LEGAL AND ETHICAL ISSUES PERTAINING TO PREIMPLANTATION GENETIC DIAGNOSIS

July 2003

Dr Christine Yap
Consultant Obstetrician & Gynaecologist
IVF Clinician
Singapore General Hospital

Ms Laura Liew
National University of Singapore

Introduction

Preimplantation Genetic Diagnosis (PGD) is a procedure that aims to weed out genetically defective embryos before they have a chance to develop. It is a procedure that is done in conjunction with *in vitro* fertilisation (IVF). Hence it is necessary to outline the legal and ethical implications of IVF as they are relevant to the discussion of the issues related to PGD.

Relevant Legal Issues

Eligibility/Access to Treatment

Currently, there is no specific legislation relating to the entitlement of a person to gain access to treatment services. In the Singapore context, due to the social and economic mores of our society, this treatment (if approved) will be restricted to only married heterosexual couples who may or may not be fertile.

However in the absence of any legislation or case law supporting this situation, potential problems may arise in the event a determined couple who does not fit into this category wants to have this procedure performed. There is nothing to stop them from trying to enforce their desire in court.

But given the prevailing situation in Singapore which is generally a non-litigious society and where such unconventionality is frowned upon, it is an unlikely scenario. However in order to avoid this problem, it is necessary to list down clearly the prerequisites that must be fulfilled in order to be eligible and have access to treatment and draw up a list of guidelines to make sure they are strictly enforced to avoid any ambiguity.

Conscientious Objection

The right to 'conscientious objection' is contained in section 6 of the Termination of Pregnancy Act (Cap 324). Section 6 provides as follows:

6. —(1) Subject to subsection (3), no person shall be under any duty whether by contract or by any statutory or legal requirement to participate in any treatment to terminate pregnancy authorised by this Act to which he has a conscientious objection.

(2) In any legal proceedings the burden of proof of conscientious objection referred to in subsection (1) shall rest on the person claiming to rely on it and that burden may be discharged by such person testifying on oath or affirmation that he has a conscientious objection to participating in any treatment to terminate pregnancy.

Although it is a provision that relates to the termination of pregnancy, it may be invoked in an analogues situation such as the performing of a PGD or IVF procedure. Essentially, the right to conscientious objection allows a doctor, nurse or other individual to refuse to 'participate' in a licensed activity to which they have such a conscientious objection. Such a matter of conscience is widely understood to cover religious, moral or other principled beliefs that lead the individual to conclude that the activity is wrong.[1]

In trying to establish when such a right may be used, difficulties may arise. It is not clear whether the individual must object to participating in a whole class of activity or whether he may also object to participating only in particular situations or parts of a licensed activity.

An example cited by Ian Kennedy and Andrew Grubb of how such a right may be exercised is as follows. Would an individual's objection to being involved in embryo biopsy fall within such a right even if he has no objection to IVF in principle? There is no clear answer though they are of the view that it may be argued that this right only permits an individual to have a conscientious objection to a class of activity but does not allow an individual to pick and choose which parts of the licensed activities he is prepared to be involved in.[2]

Consent to Use and Control of Genetic Material

Consent is relevant in two distinct ways. First, there is a need for those who are donating genetic material and those being treated for infertility to consent to the medical procedure. Secondly, the issue of consent arises with regard to the future use or storage of an individual's genetic material.

[1] Ian Kennedy, Andrew Grubb, *Medical Law: Text with Materials*, 2nd ed Butterworths, London (1994)
[2] *Ibid*

Consent to the procedure

A donor of genetic material or a patient undergoing infertility treatment must consent to the medical interventions involved. This is to avoid any later difficulties that may arise in trying to establish the legitimacy of the child born after treatment.

In Singapore, the Law Reform Committee of the Singapore Academy of Law produced a report on the status of children born through artificial conception in 1995. A bill entitled the Status of Children Act has been proposed so as to clear up the issue of the legitimacy of a child conceived in such a manner. Though not yet enacted into law, it would be useful to refer to it. The URL is as follows:
http://lwb.lawnet.com.sg/legal/lgl/html/freeaccess/lrcr/artificial_conception.pdf.

Control of gametes and embryos

The issue at hand here concerns the extent to which the providers of gametes and embryos may exercise legal control over their genetic material. Currently there is no legislation or Singapore cases which addresses the issue in question. What may be helpful here is the position in England under the Human Fertilisation and Embryology Act 1990 (Cap. 37 of 1990) ("the HFEA"). There is an elaborate scheme of consents that vests control of gametes and embryos in the providers of the genetic material. Schedule 3 to the Act requires that a gamete provider must, at the time that the gametes are procured, indicate in a written consent what use(s) those gametes may be put to. The gametes (or any resulting embryos) may only be used in accordance with those consents.

It is recommended that a regime that will specifically address this issue as to who has control over such genetic material be established. It will be prudent to state clearly who possesses such control and how excess genetic material will be treated (destroyed, used for further research, etc). It is emphasized that this issue of consent with respect to control is a very important issue that needs to be clarified before anything medical procedure begins.

The current state of the law is not clear. However there is a great potential that a Pandora's box may be opened if such a regime is not properly established before treatment begins. Issues such as whether these embryos are to be considered as human or not and who has the right to decide the fate of the genetic material are examples of the thorny issues that may arise if this issue is not properly addressed prior to the beginning of treatment.

It will be useful to see how the US attempts to address this issue. The American Bar association has come up with a discussion draft entitled 'Model Assisted Reproductive Technologies Act' which may be view online at
http://www.abanet.org/ftp/pub/family/art_monograph.doc.

Medical Confidentiality

Every doctor has a duty of confidentiality to his patients, a duty founded in the medical codes of ethics and the law. The basis of the common law duty of confidence is for the benefit and protection of the patient. Hence it is not absolute and may be waived or released by the patient.

In the context of PGD, it follows therefore that a doctor is not to disclose to the parties involved each of the other's medical information in the absence of the parties' consent. A breach of patient confidentiality renders a doctor liable to disciplinary action by the profession as well as legal liability with respect to the patient. A patient may file a negligence suit in the event any unauthorised disclosure of confidential information causes him damage.[3]

In order to avoid legal liability, a doctor must obtain a patient's consent to communicate information about his medical condition. Such consent may be obtained expressly or impliedly. Disclosure should only be done in appropriate circumstances and patients should be told when such information is to be disseminated.

Negligence

As a tort, negligence consists of a legal duty to take care and breach of that duty by the defendant causing damage to the plaintiff.[4] With respect to medical law, there are two aspects of medical negligence that are of relevance here namely negligent counselling and negligent diagnosis.

Counselling and negligence

One of the most significant issues in recent years is the amount of information which a patient ought to be given if a doctor is acting with due professional skill and care. If the doctor fails to give the patient the amount of information which ought to be given, it is now generally held to amount to negligence in law.[5]

If a genetic counsellor or doctor fails to advise prospective parents of the risk (however small) of genetic illness in the foetus, the parents of an afflicted child may choose to raise an action against him in respect of his negligence. In the United Kingdom, there is no doubt that damages will be awarded in respect of negligent counselling.[6]

The concept of informed consent whereby a doctor is under a fiduciary duty to ensure that a patient understands what the risks are involved in undergoing or foregoing certain treatment forms part of the law in the US and Canada. Singapore however does not ascribe to that practice as we follow the English position which provides that so

[3] Catherine Tay, *Medical Confidentiality: Ethical & Legal Issues*
[4] Michael A. Jones, *Textbook on Torts*, 5th ed Blackstone Press Ltd, London (1997)
[5] Douglas Cusine, *Legal issues in human reproduction*, Dartmouth Publishing Co Ltd, England (1989)
[6] Mason & McCall Smith, *Law and Medical Ethics*, 4th ed Buttterworths, London (1994)

long as the doctor follows the practice adopted by a responsible body of doctors in relation of what or what not to tell, he or she will not be negligent.

Diagnosis and negligence

The *Bolam* test is the controlling test in Singapore with respect to medical negligence. It is stated as follows:

"The test is the standard of the ordinary skilled man exercising and professing to have that special skill. A man need not possess the highest expert skill at the risk of being found negligent … it is sufficient if he exercises the ordinary skill of an ordinary competent man exercising that particular art."

In essence, a doctor will not be found negligent if he exercises reasonable care and skill. Even if there is a body of opinion that takes a contrary view, a doctor is not negligent if he is acting in accordance with such a practice. Thus liability only arises if a doctor fails to match that standard of care in carrying out his duty as a professional.

Relevant Ethical Issues

Artificial reproductive techniques raise difficult ethical issues. Objections to such procedures include the argument that they should not be acceptable because they are 'unnatural'. Such techniques are deemed 'unnatural' in the sense that the 'sacred process' of life is the prerogative of God and should not be interfered with.[7] This argument promotes the view that procreation should only be done in the way God intended which is through sexual intercourse. However as argued by Athena Liu, this line of argument is vague and is clearly not a belief rigidly adhered to by those who are prepared to use artificial techniques to procreate and thus should not seriously suggest that these people's view should be converted.

A second interpretation of the 'unnatural' argument is based on the belief that these techniques contravene the 'natural law'. The objection here is that such reproductive techniques sever the link between the natural and legitimate end of sex and are thus contrary to natural law. This view however fails to establish what useful purpose it seeks to uphold and should not pose a serious threat to such artificial reproductive techniques.

Yet another objection to such procedures is the fear of potential abuse that will lead to the development of a eugenics programme. Using PGD to avoid transmitting a genetic predisposition or a characteristic trait that is deemed undesirable or to choose the sex to select the desired qualities of the unborn child is unacceptable.[8] Hence it is recommended that PGD be strictly used only in situations where the goal is to prevent

[7] Athena Liu, *Artificial Reproduction and Reproductive Rights*, Dartmouth Publishing Co Ltd, England (1991)
[8] Supra n. 1

the transmission of a serious genetic disease. Guidelines should be drawn up and strictly adhered to so as to quell such fears that eugenics practices may emerge.

Another significant ethical issue is with respect to embryos that are not implanted. There are religious and ethical objections to such embryos being used for research and experiment purposes. These views are founded on the basis that such practices are tantamount to meddling with the sanctity of life. However, proponents of experimentation argue that embryonic research is necessary for human welfare for the development and refinement of present procedures as well as to lead to a greater understanding of early embryonic development, survival and implantation and its subsequent evolution.[9]

Conclusion

As outlined above, the legal issues pertaining to PGD should be viewed in conjunction with those of IVF as they are inextricably linked. It would be wise if a doctor is cognisant of all the possible pitfalls and take all the necessary precautions to avoid them.

As for the ethical issues, there will always be fears and objections against procedures of this nature. Sometimes the opposition may be vociferous in their objection. However, so long as there are strict guidelines in place to ensure that doctors do not attempt to 'play God' and that the sanctity of life is given its due respect, such procedures should be given the go ahead for the betterment of Mankind.

[9] Supra n. 7