MEDICAL PRACTICE

New Horizons in Medical Ethics

Research Investigations and the Fetus

This tape-recorded discussion was devoted to some problems of research investigations and the fetus, in their working papers, circulated before the discussion, Professor R. W. Smithells, a paediatrician, argues that any ethical code must err in the direction of stringency rather than laxity; Professor R. W. Beard, an obstetrician, that any progress in the prevention of serious conditions demands more knowledge about factors that may affect the fetus; and a barrister that a system of committees should be provided for by legislation to look into the validity of the proposed research on children, fetuses, and the mentally deficient. The working papers are printed below, followed by the discussion, which was chaired by a member of the B.M.J. editorial staff.

Stringency Rather than Laxity

R. W. SMITHELLS

The M.R.C.¹ makes a useful distinction between three categories of research: (a) procedures contributing to the benefit of the individual; (b) control subjects in investigations of treatment or prevention; (c) procedures not of direct benefit to the individual. The difficult ethical considerations are marginally less difficult if these categories are considered separately. In respect of (a) and (b), the arbitrary introduction of a new procedure into clinical practice may be far less ethical than doing a controlled trial. Group (c) is much more difficult and hangs entirely upon the concept of valid consent.

Young children cannot give valid consent, and no more can a fetus. Category (a) and (b) studies are subject to informed consent from the mother (and, if possible, the father). As a measure to ensure that consent is informed and freely given, the M.R.C.¹ suggests that it should be obtained by the investigator in the presence of another person. For category (c) studies the position of the viable fetus appears to be the same as that of a

minor, of whom the M.R.C. suggests that "information requiring the performance of any procedure involving his body would need to be obtained incidentally to and without altering the nature of a procedure intended for his individual benefit."

The Advisory Group on the *Use of Fetuses and Fetal Material for Research*² proposed that fetuses weighing less than 300 g are preivable and may be suitable for research purposes. It advises that, "the responsibility for deciding that the fetus is in a category which may be used for . . . research rests with the medical attendants at birth and never with the intending research worker."

Mankind has an almost limitless ability to convince himself that what he wants to do is morally justifiable. It is essential that any ethical code relating to clinical research should err in the direction of stringency rather than laxity, and no man should find himself in the position of being judge of his own morals in research.

It has been suggested that the results of unethical research should be refused publication by reputable journals. This leaves the investigator free to think that the editor is just a prejudiced old fool. Publication in journals with correspondence columns would give the opportunity for wide comment from professional colleagues. Might this be better?

Justification for Fetal Research

R. W. BEARD

The nine months the fetus spends in utero are of critical importance to subsequent development to adult life. Until

recently we have had only a hazy idea of what constitutes an ideal environment for normal development. If any progress is to be made in the prevention of such conditions as congenital defects, fetal growth retardation, and neurological damage resulting from intrauterine asphyxia it is essential to have more information about factors that may adversely affect the fetus. *Pari passu* the influence of these factors on fetal life must be

understood if, for example, the prognosis for the fetus whose mother has a metabolic disturbance such as diabetes is to be improved.

It is important to distinguish between the viable and non-viable fetus. The report of the Advisory Group on the *Use of Fetuses and Fetal Material for Research*² proposed that the dividing line should be at 20 weeks gestation obtained as a result of hysterotomy, though with the introduction of new techniques of legal abortion the previable fetus as a source of material has dwindled. In theory, any investigation should be acceptable that is not harmful to the mother. Nevertheless, aesthetic sensibilities must be taken into account and experiments that involve the destruction of a fetus that is delivered alive are unacceptable. Studies of placental transfer of non-toxic substances or involving the use of fetal tissue once death has occurred are acceptable.

Research investigations on the viable fetus are potentially very valuable, but, because of the considerable trust a mother places in the investigator when she agrees to co-operate, the investigator must take every precaution to satisfy himself of the safety of the procedure. The protocol should be acceptable to an uncommitted body such as an ethical committee and to the parents before any study is undertaken. Only an experienced investigator should undertake such work or alternatively should closely supervise a less experienced investigator.

In my view because it is not possible to interpret data on

abnormal subjects until the normal state has been defined, it is as ethically acceptable to investigate the normal as the abnormal fetus. Considerable confusion has been caused by the suggestion that no investigation on the fetus can be justified unless it can be shown to be of benefit to the actual fetus studied. In the wider sense it has been interpreted as the need to confine studies only to fetuses affected by the condition under investigation. Interpreted literally it is unlikely that any clinical research could ever start.

To a large extent the ethical and moral acceptability of any study must depend on the integrity and views on the investigator. Ethical committees perform a valuable service but can be bypassed by the unscrupulous investigator. To avoid this all protocols for fetal studies should be thoroughly discussed with members of the medical and nursing staff in a department before finally submitting them to the ethical committee.

The procedure and the purpose of the study should be explained to the patient and if possible to her husband. As part of the explanation it should be agreed that at any time the patient wishes it, the investigator will abandon the procedure. Once this has been done verbal agreement is all that is required. Written consent has no legal status and in fact may be seen as having an unreasonable influence on a patient should she change her mind after having agreed to the investigation. The investigator must accept full responsibility for any mishap attributed to the investigation.

The Legal Aspect

BY A BARRISTER

To discover the legal and ethical position on fetal research one has first to look at the rules governing research generally. Provided that the operation or treatment is not likely to result in death (or even in the acceleration of death) or in the serious impairment of the health of the subject, and provided that the doctor has reasonable grounds for thinking that if things go normally the subject will not be exposed to grave risk, a doctor will not be liable if an adult patient suffers harm in a research investigation of the sort to which he has given his consent. Fully informed consent will debar an action for trespass to the person or negligence.

The position is very different from adults. Children and the mentally deficient cannot at law be the subjects of research for they cannot give a valid consent to the research. Nor can a parent or guardian do so on their behalf. The Family Law Reform Act 1969 applies only to treatment and not to research. The critical distinction is therefore between treatment for the subject's benefit and research which will be of no benefit to the subject and may only benefit others. Treatment is paramount: no medical procedure involving the slightest risk or accompanied by the slightest pain may be inflicted on a child for research reasons alone. Research in this context will also include new and untried methods of treatment which could have the end result if successful of benefitting or curing the patient. Such methods will in any event be judged by a more stringent standard of care than that applicable to ordinary practice. The authority of the parent or guardian exists only for the protection and well-being of the child itself—not for other purposes and not for the good of other children.

There are two views concerning the nature of the legal rights of the fetus.

Firstly, that the fetus acquires legal rights when it reaches the stage of viability even though it may never be born alive. If this view is adopted then damage may accrue to and be recoverable by the fetus' estate if it is stillborn as a result of a tortious injury. The second view is that the fetus has no legal rights as such but that once it attains a

separate existence it may sue in respect of injuries done to it at any stage of its fetal existence (and perhaps before—that is, if its parents' gonads have been exposed to radiation).

There is no English authority but on the basis of Australian law the second view would be more likely to be adopted here. Accordingly the child once born would be able to sue in respect of any injury done by a researcher; and on the analogy with children the consent of the parent or guardian would be no defence. It would not matter whether the doctor had been negligent or not. Liability would be in effect absolute and damages could be colossal.

Viewing the law strictly, the fetal researcher's position is quite terrifying. He has no answer to a claim for damages at civil law. On the other hand, it seems doubtful whether he could be charged with assaulting the fetus. A criminal offence would only be committed in cases where he had been grossly negligent; then if the child died having been born alive from injuries sustained while in the womb, the offence of manslaughter would have been committed.

The individual has rights that the law protects. They cannot be infringed however great the public good to be achieved thereby. Physicians have no right to select martyrs for society and if they do so it will not avail them that their investigations was for the public benefit. To protect the researcher (for one day circumstances will arise putting a researcher in great peril) a change in the law is necessary. But is it desirable? What are the compelling medical reasons for such a change? And why should fetuses and children be in a different position from adults merely because they cannot consent other than through the agency of others? Doctors must answer these questions bearing in mind the present total legal ban in effect and bearing in mind the extent to which the same research could be done on animals.

We may now consider what sort of change is required. Research is now so specialized that in regard to any investigation only a few men have the necessary expertise to judge whether it is justified. However, such experts might be biased by reason of specialist enthusiasm or curiosity in favour of the research investigation. Though cumbersome but not more so than, say, a Mental Health Review Tribunal, a system of committees should be provided for by legislation to look in advance at the validity of proposed research on children, fetuses, and the mentally deficient.

These could sit regionally and be appointed by the Secretary of State. They might be composed of two doctors, two laymen, and a legally qualified chairman with a casting vote. An expert assessor

should give his views on the validity of the research to the committee but should have no vote. At the moment hospital ethical committees trying to interpret the Declaration of Helsinki have two disadvantages: firstly, their informality, and secondly, and associated with that the fact that they are not and do not appear to the public eye to have a sufficient degree of independence from the researcher.

The onus should be on the investigator to convince the committee beyond reasonable doubt that the proposed research is safe. Safety should be judged to be more important than the value to the public of the research. The committee should examine both research investigations that are of no benefit to the patient and untried methods of treatment intended to be of benefit if successful.

If the committee give the go-ahead, then the written consent of both parents should be obtained (though of mother alone if the parents are divorced or separated). An explanation of what is proposed should be given by a member of the research team in the presence of another doctor (preferably the subject's G.P.; otherwise a member of the staff at the hospital who is not connected with the experiment). Such an explanation avoids any difficulties later about the extent of the explanation. Also, since the researcher is in a position of trust and may well exercise undue influence over the subject to get him to consent, the presence of a third party at the explanation gives the subject a measure of independent advice relevant to her particular circumstances which the committee will not have had before them.

At any time during the research consent might be withdrawn by either parent, even orally, and notwithstanding that the researcher feels that the withdrawal is unreasonable. It should be an offence to interfere with the fetus in any way not directly beneficial to it other than in the above circumstances. This will deal with Professor Beard's "unscrupulous investigator"—that is, the sort of person who, if Mr. St. John Stevas is to be believed, will buy a living fetus in order to link it up with the circulation of a dog.

If the position arises frequently in practice, the committee should be empowered to examine research investigations on live

fetuses outside the womb. But for the time being the ordinary criminal law is probably sufficient once the fetus obtains an existence independent of its mother, it would most likely be viewed by the courts as analogous to the born child and be protected accordingly by the criminal law. The Official Solicitor or the local authority might also feel able to intervene.

In considering research on dead fetal matter the distinction must be made between the still-born child and the fetus. The child is still-born if it is produced after the 28th week and if it has not breathed or shown signs of life. Under S. 41 Births and Deaths Registration Act, 1953, the birth must be notified. It seems then to be the law that the still-born child should be buried or cremated for it is not within the Human Tissue Act, 1961. In any event the Act applies only where the deceased has given his consent to research investigation. It is arguable that the ambit of the act should be widened to take into account research investigations on children and fetuses where the bereaved parents consent.

The fetus which is miscarried and not within the above definition may be legally used for scientific purposes not constituting an affront to public decency.

Appointments of Speakers

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R. W. BEARD, F.R.C.S., M.R.C.O.G., Professor of Obstetrics and Gynaecology, St. Mary's Hospital Medical School, London W.2.

A BARRISTER, London

Discussion

PROFESSOR BEARD: Discussing Professor Smithells's three categories of research I should like to begin by pointing out that before you can get to his category (a)—procedures benefiting the individual—one usually has to go through categories (b) and (c). Take the actual problem of investigating the cause of death of a fetus of a diabetic mother. In these women between 8 and 30% of fetuses who are apparently normal die inexplicably. Studies on the mother to determine the cause have been fruitless. The only other possible approach is an invasive technique—entering the uterus in some way or other to study the fetus, but how does one do this ethically? You have to rupture the membranes of these mothers to induce labour, but is one justified in collecting a blood sample from the fetus? You are unlikely to get any information of immediate value to the fetus from that sample, but potentially it may yield results of great importance for the future.

PROFESSOR SMITHELLS: This is a difficult problem, especially when you cannot say "this is 100% safe" because you yourself have shown it is not so by describing two fatalities—admittedly both in circumstances where the investigation was clinically necessary.³

PROFESSOR BEARD: These were two cases both investigated in 1967; the fatalities have never been repeated and they were due to a technique we no longer use. Safety measures have been introduced and there has never been another case. We looked at a further 2,000 sampling procedures without mishap and concluded that the method was safe.

PROFESSOR SMITHELLS: Amniocentesis is an excellent example of a valuable practical procedure built up logically and ethically step by step, initially by research on amniotic fluid released in the normal way and then by introducing a needle through the abdominal wall; it wasn't a mad rush.

CHAIRMAN: How do we apply this to the ethics of fetal scalp puncture?

PROFESSOR BEARD: Recent work led us to postulate that the baby born to a well-controlled diabetic mother may die from hypoglycaemia due to hyperinsulinism in the fetus—though this was against the conventional view.

BARRISTER: Whether an operation is research or treatment is a question of dominant motive: that's not too difficult to decide.

PROFESSOR SMITHELLS: But can you decide retrospectively whether research was ethical or not by the result achieved? Don't you have to decide on the ethics in advance?

PROFESSOR BEARD: I don't have a crystal ball, but I think the approach is correct.

BARRISTER: Safety must be related not only to the possible risk but also to the potential good to other children.

CHAIRMAN: Doesn't this contradict your working paper?

BARRISTER: Not really: this is looking at the matter from the ethical point of view, rather than that of the law. The critical test is whether the procedure is likely to benefit the fetus or not—though, obviously, if at the same time as doing a beneficial test you take a small sample of blood for research purposes as well there can be no real objection. What I don't understand is the significance of Professor Smithells's point about control subjects in investigation of treatment or prevention.

PROFESSOR SMITHELLS: It's important to distinguish between two types of control. Firstly, there's one in which a controlled trial is involved of a topic about which doctors differ greatly. There are no ethical difficulties here. The second type of control is where you have studied a group of sick fetuses, or children, but you don't know what the normal values are. This is an entirely different ethical problem—and an extremely difficult one. I cannot convince myself that one is ethically justified in getting these values from normal subjects if this involves additional procedures.

PROFESSOR BEARD: If you accept that the extra investigation you are doing on a sick baby is of no immediate benefit, but is of general potential benefit, then the potential value of the sick and the control baby differs very little.