

Legal, ethical and historical aspects of assisted human reproduction

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Control of human reproduction

The process of human reproduction can be controlled in several ways: artificial insemination – donor, the test-tube baby procedure or IVF+ET (which would include sperm, egg and embryo donation), experimentation on human embryos, substitution of parenthood (surrogacy), genetic engineering (or recombinant DNA technology), and elective abortion. Much of the basic philosophy and rationale for this area of human activity is covered effectively by Glanville Williams (1958).

Artificial insemination – donor

This involves the introduction of semen or sperm suspensions into the female genital tract by artificial means. It is the duty of the doctor to ensure that infection is not passed on to the patient from the donor, and also that the risk of inbreeding is avoided by verifying that donor and recipient are not closely related. The doctor therefore needs to keep a detailed register of his donors, noting both the medical history and family relationships. Mishaps in either of these areas could become grounds for litigation.

The woman who is to be inseminated must give her written consent, for obvious reasons, and it is advisable, though not so critically important, that the husband should do so too. In most jurisdictions, children born from donor insemination were formerly labelled 'illegitimate' (unless the husband was prepared to commit perjury), and commonly this problem was overcome by the couple 'adopting' the child. To do that, required the consent of the semen donor, who would then have to become known, thus destroying the

incognito generally thought to be a necessary part of the arrangement. This difficulty was resolved by some doctors by mixing the semen from two or more donors, and also adding what semen the husband was able to produce, so that paternity could not be established unequivocally. Nowadays, in some legislations, the question of paternity is settled by the law declaring the husband to be the father 'by presumption', this statement being non-rebuttable. The move has become necessary, as well as convenient, because biological paternity can be established with a high degree of confidence by the technique of 'DNA fingerprinting' – individual identities can be recognized from the pattern of distinctive DNA repetitive sequences, which can be ascertained from a drop of blood or semen or a single hair-root. Lacking these legal and scientific devices, a donor's identity could be revealed often by exercise of a child's *right to know* his biological father, and the donor might then be held responsible for maintenance of the child – or if these manoeuvres failed, the doctor himself might be legally bound to provide maintenance.

In an active insemination programme, it is natural that sooner or later a child is born with a congenital defect – even with well-selected donors and no history of hereditary problems in the inseminated woman's family. Under these circumstances, a charge of professional negligence might be based on the allegation that enquiry into the donor's family history was inadequate or that mishandling of the semen was responsible. Expert witness by a professional geneticist might then be called for.

Sometimes ill effect is associated with the treatment with gonadotrophic hormones, administration of which may be considered necessary to ensure that ovulation takes place at about the same

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The author offers his best wishes to Denis New for a long and happy and healthy period of retirement

time as the insemination, so that prospects of fertilization are good. To avoid this risk, several inseminations may be made around the time of ovulation (estimated by blood hormone assay), and recognition of a preovulatory follicle may be possible with the aid of ultrasound scanning or nuclear magnetic resonance imaging

***In vitro* fertilization and embryo transfer (IVF+ET)**

To control the medical and biological procedures constituting or potentially supplementary to IVF+ET, there are stringent legislative measures in some jurisdictions, backed by criminal sanctions, while in others regulation of all activities depends upon a voluntary code of conduct. There are reasons to prefer the voluntary control (Scott, 1987; Warnock, 1986). These include the fact that the methods used are continually being changed and often improved. Legislation tends to be relatively inflexible and thus likely to become outdated. The main features thought to require statutory control are:

- 1) The prohibition against fertilization between animal and human gametes. There is, however, the highly valued 'hamster egg penetration test' for helping in the diagnosis of infertility in men. In this test the prospects of extensive development occurring are virtually nil, but some people may detect here 'the thin end of a wedge', and so object on principle, suspecting the possibility of experimentation by the operator.
- 2) The adequate trial or consideration of other possible remedies before IVF+ET is embarked upon. This would appear to be common sense, and several more conservative measures can certainly be considered, such as those identified as DIPI (in which sperms are injected into the peritoneal cavity near oviduct openings) and GIFT (in which eggs taken from follicles are placed in oviducts with sperms).
- 3) The provision by the couple of evidence that they are formally married, and consent to the projected treatment. The need for consent is hardly likely to cause dissension, but opinions are certainly divided on the subject of marital status, where perhaps regulations concerning adoption can provide suitable guidance. Whether lesbian couples (two women) should be assisted into 'parenthood', with the aid of donor semen, probably has few protagonists, though much of the opposition may be attributable to prejudice; from the resulting child's point of view, the arrangement could be entirely satisfactory. For a 'gay' couple (two men), on the other hand, the extreme proposition, involving donated embryos and a theoretically possible 'ectopic' (intraperitoneal) pregnancy, could be contemplated. This would be relatively simple to initiate, and would have to be terminated surgically, but the idea should be firmly excluded, if only because of the risk to the life of the recipient.
- 4) The performance of the IVF+ET procedure in approved clinical premises and by approved medical staff. These conditions seem wholly acceptable, an important point being that 'clinical' and not 'hospital' facilities are specified, the latter involving unjustifiable expense, unless medical complications were anticipated.
- 5) The establishment of an independent ethical committee whose approval is required for any variations in technical procedures, especially if calculated to impair the embryo's capacity for full normal development. Difficulties here are twofold: the ethical committee may feel bound to permit no risks at all, and so forbid any deviation from established procedures, a policy that could preclude the adoption of important improvements, or it may feel partisan to

the clinical team, and so approve proposed moves incurring major risks to embryos or patients, if a successful outcome could win wide acclaim. Indeed it is scarcely possible to steer a middle course consistently.

- 6) The keeping of detailed and proper records. There should be no argument here.

Experimentation on human embryos

Many opinions have been expressed on the subject of experimentation on human embryos. In Victoria, Australia, the relevant sections of the Infertility (Medical Procedures) Act 1984 became law in August 1986, and these allow experimentation on embryos in the first 14 days of pregnancy, subject to the approval of an ethical committee. Because of consistent failure to obtain such approval, the medical community concerned arranged for the Infertility (Medical Procedures) (Amendment) Bill to be brought forward in 1987; this was designed to permit experimentation on the human *egg*, after sperm penetration but before completion of the fertilization process at 'syngamy', namely the union of the chromosome groups. Such a preparation is, by definition, not a *fertilized* egg and certainly not an embryo, and yet could yield useful information on both the maternal and paternal chromosomal status, as well as on the capacity for fertilization. Some objections, however, were raised even to this proposal.

If embryos are produced in an IVF+ET programme *in excess* of the number required for return to the patient, this can be a problem. Prospects of establishing a pregnancy appear to be optimal following the insertion of three or perhaps four embryos, provided these are of good quality, i.e. cleaving regularly and of normal appearance, but to obtain this number it is necessary to begin with several more, because of the uncertainties of fertilization and early development. If more than four embryos eventuate, a decision must be made on the fate of the extra or 'spare' embryos. Generally, these are regarded as being the 'property' of the couple under treatment, and they can be donated to another couple or cryopreserved for later use should the pregnancy attempt prove unsuccessful. If this pregnancy is fruitful the 'owners' may request a second pregnancy, or donate the embryos to another couple or to the clinic for use in research, if that course of action is not against regulations. Alternatively, contact with the couple may be lost for one reason or another, whereupon the clinic itself is faced with having to make the decision – donation, research or destruction – and it is possible that, in certain areas, all three courses of action are closed by law. A few clinics try to avoid this dilemma by returning all embryos to the patient; occasionally this results in a dangerously large pregnancy, whereupon fetuses above a certain number have to be 'terminated', which many people would class as an ethically unacceptable procedure.

Eggs can of course be fertilized with sperms from the husband, if he can provide them, or from a donor, in which case considerations are similar to those set out above in the section Artificial insemination – donor. Eggs may be donated by another woman, fertilized with the husband's sperms and then transferred, or embryos can be donated and transferred; in neither case is there any likely legal difficulty over parenthood (generally speaking, the law considers the woman giving birth to be the mother), though the child may later claim the right to know its *genetic* mother.

Substitution of parenthood

This process, also referred to as 'surrogacy', is 'as old as the hills': in *Genesis* xvi, 1-4, we are told how Abram's wife, being infertile, asked Abram to go to her maid, for "it may be that I obtain children by her"; then in xxx, 1-5, Jacob's wife, also being infertile, asked Jacob to cohabit with her maid – both maids duly bore children on behalf of their mistresses. In the modern context, there are several variations on the theme (but without the extramarital intercourse) depending on whether a couple provides both sperms and eggs (or sperm o eggs, with the help of a fourth party), or only embryos, for the establishment of pregnancy in another person. Legal problems arise when the substitute refuses to part with the child after birth; she could be given a court order to part with the child, but courts are often reluctant to do this, even though she may have been under formal contract. Many jurisdictions regard the woman giving birth as the mother, *ipso facto*, even if it did all start with someone else's egg or embryo. Because of difficulties such as these, the procedure may be declared illegal (Scott, 1987).

Such measures may be considered needlessly draconian, for there plainly can be circumstances (as, for instance, when a woman's infertility is due to congenital lack of uterus or to hysterectomy for cervical cancer) when a pregnancy is not possible and yet the couple hopes for a child with the normal parent-child genetic relationship, rather than adopt an unrelated infant, so that a surrogacy arrangement would be the best, indeed the only, solution. There are instances in which a member of the immediate family has helped out in this way – recent cases include a sister, a mother, and even a grandmother. Here, financial reward was presumably not expected, but if the surrogate is quite unrelated, some sort of reward, in addition to insurance against risk, is surely justified. The proceedings could be under the control of something having the legal status of an adoption society, which could also serve as a kind of clearing house, with a dossier of women prepared to function as surrogates and found to be suitable for the task, and such a service would need some measure of publicity. Alternatives to total prohibition do merit careful consideration.

Genetic engineering

In a strict sense, genetic engineering could be said to have begun with the observations made by Fred Griffith (1928) in the UK; he reported that some of the heritable characteristics shown by bacteria when they are grown in laboratory culture systems could be exchanged between two strains of the same organism (*Streptococcus pneumoniae*) by means of cell-free extracts, and in 1944 workers at the Rockefeller Institute in the USA established that the 'information' that passed from one strain to the other was, as it were, written into the structure of molecules of DNA (deoxyribonucleic acid). The process was termed 'transformation'. Later other people in the USA found that viruses were capable of transferring the DNA molecules from one bacterial strain to another, or from one mammalian cell to another, or even between viruses and mammalian cells; this method of information exchange was identified by the names 'transduction' or (later) 'transfection'.

Elective abortion

Under English law, a pregnancy may be terminated if 'continuation of the pregnancy would involve risk to the life of the pregnant

woman...greater than if the pregnancy were terminated'. It is well recognized that continuation of any pregnancy involves greater risk than termination; that would seem to leave the fetus with no protection at all, but most doctors were prepared to interpret the law as it was presumably intended to be, and offer termination only on sound medical grounds. However, in the course of time, interpretation has become more liberal. At a recent international medical conference, the situation was summed up by an obstetrician quite simply: 'The Act provides for two doctors to allow abortion when they and the woman feel it is the best solution to her problems'. In the United States, the Supreme Court has ruled that, during the first trimester of pregnancy, a woman has a constitutional right not to have a child if she does not want it. The philosophy is reinforced by court cases in which parents claim damages from doctors for not informing them adequately about the possible birth of a defective child, thus allowing them an opportunity for abortion, and handicapped children sue doctors and even parents for 'wrongful birth'.

There are, however, indications of growing opposition to abortion, and not only to that but even to antenatal diagnosis, which of course often provides the reason for abortion. The mounting feeling – which could be termed 'humane thinking' – is that even a genetically defective fetus has a right to be born and experience life outside, though it may be short and nasty, and publicity has been given to accounts by people who have wittingly become the parents of handicapped children, claiming that the experience has enriched their lives. This, of course, must depend very much on the people involved, for the necessary tolerance and dedication are not granted to everyone; so the decision not to abort a genetically defective fetus must remain one essentially for the parents to make. The change in popular outlook is already being reflected in an increase in the frequency with which defective births are being reported.

In recent years, the rights of the fetus have become subjects of debate in rather a different connection, namely the use of fetal brain and adrenal gland tissue for the treatment of degenerative brain conditions in adults. If the fetus is obtained following an abortion quite unconnected with its subsequent use, there can be no serious ethical objections to the procedure (though some do demur), but there is a clear possibility that the provision of material for the treatment of a relative or friend, or in frankly commercial circumstances, could prove to be an adequate motive for an induced abortion.

There could, of course, also be cases of women becoming pregnant with the purpose of supplying fetal material, especially if such transplants prove to be the only effective means of treatment, and from some points of view the procedure is morally defensible if the rights of an adult person are held to prevail over those of the fetus.

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