believes that applying the Code to all online claims would go too far into regulating the 'relationship' and would, moreover, prove impossible to enforce effectively'. They suggested we take up our complaint with our local Citizens Advice Bureau or Trading Standards Department.

What we told the Advertising Standards Authority

We pointed out to the ASA that:

1. The Babybond website claims that ultrasound provides the 'ultimate bonding experience' and '[the] scan is purely optional and is not part of your usual antenatal care' and that it is provided 'to ensure that Babybond customers receive the ultimate bonding experience'. It clearly indicates that this service is being offered for non-clinical reasons, and it is not providing what scans were intended to provide in a medical sense-clinical information about the baby.
2. Furthermore, should the sonographers identify any problem with the baby they have no duty to inform the woman, her doctor, or to provide immediate counselling and support if anything is amiss (for example, if the baby proves to be dead on examination). (They may, however, have a duty under their professional body but we do not know their qualifications or what professions

they belong to).

3. The research on the effects of ultrasound scans and bonding is contradictory, and it is misleading the public to inform them otherwise.
4. The sex of the baby may become obvious during the scan. This is a sensitive issue, and prior knowledge of the sex may have an adverse, rather than a positive, effect on the view of either parent towards the child , and therefore on bonding.
5. The claim that 'obstetric ultrasound now has an established safety record' is dishonest. Although there has been very little research on longer term effects of ultrasound exposure in the fetus, all of it was done with earlier equipment which emitted much less power and gave the fetus a much smaller dose than the sophisticated equipment that is currently being used. Research by Lorenz showed that preterm labour was more than doubled in the ultrasound group; Saari-Kemppainen's research revealed 20 miscarriages after 16-20 weeks in the screened group and none in the controls; Davies research had 16 perinatal deaths of normally formed infants in the Doppler group compared with 4 in the standard care group; Taskinen's research found that if the physiotherapist was pregnant, handling ultrasound equipment for at least 20 hours a week significantly increased her risk of spontaneous abortion and the risk of spontaneous abortions occurring after the tenth week was significantly increased for deep heat therapies given for more than 5 hours a week, and ultrasound more than 10 hours a week. What concerns us most is the fact that 3 and 4D ultrasound scanning is far more powerful than previous scanning equipment. It has been subjected to very little research investigating its safety and none looking at potential long term effects. We are concerned that women are being encouraged to expose their babies unnecessarily to high intensity ultrasound scanning for pleasure, and there are no warnings of the possible adverse short or long term effects.

Rent your own Doppler machine

We also wrote to the ASA about a Baby Beat's advertisement for a hand-held Doppler device that parents could use at home as often as they like. The advertisement appeared in Tatler Magazine. We pointed out that no adequate research has been carried out to determine the safety of hand-held ultrasound Doppler devices, and what level or frequency of exposure might present a risk. Unfortunately these devices were introduced without basic evidence from a randomised clinical trial. Indeed it would now be difficult to do such a trial since it would mean preventing exposure to other types of ultrasound equipment to the research subjects. What is clear, however, is that there is no evidence that the equipment is safe, as the manufacturers claim. We do know, however, that Doppler ultrasound exposure from other equipment has proven adverse effects. In a randomised trial in Australia, exposure to diagnostic Doppler scans was shown to reduce fetal growth (Newnham, 1993). In a British randomised trial of Doppler scans, there was a statistically significant increase in stillbirths in the Doppler group-16 deaths of exposed babies and only 4 in the unexposed controls. This quadruple increase in stillbirths has never been explained (Davies, 1992). Although hand-held Dopplers to hear the fetal heart will obviously produce lower exposure, no-one knows at what frequency or duration of exposure that may be a risk.

Parents are told they can listen to the baby 'as early as 10 weeks of pregnancy', when major developments are taking place, and it is particularly important to avoid any adverse influences. 'Anytime you wish' implies there is no limit on frequency of exposure, and the blanket assurance of safety could encourage parents to use it frequently. This exposure will be in addition to exposure which the baby will receive from healthcare professionals during regular antenatal care. The web site enhances the misleading suggestion of safety by claiming that: 'Baby dopplers have an incredible safety record. They have been used daily for the last thirty years around the world; it is estimated there are around five million in use every single day. No adverse effects to either mother or baby have ever been reported'.

Just because adverse effects have not been proven (or sought), this does not mean that the equipment is totally safe for unborn children, and advertisers should not claim that it is. Lack of evidence of risk is not evidence of safety. Our complaint about the Tatler magazine advertisement was also dismissed by the ASA on the grounds that it was over three months old, and, like our other complaint, claims made on the web would not be investigated either.

Professor Stuart Campbell

Professor Stuart Campbell who was quoted as stating that 'A great deal of research has been done over the past 30 years to investigate if fetal ultrasound has any effect on the baby and there is no evidence whatsoever of harm' was asked to justify his claims in the light of the research quoted above. He has not replied.

Using women and babies as guinea pigs

If ultrasound had been a drug it would not have been allowed on the market without rigorous testing. Because it is medical equipment the government has allowed, unregulated, any development the enthusiasts want can be introduced without any rigorous trials. Women and babies are being used as guinea pigs in unregulated medical experimentation without being told the possible adverse effects on their babies. The present lack of control is a public health issue and a national disgrace. AIMS will now be approaching the government and asking for rigorous constraints to be introduced and for women to be properly informed of the risks before they submit to yet more ultrasound examinations. In the meantime, if you see an ultrasound advertisement in a magazine do send a copy to AIMS.

References

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