

SAFETY ISSUES IN FETAL ULTRASOUND

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Background

Recent expanded availability of fetal ultrasound for bonding/entertainment and a new study indicating effects of ultrasound on the developing mouse brain require a reassessment of safety issues. The ultrasound community, prospective parents and society in general should be more informed, especially about some of the information that many would like to ignore. Although I share the general view that there are probably no significant adverse effects of ultrasound on the fetus, safety should not be treated as a proven fact.

Summary

1. There has been about a 1000-fold increase in the time-averaged intensity of ultrasound generated by equipment for obstetrics since around 1980.
2. Much of this has occurred because of the indifference of medical users to outputs when buying equipment. The opposite trend has been the case in mammography.
3. Pressure variations in the ultrasound pulse are large and not intuitively trivial.
4. Not all follow-up studies of exposed fetuses are reassuring. Also, the diagnostic intensities used for fetal ultrasound are similar to those used therapeutically in devices that speed up healing of fractures.
5. The permissible pulse intensity, as measured by the Mechanical Index (MI), for the fetal eye is up to 1.9 as part of overall exposure regulatory limits. For ophthalmic ultrasound following birth it is 0.23. Why does the fetal eye receive less consideration?
6. Dose-dependant effects of diagnostic ultrasound on fluids can be demonstrated with high-resolution probes – see video clips and discussion.
7. The medical profession does not have a good record for anticipating the problems its activities can cause.
8. I believe that commercial entertainment fetal ultrasound should be discouraged. I also believe that the major causes of needless ultrasound exposure to the fetus are indifference on the part of the medical user community and suboptimal leadership from professional organizations and regulatory authorities with regard to clinical examinations.

Recommendation

Probably the only way to ensure implementation of the ALARA (As Low As Reasonably Achievable) principle in fetal ultrasound is to encourage patients as well as users to take an interest in equipment issues and output displays.

Discussion and Documentation

1. A little physics: Diagnostic ultrasound is emitted in short pulses lasting in the order of a microsecond (millionth of a second). The system then waits a fraction of a millisecond (one thousandth of a second) for the returning echo. Pulse intensities are measured in W/cm^2 (Watts per square centimetre) and time-averaged intensities in mW/cm^2 (milliwatts per square centimetre). The time-averaged (formally expressed as I_{SPTA}) intensity quoted for the ADR 2130 used in the Norwegian handedness outcome study around 1980 was $0.11 \text{ mW}/\text{cm}^2$ (1). The ADR was a widely used unit at that time, and the only one I had access to for about 2 years. Results of this study raised the question of effects of prenatal ultrasound on subsequent handedness. A Mayo Clinic demonstration of fetal stimulation by diagnostic ultrasound (combined standard imaging and pulsed Doppler) using an Acuson 128 XP gave the standard imaging (B-mode) intensity as $144 \text{ mW}/\text{cm}^2$, quoted from the 1995 service manual (2). The authors of this article describe the output value as typical of modern scanners. There are technical arguments about how comparable the measurements related to these two studies are, but there is as much reason to believe that the more than 1000-fold increase is an underestimate as an overestimate (31).

The current regulatory upper limit for I_{SPTA} is $720 \text{ mW}/\text{cm}^2$, except for ophthalmic ultrasound where the limit is $50 \text{ mW}/\text{cm}^2$ (9c, 15a). Although not of direct relevance, a recognized authority in ultrasound physics has noted that the threshold for pain in the audible sound range, usually given as 130 dB, represents an intensity of $1 \text{ mW}/\text{cm}^2$ (3). (Ultrasound at diagnostic frequencies is completely blocked by air and therefore is not a hearing hazard to operators or patients.)

2. In general, practitioners of fetal ultrasound operate on a Titanic Mentality: Safety is assured, therefore precautions are unnecessary. I would be happy to be proven wrong. Tina Ureten, the operator of a chain of commercial entertainment/bonding fetal ultrasound facilities in Canada (UC Baby), made this point in a spirited response to criticism in the Aug 26, 2003 edition of The Medical Post (Canada): “Ultrasound has been used extensively by Canadian doctors and health practitioners for more than 40 years without any concern.” This background of indifference has caused difficulties for me in trying to have output intensities given serious weighting in the tendering and selection process for new equipment. Vendors repeatedly tell me that they have not previously been asked for this information, and without precedent or support from the wider user community it is hard for someone in a small facility to insist on treating acoustic outputs as a priority in the purchase process.

Equipment choice can make a difference. The General Electric Logiq 9 provides satisfactory fetal imaging for most circumstances with a default Mechanical Index (MI – described in section 3) of about 0.2 using its fundamental frequency. A recent report (4) gives an MI value of about 1 for second-trimester fetal imaging with the equipment that the authors were using (Philips HDI 5000), which is a similar value to our Toshiba Aplio.

While it is not possible to know how much of the rise in acoustic intensities over time was really necessary for essential image improvements and also to satisfy increased penetration requirements in our increasingly obese populations, I have not seen a 1000-fold increase in image quality since 1980. Comparison with mammography, where there has been intense consumer-driven demand for dose reduction and image improvements, is instructive: “Standardization of mammography led to a decrease in mean glandular dose from 14 to 1.8 mGy with concurrent improvement in image quality” (5).

3. More physics. The ultrasound pulse lasts a microsecond or less. It is carried by high-frequency waves of positive and negative pressure peaks and troughs – the frequency is around 3-4 MHz (3-4 million cycles per second) for usual obstetric ultrasound. There has been a preoccupation with the negative (or rarefactional) component of the wave because of the possibility of creation of transient microbubbles which cause major effects when they subsequently collapse. This phenomenon of cavitation is unlikely to occur in the diagnostic range, which has been the basis for much of the reassurance given by regulatory authorities and professional organizations. For reasons beyond my comprehension, ultrasound authorities seem to reject or ignore the possibility of other mechanical effects in safety considerations. Perhaps this illustrates the Mark Twain observation: “There is something fascinating about science. One gets such wholesome returns of conjecture out of such a trifling investment of fact.”

FDA-approved low intensity pulsed ultrasound therapy for speeding up the healing of fractures using the Exogen device creates food for thought with regard to mechanisms. The ultrasound frequency is lower than in the diagnostic range, about 1.5 MHz vs. at least 2 MHz, and the pulsing pattern is different. The mechanical intensities are below a cavitation threshold despite the clinically demonstrable biological effect. There is no significant tissue heating (6). Low levels of time-averaged exposure are advertised with intensity values similar to a fetal sonogram (7). According to a company website, the therapeutic effect is due to mechanical activation of integrin systems (6) which then promote the healing process. Accelerated fracture healing has also been described in a mouse model using a diagnostic ultrasound system (8).

The Mechanical Index (MI) is a measure of pressure fluctuations within the ultrasound pulse and, to some degree, also of the overall energy of the pulse. It is defined as the maximum negative (rarefactional) pressure in Megapascals (MPa) divided by the square root of the probe frequency in Megahertz (MHz). It is the required onscreen measure of acoustic intensity for standard B-mode imaging and can be observed by the operator or others in the room. Using an MI of 1 and a probe frequency of 4 MHz - reasonably typical values for obstetric ultrasound screening in the second trimester (4) - peak negative pressure would be 2 MPa. The corresponding positive side of the ultrasound wave would be similar in the other direction, giving an overall pressure difference within half of a 4 MHz cycle of 4 MPa, equivalent to being submerged or brought up from 400 metres (1300 feet or ¼ mile) underwater in 1/8 of a microsecond. Although the 1/8 microsecond in which this 400 metre movement would occur makes the analogy impossible – it would be 10 times the speed of light – the point is to emphasize that

pressure fluctuations within the ultrasound pulse are large, rapid and far from intuitively trivial.

Derating: Actually, I have oversimplified the MI above, as some allowance is now made for attenuation or weakening of the ultrasound beam as it passes through tissue by introducing a reduction factor to the value that would be measured in a water bath situation – a process called derating (9a). The official FDA definition of the MI (9b) would result in a value at a depth of 5cm, using a 3-4 MHz probe, of about one-third of that which would be measured if there were just water intervening. In fetal ultrasound there may be a considerable component of fluid (maternal bladder or amniotic fluid) in the beam path and therefore MI (and other current measures of ultrasound intensity) can be more than the derated onscreen values displayed would indicate. Historical comparisons of intensities are made difficult, as this derating process was introduced in 1985 (16); the comparisons in the first paragraph in section 1 above are probably complicated and amplified by this point. Actually, I_{SPTA} is more correctly currently represented as $I_{SPTA.3}$, with the .3 addition to the subscript indicating part of the formula for derating.

Tissue Harmonic Imaging: The peak positive pressure in the ultrasound wave can be high enough to transiently increase tissue density and thereby increase the speed of sound; corresponding maximum negative pressure will be low enough to reduce tissue density and slow down the speed of sound. Under these circumstances, higher frequency harmonics of the fundamental frequency are generated as the pulse progresses through tissue. These harmonic frequencies can provide improved imaging: Tissue Harmonic Imaging (THI). While there are circumstances where this is necessary, some manufacturers tend to use THI as part of default settings on their equipment. Using harmonic imaging means that the examiner tends to end up with higher MI values than for fundamental frequency imaging. Improved receiver sensitivity or signal processing cannot eliminate this.

Not all systems have retained the ability to provide satisfactory fetal imaging on fundamental frequency, and therefore their MI values cannot be lowered below the effective threshold for creating harmonics. As noted before, the GE Logiq 9 can usually provide satisfactory imaging of the fetus on fundamental frequency with a default MI around 0.2; this value inevitably jumps 3 to 4-fold on harmonic settings (still legal – regulatory maximum is 1.9). I believe that manufacturers should be encouraged to optimize the fundamental frequency approach, as it does not have an inherent requirement for relatively high intensities. I have no relationship with General Electric, and would be interested to learn of other units that can match the Logiq 9 with respect to providing satisfactory fetal sonography at low MI values.

4. The new mouse study: Recently an article has been published with findings of ultrasound effects on neuronal migration in fetal mice (10). The results have been largely dismissed by the ultrasound establishment, in part because the entire mouse fetus, including the brain, was exposed during the experiment and there was a threshold duration of 30 minutes for the effect to be documented. This is far longer than any

particular area of the much larger human brain would be exposed to in a standard screening second trimester examination, and there are thicker cranial bones surrounding the brain than in the fetal mouse, causing attenuation of ultrasound. Two points in response: (A) The derated MI 0.66 used in the fetal mice study was in the usual diagnostic range, but the time averaged (I_{SPTA}) levels were much lower - 0.6 mW/cm^2 allowing for attenuation; compare with the value in reference 2 of 144 mW/cm^2 (32). The low value in this experiment may be explained in part by the ultrasound probe used, which has three transducers with different frequencies mounted on a rotating head. Only one of these was selected, implying that 30 minutes of apparent exposure should be divided by three to arrive at true exposure duration - about 10 minutes. This sort of multifrequency mechanical probe arrangement is not used clinically in current-generation scanners which “sweep” electronically. (B) Screening ultrasound at 11-13 weeks for Down’s syndrome detection is increasingly promoted. Exposure of the smaller fetus at this stage of pregnancy, including the much of the, brain, may be quite lengthy: “A minimum of 20 minutes was reserved for the assessment” (11). Cranial bones are less dense at this stage.

Considerable caution must be exercised in assessing the results of this study, which needs to be replicated by others and with equipment relevant to current clinical practice. Humans are not mice. Even a somewhat skeptical commentary (12), however, was tuned to clinical concerns: “Application of the principle of as low as reasonably achievable (ALARA) in US is recommended by practice guidelines and is a responsible guide for all fetal and pediatric imaging studies. This principle holds that the goal of a study is not an image with the maximal quality achievable but one that is sufficient to make a diagnostic judgment with the least possible exposure.”

If the experimental finding is a true ultrasound effect, it is occurring at a level below heating or cavitation. Speculations include acoustic streaming, shear effects, and radiation force (10, 12).

Studies from Norway and Sweden have raised the possibility that fetal exposure to diagnostic ultrasound may have some effect on subsequent handedness. A review and critique of these has been published (1). An interesting demonstration of fetal stimulation (increased movement and heart rate) by exposure of the fetal head and ear regions to simultaneous imaging and pulsed Doppler involving a small number of subjects has been reported from the Mayo Clinic (2). The mechanism is thought to represent a response to repeated pulses impinging on the fetal ear. While diagnostic ultrasound itself uses frequencies well above the hearing range, the pulses of ultrasound energy are delivered with a repetition rate that is in the hearing range; this is a biological effect on the fetus unrelated to heating or cavitation. Like the authors of this 2001 article, I hoped to see this experiment repeated with a range of exposure conditions, and also with larger numbers of subjects. A PubMed search indicates that this has not yet happened.

The use of “low-dose” therapeutic ultrasound for fracture healing has already been noted in section 3. Specialized diagnostic ultrasound has been shown to have a therapeutic role in some stroke situations by helping thrombolytic treatment for blood clots involving the

middle cerebral artery; this made the grade to publication in the New England Journal of Medicine (13) with commentary and mechanism speculation (14). The device was different from those used in fetal scanning, there was a deplorable absence of ultrasound intensity measurements/calculations and the duration of exposure was beyond most fetal situations, but the point remains that ultrasound exposure in the diagnostic range of intensities can have demonstrable biological effects.

5. In 1992 the regulatory acoustic intensity limits were raised about 7.5-fold for general imaging, including obstetrical ultrasound, but relatively lower limits were retained for ophthalmic ultrasound. The resulting limits for current equipment complying with the output display standard are described in an FDA document: maximum permissible MI for non-ophthalmic applications of 1.9, but maximum permissible MI for ophthalmic applications of 0.23 (9c). This leads to a bizarre inconsistency – the fetal eye is allowed to be exposed to much higher levels of ultrasound than the eye following birth. Given that an MI of 1 is common in fetal ultrasound this is of some concern, especially with reference to extended exposures of the fetal eye during first trimester screening of nuchal thickness for Down's syndrome and also in entertainment/bonding ultrasound with lengthy visualization of the fetal face. The pretty 3D pictures one sees of fetal faces, including the eyes, were probably obtained with MI intensities above the regulatory limits for ophthalmic ultrasound. Health Canada has followed the FDA example in its regulations (15a). I have been unable to obtain an explanation for this inconsistency from the relevant experts at Health Canada. My cynical guess is that the problem will be quietly solved by the regulatory authorities by eliminating the specific limits for ophthalmic ultrasound.

Here is another inconsistency: Exhortations to observe the ALARA principle in obstetric ultrasound are found in many sources (e.g. 9d, 12, 15b, 17). There is, however, no regulatory requirement to display onscreen MI values if the system cannot exceed an MI of 1, and no requirement at all to display an MI value below 0.4 (17). This hampers serious attempts to minimize exposure; in this framework anyone wanting to generate exposures to the fetal eye below the ophthalmic MI limit of 0.23 may not have the onscreen information to do so with any precision. Our Toshiba Aplio does not usually display MI values below 0.4 in obstetrical mode, but some other systems do. These regulations probably derive from preoccupation with known mechanisms requiring relatively high intensities such as cavitation and hemorrhage in gas containing organs. As noted previously, both intuition and some scientific findings suggest the existence of other mechanisms.

Exposure limits are somewhat arbitrary, given the paltry amount of clinical and experimental data, but prudence would seem an important underlying principle. In view of this, a debate about removing all upper limits (16) strikes me as being of questionable social responsibility.

6. Video clips of skim milk study, using the high-frequency (at 14 MHz) high-resolution matrix probe with the Toshiba Aplio. I noted the effects originally when doing scrotal ultrasound when fluid was present around the testicle and showed marked dose-

dependant motion and turbulence, leading to this small “experiment”. The skim milk was decanted carefully from a container which had not been shaken and was allowed to stand for a couple of hours.

B-mode (standard two-dimensional) imaging: The power setting on the machine was turned down for the initial image then progressively turned up. Note increasing flow with increasing intensities, shown by MI values in the upper right side of the screen, which illustrates the known process of acoustic streaming. Also, with higher MI values there is the appearance of bright spots (echogenic foci), especially in the near field – the image looks like a snowfall. I cannot give an explanation for the echogenic foci, and have been unable to see anything visually using a glass container, dilution of the skim milk, transillumination and a magnifying glass. The main thoughts that cross my mind are some sort of transient condensation of skim milk particles, air brought out of solution and cavitation. It would be interesting for real scientists to examine this, especially with a degassed fluid sample. I have checked this experiment briefly with the corresponding probe for the GE Logiq 9 and similar effects are demonstrable at similar MI values; this provides some reassurance that output data from different companies are comparable. Requirements of the FDA document of reference 9 indicate that manufacturers’ measurements should be reasonably standardized.

Pulse-Wave (PW) Doppler used for flow measurements: Apologies for the interference signal. Increased flow is demonstrated along the thin PW path shown by the dotted line, with Bernoulli effect (?) pulling in adjacent fluid. Note that, despite the increased flow with PW Doppler, it appears that echogenic foci are not so much generated by it but are drawn in from adjacent fluid. This may be related to the lower peak pulse intensities in PW Doppler than in conventional imaging ultrasound, even though the energy intensity along the narrow beam path is greater than in the surrounding image. Note the Doppler tracing across the bottom of the image, with flow rate away from the probe of about 4cm/sec; the tracing shows “bumps” when there is an echogenic focus in the PW stream. In this case ultrasound is both causing fluid motion and measuring it.

Color Doppler (used for visual demonstration of flow): Note the increased flow rate compared to the B-mode imaging. Color Doppler, as I understand it, is generated by using pulses similar to those in imaging but with higher repetition rates along each line of the color image. Moving reflecting particles or bubbles cause phase shifts in the returning echoes; this information is used to determine flow rates which are then displayed with color. Using pulses similar to B-mode may explain why color imaging produces not only increased flow rates but may also be adding echogenic foci as well. Note that adjacent fluid is also pulled into the increased flow in color the color box. Flow rates with PW and color Doppler can be altered by changing power settings – these video clips were taken on the default (maximum) setting.

This experiment was done with a high-frequency high-resolution probe that is not used in transabdominal fetal ultrasound, but should help illustrate that acoustic intensity as measured by onscreen MI values can have ramifications with respect to whatever is being exposed. It also helps to document the particular influences of the use of PW and color

Doppler. I cannot demonstrate the effect with the lower frequency probe we use for transabdominal fetal ultrasound, but this has nowhere near the resolution although MI values are similar. Effects can be demonstrated on transvaginal ultrasound, where fluid motion produced by PW or color Doppler can help characterize pelvic cysts as being fundamentally fluid even when they have internal echoes suggesting a solid nature; I have seen motion in a cyst on transvaginal B-mode without color. This might raise some questions when the same probe is used for fetal studies. The ultrasound frequency of transvaginal probes is intermediate between high-frequency high-resolution and conventional transabdominal imaging probes.

7. Perhaps the most interesting example of unintended adverse consequences in obstetrics is the history of the use of diethylstilbestrol (DES) (18, 19). Reference 18 is a Centers for Disease Control (CDC) summary with relevant links. The drug was prescribed to prevent miscarriages; although it was shown to be ineffective in 1953 it continued to be used until the unusual complication of clear cell adenocarcinoma of the vagina in some of the daughters of women who had taken the drug in pregnancy was recognized in 1971. If this distinctive adverse effect had not occurred when, if ever, would the increase in more commonplace problems of infertility and complications of pregnancy in women who had been exposed as fetuses have been recognized? A reliable source tells me that she heard a radio interview some years ago in which it was mentioned that the first recognition of the DES-carcinoma of the vagina association was by a group of mothers of affected daughters conversing in an elevator and not by the preceding medical investigational interviews. Reference 19 has an ad from 1957 recommending one brand of DES for all pregnancies.

8. Like others involved in fetal sonography, I and the technologists who work with me are already involved in entertainment/bonding ultrasound, as patients and their families expect to be shown the fetus following the diagnostic aspects of the examination. The current question is: can extension of this established limited practice be justified for more lengthy 3D and real-time 3D (4D) fetal viewing? Prominent academics who have examined this can be quite enthusiastic (25), and there is information to suggest increased bonding and possibly improvement in undesirable maternal behaviors such as smoking and alcohol consumption. An obstetric intervention of unproven safety should be of proven benefit; we need accumulated data from careful randomized studies with extended follow-up documenting real benefits before this practice can be justified on a wider basis. Until there is such a body of scientific data confirming the benefits of 3D/4D entertainment/bonding ultrasound in unselected patients, its dissemination into commercial facilities should be strongly discouraged.

Now for the tough part. In section 2 I noted the general absence of interest in fetal ultrasound safety issues amongst relevant medical professionals. Actually, I have the feeling of having just committed a social indiscretion in a crowded elevator when I take discussions with them beyond pious platitudes into practical measures. The limited number of those interested in bioeffects has been noted elsewhere (20). I do not recall ever seeing the issue of safety as part of the program of obstetrical ultrasound courses directed at obstetricians/radiologists/sonographers which I receive by mail or e-mail. It

was not part of the October 2006 Advanced Sonography Symposium in Ob/Gyn presented by the Brigham and Women's Hospital Department of Radiology and Harvard Medical School that I attended in Boston. It is not part of the proposed program for an obstetric ultrasound course in February 2007 to be presented by the Mount Sinai Hospital and the University of Toronto.

Over the years I have had considerable correspondence with our Canadian federal regulators about fetal ultrasound safety issues. I have been impressed by their responses, but not favorably. They have not yet provided me with a promised (over a year ago) expert answer to the problem of inconsistency of fetal versus postnatal regulatory limits for eye exposure. Twenty years later I am still dismayed by the response from the Canadian Association of Radiologists to an attempt to interest them in acoustic outputs.

The following is painful to relate. In December 2005 an article was published in the Journal of Ultrasound in Medicine on "Acoustic output as measured by mechanical and thermal indices during routine obstetric ultrasound examinations" (4). To my knowledge and that of the authors, this is the first time that acoustic outputs in real-world obstetrical settings have been addressed and I felt that encouragement and commentary was warranted. I therefore submitted a letter to the editor with a couple of questions and further material largely representing a condensed version of some of the matters discussed in this website (21). I included the observation about the 1000-fold increase in I_{SPTA} intensities from around 1980 to the late 1990's described in section 1. In order to keep the letter brief and readable I did not give the numbers but did give the references. Apparently the authors did not read the references, as their response (22) disputed this assertion: "We find the comments in paragraph 4 surprising, to say the least. A 1000-fold increase in I_{SPTA} ?" They then went on to a discussion of the mere 7.5 to 15-fold increase in regulatory limits over the same timeframe. The senior author, Dr. Jacques Abramowicz, is the Chair of the Bioeffects Committee of the American Institute of Ultrasound in Medicine, which he points out in his reply. I sent him an e-mail asking him to submit a correction for publication in the JUM; I received no reply for rebuttal and have not seen any correction in print. Since their published response was framed as a question I subsequently submitted another letter to the editor with the relevant I_{SPTA} values and page citations to answer this point, but the letter was rejected for publication.

Miscellaneous Items and Musings

One regrettable consequence of this website may be increased anxiety in pregnant women who are having sonograms. I very much doubt that there are any fetal consequences; the purpose here is to encourage nuts-and-bolts prudence by the ultrasound community. Sadly, this community will not do much on its own and some gentle prodding by patients/clients is the only way that I can see to improve the situation. Is it not peculiar that medical users tend to be self-righteously critical of commercial fetal viewing facilities because of safety concerns?

Thermal Indices: Increase in tissue temperature caused by ultrasound was the earliest mechanism considered for potential biological effects. “The TI gives a relative indication of the potential for temperature increase at a specific point along the ultrasound beam.” (17). One related index - TIB - assesses the particular potential for heating adjacent to fetal bones. Reference 17 elaborates on the difficulties with using the TI and related indices. Only the MI is required to be displayed in B-mode; for Doppler and color-flow imaging the TI is supposed to be displayed as the overall energy intensity is relatively higher. TI indices may be displayed with B-mode. TI/TIB values are low for B-mode imaging, but relatively higher for color and PW Doppler. Looking at the video clips helps explain why, with markedly increased flow effects reflecting higher energy inputs.

The conventional wisdom is that one can draw considerable reassurance from the fact that B-mode ultrasound is unlikely to cause significant heating (4). I find high TI/TIB values to be rather disturbing, but do not take much reassurance from relatively low values in view of considerations surrounding mechanical effects previously outlined. I seem to recall a radiology text I once owned mentioning that a fatal whole-body dose of ionizing radiation would only raise body temperature by 0.001 C.

Ionizing radiation comparisons: Some years ago I spent time as a medical advisor (from Prince Edward Island!) to our then Atomic Energy Control Board, and retain an interest in risk evaluation of ionizing radiation. The most recent overview publication is the BEIR VII document from the (US) National Research Council (23). It notes the absence of genetic effects demonstrable in humans, including an extensive follow-up of 30,000 children of exposed atomic bomb survivors. Given findings obtained from laboratory studies, genetic risks are very low and “one would not expect to see an excess of adverse hereditary effects in a sample of about 30,000 children” (page 9). Approximate genetic risks are projected from experimental data (page 12). While attention has been shifting to radiation-induced cancers, minimizing gonadal exposure in diagnostic examinations remains important. Gonadal exposure is given a significant weighting factor in calculation of whole-body equivalent doses when studies are confined to a limited part of the body. So, with the comparatively puny data base for reassurance for fetal ultrasound follow-up, why do users tend to act as if fetal sonography is known to be harmless? The information deficiency is especially true for higher output equipment following the increase in regulatory limits in 1992. Do we have a double standard?

Detecting the risk of breast cancer induction from ten years of annual mammography as an increase over “natural” cancer risk by patient follow-up would require cohorts of tens of millions of women (24) and decades of observation. Risk estimates for mammography are derived from higher dose exposures, with extrapolation to the diagnostic range on a linear no-threshold assumption. This assumption is conservative and reasonable, but not universally accepted.

ALARA in practice: Easier said than done in terms of downward adjustment of power settings during examinations. This is especially true when using harmonic imaging; I find that our Toshiba Aplio can only create satisfactory fetal images on harmonics. With

the real-world pressure to get the optimum study in a reasonable time, constant twiddling with the power and gain settings is probably not practical. Dr. Abramowicz, in response to my question about whether there was downward adjustment of power settings in the observational study of which he was the senior author, replied that “examinations were usually performed with default settings” (4,21,22).

What to do? My answer:

Those who buy equipment for fetal ultrasound should seek out units and probes that will provide satisfactory images on the lowest default MI settings. A starting point would be to keep MI values below 0.23 to ensure that fetal eye exposure is no more than the regulatory limits following birth.

Not only will this result in minimized exposure, but it will create market pressures to bring intensities down in general. Additionally, manufacturers should be encouraged to provide an option for automated real-time adjustments within their systems so that intensities will be dropped when the signal path passes through significant amounts of non-attenuating fluid (maternal bladder, amniotic fluid) before reaching the region of interest as identified by the focal zone selected. This should be a simple exercise for programmers. I do not want to inject an adversarial element into the experiences of individual patients, but if they politely encourage the user community perhaps some progress can be made about equipment selection. I have seen no evidence to suggest that any other approach will work.

Who guards the guards? This ancient question (Quis custodiet ipsos custodes?) applies in surveillance of modern technology. Evaluation of safety issues in obstetric/fetal ultrasound should be transferred to some organization with no vested interest and not encumbered by the work patterns of government departments. There should be more representation from younger individuals – at present there are too many of us older folks with baggage. We also need a lot more research, although where the money for it would come from is uncertain. Maybe it sounds delusional, but could the Bill and Melinda Gates Foundation spare a few million for this orphan area?

Justification. The ALARA principle, as borrowed from radiation protection, has two pillars: justification and optimization. So far this site has largely addressed the optimization aspect in fetal ultrasound – minimizing exposure in an examination that is considered necessary. Some space for examining justification of fetal examinations is required. Most recently this has been brought up by the use of 3D/4D sonography for entertainment and bonding purposes, especially with independent commercial facilities offering this service - discussed in section 8.

Prudently applied, 3D ultrasound can actually shorten exposure duration compared to conventional 2D imaging by taking five 3D volumes of the fetus and then using them “offline” to generate images by slicing in desired planes (26). “It took a mean time of 1.1

minutes to obtain the 3D volumes...With the standard 2D technique, the structural surveys were done in a mean time of 13.9 minutes”.

Although screening ultrasound is now entrenched practice, the benefits may not be as dramatic as one might think. A Cochrane review of nine trials showed earlier detection of multiple pregnancies and reduced rate of induction of labor for post-term pregnancy, but no differences for substantive clinical outcomes such as perinatal mortality. When a search for fetal abnormalities was part of the examination, there were increased numbers of pregnancy terminations for fetal anomalies (27). At the time that screening ultrasound was becoming popularized I wrote an article (28) hoping to stimulate discussion and debate, but without success. I have to admit that increasing patient obesity now renders it harder to make reliable clinical assessments.

Detection of fetal anomalies can be therapeutically important, but screening can also cause anxiety and distress when “soft markers” for chromosomal abnormalities or anatomical findings of questionable significance are detected. One such situation is to encounter mild fullness of the drainage of the fetal kidneys; despite knowing that this finding is almost certainly within normal limits the examiner may decide that it is medicolegally a good idea to suggest a repeat study later in the pregnancy. This sort of problem has been elegantly summarized in the title of an article “Antenatal diagnosis of renal tract anomalies: has it increased the sum of human happiness?” (29).

An encouraging development has been prevention of neural tube defects (spina bifida etc) with folic acid before and around conception. Will there be further progress along these lines?

A disturbing consequence of the ability to identify fetal gender has been termination of female fetuses in some societies; it has been estimated that up to 10 million female fetuses have been aborted in India in the last 20 years (30). It would seem that fetal ultrasound has ended more life than it has saved. I am pro-choice with misgivings, and find this to be an illustration of Bouchier’s Columbus Principle: Any new activity will cause more trouble than you can possibly imagine.

A personal note:

I am a very busy community hospital general radiologist and have now spent way too much time and effort trying to fill a gap left by those in academic circles. What I have written is on best-efforts basis. I would like to hear from those with reasoned criticisms or with new ideas or information. A put-down is not a rebuttal. I certainly cannot match the publication and organizational credentials of those who take an “establishment” view. At the risk of being tacky, however, I obtained an undergraduate science degree at 18 and scored in the 99.9th percentile of part 3 of the US National Boards (1971), and so do not feel totally intellectually overwhelmed by them.

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References

(Some of the references were added to the text during revision, explaining their out-of-order appearance in the text; I don't have the energy to redo the whole lot, and would almost certainly make a systemic mistake that would add confusion)

NB. At the time of writing it is possible to get full-text access to the Journal of Ultrasound in Medicine for a month for \$25. Free abstracts are available anyway. For a given reference google JUM, then go to Quick Search, enter volume (number given after year of publication) and first page number.

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31. Afterthought “reference”: A data sheet I obtained around 1984 for “ABSOLUTE MAXIMUM ULTRASOUND EMISSIONS: ADR TRANSDUCERS” provides an interesting perspective on output evolution. To clarify some information extracted from this sheet given below: I am reasonably certain that the 3.5 AA was the common initial linear probe and the 13mm EFT was a mechanical sector added to the product line later. POWER refers to the total acoustic power emitted, SPTA to the (spatial-peak) time-averaged intensity and SPTP to (spatial-peak) temporal-peak intensity i.e. the pulse peak intensity. While SPTP is usually given in W/cm², on this sheet it is given in mW/cm². Values are for standard B-mode imaging. Whatever the shortcomings of the measurement methodology were at that time it was presumably consistent, making the results comparable. An approximately 300-fold increase in intensity is noted; this is before the major increase in regulatory limits. The information thus provides support for the impression that there has been a 1000-fold increase from around 1980 to the late 1990’s.

	3.5 AA	13 mm EFT
POWER (mW)	.11	23
SPTA (mW/cm ²)	.025	7.8
SPTP (mW/cm ²)	1470	456,000

32. I assume that the 1995 value for I_{SPTA} for the Acuson 128 XP in reference 2 is derated. Even if is not, and were to be reduced fourfold to allow for attenuation before reaching a human fetus, it would still be much larger than 0.6 mW/cm².