Ultrasound? Unsound

Reprinted October 1996

Published with financial support from the British Maternity Trust

ISBN 1 874413 05 3

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Introduction

In March 1993 AIMS decided to bring out a special AIMS Journal on ultrasound. Since then a number of important research papers on ultrasound have been published. As copies of the AIMS Journal (Vol 5 No 1 Spring 1993) are now sold out, AIMS decided to publish this special updated edition and that this reprint would be more accessible published in a book format. It includes updates that have appeared in later editions of the journal, and a letter which the World Health Organisation issued in December 1993.

AIMS has been writing to Ministers of Health for the last twelve years about antenatal
scanning and our growing concern. The time has come for re-assessment of risks and benefits, and for us to share our anxieties with our readers more fully, because:

1. Scans which were originally intended for woman with potential problems are now given to almost every pregnant woman and are part of routine care.

2. There is no adequate evidence that this is beneficial and huge resources are involved.

3. The number of scans per baby has increased – some members report nine or more.

4. The machines have become more powerful and there is inadequate information or control on levels of output.

5. Many scans are being carried out by staff who are poorly trained and do not understand potential risks and how to minimise them.

6. Scans are being used on more women in very early pregnancy when major organs are being formed.

7. With the development of the vaginal probe the ultrasound now gets nearer to the baby with less intervening protective tissue.

8. There is more use of Doppler ultrasound (which may carry greater risk) to study blood flow in the uterus and the baby.

9. Some clinicians and researchers are exposing woman and babies to long periods of ultrasound – an hour or more.

Ultrasound? Unsound

Medical techniques, which may be of considerable value to some, leach automatically into routine use for all without prior study of the benefits or consequences. This applies to medicine as a whole, but in the last 25 years it has been particularly the case in obstetrics. AIMS saw it happen with induction of labour, we saw it happen with augmentation , and now we see it with ultrasound.

For twenty years AIMS has been reading the literature, and drawing attention to adverse effects of obstetric care. We often knew about these from our members long before they actually appeared in medical journals and we know of others which do not get into the literature at all.

AIMS has also pointed out that many of the subjects chosen and funded for research were nowhere near the top of our list of priorities, but consumers had no effective say in where the research money went. For example, who has done a study on the effect of moving a woman in advanced labour from one room to another? It is something no farmer would do with livestock.

AIMS members have written to ministers, lobbied the media, spoken at many seminars, lectured all over the country and written in medical and nursing journals. (See Beech and Robinson).

We have never asked for antenatal ultrasound to be banned or over-restricted. All we have asked for is proper studies to evaluate its effectiveness and potential risks.

Alice Stewart, who discovered the risks of antenatal x-rays, was challenged by other doctors who implied that she was trying to take away an essential diagnostic tool. She responded that of course she was not but that most x-ray examinations of pregnant women at the time were done purely as a matter of routine (Stewart et al, 1956).

Forty years after he had pioneered the use of ultrasound in obstetrics in Glasgow, Professor Ian Donald, wrote:

"Perhaps the time has come to stand and stare and to take stock of where we are going... bearing in mind that sonar... must never lose (its) subservience to the medical art and the paramount importance of the patient... Viewed with this sense of proportion sonar comes as a commodity only, though with many uses. Out of control it can be an obsession, a tail that wags the dog... Sonar is not a new medical religion... nor an end in itself. A tool exploited for its own sake is no better than a saw given to a small boy for cutting wood, who must presently look around the house for suitable objects of furniture inviting

amputation... the possibility of hazard should be kept under constant review." (Donald I, 1980)

> ***"The casual observer might be forgiven for wondering why the medical profession is now involved in the wholesale examination of pregnant patients with machines emanating vastly different powers of an energy which is not proven to be harmless to obtain information which is not proven to be of any clinical value by operators who are not certified as competent to perform examinations." Meire HM 1987***

Whose Risks...and Whose Benefits?

When experts write about risks and benefits of various forms of screening, they often assume that their assessments will be the same as ours. Services are planned on the basis of their values, which may differ from those of many of us. Adjustments are made later – after the complaints arrive.

> ***"The potential for reducing perinatal mortality may be even greater as in six cases the parents elected not to intervene despite the identification of a potentially lethal abnormality."*** **Chitty et al, 1991**

> ***"As a pregnant woman I felt unable to protest at my treatment – the words 'safety of the fetus' only had to be breathed to make me silent."*** **Lambley J, 1985**

Even if "benefits" of antenatal scanning outweigh "risks" overall, this does not mean that for any individual woman the risk/benefit ratio is advantageous. For some families certain risks, however remote, are unacceptable and some benefits are unimportant.

There is no doubt that obstetricians have found ultrasound research stimulating. For the first time they can "see" the baby, whereas before they were more dependent on physical examination and information which the mother herself provided. Their understandable enthusiasm about potential benefits has been conveyed to woman, the media, and health authorities. What most lay people do not realise is that much of the achievement lies in identifying problems which they cannot yet successfully treat (like intra-uterine growth retardation). Even for those which are treated, there may be little or no evidence that treatment before birth is more successful than treatment afterwards.

More information does not necessarily mean improved outcome. In a study published last year from Denmark (Larsen, 1992), 1,000 high-risk woman were given screening at 29 weeks and every third week until delivery to estimate fetal weight. Obstetricians were only told the results for half the woman. This did not improve fetal outcome, there were more perinatal deaths in the revealed group (7 v 4) and that group spent more time in hospital at more cost, but to no benefit.

One example of how cost and benefit may be interpreted surfaced when women in Barnsley who were candidates for amniocentesis, were told they would only be given the test if they would agree in advance to have an abnormal fetus aborted. The "cost" of the amniocentesis to the taxpayer was only considered justifiable if a "benefit" could be obtained by savings for society of the cost of supporting a handicapped child. Some families who contacted AIMS assessed benefits differently. They wanted to know about abnormality so that they could prepare both emotionally and financially for the best possible care of a child with problems. We had to reassure some women that, if they altered their decision, no one could compel them to go through with an abortion they did not want. This was an interesting and ominous example of how health authorities can behave.

Farrant (1985) found that three- quarters of consultants required woman to agree to termination before doing an amniocentesis:

"This policy reflects the medical and administrative view that the whole purpose of pre-natal screening is the abortion of an abnormal fetus." She concludes *"Because prenatal screening has not been developed with the interests of women primarily in mind it often fails to take into account women's needs and it has also increased the potential for others to control women's reproduction."*

Better concealed and more subtle pressure may be harder to identify. Another example of how information is controlled concerns the issue of fetal sex. Before ultrasound women didn't know the sex of their baby until it was born – though even though then it was usually announced by the midwife or doctor rather than the mother seeing for herself. Announcing *"It's a boy!"* was the perk of the accoucheur. When women found out that ultrasound identified the baby's sex this was seen by many as an advantage, though there were some who did not want to know. Many were extremely angry when they were told *"we know the baby's sex but we are not going to tell you."* AIMS has received a number of indignant letters and telephone calls about this over the years. Once again, technology was used to empower professionals, not to empower women. We do not, of course, deny that there are serious ethical issues about terminations on the grounds of sex alone, but these have not been adequately explored.

There is no doubt that nowadays hard financial decisions have to be made and obstetricians have to justify money spent on equipment and staff by better outcomes, i.e. more live babies or healthier babies. In a number of reports we have seen, the detection and abortion of abnormal babies is claimed as the major economic benefit of ultrasound screening.

We do not doubt that early termination is a great benefit for many families in these circumstances and we absolutely support their right to choose what is best for them. It is they who have to live with the results of their decision. The choices they make will be affected by the information they are given, its

accuracy and how it is presented. The support which Health Authorities and Social Services provide for handicapped children may be a factor. As Green (1990) concluded: *"The concept of free choice is a dubious one at the best of times. In the case of pregnant women the social pressures…to terminate an affected pregnancy are considerable."*

> *"**But there is overwhelming evidence in the literature that ultrasound is non-mutagenic… In 20 years of use there has not been any evidence of damage to the fetus. Quite the reverse; there is good evidence that it can reduce infant mortality."***
>
> **Professor Stuart Campbell, DOCTOR, 17 May 1984**

Marteau's study has shown that counselling by obstetricians was systematically biased towards encouraging women to undergo tests and have a termination if any abnormality was detected, rather than providing women with information and the support required to make an informed choice.

The quality and style of counselling most women actually receive has not been investigated, and should be part of health authorities' quality assurance studies. Skilled, non-directive, counselling can only be done by those who are adequately trained and it is not cheap. Barbara Katz Rothman (1988) in her splendid book THE TENTATIVE PREGNANCY elaborates on the difficulties of providing truly non-directive counselling. There are innumerable references in the medical studies to patients being "counselled" by their obstetricians when abnormalities are found. It is assumed that the medical or midwifery training automatically provides the ability to counsel. None of the studies we have seen point out that true counselling requires specific training and is in fact a difficult art.

Another "benefit" of termination of abnormal pregnancies is the reduction in perinatal death rate. (The perinatal death rate means the number of babies per 1,000 births who are stillborn or die shortly after birth). A fall in this rate is often used as an indication that the heath of the population has improved. Many of the full-term babies who die had not developed normally in the womb and had no hope of survival. If those with serious problems are discovered early and the pregnancy is terminated, they no longer appear in the perinatal mortality statistics.

Abortions have, therefore, made a substantial and largely unacknowledged contribution to the fall in "perinatal" deaths. From a study produced in the Northern Region (Northern Region Survey Steering Group, 1992) we know that half the fall in perinatal mortality rate between 1982 and 1990 was due to the increase in terminations of abnormal babies. Fortunately, in that Region the incidence of malformations in miscarriages and abortions is carefully recorded. If this is not done and for some reason lethal abnormalities were to increase, provided the babies aborted, the mortality rate would not rise and might even fall – and no public concern would follow.

Unfortunately, many reports do not clearly give information on parental choices. However, if one compares information published from different centres, the likelihood of parents choosing abortion for babies with similar malformations varies substantially from one centre to another. Many such defects have a high chance of being successfully repaired with good outcomes for the child.

Early detection of abnormality is seen as an unequivocal benefit. But, unless there is a fall in the incidence of abnormality itself, there is no decline in family tragedies. An American paediatrician wrote movingly of her own shock at learning that she was carrying an abnormal baby and her grief and need to mourn (Brown J, 1989).

For many, perhaps most parents, abortion will be seen as the lesser disaster. They feel this is a better option for them than continuing a pregnancy which may lead only to a dead or dying child or one which will survive but lead a life of suffering or one which can never be fulfilling.

The cost benefits for health and social services are assumed (although they have not been adequately quantified for the many different conditions involved). This therefore releases resources which may be used for other essential forms of health care.

However, true prevention would mean the conception of healthy babies rather than children who have serious problems. One potential benefit of scanning from the consumer view which has not been realised is primary prevention. In early pregnancy parents can give a good recent history of diet, occupational and environmental exposures etc. so that effective epidemiological research could be done to identify causes; there has been surprisingly little spin-off of that kind.

If the pregnancies are terminated we know that mothers grieve and suffer as would be expected. Many, perhaps most, find this better than carrying to term an abnormal baby. But we do not know whether for all families the long-term grief is reduced by earlier rather than later, loss. A full-term birth may mean a child which is known, acknowledged, and offers the family the opportunity to care for it more completely before it dies. It needs a very experienced counsellor to explore both options and enable them to come to the right decision for them.

In a recent article in The Practitioner (Watkins D, 1989) a woman GP describes how one of her patients, in her third pregnancy, was told that the baby was anencephalic and the obstetrician advised termination. Such babies invariable die soon after birth, although half will abort spontaneously before that. The couple told their GP that they wanted to give the baby all the love and care they could provide, and the GP supported their decision. The parents obtained a picture of what an anencephalic baby would look like, so they knew what to expect. They discussed the decision with their children, who helped to choose a name and clothes for the baby.

The delivery was carried out in hospital under the care of supportive midwives and the child was stillborn. The geneticist commented:

"I was most interested to find that your patient is much more emotionally intact three months later than the majority of women I have seen who have undergone a later termination on genetic grounds... I found it most instructive to learn that the mother still found the pregnancy and birth fulfilling."

A study by Delight and Goodall (1990) showed that parents who took their dying children home rather than leaving them in hospital often had a better emotional recovery. A crucial factor however was the family making the right choice for them.

One cannot talk about risks and benefits for scanning as a whole. Risks and benefits are likely to be very different for different types of ultrasound, different stages of pregnancy, different machines, different centres, different sonographers and different conditions in pregnancy.

Women should be informed of the purpose of each type of ultrasound scan so that they can decide whether it has benefits for them. For example, a woman might wish to opt out of a dating scan in early pregnancy especially is she is sure of her dates, but opt into a later scan to detect major abnormalities which has a better chance of picking up problems when done a few weeks later. She may wish to opt out of a scan in late pregnancy which will be detecting serious malformations at a time that is too late for termination and will be also looking for a growth retarded fetus when there are no clinical indications that she has that problem. The disadvantage of opting out of this scan is that it misses the small number of babies with a treatable condition which will benefit from early treatment or surgery immediately after birth, or will do better with a caesarean delivery.

At the moment no one is putting these specific choices to woman.

Induction of labour

There are of course other reasons, apart from detecting abnormalities, for using ultrasound on pregnant women. One of those which has been studied is whether it can be used to lower the induction rates.

From 1974 consumers had been criticising induction of labour, and the publicity from this had undoubted effects (Robinson J, THE TIMES, 1974). One of the benefits obstetricians proposed for routine antenatal ultrasound was that it would enable them more accurately to calculate expected date of delivery and avoid unnecessary inductions, and inductions for supposed post-maturity. It would also, of course, avoid embarrassment to obstetricians, if the number of complaints in our files about the many babies born too soon were anything to go by.

Induction – a technique appropriate for some women – had become routine for many, with disastrous results, so a new expensive intervention – scanning – originally intended for specific women was to be used routinely to counteract it. All we asked for was intelligent clinical assessment before women were induced in the first place. It is particularly interesting to look at the effects on induction rates in four different studies.

Induction Rates

	Ultrasound Group	Control Group
London, 1982	**19.0%**	**19.6%**
Alesund, (Denmark), 1984	**1.9%**	**7.8%**
Trondheim (Norway) 1984	**6.5%**	**7.9%**
Glasgow, 1984	**31.0%**	**29.0%**

Data obtained from Thacker, 1985

It is clear here that apart from Alesund, where induction rates were already low, ultrasound examination had little or no effects. But what is noticeable is the huge variation in induction rates between different centres, which could not possible have medical justification. In essence, the induction rate depended on the culture of the obstetric unit more than anything else. It was not in essence rationally determined and therefore ultrasound, if it did make a difference, was only going to affect it marginally anyway. We suggest that anthropologists may have more to offer if we are to bring about changes than the gathering of more scientific or pseudoscientific data.

Who Uses Ultrasound?

If you have an x-ray done it is usually carried out by a radiographer who has had a three-year training, not only in the techniques, but also how to minimize exposure and fully understand the physics involved.

> ***"We still have a problem with ultrasound in the District General Hospital, where very often, even now, machines have been provided ostensibly for obstetric ultrasound which are not being properly used. They have been given to people who have not been trained."*** **Fairweather, 1983**

One of the most scandalous aspects of the uncontrolled and rapid rise in exposure of unborn babies to ultrasound, is the failure to ensure that potentially dangerous equipment was used only by those who were adequately trained and at least understood the possibility of risk. Anyone can but a scanner, and anyone can use it. Fundholding general practitioners are now buying equipment to do their own ante-natal scanning.

Scans on pregnant women are carried out by a whole variety of people, some of whom have no specific training and have learned by "sitting with Nellie." A properly trained sonographer can obtain the necessary information from the scan more quickly, thereby reducing exposure to the baby.

Scans are carried out by doctors of all grades, midwives, radiographers, and others. It requires considerable experience to be able to interpret accurately the image seen in the screen.

When the service began to develop, antenatal scanning could have been done by staff who had a variety of skills – each one of whom would acquire experience by practising on many trusting women. The likely candidates were:

RADIOGRAPHERS who have long training in imaging equipment, including the physics and potential hazards;

DOCTORS of all grades, working in obstetric departments, most of whom have less knowledge than radiographers of imaging technology but more knowledge of obstetric problems;

MIDWIVES whose training on technical matters is less that that of radiographers or doctors, but who are better qualified to look after normal pregnant women.

As the use of the technique expanded rapidly there seems to have been no concerted attempt by the Department of Health, the Royal Colleges, District Health Authorities, or anyone else, even to look at the economic and manpower implications, and insist on basic training requirements to ensure efficacy and safety of use for the most vulnerable patients of all – unborn children. The Department left the Royal Colleges to arrange things for themselves and imposed no standards.

> ***"One maternity department decided to set up a scanning facility to be working within 24 hours. After rudimentary instruction the midwives were left alone with the apparatus and a patient to familiarise themselves with the instrument panel and with the ultrasound picture."***

The radiographers had more knowledge of radiation but antenatal use of scanning had been developed by an obstetrician. Radiographers were also handicapped because they were not expected to discuss findings with patients. In 1983 the Disciplinary Committee of the Radiographers Board issued a statement saying:

"No registered radiographer should knowingly disclose to any patient... the result of any investigation." (Whitcombe and Radford, 1986).

This meant that the reassurance and feedback that women naturally wanted could not be provided by the people with the greatest skill in the use of the technology. They are now allowed to give out information provided a local protocol exists.

A number of obstetricians were particularly interested and spent a great deal of time on scanning, but standards varied greatly from one hospital to another. As

routine use spread there was more work than they could do – and in any case routine work is boring to the specialist. If women were to be given the feedback necessary to prevent the dissatisfaction which was emerging, scans would take more time. This led to the rather belated recognition of the midwife's skills in communication.

Midwives were often better than radiographers and obstetricians at supporting women before, during and after a scan, and were perceived as having more time. They allowed themselves to be recruited into this work, often with inadequate training. Midwives can be wonderfully supportive, but like many doctors, without adequate training, they are unlikely to understand the potential danger of the equipment they are using.

The sonographer who is warm and informative, rather than cold and clinical, and spends more time making sure you and your partner can see the baby's little hands and feet on screen, is also increasing exposure time.

There was also a danger to the midwives themselves. With increased reliance on technology not only can "hands on" skills atrophy, but their clients begin to think that only high-tech care is of real value. We might even suggest that the supportive skills of the true midwife were very useful in selling the technology to mothers, just as the smile on the face of the air-hostess has been used to sell British Airways.

For all professionals, longer experience can increase self- confidence but does not remedy crucial defects in base-line knowledge. The scenario described by Proud (1981) may be more common than many un-suspecting patients realise.

Antenatal scans are carried out by a wide range of people with entirely different types of background training and we do not even know what percentage of them has a Diploma in Medical Ultrasound (DMU), but we suspect that it is small and there is no legal requirement to obtain one. Nor do we know whether the requirements of the Diploma itself are really adequate to provide an acceptable level of protection. New equipment evolves rapidly and some who hold the Diploma will not have been trained in vaginal ultrasound or examined its potential risks.

> ***"There is no evidence that anyone – either the baby, mother or operator – has suffered any harm as a result of using it."***
> **Bella Magazine, April 1992**

> ***"I wouldn't work with ultrasound if I wasn't convinced of its safety."***
> **Dr Margaret McNairy**

A risk to sonographers?

We know that radiographers have to be protected against prolonged exposure to x-rays – they wear lead aprons and stand behind shields when the machine is

activated. One of the questions which has hardly been raised is whether those using ultrasound equipment may themselves have any risk.

Physiotherapists use ultrasound equipment to treat a number of conditions. A study done in Helsinki, published in 1990, (Taskinen et al, 1990) found that if the physiotherapist was pregnant, handling ultrasound equipment for at least 20 hours a week increased the risk of spontaneous abortion significantly. Also, 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.

The authors concluded:

"...the findings that high exposure to ultrasound increased the risk for late spontaneous abortion, raises the question of the potential hazards of diagnostic ultrasound commonly used during pregnancy."

AIMS Raises Some Questions

The first worrying evidence we saw was a paper from the USA by Dr Dorothy Liebeskind, Assistant Professor of Radiology at the Albert Einstein College of Medicine, USA, in RADIOLOGY in 1979, about the effects of diagnostic levels of pulsed ultrasound on the growth pattern of animal cells which persisted for many generations. This was followed by other papers which showed changes in the surfaces of cells in RADIOLOGY IN 1979 (Liebeskind et al, 1979) and *"the persistence of abnormal behaviour...in cells exposed to a single dose diagnostic ultrasound ten generations after insonation"* in the British Medical Journal of Cancer in 1982. She concluded *"If germ cells were...involved, the effects might not become apparent until the next generation."*

It has become fashionable – and convenient – to dismiss Liebeskind's work because a number of other centres were not able to replicate it. But four researchers elsewhere have done so. It was not repeated by two who did not use *pulsed* ultrasound (Bases R, 1990).

In October 1982 AIMS wrote to the then Minister of Health – Dr Gerard Vaughan – telling him of our concern about the widespread use of ultrasound before it had been evaluated. To our astonishment he replied that the Medical Research Council has considered the possibility of a trail to assess potential benefits and hazards of using ultrasound in pregnancy in 1976 and had rejected it:

"Since there was no reason to believe that the use of such techniques was likely to lead to any increase in the incidence of gross anomalies in the offspring, a trial would have been unlikely to have done more than to show whether these techniques were responsible for any subtle anomalies that might appear. However such anomalies are extremely difficult to assess and it would have been virtually impossible to distinguish between any which might have been

caused by ultrasound and those due to other environmental factors. In light of the Council decisions, the Board concluded that a trial would not lead to any firm scientific conclusion.

In the four years since then, the use of ultrasonic techniques have become so widespread that a controlled trial along the lines originally proposed would no longer be ethically possible."

It was, apparently, "ethically possible" to expose almost every unborn child in the United Kingdom to a procedure whose safety had not been evaluated – and is still not properly evaluated more than twenty years later.

> ***"Some 100 million people throughout the world are walking around having had scans before they were born, and there never has been a shred of evidence that it does any harm."***

Professor Stuart Campbell, SUNDAY TIMES, 10 June 1984

In the Medical Research Council Annual Report for 1975-6 the Cell Biology and Disorders Board stated they had:

"...decided to launch a multicentre prospective trial to assess the benefits and hazards of using ultrasound during pregnancy. Although at present there is no reason to believe that ultrasound harms the fetus it is desirable to examine this on a sound statistical basis; at the same time evidence of the positive advantages of the use of these new diagnostic procedures in pregnancy will be assessed."

If that decision had been followed though we would now have had children up to 17 years old followed up for possible long-term effects.

A pilot study was in fact carried out for several months. In 1985 the former director of the MRC Radiological Unit revealed that the Cell Board had decided not to proceed because there were doubts *"...as to whether the paediatric assessment would reach any definitive conclusions. There was no evidence from animal studies that the use of ultrasound was likely to lead to any increase in the incidence of gross anomalies, and so the primary aim of such a trial would be to show whether ultrasound in pregnancy caused any subtle anomalies in the offspring. Any assessments of such effects would be very difficult in view of the need to distinguish these effects from postnatal environmental changes. In view of these reservations about whether the trial would lead to any valid scientific conclusions the Board did not consider that in the present financial climate they could agree to a substantial investment of their resources in this trial."* (Mole, 1986)

This is one of the most extraordinary decisions by any research institution. Since we do not know when this decision was taken, we do not know what had been published by then identifying the possibility of subtle effects, but what we do find extraordinary is their apparent total misunderstanding of the purpose of a randomised clinical trial. It is

the existence of an exposed group and an unexposed control group which enables us to distinguish possible effects from postnatal environmental changes. We find it hard to believe that such an eminent group of people could not grasp the fundamental principles of epidemiological research, which as lay people we have not found it at all difficult to do ourselves, or to explain to other groups of ordinary women. The loss of the full-scale trial also meant that it was impossible adequately to estimate the efficacy of this expensive intervention.

> ***"There are 50 million people walking around today who were scanned in the womb, and there is not even laboratory evidence to indicate that it is a hazard. The main risk is of inexperience operators getting false results, but with improved training courses standards are improving daily"***

Professor Stuart Campbell, Mother and Baby, May 1990

Mole suggests that two other countries were considering doing similar studies and it was likely that if a protocol had been approved as ethical by the Research Council here they would have gone ahead also. Unfortunately, the decision to reject the study was taken without consumer organisations having an opportunity to take part.

Policy makers may too easily reject important research projects for fear that they may be politically un-acceptable. The MRC apparently believed that it would be wrong to "deprive" half the unborn babies in a trial of ultrasound – although the benefits had not been proved and the risks were unknown.

By the time chorionic villus sampling (CVS) came into being as an alternative test to amniocentesis for handicapped babies, we were more experienced, we knew that the earlier diagnosis for mothers would be seen as an improvement – but at what cost?

It was AIMS which led a group of consumer organisations to discuss the issues and support the introduction of CVS only in the context of a clinical trial, before it became widely used. As a result, the relative risks of the two alternative procedures are now better understood, and parents, as well as doctors, are able to make informed choices.

By 1980-81 the MRC Annual Report referred to ultrasound only as important in preventing disability, and they referred to ultrasound as "*as safe method of monitoring fetal development"* although in the meantime no adequate evidence of safety, or even efficacy, had been produced.

In the United States a more cautious approach was adopted. Their Department of Health and Human Services commissioned an OVERVIEW OF ULTRASOUND by Harold Stewart and Melvyn Stratmeyer, published in 1982. This extensive and comprehensive review of literature was far from reassuring. The question of subtle and/ or, long- term effects remained unanswered. Animal studies suggested the possibility of damage to the immune system, as well as

neurological and behavioural effects on rats. The authors concluded, *"the potential for acute adverse effects has not been systematically explored and the potential for delayed effects has been virtually ignored."*

In the USA a large Consensus Conference was called by the National Institutes of Health in 1984 which was attended by both experts and consumers where the whole issue was debated. This is in marked contrast with the British response to an issue of great public concern. In 1985 a private meeting was held at the Medical Research Council consisting only of invited experts with no consumers present, and the proceedings were not published.

Our postbag and phone calls form women about their ultrasound experiences increased and it was clear that some who wanted to refuse routine scans were being pressurised, and that scans were providing misleading information.

So, in 1984 we wrote, once again to the Minister of Health, now Kenneth Clarke, expressing our concerns that ultrasound examinations were being carried out routinely on pregnant women, that no records were kept of the levels of exposure and no long-term studies of long-term effects were being carries out. We said that we wanted an Office of Technological Assessment to be set up. John Patten MP replied referring us to the answer to a Parliamentary Question on 24th May saying *"as the use of ultrasound is a matter for clinical judgement, such tests should not therefore be performed as a matter of routine."* This statement corresponded with those of the World Health Organisation and the USA Food and Drug Administration, both of whom had rejected routine screening.

> ***"The fact that money was available to buy machinery and set up an untested procedure but not available to set up the randomised controlled trial that the MRC had requested demonstrated that such decisions were made not on the basis of an objective analysis bit in response to various lobbies. It should be ensured that the lobby of women wanting improvements in maternity care was stronger than those of the manufacturers of machines or of the medical establishment."***

Female obstetrician speaking at the Royal College of Medicine's Conference on Ultrasound, London, 1986.

It seems as if, at last, we were having an effect because the Minister told us that the Chief Scientist of the Department of Health had asked the MRC to consider convening a meeting of experts to consider the benefits and possible risks of obstetric ultrasound. In March 1985 a top-level meeting was held at the MRC head office. It was chaired by Professor R E Coupland, chairman of the MRC Non-Ionising Radiation Committee, and it was attended 37 top experts – including 18 professors, their specialties included epidemiology, paediatrics, cell mutation, radiation science, neuro-science, pathology, physics and obstetrics. It was some years before we obtained a copy of the report of that meeting and learned what had happened.

In 1985 we were pressing the Department again. We told the Minister of our continued concern that there was still no evidence that routine ultrasound was medically effective, cost effective, and did not cause long-term damage. By now the RCOG had published their report on ROUTINE ULTRASOUND EXAMINATION IN PREGNANCY and AIMS prepared a detailed critique of it (copies available from AIMS). We said it was unscientific in its approach and it had been very selective in the research papers which were quoted. Our criticisms were validated by the British Journal of Obstetrics and Gynaecology (May1985) which said that *"the scientific analysis did not show rigor which normally would be expected of its scientific committee."* When our criticisms were reported in the NEW SCIENTIST (17th May 1984) Professor Stuart Campbell dismissed them saying *"they show how desperate they are to cause trouble."*

In April that year Beverley Beech co-chaired a conference at the Royal Society of Medicine on Ultrasonography at which Nancy Stewart, an AIMS' member, presented a paper on "Women's views of ultrasonography in obstetrics" and quoted actual experiences of women including that of one woman who was told "*we can't find the baby's head you will have to come back next week."* The woman spent a week worrying that her baby had not head when in fact the ultrasonographer merely meant that she could not find the head on the screen. Nancy expressed the anxiety of many of us the danger that excessive reliance on ultrasound could cause a further deterioration in the sensitive use of hearts and hands – the tools of traditional midwifery skills. There was also the fear that medical expertise was being fostered at the expense of the mother's expertise *"what effect may there be on a woman's confidence in the messages of her own perceptions and intuitive awareness if her sense of pregnancy and her baby depend on sophisticated medical technology?"* (Stewart N).

The following year (1986) we approached yet another Minister of Health, Barney Hayho, and again expressed our concern at the widespread and unevaluated use of ultrasound and pointed out that a Government greatly concerned with saving money had overlooked the fact that the medical profession was spending large amounts on a technique which had yet to be proved safe or cost effective.

In 1991 AIMS gave both written and oral evidence to the House of Commons Select Committee on Health for their investigation of maternity care, Three pages of our submission, CHILDBIRTH CARE – USERS' VIEWS, expressed our anxieties about ultrasound and quoted published research which supported our views.

The NHS has continued to have serious financial problems, yet the spread of routine ultrasound, the benefit of which has never been established, has continued unabated.

Dublin Guinea Pigs?

> **The Republic of Ireland has a population with a modern system of health care which has not yet developed widespread use of antenatal**

ultrasound. This was suggested as a good area to carry out a randomised control trial with long-term follow-up because women did not normally receive screening and therefore would not be "deprived" in a control group. It is, of course, always difficult to organise such large scale studies which involve the co-operation of many different clinicians. To our concern the idea of a randomised controlled trial of ultrasound in Ireland, with informed consent, was strongly opposed by the former AIMS' group in Dublin, on the grounds that they did not want their women experimenting on.

We did not want Irish women to join the rest of us in becoming part of one huge uncontrolled experiment from which we shall never get adequate information for mothers to give truly informed consent.

In a randomised trial half of the patients – the control group – do not get the "benefits" (if any) of the new treatment, but they have no risks of adverse effects (if any), and they are required to give informed consent – which is more than scanned women in the UK are doing at the moment.

We appreciate that there are different points of view on such an important topic, but we do hope that women in Ireland will discuss the issues. AIMS does have an active group in Cork. The contact is Maire O'Regan, 18 Firgrove Drive, Bishopstown, Cork who would be glad to hear from any women in Ireland.

Dyslexic – A Possible Side Effect

When Dr Doreen Liebeskind was asked what problems should be looked for in human studies. She suggested "*Subtle ones. I'd look for possible behavioural changes – in reflexes, IQ, attention span." (Bolsen B). Professor Arthur Bloom, a paediatrician, asked "Why would you want to look for dyslexia?"*

The first evidence we saw of possible damage to humans came in 1984 when American obstetricians published a follow-up study of children aged 7 to 12 years, born in three different hospitals in Florida and Denver, who had been exposed to ultrasound in the womb (Stark at al, 1984). Combined with a control group of children who had not been exposed they were more likely to have dyslexia and to have been admitted to hospital during their childhood, but no other differences were found. However, this study certainly did not prove that ultrasound caused dyslexia. It was not a randomised study and there was insufficient information as to the stage of pregnancy at which ultrasound was used, and how often, and for what reason. There was another problem in that it could only look at children who had been born alive and who had survived until at least the age of seven. Nevertheless, the increase in dyslexia had shown up separately at three different hospitals and this at least raises the possibility of subtle damage.

It is interesting that the summary of the findings from the study, which is printed at the beginning of the paper, makes no mention of the statistically significant increase in dyslexia in the exposed group. Most busy doctors only have time to scan the summaries in medical journals. At an NCT conference held shortly after this paper was published an obstetrician was quoting this study as totally reassuring. He was surprised when Beverley Beech and Jean Robinson, who were in the audience challenged him and mentioned the dyslexia fears – of which he was completely unaware. This was not the first time that we have found adverse effects not mentioned in summaries but only tucked way in the small print.

A more reassuring study finally emerged in THE LANCET (Salvensen et al, 1992). Doctors in Norway were able to look at over 2,000 children aged 8 to 9 years who had been studied at birth because their mothers had been randomly allocated to have routine screening when 16 to 22 weeks pregnant, whereas most of a control group had not. There was no decrease in reading and writing skills or other problems in the exposed children. This study is reassuring but does not prove that ultrasound exposure cannot cause dyslexia. The authors pointed out that the scanners used in those trials gave lower intensity of exposure than most scanners nowadays. Secondly, although most of the children would have had two or more ultrasound exposures the total numbers are not given and many pregnant woman nowadays are getting four or more – some women who contact us have reported having eight or more. Thirdly, this was "real time" ultrasound which, as the author points out, is likely to be safer than pulsed Doppler ultrasound which has higher intensity levels.

How Accurate is Screening?

True consent for any procedure means that you understand and accept possible risks. How many women when they have a scan are told that an abnormality may be diagnosed – but the diagnosis could be wrong – even if it is confirmed by a second scan?

One of the reasons given for an early scan for all women is to date the pregnancy as accurately as possible. One of the main advantages claimed for this by obstetricians, is that there will not then be so many inductions of babies which are thought to be post-term and turn out to be nothing of the kind. They do not mention nowadays the lack of scientific justification for mass intervention in the first place. So widespread ultrasound was to be used to correct a problem which they themselves had created.

No test is 100% accurate. Ultrasound dating can be wrong. We have ample evidence that it happens, but there is no adequate report in the literature about how often it happens. The main problem is that if there is a clash between the date the pregnancy started given by a woman who is absolutely certain and the ultrasound estimate, it is the technology that the obstetrician believes. We know from many indignant letters that seriously overdue babies were not induced when they should have been and that inductions were carried out on supposedly "post-mature babies" which turned out to be premature.

At the Royal Society of Medicine 'Forum on Ultrasound in Obstetrics' in 1985, a midwife in the audience suggested that claims made for ultrasound's ability to diagnose growth retardation overlooked the fact that babies grow at different rates and in spurts. She said a baby suspected of growing too slowly one week might have caught up by next and this would be observed if the woman was being seen regularly by the same professional, she also said that insufficient attention was given to eliciting diet and lifestyle from mothers whose babies did not appear to be growing at the expected rate, and attention given to these simple matters might prevent the need for technological intervention (Anon, 1986b).

> ***"Before the development of prenatal testing for fetal abnormality the fetus was assumed to be healthy, unless there was evidence to the contrary. The presence of prenatal testing and monitoring shifts the balance towards having to prove the health or normality of a fetus."***
> **Marteau TM, 1991**

Charts showing the rates the fetus is "supposed" to grow may not be applicable to all women and particularly to all ethnic groups. One woman obstetrician has expressed doubt as to whether the standard charts were applicable to the Bengali women for whom she cared. But we simply do not have information on this.

Another hazard of an early scan is that the placenta is located and at that time many of them will appear to be low – lying and the mother will be classified as having a higher risk of placenta praevia – that is the placenta may be growing over the birth outlet leading to haemorrhage and possible death of the baby when labour begins. The problem is that almost all women who are considered to be at risk at this stage will not in fact have the problem at all. In a study in Finland (Saari-Kemppainen et al, 1990) 4,000 women who were scanned at 16-20 weeks, about 250 were diagnosed as "placenta praevia". When it came to delivery there were only 4 placenta praevias – and one of those had not been diagnosed. So, 246 women had presumably been worried unnecessarily and thought they might need a caesarean section.

This misleading diagnosis of course requires the baby to be exposed to one or more scans in later pregnancy to see if the placenta is still badly placed now the uterus has expanded.

Only one per 1,000 women in the Finnish study had true placenta praevia compared with the 64 per 1,000 in which it was thought to exist from the early scan. Among the 4,000 women in the unscreened control group there were also 4 cases of placenta praevia, they also had caesarean sections and none of their babies died. In fact no studies exist which demonstrate that early detection of placenta praevia by ultrasound improves the outcome for mother and baby.

As with all screening procedures, identification of a potential problem is one thing – proof of benefit as a result is something else. This must be borne in mind when resources are being allocated and women and babies are submitted to potential but unknown risks. AIMS wants these questions to be studied properly at the beginning before enthusiastic practitioners rush to adopt the latest exciting procedure and start selling it to their patients.

There are a number of damaging possibilities following a "false positive" result. First of all, the pregnancy is naturally going to be more stressful and other studies have shown that under stress women who drink and smoke are more likely to increase their consumption.

It may be that the alleged abnormality is not too serious but the expectant parents will experience a much more stressful pregnancy and it could affect the mother's feelings for the baby. An important long-term follow-up study in Sweden (Fyro and Bodegard, 1988) has shown that when tests had shown a thyroid abnormality in some newborn babies and the results turned out to be wrong – the babies were in fact perfectly normal- a small percentage of the families had abnormal relationships with the child years later.

In a study of routine scanning at Ascot described by Luck (1992) records were kept of the effect of anomalies on the attitude of parents and the extended family. She points out that the news of a minor anomaly can alter the parental outlook and effect prenatal bonding.

A further possibility is that the mother will undergo treatment or more investigations, or both, during pregnancy, and that the baby will have extra, possible hazardous, treatments after birth.

Finally, of course, the mother could choose abortion. It is clear from the literature that terminations are carried out because of a false ultrasound diagnosis of abnormality but we know that they are greatly underreported and in published studies researchers are remarkably coy about reporting figures and details. When we give talks to audiences of midwives, we find it is a problem that many of them are familiar with. They are greatly concerned about the ethical difficulties when they know that patients have not been told.

Accuracy and interpretation of scans varies enormously from centre to centre and also with the experience and training of the operator. There is a huge variation in the degree of training and the quality of training of staff carrying out the screening, and there are no required standards.

False negatives also occur – that is the baby is reported normal from the scan but in fact has a major abnormality which should have been picked up. These are in fact more common than false positives. The chances of this happening also varies from place to place, and parents are falsely reassured. We do not know if the effect of having a handicapped baby after being reasurred by scans and other tests is any greater or different from the impact before those tests existed and a more fatalistic attitude may have been more common. One thing

is clear, for true consent mothers should be told "the results are not 100% accurate."

Even if the results are right in that there is a problem with the baby, it is clear from the literature it may be different from the one which is diagnosed – more serious or perhaps less so, and even if the diagnosis is right they may not be able to tell you the degree of health problems your baby will have and what the results mean in the degree of handicap or illness to be expected.

Two Oxford paediatric surgeons described a series of cases where problems had arisen from antenatal diagnoses. One baby was diagnosed as having an abdominal wall defect and was delivered by caesarean section. The mother rejected the baby for three months, but subsequently accepted it. Another child had unnecessary surgery because a cyst in the abdomen was diagnosed; it would have almost certainly have resolved but surgery was carried out to relieve the mother's anxiety, without the scan, no one would have known the cyst existed. The authors comment on the difficulties of mothers who still have months of pregnancy remaining faced with the knowledge that they are carrying an abnormal baby. *"Enormous feelings of fear, guilt and inadequacy develop, and reassurance that the eventual outcome should be satisfactory may be to no avail."* (Griffiths and Gough, 1985)

An illustration of potential problems came from a study done in Luton (Chitty et al, 1991) where routine screening identified 130 abnormal babies. However, 2 babies were diagnosed as having serious problems and mothers were referred for a second opinion. The second opinion confirmed that both babies had an abnormality. Fortunately, neither mother chose abortion because both babies were in fact normal at birth. The authors conclude that *"high levels of anxiety can be caused not only with false positive diagnosis but also after identifying minor (possibly normal) variants."*

The following year a report form Heatherwood Hospital, Ascot, (Luck CA, 1992) described a 4-year study. Scans were done by very experienced radiographers all of whom had a Diploma in Medical Ultrasound which suggests that the quality of service here is likely to be above that of most district general hospitals. There were two false positives in 4 years but both occurred in the first six-months of the programme.

Another study in South Wales (Roberts et al, 1983) looked at neural tube defects. In the first phase out of 18 fetuses thought to have open spina bifida, only 6 had the condition. By the time a second study was done detection rates had improved – 20 babies were thought to have open spina bifida and only 4 diagnoses were wrong. The authors also referred to the social, personal and emotional costs of false positive diagnoses but they do not say whether any of the babies in the study were aborted.

Yet another example of problems with scanning was highlighted by the Helsinki trial (Saari-Kemppainen et al, 1990). At one hospital only a third of the malformed babies were detected (36%) and at another over three-quarters

(76.9%). So, at the first hospital all the women who had ultrasound exposure got only a third of the "benefit" obtained by the women at the second hospital. This is an example of how risk/benefit ratios can differ.

Thirty abnormal babies were suspected – but ten of them were normal – so a third of the women had been worried unnecessarily. Eleven women chose abortion, but we are not told how accurate the diagnosis of abnormality in those babies was.

It is true that perinatal mortality was lower in the screened group. This was largely because of terminations. The perinatal mortality statistics, therefore, look better. But this does not mean that more babies lives have been saved; babies died anyway – some of them just died sooner in the screened group. This study is often quoted as showing that routine scanning is beneficial and that it actually reduces perinatal mortality rate.

One of the most important studies has been going on in the Northern Region Health Authority where, since 1984, confidential information has been collected on all babies born with serious abnormalities or on miscarriages or abortions. Reports are made as soon as a suspected abnormality is diagnosed in pregnancy so that the accuracy of the diagnosis can be checked when the baby is born. This is a well organised continuous survey in which all the obstetricians and paediatricians have co-operated, greatly to their credit.

From the latest report last year (Northern Regional Survey Steering Group, 1992) we can see that between 1982 and 1990 the perinatal mortality in the region fell from 11.7 to 8.1 per 1,000. At the beginning nearly a quarter of perinatal deaths (23%) were due to congenital malformation by 1982 it was only 14%. So nearly half the fall in perinatal mortality was due to the increase in terminations. There had been no decline in the proportion of babies who developed fatal abnormalities.

These researchers also reported a large variation in the success rate with which different maternity units identified problems from ultrasound. The variations did not depend on the size of the unit, the type of the equipment, or the amount of ultrasound work they did. The authors commented that if all the units had been as good as the best 100 more babies with serious problems would have been identified every year.

If mothers are having ultrasound scans, might informed consent not include the success rate of the unit she is attending? If there are risks, then clearly the risk/benefit ratio varies greatly from hospital to hospital and we look forward to other health authorities taking to this system.

Finally, the authors report that for a number of serious conditions more than 10% of antenatal diagnoses were completely wrong. As in most other published studies, however, no information is given on number of babies aborted which turned out to be normal. However, in another report on the survey (Atkins and Hey, 1991) somewhat more detail was given. Two pregnancies were terminated

because it was thought that the kidneys were undeveloped, but in fact the autopsy showed no problems. With neural tube defects, however, all the aborted babies in fact did have the condition. 55 babies were diagnosed before birth for having "cystic hygroma", 33 pregnancies were terminated. Of the remaining children only two survived, but three of the 33 aborted babies were found to be perfectly normal at autopsy and the only defect in one of the others was a cleft lip. The authors say *"Caution is necessary in recommending termination of pregnancy on the basis of single ultrasound examination even when the scan appearance is typical…in some cases such cases are only a transient feature. It is possible that some screening programmes currently do more harm that good antenatal diagnosis does not always increase a child's chance of survival."* There is also the possibility that abortions are done in cases where the outlook is good. For example, three-quarters of children with abdominal wall defects survived but a few parents had terminated the pregnancy. We do not know in these cases what information or support they had been given or whether uncertainty itself about outcome proved an intolerable burden.

One of the latest studies to be published appears in ARCHIVES OF DISEASE IN CHILDHOOD (Scott et al, 1993). This looked particularly at kidney and bladder problems diagnosed in unborn children, 421 were suspected of having hydronephrosis (kidneys enlarged with water because drainage is blocked), but in more than half the babies the diagnosis was wrong and the baby was normal. 421 cases were diagnosed but 233 of the babies were found to be unaffected.

Other conditions had a greater chance of being correctly diagnosed but there were still a number of false positives. For example, 33 babies were thought to have abnormal development of both kidneys but 9 of those did not have the condition. A third of the 179 deaths reported in this study were caused by termination of pregnancy, but, the authors do not say whether all those babies were correctly diagnosed. What is clear is that almost all of them did have autopsies, although the results are not given. It is also clear from this study that scanning at 16 weeks or less is almost useless in detecting the fetus with urological problems because at that early stage almost three-quarters are missed. Some abnormalities are unlikely to be detected until late pregnancy.

We should make it clear that we are not criticising faulty diagnosis as such, but we do think that statistics should be presented honestly. The babies who died unnecessarily should in fact be included in the perinatal mortality statistics, because that is where the information on their deaths truly belongs, and parents should be honestly informed about false positive risks as well as false negative. When we calculate the price for screening programmes those children's deaths should also be remembered, and we are profoundly grateful to the Northern Region for the provision of this valuable information.

In 1990 a midwife approached AIMS for advice on an ethical dilemma, she had booked a young woman who mentioned her worries about this second pregnancy – the first baby had been aborted due to hydrocephalus. On perusal

of the previous case notes the midwife found that the post mortem report revealed no abnormality. The mother was unaware of this.

AIMS' advice was that the mother should be told, and when she was her reaction was positive. She felt that errors in judgement do occur, it was a tragedy, but now she felt relieved that she was not carrying a damaged baby, and would now be able to face the future and the impending birth in a positive frame of mind.

Post Mortem

Good post mortem studies are essential for babies who miscarry or are aborted because of serious abnormality, as well as babies who are stillborn and who die shortly after birth. Such studies must be performed by experts and can provide information on the accuracy of the diagnosis, extra problems which may not have been suspected beforehand for the doctors, but also information for parents to understand and come to terms with what has happened and also enable them to think about future pregnancies. In some cases parents can contribute information about exposures to drugs or chemicals or illness which may have been related to the defect in the child.

If an adequate report is to be done on the baby aborted for abnormality, the pathologist and other departments should be informed before the termination is carried out, and any mother who has to have a pregnancy terminated in this way may like to ask whether these facilities are available and if this information is important to them they may want to have the abortion done elsewhere. The fetus and the placenta have to be taken as quickly as possible to the laboratory, they should be placed in a sterile, dry, container. Tissue fixatives should not be used because it prevents some laboratory studies which may be important from being done (Keeling, 1983).

The parents, of course, have a right to see the full results of the post mortem, although in our experience this is seldom offered and sometimes refused. Parents should make it clear, if necessary in writing, that they only consent to a post mortem providing they will be given access to the results.

What Went on at the MRC

Extracts from a report discussing the risks and benefits of obstetric ultrasound

Following instructions from Kenneth Clarke, when Minister of Health, the Chief Scientist at the Department asked the MRC to convene a meeting of experts, to consider the benefits and risks of obstetric ultrasound. This was held in March 1985, and chaired by Professor Coupland.

Dr R C Preston, of the National Physical Laboratory (NPL), pointed out that there was inadequate information on the power output on ultrasound equipment used in obstetrics. Although it was known that different equipment varied widely, manufacturers were not required to supply such information. The NPL had found that maximum output levels in machinery they tested was higher than that given by the other published surveys. In fact they had to re-assess their measuring system in order to cope with the high pressure levels from one particular scanner. The figures published by the RCOG in their report were lower than those found by the NPL by a factor of 40 and 500. It is therefore quite clear that published data did not give a true indication of potential risk to the public. He pointed out that the acoustic outputs of Doppler devices were inevitable higher than imaging systems and duplex systems use both Doppler and real-time imaging at the same time which meant that exposure will be even higher.

Dr J Bang form Copenhagen said that the current estimates of the ultrasound exposure of the fetus needed to be reviewed as the amount of power lost as ultrasound passed through intervening tissues was less than had been thought.

Professor R L Gardner said that animal experiments indicated that the central nervous system would be most at risk of damage; the effects were likely to be subtle.

It was agreed that one possible topic for investigation was possible damage to the inner ear, particularly at later stages of pregnancy.

Dr Liebeskind's work was referred to but dismissed. However, only her first paper (published in SCIENCE) was mentioned – not her latest work published in the BRISTISH JOURNAL of CANCER (Liebeskind D et al., 1982), and the conclusion at the meeting was *"it was agreed that it would be inappropriate to attach any significance to the results reported."*

Concern was expressed about exposure to ultrasound in the first eight weeks of pregnancy and high risk patents in this group were those who had a suspected ectopic pregnancy (i.e. outside the uterus, usually in the fallopian tubes), those undergoing in-vitro fertilisation and those who were having chorion villus sampling.

The Chairman concluded *"the data on the possible mutagenic, carcinogenic and structural effects was reassuring: there was very little evidence of any adverse effects and the studies which indicated risks were open to serious criticism. The genetic studies had however been carried out at temporal peak output levels lower than those associated with some modern equipment: there was therefore a need for some basic biological studies to determine whether the higher levels of exposure were associated with genetic or cellular damage."*

We find it astonishing that the Committee found the already published data reassuring. We can only conclude that they were not adequately informed of studies which had been published up to that time.

The Committee were reassured because there was no unequivocal evidence of genetic hazard, but there was evidence, to put it mildly, of the possibility of hazard. They recognised the need for further studies. The Committee did say that everyone giving scans should be well trained and training programmes should be set up. There was, however, no recommendation that untrained personnel should not be allowed to do scans.

They concluded:
"Although at present there is no reason to believe that ultrasound harms the fetus, it is desirable to examine this on a sound statistical basis; at the same time evidence of the positive advantages of the use of these new diagnostic procedures in pregnancy will be assessed."

A small working party was to be set up to devise appropriate studies and to advise the Council. There have been no reference to its work in subsequent MRC reports.

Is it safe? Is it necessary? Two very important questions to ask ourselves and the medical establishment.

How Much Ultrasound is Your Baby Getting?

Calculating the "dose" of ultrasound given out by any one type of machine in different types of examination is extremely complicated, but machine output figures are only part of the story. The exposure to the baby is based on estimates and there are no exact data for exposure. American women have known this for many years. At a Consensus Conference run by the National Institutes of Health in 1984 the problem was discussed. In order to calculate outputs, manufacturers of ultrasound equipment must make assumptions about peaks and averages and the way operators use scanning devices. The output information cannot really tell us about the dose absorbed by the mother or baby. The beam is reflected or scattered by some tissues, and absorbed at differing rates by others, depending upon their characteristics, thickness, hoe well they conduct ultrasound energy, and the character and quality of other structures that the beam has to travel through.

We suggest that every woman keeps a record of the ultrasound exposure her baby receives before and after birth. When a midwife listens to the fetal heart with a Sonicaid or similar hand-held device, this has the advantage that you too can hear the fetal heart – but this technology has a price. Many women do not realise that their baby is being exposed to Doppler ultrasound – albeit a small dose. The baby's heart can be heard perfectly well with an old-fashioned ear-trumpet, called a Pinard stethoscope. As midwives use more technology their listening skills may suffer.

Then, of course, there is the scan. The latest approach is to use a probe in the vagina which gets even nearer to the baby, so the ultrasound does not go

through the mother's tummy and so much fluid around the baby, so the baby may be less protected, no one knows whether this is less safe than abdominal ultrasound, but a number of experts are voicing concern.

> ***"The baby was moving around so much that the technician couldn't take any measurements...so another appointment was made... another hour of lying down...there were loads of technicians, about five, all eager to try out their new baby of a machine on my new baby."***
> **Letter to AIMS, 1992**

> ***"Power outputs of machines have risen steadily over the past 15 years. The output at the transducer face of some modern equipment in imaging mode is some hundred times greater than transducers in common use 20 years ago. As power outputs increase there is a proportionate increase in risk."***
> **Blauclak, 1992**

If a mother needs amniocentesis or chorionic villus sampling, ultrasound is used to locate the baby and the placenta, so more exposure is involved.

Electronic fetal monitoring, which is now used routinely, at least for the first half-hour of hospital labours, again uses ultrasound and many women do not realise this. The information collected from the monitoring equipment, which is placed on the mother's tummy is collected by the use of ultrasound energy. The transducer is placed where the baby's heart can be heard. The use of these machines over a long period of time (sometimes over several hours) exposes both baby and mother to ultrasound energy.

No benefit had been demonstrated to babies from the use of routine electronic monitoring as compared with intermittent listening to the baby's heart with an ear trumpet.

There are different kinds of ultrasound – used for different purposes. Doppler is considered by a number of experts to be more likely to carry a risk. With "duplex" examinations, the baby is exposed to two kinds of ultrasound at the same time, both continuous wave Doppler and pulsed wave Doppler.

After the baby is born ultrasound examination may be used to identify problems. For example, babies in intensive care often have brain scans – sometimes a considerable number of them. Any doctor suggesting such a procedure should explain to the parents why s/he thinks it is necessary so that valid consent can be obtained. Parents should not allow their babies to have ultrasound examinations unless they have been told why and agree it is necessary.

Some ultrasound examinations are carried out on normal newly-born babies for research purposes. If parents are asked to consent to these they should first find out whether the study has been approved by the local district Research

Ethics Committee, and ask for information in writing about the study before they consent.

Women are usually reassured by being told that the dose from any one procedure is tiny. What we do not know is whether repeated exposures increase risk of harm (Baker and Dalrymple, 1978). Therefore, it might be wise to avoid unnecessary exposure.

Jumping Babies

> ***"...it had both hands up to its ears in the fist fashion...we also got the profile of its hands over its ears."***
> **A mother describes her baby**
>
> ***"When it came to give birth, I suffered a 14 hour labour and then it was found that the baby was getting very distressed and I was not dilating, and therefore had to have an emergency caesarean section...he was distressed because he had a very long cord and he was "trussed up" like a chicken – it was wrapped round his legs, arms and neck."***

For years our members have been telling us that sometimes their babies "jump about" when they are given ultrasound. The movements are not like the normal movements that a mother is used to feeling. No one knows the reason for this.

Many women have had their questions dismissed, and when one women said *"she (the baby) is protesting at being woken"* the technician replied, *"the baby is unable to hear the scan."*

Another mother reported: *"The gynaecologist got very frustrated because he could not get a clear picture because she would not sit still for more than a few seconds. At first she would move to a totally different part of my womb, then, when she was bigger she turned round and round (helped by the fact there was excess amniotic fluid around her)."*

Yet another mother reported that *"she (the baby) was extremely active until I wanted a picture of her, then she put her head as low as possible in my pelvis, where the ultrasound seemed to have difficulty in getting a picture."*

The National Childbirth Trust (Lambley J, 1985) had similar information from its members. One woman wrote: *"The baby jumped away every time the ultrasound probe was positioned"* and another wrote *"The scan upset the baby...it moved and thrashed violently the whole time and also caused the onset of birth three hours later."*

As early as 1975 a study was published in the BRITISH MEDICAL JOURNAL (David H et al, 1975) showing increased movement. The women did not know whether the ultrasound was turned on or not, but where was a marked increase in the baby's movements during the time they were subjected to ultrasound.

The authors commented *"Through we do not know why the fetus responds to Doppler ultrasound it is a procedure without known risk."* That was written eighteen years ago, but no one since then has expressed concern that the fetus might be moving around in response to something unpleasant happening.

After experiencing "jumping", a number of mothers have asked us whether ultrasound increased the chances of some babies being born with the cord around their necks. What was the incidence before the widespread use of ultrasound?

For many babies the condition causes no problems, but for some it can result in a caesarean.

Unfortunately, as practically everyone is exposed to ultrasound in pregnancy, no one can assume that such problems have been caused by ultrasound. Had ultrasound been subjected to a large enough randomised trial at the beginning we might now have answers to these questions, and thirty years of data to examine.

Is There a Miscarriage Risk?

Follow-up studies of children who were or were not exposed to ultrasound in the womb, can, of course, only look at the children who survived. One of the questions we were asking from the beginning, which seems to have had curiously little attention from researchers, is whether the pregnancy is less likely to come to term.

> ***"Follow-up of the millions of babies, now adults, exposed to ultrasound before birth 20-30 years ago has made it possible to give the reassurance that this procedure is as close to being totally safe as any medical examination."***
>
> **Dr Tony Smith, 1992**

Two studies published in 1990 suggested the possibility of increased risk of premature labour. In Michigan, obstetricians were studying 57 women at risk of giving birth prematurely. Half of them were given a weekly ultrasound examination and the rest had pelvic examinations instead (Lorenz, et al. 1990). Preterm labour was more than doubled in the ultrasound group, 52% - compares with 25% in the controls. Although the numbers were small the difference was unlikely to have emerged by chance.

In the discussion which followed presentation of the paper one doctor suggested that the full bladder necessary for this type of examination could have had an irritant effect. So if there was a causal effect here we do not know if it was the ultrasound itself or the pressure of the full bladder. In any event more babies were lost.

The results of a large trial from Helsinki were published in THE LANCET in the same year (Saari-Kemppainen et al, 1990) over 9,000 women were randomly

divided into groups which did or did not have routine early ultrasound scans. (This study is discussed more fully on page 20). One of the things we noticed, which we pointed out in a letter to THE LANCET (Beech & Robinson, 1990) was that there were 20 miscarriages after 16 to 20 weeks in the screened group and none in the controls. The authors do not comment on this surprising difference.

Home monitors

The idea of having a portable little device where you could monitor what was happening to the uterus in your own home and go for help quickly if pre-term labour was threatening sounds wonderful. There has been considerable publicity about these machines in women's magazines. One study in the States, suggested that there use did reduce pre-term deliveries (Morrison et al, 1987). A more recent study in France, however, did not find any benefit (Blondel et al,1992). 168 women were randomly allocated either to have the activity of the uterus monitored by a machine at home every day, with weekly visits at home by midwives employed by the machine's manufacture (Tokos), or to have home visits by community midwives. The monitored group were telephoned every day and transmitted the data down the telephone. The monitor was used for an hour every morning and again in the evening. Six of the monitored babies died compared with three controls, 32 of the monitored babies arrived before 37 weeks compared with 22 of the controls and the authors concluded that home uterine activity monitoring was not shown to be of benefit, compared with home visits by midwives.

What it does show is that benefits to improving pregnancy outcome have not been proved and possible adverse effects cannot be dismissed.

Apgar scores

The Apgar score, devised by Dr Virginia Apgar, is a means of assessing the condition of the baby at birth. It is given a mark from 1 to 10 (one is the lowest, and ten would be for a baby in good condition). The baby is assessed at one and five minutes after the birth.

In four randomised clinical trials to assess the efficacy of routine ultrasound screening, every single one reported lower Apgar scores in the ultrasound group than in the controls, although the differences were not statistically significant (Thacker, 1985).

A growing area of study has been Doppler ultrasound looking at blood supply to the uterus. In one such randomised study reported from Western Australia (Newnham et al, 1992) of over 500 women with pregnancy problems the babies who had ultrasound were more likely to have a low Apgar score and a greater chance of fetal distress after induction of labour, although other studies have not found this result. (We do applaud the fact that when continuous wave Doppler systems first became available, doctors in Western Australia agreed not to use them until their value had been shown in properly designed research).

Doppler ultrasound

Doppler ultrasound is being used more often on pregnant women and babies because it can provide information on blood flow in the arteries. In 1992 a team at Queen Charlotte's Hospital in London reported a study designed to see if this could be used routinely to identify problem pregnancies. Controls had routine care, but the Doppler group had one or more extra scans. They concluded that routine Doppler did not offer any benefits. In fact those babies did worse. Four times as many babies died in the Doppler-exposed group. On the 1249 Doppler studies women, 16 lost normal babies. Most of these women were low risk. In the 1229 "controls", only 4 normal babies died. This study does not, of course prove that Doppler is dangerous to babies – other studies have not shown such an effect – but it is worrying. The authors quote other studies to demonstrate lack of such a risk – but in two of those studies ALL the women had Doppler, so there was no unexposed group, and in many cases all the researchers have used different types of machine (Davies, J. 1992).

An effect on Myelin?

One of a number of worrying animal studies was reported by Ellisman (1987) and colleagues from the University of California in San Diego. They exposed three to five day-old rat pups to diagnostic levels of diagnostic ultrasound for 30 minutes. In the exposed animals there was damage to myelin which is the substance surrounding nerves. The development of myelination in rats at that age is similar to that of the human fetus at 4-5 moths of pregnancy. This again raises the possibility that ultrasound has the potential to damage the central nervous system.

Cancer Risk?

Cancer has never been our major worry about ultrasound and there is no evidence that it increases cancer risk. However, in view of what had happened with antenatal x-rays and the subsequent increased risk of childhood cancers (Stewart, 1956) there were understandable fears that the same might apply with ultrasound.

Everyone breathed a sigh of relief when two studies, published in THE LANCET (Kinnier, Wilson and Waterhouse, 1984, Cartwright, 1984) showed no increased cancer risk in childhood related to ultrasound exposure in the womb. *The Oxford Survey of Childhood Cancers,* reported by Kinnier Wilson) had first started including questions on ultrasound to mothers of children with cancer in 1972. They asked the same questions of mothers of children from similar families who had not had cancer (this is called a case-control study). There was no overall increase although they did find that children who were 6 or more when they got leukaemia were more likely to have been scanned in the womb than the control group. The Cartwright study which has a smaller number of subjects, found no excess. The conclusions were that the risk for children over 5 remained unresolved but was probably unlikely to be real. What did emerge

from both studies was how rapidly antenatal scanning had increased from 1970 when information was first gathered to 1980. The researchers pointed out that as routine use spread there would no longer be an unexposed group and it would be impossible to do such research.

> ***"It should be performed only by qualified personnel using techniques which minimize patient exposure, i.e. minimum output and examination, dwell time consistent with acquiring the required acoustic diagnostic information. Frivolous and unwarranted use of the method are considered to be unacceptable and unethical practice and are strongly discouraged."***
> **Kossof, 1990**

Since then the cancer safety question has been regarded as "settled", but it is not. The studies did not eliminate the possibility of an increased risk of cancers in later life – such as cancers of the breast or ovary for example, although, of course there is no reason to suppose that there would be such an increase. Of greater concern to us is the fact that those studies were done at a time when fewer ultrasound examinations were made, and the equipment was very different and had lower outputs. Vaginal probe ultrasound had not even been invented.

When the Cartwright study began in 1972 only 3 % of mothers in their study had scans. By 1981 it was 70-80%. Moreover, the number of scans per baby was far fewer than it is nowadays. Most women had only one or two. Our impression now is that four is more likely and considerable numbers of women report more.

Length of exposure

The two cancer studies which provided reassuring information from "normal" antenatal scanning, can tell us nothing about any potential risk from the long exposures of 30 minutes upwards used in research studies. Since ethics committees have approved the studies and women have "consented", this presumable has been done on the basis of irrelevant data.

Do ethics committees realise that *"All national ultrasound societies advocate that ultrasound should be used prudently"?*

Kremkau (1983) points out that exposure can be minimised in three ways:

1. Using ultrasound only when indicated.

2. Minimising exposure time

3. Minimising exposure intensity.

Patient exposure time should be limited to that required to give the information necessary for proper diagnosis.

It is obvious from the increasing number of research papers published, that many babies are exposed to long periods of ultrasound during studies which are trying to establish what happens in the womb. Many of these are unlikely to be of direct benefit to the individual mothers or babies concerned and therefore should be classified as "non-therapeutic research". This is research which is not designed to provide clinical benefit to individual patients in a trial and therefore the ethical standards required, particularly for children, are rigorous and no element of risk should be involved.

In one such study in Aldershot, breathing activity and movements of the fetus were recorded (Roberts et al, 1992). 21 women with normal pregnancies were studied for 24 hours – i.e. three 45 – 60 minute sessions every eight hours. 20 women whose babies had been diagnosed as growth retarded by ultrasound were also studied.

One example of extended exposure, is described at King's College Hospital, London, reported in 1988 (Pearce et al.). 34 women had duplex Doppler ultrasound studies of blood flow done every 16 to 18 weeks until they delivered. Ten of them were studied in the last trimester every 4 hours over a 24 hour period and another 5 were studied for 30 minutes before and 1 hour after a meal.

During one of the newest studies done in Oxford, individual exposures were not lengthy but they were of an unusual kind. Doppler ultrasound was used to study before birth the blood flow in an artery in the baby's brain. 23 healthy women agreed to take part, although two dropped out and three had to be excluded because they developed problems. So, 18 women completed the study by having 5 examinations done in their babies plus a 60 minute session when the heart-rate was recorded, by electronic fetal monitoring. The information gained from these women was then used to study a further 27 with problem pregnancies in a similar way.

Studies have also been made of breathing activity before and after the mother is given drugs like diazepam and pethidine. In these studies ultrasound recordings were made for half and hour before and after the administration of the drug (Lewis PJ and Oliver E).

In a study at Queen Charlotte's, London, researchers were looking at the effects on breathing movements of adding liquid when there was not enough amniotic fluid surrounding the baby. Fetal breathing movements were recorded continuously for 40 minutes before and 40 minutes after the infusion (Fisk et al, 1992).

Two radiologists have suggested on the basis of animal studies that there is at least a theoretical risk for repeated ultrasound exposures (Baker and Dalrymple, 1978).

Women are unlikely to consent to their unborn children being research subjects unless they are told that it is safe. We wonder how doctors and ethics committees can give such assurances when no data exists for such lengthy exposures. AIMS wants all ethics committees to require retention of records for future follow-up id unusual or lengthy exposure is involved.

Future Generations

The possibility of damage to future generations is one that has been of particular concern to us and to many of our members. An interesting example of how something which affects the mother might present later risk to children was suggested by Bound JP et al (1991).

It was discovered that mothers born before 1950 had a much greater chance of producing a baby with spina bifida. At the time when these mothers were small it was common for babies to be given teething powders which included mercury. For example, 40% of babies in Manchester and Salford were given them. From 1948 onwards warnings were given that mercury could cause Pink disease in infants and exposure to this dangerous substance in babies rapidly fell. The authors suggest that the mercury preconditioned the girls when they grew up to produce children with spina bifida and this could have happened due to damage to germ cells. It is too late now to be able to prove a cause and effect relationship but it does suggest how vulnerable the undeveloped egg may be to toxic damage when the future mother is still a baby herself.

Transvaginal ultrasound

The latest development is a probe which is inserted into the vagina (or can be used in the rectum) and ultrasound signals from the probe can then reach the baby without having to first pass through the protective wall of the abdomen and then the amniotic fluid before reaching the baby. When ultrasound goes through that route its power is reduced by the obstructions it meets on the way. The vaginal probe gets much nearer. It is covered with a condom to protect against transmitting infection, but occasionally condoms can break and then there is a slight infection risk.

One enthusiast explains:

''*by comparing the insertion of the probe with the insertion of a tampon, speculum examination, or pelvic bimanual examination, the patient's fears are quickly dispelled…after an explanation patient acceptance is almost universal. The relative discomfort does not reach a level such that the procedure has to be interrupted before its completion.''* Kurjak A, 1991).

After the probe is inserted it is rotated and moved in at various depths. A newly published book mention that there have already been a number of medico-legal cases (details are not given) but it suggests that there should be a third party present who is **''**aware of normal practices'' (Meire, 1993).

The medical director of an IVF (In Vitro Fertilisation) centre R K Goswamy (1992) described the procedure enthusiastically in the BMJ last year. He pointed out that for abdominal ultrasound the patient had to drink a litre of water and wait for an hour before the examination could be done and commented *"this complicates its routine use by gynaecologists."* It is strange how little had appeared in the literature about the considerable discomfort and possible embarrassment for women who have been waiting around with bursting bladders. At least the transvaginal route makes this unnecessary.

> ***"Although intravaginal ultrasound is a technique which had been used extensively and so far no hazards have been discovered it cannot be guaranteed that the procedure will not cause damage to the patient, nor to a fetus if the patient is pregnant. In the case of pregnancy it cannot be guaranteed that the procedure will not initiate a miscarriage."***
> **Consent form patients are required to sign by American Gynaecologists. Craig M, 1993**

One clinician has commented that some transvaginal probes are less well tolerated than others, but he gives no further details. An ethics researcher has commented:
"The shift from a non invasive technique to an invasive one ought to make the practitioner wary, because the potential for harm increases. Transvaginal scanning is an area worthy of special consideration, particularly since the term "diagnostic rape" has been coined to describe it." Blauciak J, 1992.

Women's acceptance of this technique is recorded in medical journals only on the evidence that doctors believe women accept it, and, understandably prefer it to the full bladder requirement of abdominal route (we do not know, of course, if this is true for all women even if it is true for the majority). We have seen no independent sociological research which directly gathers the views of women themselves.

This type of equipment is now routinely used in IVF clinics. In the United States and Germany transvaginal scanners are uses routinely for gynaecological examinations without any evaluation of possible risks, despite the increased ultrasound exposure risk which comes from two sources – the type of machine used and the lack of intervening protection.

Transvaginal ultrasound is particularly effective for identifying and monitoring pregnancy in from the very earliest stage. This has led to an upsurge in ultrasound studies of the embryo and tiny fetus. Obstetricians have, apparently forgotten the early warnings that ultrasound might be safer is doctors avoided exposing the baby during the early period of organogenesis, i.e. when the major organs re being formed.

One of the anxieties about the probe is that the transducer at the end increases in temperature and the probe is remaining in the same place and is not moved

around to the extent that a transducer scanning your tummy would be. One gynaecologist writes:

"In transvaginal scanning the transducer is placed close to the fetus, some, therefore, have expressed concern that, if the same acoustic output is used in the transvaginal as in the transabdominal technique the fetus would be insonated with more energy. ...An alternative point of view which has been put forward is that a transvaginal examination should allow lower fetal exposure. Because the transducer is closer to the fetus it is an efficient receiver of the signal reflected by the fetus." (Kossoff G, 1991)

Transvaginal ultrasound is increasingly used in gynaecology, for example, to detect ovarian cysts and for early detection of ectopic pregnancies (pregnancies within the fallopian tube – which are life threatening to the mother). However, every potential operator will have to practise on a number of women before acquiring the level of skill necessary for accurate diagnosis. Goswamy comments that the full potential of transvaginal ultrasonography is not being realised because of the reluctance of many consultants to acquire new skills and the problems of obtaining new equipment in the cash-starved NHS. However, *"manufacturers are coming to the rescue by producing smaller and cheaper machines."*

> ***"...because the new scanner is so good at picking up problems in early pregnancy... although transvaginal scanning uses an internal probe, doctors emphasise that it carries no risk of miscarriage."***
> **Mother and Baby Magazine, May 1990**

Transvaginal ultrasound is used to look at ovaries so that there could be effects on eggs even before pregnancy. There is one interesting and clear example of ultrasound examinations having a biological effect – it cam cause premature ovulation. In 1982, a team in Clamart, France, who were working on in-vitro fertilisation, found that women who had ultrasound examinations as the follicle was ripening were more likely to ovulate soon afterwards. We do not know if the effect is direct or indirect but they warned clinicians against ultrasound examination of the ovaries during the final days before ovulation, because of possible effects on the wall of the follicle.

Ultrasound and the Newborn

Our worries about the effects of ultrasound on babies do not end with birth.

Newborn babies on intensive care often have head scans, particularly to detect haemorrhage in the brain. It is an important diagnostic tool. Sometimes these scans are done daily. Portable scanners make it easy to do this without moving the baby.

> ***"Studies on cerebral blood flow that use pulsed Doppler expose the intervening developing and myelinating brain to the maximum intensity so that the more reassuring in-situ intensity is***

inappropriate when considering the possible bio-effects. Despite this knowledge, in-situ values are already being quoted in duplex Doppler studies of neonatal brain even in the very premature."

Many healthy babies are exposed to ultrasound examinations for research purposes and mothers agree because doctors assure then they are safe.

As Chiswick (1984), wrote in the BMJ *"Tired of reassuring mothers that the soft spot on top of baby's head is harmless and will close, neonatologists are now exploiting it as the window to the brain."* They had made an exciting discovery that this spot gave them wonderful ultrasound access to the baby's brain, with the minimum barrier in between. This has led to a number of studies, for example, in Munster in Germany paediatricians studied blood flow in the heads of 84 healthy babies with Doppler ultrasound by attaching the transducer to the fontanelle (Pfannschmidt and Jorch, 1989). No mention is made on the article of parents giving informed consent.

Professor Kenneth Taylor, who is Professor of Diagnostic Radiology and Chief of the Ultrasound Section at Yale University, has expressed particular concern about this. *When a transducer is put in the anterior fontanelle of a neonate, since the ultrasound energy cannot escape and will be continuously reflected inside the cranium until it is totally absorbed. Because the cranium is a bowl focusing effects may occur that could subject the central parts of the brain to quite high local intensities. It is possible that the neonatal brain is the most vulnerable to ultrasound exposure... I would not let anyone near my infant's head with a transducer unless I knew what the output was."*

In a recent study done in Bristol 42 mothers of newborn babies were asked to consent to a "head Scan" of their infant. 32% of them refused, whereas it is rare for women to refuse scans of their baby before birth (Thorpe K et al, 1993). It seems from this study that once a baby was delivered the mothers were more conscious of its fragility and the importance of the brain and some felt it was more at risk from its own exposure that from being scanned while it was still in the womb and perceived protected by the mother's body.

"Ultrasound waves are used in the same way as x-rays, to give a picture of the baby, only they cause neither the mother nor the baby any harm."
Stoppard, M. 1982

Professor Taylor recommends that when consent is obtained from parents and ethics committees agree to research proposals, the conditions of exposure should be summarised to indicate how investigators minimised the dose (Taylor, 1987).

In Leicester, a Doppler ultrasound study was done on cerebral arteries in 27 very low-birthweight babies, and published in 1988. It was approved by the hospital ethics committee although no mention is made of parents' consent. The cerebral arteries were viewed through the fontanelle, and ultrasound

examinations were carried out every day for the first seven days of life. It appears that this was non-therapeutic research – in other words it was not intended to provide any clinical benefit to the babies being studied (Evans, 1988). It would be interesting to trace these 27 children and, if possible, compare them with a case control group of similar infants to see how they have fared.

Women's Feelings About Ultrasound

Consumer acceptance of antenatal scanning has been high. An early major problem was failure to give women information about what was happening and to treat it as just another examination. Obstetricians soon learned that unless they improved communication anxieties created would outweigh possible benefits from the mother's point of view. There are still problems about admittance of partners in some centres, and such restrictions cause indignant protests.

As most pregnancies are normal the majority of clinic attenders will be getting good news. They have been encouraged to regard seeing the image on the screen almost as a social event which makes the rather tedious visits to the clinic worthwhile. For the minority who receive bad news, this makes the shock possibly greater. They went to confirm that all was well not fully taking in the fact that part of the rationale was to screen for abnormality.

> ***"Today, according to ultrasound pioneer Professor Stuart Campbell that first scan has almost pre-empted the birth as a special occasion."***
> **Mother and Baby Magazine, May 1990**

None of the studies we have yet seen, whether medical or sociological, describe the subtlety and wide variations in women's feelings and reactions. It is clear that giving women information and allowing partners in has made a difference. Many parents are delighted to see the baby on the screen. But there are those who find it intrusive: *"I did feel horrible afterwards it was an intrusion into the baby's privacy and mine."* or *"Instead of bringing me closer to my baby, it seemed to take it away from me and make it public property."* Lumbley J, 1985).

Barbara Katz Rothman (in THE TENTATIVE PREGNACY) shows that pre-natal diagnosis changes women's experience of pregnancy – and this is true even when the results are normal. For example, women who had amniocentesis were less likely to remember when they had first felt the baby move and they began wearing maternity clothes later than other women.

Despite the Department of Health statement that antenatal scanning should not be done routinely it seems now to be standard procedure at most British hospitals. Seven years ago a study was done in Manchester comparing women's attitudes at two hospitals, one of which did routine screening. The researcher, Beverley Hyde, found that women given routine scanning were more likely to think it a good idea – after all anything which was automatically provided must

be safe. *"The assumption that all attenders will be offered a scan means that women will be encouraged to pin their hopes for reassurance on the forthcoming ultrasound examination; they are told, either directly or by implication that their doctors are of the opinion that all pregnant women should be scanned, with the result that they are strongly influenced to believe this also." At the hospital where it was not used for everyone, women were more cautious in their expectations."* (Hyde B, 1985).

The implications of this study are profound. We are told by obstetricians and midwives that women like having antenatal ultrasound but it was the fact that it became routine in this country, despite the warnings of the World Health Organisation, the Food and Drug Administration in the USA and the Department of Health that made women accept it with less questioning and anxiety than otherwise would have been the case.

> ***"If exposure to ultrasound…cause death of cells, then the practice of ultrasonic imaging at 16 to 18 weeks of pregnancy will cause loss of neurons with little prospect of replacement of lost cells…"***

The bonding argument

One of the claimed benefits for ultrasound screening has been that it enabled mothers to "bond" with their babies although, in fact, the evidence for this is poor. It is ironic, therefore, that in a report of two cases given by American doctors of mothers' favourable reactions to ultrasound, the claim was made that scans might result in fewer abortions – they would not terminate a pregnancy once they had seen the baby on the screen. Apparently, in the United States some communities, and even one State had debated legislation requiring that a picture of a human fetus be shown to a woman who requested an abortion. Fletcher and Evans wrote *"a court-ordered ultrasound viewing would be a potent (and unfair) manuver in the hands of those who represent the interests of the fetus in a dispute over proposed fetal therapy. Of course ultrasound could be used to the same end by those who oppose abortion itself."* (Fletcher and Evans, 1983).

Identifying malformed babies is one of the major purposes of antenatal scanning. If seeing the fetus on the screen really does increase bonding the choice of abortion may be more painful for the mother than it used to be.

Professor Stuart Campbell, who claims that maternal fetal bonding is accelerated describes his procedure which follows the discovery of an abnormality when parents are shown a review of the video tape *"to instil a sense of realism into the decision making process."* (Campbell S, 1983)

Blauciak (1992, p91) points out that women with a history of threatened abortion are particularly vulnerable to the visualisation of the fetus, because it poses a threat to their coping strategy, which is to delay attachment to their baby until they are sure it is viable.

Even if "bonding" takes place earlier than would otherwise have been the case, there has been no discussion as to whether this is in fact an advantage for the majority of women, some of whom will miscarry anyway. Perhaps Nature intends attachment to the baby to grow during the long months of pregnancy. Mothers loved their newborn babies long before professionals discovered bonding. Almost all the problems we see are caused by bad hospital birth experiences.

The following is Mother and Baby's advice to women having a scan:

HELLO BABY!

Seeing is believing. Thanks to the wonders of the ultrasound scan you can now see pictures of your baby at 20 weeks or less. Kate Taylor takes you through the excitement of a scan:

> DON'T wear your best silk shirt.
>
> Do wear decent knickers – they'll give you confidence
>
> Don't worry – your ultrasound scan in pain-less and is thought to be completely safe.
>
> Do ask lots of questions. (Ed. Note: But Mother and Baby give no guidance on what to ask).
>
> Don't become anxious needlessly about anything you don't understand about the scan.
>
> Do persuade your partners to come if the hospital will allow it – it's a really wonderful moment to share!"

(Ed. Note: Is it any wonder that women are so woefully uninformed about scans and consider then absolutely essential?)

Quality of diagnosis

Most women when having ultrasound, do not realise that a suspected abnormality can appear which was either totally wrongly diagnosed in the first place or which can be the correct diagnosis of a temporary condition. Lilford (1990) describes three such cases, in Leeds, where all the children were healthy after birth.

A study of antenatal diagnosis of urinary tract abnormalities from Glasgow (Greig et al, 1989), reports on 62 babies in which problems were diagnosed. Five of these were, in fact, normal at birth – in three of them repeated scanning had shown a problem which got better by the time the baby was born, so they

seemed to have a temporary problem and two appeared to have false positives in which the babies didn't have a problem at all. 15 babies had been aborted and autopsy findings had confirmed the diagnosis of problems, but presumably it is not impossible that a small percentage of aborted babies in fact have a temporary problem.

Consent

From her work at the Patients' Association for three years, dealing with 100 complaints a week about health care, Jean Robinson soon became aware that consent problems were far more common in maternity care than in all other types of health care combined. There seemed to be three reasons for this:

1. That women felt intensely vulnerable and at the mercy of their attendants while in labour.

2. "Shroud waving" was frequently and effectively used at the slightest indication that women were getting uppity.

3. Attitudes to "patients" in maternity care were different to those in other forms of health care, these were the only sane inpatients who were likely to be given treatment which they had specifically refused.

When Alphafetaprotein (AFP) screening was introduced both AIMS and Community Health Councils began to receive protests from women that a test identifying a possible abnormality had been given without their knowledge, although they themselves were strongly opposed to abortion and would not have wished it to be done. Marteau et al (1988) found that a sizable minority of women did not know that they had an AFP test.

The track record of obstetrics on consent issues is less than satisfactory so our concern on scanning is understandable.

In a study of 112 women interviewed after they had an amniocentesis, 24% were unaware that it carried a risk of miscarriage and 86% were unaware of any other possible hazards. Four women under 40 who had been told about possible risks had all been given information in an attempt to persuade them to change their minds about wanting the tests. (Farrant, 1985). Farrant reports that 5 of the 10 non-English speaking women had an amniocentesis without any idea of its purpose, hazards, or results.

Potential damage

When the first "usual" scan takes place at 16 – 20 weeks, Mole (1986) points out that the most vulnerable organ is then the forebrain. Neuroblast division occurs between the 10th and 20th week of pregnancy "*If exposure to ultrasound… causes death of cells, then the practice of ultrasonic imaging at 16 – 18 weeks of pregnancy will cause loss of neurons with little prospect of replacement of*

lost cells… The vulnerability is not for malformation but for maldevelopment leading to mental impairment caused by overall reduction in the number of neurons in the future cerebral hemispheres."

Screening in later pregnancy at 32 -34 weeks could cause irreplaceable loss of cells in the cerebellum. Mole suggests that two possible sites for localised damage are the relay system between retina and visual cortex and cochlea of the inner ear leading to possible loss of visual acuity over small areas or of hearing over a narrow range of sound frequencies.

Another woman who had 11 scans, is now very worried about her child's hearing. Her worries that the problem is connected with ultrasound are probably completely groundless, but where is the research that shows 11 scans are safe?

As early as 1978 the possibility of neurological effects was raised, in an American study (Scheidt et al, 1978) babies who had amniocentesis with ultrasound were compared with babies who had amniocentesis without, and all had a detailed neurological examination (this is the only study in which we have seen this done). The ultrasound group were found to have more abnormal grasp and tonic neck reflexes at birth, although there were no significant differences found by the time the babies were a year old.

> ***"The ENT (ear, nose and throat) specialist said it is due to abnormally developed Eustachian tubes – they were exceptionally very narrow…He said that the problem was a developmental one – that when the ears were forming…something went wrong and the tubes developed very narrowly."***

It is surprising that after the publication of this study, later research protocols did not include neurological assessment of exposed and unexposed babies, particularly since animal studies had already suggested the possibility of neurological consequences.

Perhaps we should mention here that a number of midwives in Germany have expressed concern to us about the apparent increase in the number of four year olds who are now wearing glasses and are querying the frequent ultrasound exposures they have had could have been related.

In-vitro fertilisation

A number of reassuring statements have been made about ultrasound on the grounds that routine examinations are carried out after the crucial early period when major organs are developing. However, there has been little discussion of the risks for women undergoing IVF and further examinations thereafter to see if the procedure has been successful, and now that vaginal ultrasound has been discovered more examinations are being conducted early without any major discussion of a quite different category of potential risk.

Women who have in-vitro fertilisation are not only likely to have more ultrasound examinations than the average women during pregnancy, but also to have them much earlier in pregnancy while the embryo is developing and at the sensitive period when major organs are being formed. For example, at King's College, London, women apparently have routine scans at 7 weeks to confirm pregnancy (Waterstone and Campbell, 1993). In this study three different pocket fetal heart detectors were tried out, one after the other, on 32 women, to see which was the most effective at 9 and 10 weeks, followed by vaginal ultrasound. Three women miscarried.

Some of the problems which concerned us had not even been studied, either because the professionals had not thought about them, or if they had they thought the studies would be too expensive, e.g. following up groups to find out long term risks. Nobody asked us whether it was a cost we would be willing to bear or if we thought spending money on these studies was more important than some of the things they chose to research with taxpayers money, and persuaded the Medical Research Council to pay for. There is no real consumer voice in the assessment of research priorities.

Already some doctors are operating on babies in the womb to see if defects can be remedied. Such surgery, which poses risks for the pregnant woman and we can forsee the time when the kind of shroud-waving which persuaded women to have inductions, electronic fetal monitoring and ultrasound scans will be persuading women to undergo life-threatening risks to themselves when the womb is cut open, the baby removed, operated upon and replaced before birth.

Policy for the Future

Information for parents

The purpose and nature of any individual ultrasound exposure to the baby, before or after birth, should be explained to women. They should be told what will be learnt from it, whether the information can be obtained in any other way, and how necessary it is for care. They should also be told about accuracy of results for that type of investigation, at that stage of pregnancy, for that clinic, and how far the information sought has proved in practice to be of benefit on the basis of published studies. In case of termination for abnormality, all parents should have a copy of the post-mortem results.

Training for staff

No fetus or baby should be exposed to ultrasound except by someone who has been specifically trained to use it, and has a recognised qualification, or is in training and is under the supervision of qualified sonographer.

Safety of equipment

The EEC has a Medical Devices Directorate which is establishing standards for ultrasound. The Department of Health should adopt as soon as possible a standard with which all manufacturers must comply. There should also be regular checks on output of machines in use.

Better evaluation of effectiveness

The Department of Health should monitor effectiveness of all aspects of ultrasound screening in pregnancy.

Numerous studies now show that information gathered from routine antenatal ultrasound brings no benefit to most women or babies. By attending for scans women often become locked in to a hospital model of care.

There should be a request to report to the Department of Health diagnosis of abnormality and outcomes and post-mortem results for all terminations.

Better evaluation of cost

Costs include: testing and re-testing of equipment for output and safety. There is the cost of training sonographers to achieve optimum safety and minimise false positive and false negative results. There are also "opportunity costs" – i.e. when resources are used in one area, the opportunity is lost to use them in another. Midwives doing scans are not available to give the continuous care in the community recommended by the House of Commons Select Committee. There are other, so far unquantified costs- properly trained counsellors and the provision of neonatal pathologists to carry out post-mortem studies. Both these skills are already in short supply.

Ethics Committees

When considering protocols which include ultrasound exposure for the fetus or infant, ethics committees should ensure that they have up-to-date information on known risks and safety standards.

They should insist that names of all research subjects are kept, for future possible follow-up, when research is approved for pregnant women and children, so that any long-term unknown hazards might eventually be identified.

Office of Technology Assessment

Patients exposed to new technology, have less protection that those exposed to new drugs. The Food and Drug Administration (FDA) in the USA has a section which looks at devices used in medical care. A similar department here is long overdue.

Research Priorities

We need a stronger consumer voice at the Department of Health and at the Medical Research Council on research priorities. It seems strange that it has been so difficult to achieve this – especially as in our evidence to the Select Committee, we pointed out that the things we wanted were likely to be cheaper then care we were forced to accept.

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Further Developments

The first edition of AIMS' special Ultrasound? Unsound was published on 31st March 1993, and the following day Beverley Beech left for Australia clutching a large box for distribution there. She was met with considerable interest and appeared on a multitude of TV programmes (one with the President of the Australian College of Obstetricians and Gynaecologists, who defended routine ultrasound scanning on the grounds that the first ultrasound examination "is a social occasion".)

Here in Britain, alerting the media was undertaken by Jean Robinson who, not for the want of trying or lack of intensive lobbying, failed to encourage the press to raise public awareness.

The Evening Standard, to its credit, carried a small piece and both the Nursing Times and Minerva, in the British Medical Journal, drew attention to the Journal – otherwise silence.

The silence, though, is not caused by lack of interest in ultrasound, a few weeks later The Independent published the following:

Early detection of Down's Syndrome risk

Ultrasound scanning can pick up pregnancies most at risk of Down's syndrome as early as 11 weeks, according to a specialist in foetal medicine, Dr Kypros Nicoliades, professor at King's College Hospital, London, says the preliminary results of a study he is conducting suggest

that about 90 per cent of babies born with Down's syndrome have a fluid-filled space behind the neck that can be detected early.

In a report in GENERAL PRACTITIONER, Dr Nicolaides estimates that any woman whose scan reveals the presence of the fluid runs a risk of having a Down's syndrome baby 10 times higher than that calculated by maternal age alone, and should be offered further antenatal tests. He is hoping to screen 20,000 women before the end of the year to confirm his results. THE INDEPENDENT, Update, 4th May 1993.

When AIMS spoke to Celia Hall, the Health Page editor, asking her why THE INDEPENDENT was keen to publicise and promote the "positive" aspects of ultrasound and not inform women of the risks AIMS was told "We covered that issue four or five years ago when there was a big controversy about it".

Meanwhile the manufacturers have developed a new wheeze: Pregnant Pause.

"The wait for a pregnancy scan to check all is well seems to take forever. However, things could soon be different. London's maternity hospitals have been testing pocket scanners suitable for use by GPs and midwives. They're cheap, simple to use and are likely to become a standard piece of surgery equipment over the next few years, enabling us to have early scans carried out by our own doctor."

No mention of the potential risks or inaccuracies.

Latest Research

Two important articles supporting AIMS' case have recently appeared in the BRITISH MEDICAL JOURNAL.

The first came from two Swiss doctors, who did an analysis of all the randomised trials which could show where routine scanning could reduce illness and death in babies. When added together, the studies covered nearly 16,000 births. There had been no improvement in the condition of babies measured by the apgar score when ultrasound was used compared with those who did not have it.

There WAS a reduction in perinatal mortality – but not because babies were saved but because they had died earlier, having been aborted. Malformed babies make a major contribution to perinatal mortality.

They concluded that routine ultrasound scanning is useful if explicitly declared as a prenatal screening for malformations to which a pregnant woman would have to consent. If a woman does not consent to screening for malformation, routine scanning is not indicated.

The authors also refer to the risks of babies being diagnosed as malformed when they are in fact normal ("false positive" diagnosis).

This article absolutely supports the AIMS conclusion after our study of the literature: benefits from routine scanning have not been proved. The one thing scanning can do – although imperfectly – is screening for malformation. The success rate varies for different types of abnormality and with the expertise of the screener. Mothers should knowingly opt in to this only if they want it. Such screening involves one scan – later in pregnancy than the dating scan which at present mothers are given routinely. (*Does routine ultrasound scanning improve outcome in pregnancy? Meta-analysis of varies outcome measures.* Bucher, H and Schmidt J, BMJ 1993, Vol 307, pp 13-17).

More left handed babies?

The second paper, from Norway by Dr Kjell Salvesen and others, gives a further report on children aged 8-9 who were randomly allocated to have routine scanning or not in the womb. In an earlier paper the authors found no increase in dyslexia and we commented on it in the last issue. In this they find an increase in children not being right handed. The differences were not large, but it does suggest the possibility of an effect on development of the brain. However, no other neurological differences were found between the two groups.

It should be noted that in this study the babies usually had only two scans and the first was usually around 19 weeks when major organ development has taken place. This is later than the first scan in many British pregnancies. The scanners used in the Norwegian study emitted very low dose of ultrasound – lower than exposures from many machines nowadays – and it was real time, not Doppler. Nor were women having the vaginal probe ultrasound AIMS is worried about, where a higher dose is likely to reach the baby. The authors also point out that the control group was not totally exposed to ultrasound. Many babies in both groups would have been exposed to fetal heart detectors and electronic fetal monitors. If those also affected the baby, it could reduce the size of the difference found between the two groups. (*Routine Ultrasonography in utero and subsequent handedness and neurological development,* Salvesen, K. et al BMJ 1993 Vol 307, pp 159-164).

A second study has been published from the United States, showing similar results. 15,000 low risk women were randomized to have either two routine scans or to be in the control group who were given a scan only if their obstetrician thought they had a problem. 55% of the controls had no scans. There was no difference in the outcome in the two groups – either in perinatal mortality or in sick babies. Scans in the U.S. cost $200, and the cost of doing routine scans for pregnant women is estimated at more than a billion dollars. 1

So we now have further evidence of lack of effectiveness of routine scanning. What has been shown to work (with varying degrees of success at different centres) is scanning for detection of major malformations. This has to be done

later than the current early dating scan to pick up the maximum number of problems – 18-20 weeks – and should be done only if the mother 1 knows and consents to the purpose of the scan 2 is told that it is not 100% accurate and there could be a false positive and false negative result.

It is important to note in this study that only 17% of abnormalities in babies were detected before 24 weeks compared with 52% in five European studies (the pick-up rate is in Europe varied from 20% to 84%). So all these low-risk babies had ultrasound exposure with a less than 1 in 5 chance of abnormalities being detected compared with 50/50 chance in Europe. This begs the question: if the quality of scanning in the US is such that major defects are missed, how good is the information they are getting on the size of the baby or even how many babies there are?

This emphasises the point that when a mother consents to an ultrasound scan to detect abnormalities, or indeed for any other purpose, she needs to know the accuracy of the results at the particular centre where she is being investigated in order to give adequate informed consent.

Another study, from Perth in Australia 2, suggests that too much Doppler ultrasound exposure may reduce babies' growth in the womb. If so, it is the ultimate irony. The Doppler measurement of blood flow to the fetus, which was developed in order to detect, and if possible help, the growth retarded fetus, may actually create the very problem it was designed to detect!

2834 women were randomised either to "intensive" care which was scan at 18 weeks plus 5 Doppler blood flow studies at 18, 24, 28, 34 and 38 weeks, or to have "regular" care which was one scan at 18 weeks and others only if thought necessary. In fact nearly half the regular group had two, three or more scans. The number of growth retarded fetuses was increased by about a third in the "intensive" group – though the average weight reduction was only the average 25g. per baby. The authors conclude that repeated ultrasound scans and Doppler flow studies should be restricted to those women for whom the information if likely to be of clinical benefit.

When Jean Robinson discussed this paper on the BBC *Today* programme with Professor Stuart Campbell, he dismissed it as a "statistical blip", despite the fact that there is considerable supporting evidence from animal research. Numerous studies on rats, mice and monkeys over the years have found reduced fetal weight in babies which had ultrasound in the womb compared with controls. What Newnham et al do not mention, is that in the monkey studies, the ultrasound babies sat or lay around the bottom of the cage, whereas the little control monkeys were climbing up the bars and were up to the usual monkey tricks.

In those two studies the baby monkeys had been exposed in the womb to many ultrasound scans – far greater than women have. But each scan was no longer than many carried out here, and they were ordinary real-time scans with no greater intensity or exposure. How many exposures are too many? What is

the mechanism by which growth is affected?? How many exposures are necessary to affect behaviour? What happens when monkeys grow up – do they reproduce as successfully as the controls? These questions and many others are still unanswered. And, of course, monkeys do not learn to read, write, multiply, sing opera, or play the violin.

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2 Newnham JP, O'Dea MR-A, Reid KP, Diepeveen DA. *Doppler flow velocity waveform analysis in High risk Pregnancies: A Randomised, Controlled Trial.* BJOG 1991; 98: 956-63.

The letter THE LANCET Did Not publish

This letter drawing attention to the Queen Charlotte study on Doppler ultrasound, was sent to the Lancet in June 1993, but not published:

"We have previously expressed our concern at the possible risks of both increased miscarriage rate and long term hazards to children from routine antenatal ultrasound scans.1 Growing anxieties expressed by parents who are members of AIMS led us to produce a critical consumer evaluation of risks and benefits of ultrasound screening. 2

Last November in a randomized study of 2,475 women Davies et al 3 reported a fourfold increase in perinatal deaths in babies exposed to routine Doppler ultrasound examination of umbilical and uterine arteries at 19-22 weeks and 32 weeks. (16 vs 4 perinatal deaths of normally formed infants).

Whilst concluding that they had not demonstrated any improvement in neonatal outcome, the authors dismissed the large difference in deaths by commenting that a meta-analysis of four randomised studies 4 had shown Doppler scans to be associated with reduced perinatal mortality. We suggest, however, that this analysis gives little reassurance to consumers asking whether the pattern of screening used by Davies et al may actually be hazardous to the fetus because:

- *The meta analysis covers only high risk pregnancies, where the risk/benefit ratio will be different.*
- *None of the studies appears to have used Doppler screening as early as 19-22 weeks, as in the Davies study.*
- *In two of the four studies there was no unexposed control group. 5,6*

- *In the third study 7 Doppler screening of the umbilical artery only was allowed on clinical indication and less than half the "treatment" group were in fact exposed.*

- *The fourth study did 8, like Davies et al, use waveform analysis in both umbilical and utero-placental arteries in 254 of 505 women. However, average gestational age at enrolment was over 32 weeks, and the majority (about 60%) had only one exposure. Perinatal deaths were the same in both groups, but low apgar scores were more common in the exposed group,*

It has been suggested that there is at least a theoretical risk from repeated ultrasound exposures. 9 However it is impossible to find out from any of the studies quoted, what the total exposure to different kinds of ultrasound may have been. As well as Doppler examinations, the women in all the studies have apparently also had an unstated number of real-time scans, as well as fetal heart monitoring. Another problem is that different equipment was used by different researchers, and output of machines may vary substantially. The apparent lack of short term risk from ultrasound exposure in one study, may not be applicable to another.

In order to assist parents and future researcher, AIMS has published a form2 My Baby's Ultrasound Record which sonographers can be asked to complete, giving type and duration of all ultrasound examinations, so that estimated exposure to the fetus and new-born can be recorded."

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Further News of jumping Babies

Beverley Beech and I often teach on midwifery courses. One member of a class recently was a midwife who was 5 months pregnant, and works in an ultrasound clinic. She says that when she uses Doppler, the baby in her own womb jumps about abnormally, but when she uses other ultrasound it does not.

We would welcome more feedback on jumping, or other ultrasound experiences.

In December 1993 the World Health Organisation issued the following letter:

Routine Ultrasound During Pregnancy

We should like to call your attention to the attached two extremely important scientific papers published this fall. Both papers report on large randomized controlled trials which, as you know, is by far the most valid of all scientific methods.

The American paper has been carefully evaluated by the National Institutes of Health in Washington DC and there can be no question of the results. This paper shows that there is no benefit from routine ultrasound scanning of all pregnant women and the authors recommend that there be no further routine scanning.

The second paper reveals the possibility of serious risks associated with routine scanning. As you will see, the experimental group with intensive scanning had over one-third more cases of intrauterine growth retardation. Clearly, more research needs to be done to determine whether or not such a serious risk exists, but the authors of this paper recommend that for the present time there be no more routine scanning.

It is fair to say that at the moment the best research shows no benefit from routine ultrasound scanning and the real possibility of a serious risk. Add to this are questions of costs. We have data from Member States showing that they

spend more money on ultrasound scanning during pregnancy than on all other health services for pregnancy combined.

For all these reasons, we urge you to reconsider all present policy with regard to routine ultrasound scanning during pregnancy, based on these important scientific papers.

Mark S Tsechkovski
Director, Disease Prevention and Quality of Care

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Ultrasound and Delayed Speech

A recently published Canadian study suggests that ultrasound exposure in the womb may cause development of speech in children to be delayed.

In Calgary, Alberta, a professor specialising in Ear, Nose and Throat problems, James Campbell, noticed that he was seeing more children who had delayed speech development. Their hearing was normal, and they seemed to have no social or other causes which would account for their problems. He carried out a research project with a professor of Family Medicine, Wayne Elford, and a statistician Dr. Rollin Brant. Antenatal records of 72 children with delayed speech of unknown cause were compared with those of 142 controls who were similar sex, date of birth and birth order within the family. The children were similar in social class, birthweight and length of pregnancy. About three-quarters in both groups were boys; males are more likely to experience such problems.

The children with speech problems were twice as likely as controls to have been exposed to ultrasound in the womb. 61% of cases, and only 37% of controls, had had at least one exposure. What is rather puzzling about the study, is that it did not seem to matter in what stage of pregnancy the ultrasound was used; the risks seemed elevated in every trimester. The authors conclude: *"If no obvious clinical indication for ultrasonography exists, physicians might be wise to caution their patients about the vulnerability of the fetus to noxious agents."*

Such a case-control study does not, of course, PROVE that exposure causes speech delay, but it certainly suggests that it might. When we put this together with the Denver study (Stark et al, 1984) which suggested an increase in dyslexia, and the Norwegian study (Salvesen K, 1993) which showed an increase

in left handedness, and animal studies which suggested neurological damage, there is growing evidence that ultrasound exposure before birth may affect the development of the brain.

> ***"...some of the interventions of recent years...have gained acceptance because of the assumption that they would increase the likelihood of a safe outcome. It is important that benefits are proven rather than assumed."***

Cumberlege Quote (2.1.3)

After reading the study, we sent a press release to all major newspapers and journals. Only the DAILY TELEGRAPH did a news item. Yet this could be a major problem affecting thousands of children in this country and all over the world. Compare this with the huge front page headlines on the possible dangers of water births – hitherto used by few women – following a press release based on second hand anecdotes from the RCOG!

We wrote to the Chief Medical Officer at the Department of Health, with copies to the Chief Medical Officers for Scotland, Wales and Northern Ireland, drawing attention to the study and asking if at least a study could be done here comparing children with severe speech problems with controls to see if there were differences in ultrasound exposure. We have been contacted by mothers of some children who had frequent or prolonged ultrasound exposure. It would be virtually impossible now, of course, to find a sample of children who had no ultrasound exposure, but at least we might look at differences in duration or frequency, where these are known.

Dr. Calman at the Department of Health responded by pointing out further problems in the design of the study; for example, the authors do not say if the researchers studying the records of both groups of children knew which was a problem child and which was a control. If researchers are "blind" to which is which, there is less likelihood of unconscious bias entering the study. We had already pointed out that since we don't know why mothers had scans, these could have been used more in problem pregnancies, which are more likely to produce children with handicap. He also reiterated points AIMS has already made – the difficulty of finding unexposed controls, and the fact that different machines would have given different "doses."

However, a less-than-perfect study does not mean that the results are untrue. The problem can still exist. Difficulties in doing further studies do not make them impossible. The only way we can find out is if researchers elsewhere take an interest in this hypothesis and see if it can be validated or disproved in other studies. The question of a possible effect on speech has already been raised and it is not going to go away.

Meanwhile we have a number of letters from women who had frequent or prolonged ultrasound in pregnancy and who have written to us about their children who have unusual speech or other problems of unknown origin (all boys).

We would like to hear from anyone else who had numerous or long scans as to how their children are getting on; we are as anxious to hear from those who have normal children as any who have children with problems.

References

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3 Campbell J D et al. *Case-control study of prenatal ultrasonography exposure in children with delayed speech.* CAN MED ASSOC J. 1993, 149 (10) pp 1435-1440.

More about AIMS

As a campaigning volunteer pressure group AIMS has been in the forefront of the childbirth movement and has provided much of the dynamism for change in all aspects of maternity care. AIMS furthers the cause of parents' right to make informed decisions about their care and has consistently supported the midwife in her role as practitioner in her own right.

A major part of our work is supporting and assisting people who need help, either in getting the kind of care they want, or in complaining about unsatisfactory care they have had. We believe that parents must have a place to turn to for support and encouragement.

As a volunteer pressure group, we receive no funding from any public body or charity. We all freely donate our time to answer letters, do research, respond to telephone queries, support individuals who need urgent help, attend conferences and produce our informative AIMS JOURNAL.

All these activities take a great deal of time, energy and money. Help support this important work so that we can continue to fight for improved maternity care for all women, and continue to help people like yourself.

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