

Lecture Notes 2009-2010. Code: Med.06.01-v4-01.10)

Medical Law

Topic 6 (of 10) **Lecture 1** (of 1)

**Designer Babies:
The Law and Ethics of Assisted Conception**

Aim:

To outline some ethical and legal issues associated with assisted reproduction and the notional concept of designer babies.

Objectives:

After carefully reading these notes and other prescribed readings for this lecture, you should be able to:

1. Discuss the meanings of infertility and the provision of infertility treatment in the context of the allocation of scarce medical resources and the medicalisation of personal and social matters;
2. Discuss and critically evaluate provisions of the *Human Fertilisation and Embryology Act 1990* as amended by *Human Fertilisation and Embryology Act 2008*;
3. Discuss the ‘advances’ in developing the concept of designer babies and the need, if any, for further ethical and legal regulation.

Social Consequences of Infertility

Marriage, for the purpose of procreation has been approved by Christianity, English Law and society, generally. However, with regard to the *failure* to procreate, *Gillian Douglas*¹ says:

“ ... the facilitation of conception, for those who have difficulty in procreating, has ... always been a concern. The social, religious or cultural need to produce an heir (usually male) to carry on the family line placed great pressure on men and women experiencing problems in doing so.”

[Indeed:] “The infertile may be seen as culturally deviant because of their failure to have children in a society which expects couples to procreate. They may suffer the additional stigma of being accused of immorality, because they are prepared to *pay*² for treatment to achieve a pregnancy, when procreation is supposed to be above commodification.”

Just how many people or ‘couples’ are infertile and what is meant by ‘infertility’ are debatable issues. First, in the preface to her book, *Babymaking* (1988), *Susan Downie* asserts that:

¹ **Douglas, G.** *Law, Fertility and Reproduction*. London: Sweet & Maxwell, 1991, p103

² *ibid.*, p104, emphasis as in the original.

“Assisted reproduction is advancing at such an extraordinary rate today that ... it directly affects ... an estimated 35-105 million people, or one in six couples worldwide ... ”³

Perhaps it isn't so surprising that great uncertainty is reflected in such a remarkably wide ranging estimate, however, given that:

- ‘couples’ includes an unknown (estimated) number of cohabitantes;
- that the estimate is trying to incorporate the results of studies indicating a higher rate of infertility in Africa and other developing countries but a smaller rate in America, where infertility is assessed as about one couple in twelve; and
- there is no clear definition of ‘infertility’.

Moreover, there is no consensual approach as to:

- whether infertility is an ‘illness’ to be overcome by medical treatment; if it is, there is no uniformity in advocating what treatments for the alleviation of infertility should be legally permissible;
- whether the law should have a role to play in regulating such treatments and if so;
 - who should regulate the provision of infertility treatment;
 - who the treatments should be provided for;
 - who should pay for them;
 - who could donate the gametes used in the infertility treatment;
 - how many times treatment cycles could or should be performed if pregnancy does not occur after the first cycle; and
 - how should the welfare of a child conceived and born as a result of assisted conception relate to the needs of its parent(s) for a child?

Attempting to Define Infertility

There is no absolute definition of ‘infertility’: it is an umbrella term that covers different types and spans various times. *Dickens*⁴ has expressed the view that:

“Infertility includes ... [the] inability to conceive or impregnate, and pregnancy wastage, meaning failure to carry a pregnancy to term through spontaneous abortion and stillbirth. Infertility includes primary infertility, where a couple has never achieved conception, and secondary infertility, where at least one conception has occurred but the couple is currently unable to achieve pregnancy.”

Moreover, as *Douglas*⁵ notes:

“To constitute a problem, such inability to produce a child must have continued for a certain length of time. It has been estimated that 63% of normally fertile women having unprotected sexual intercourse with a fertile partner will conceive within six

³ *Ruth Deech*, former Chairman of the *Human Fertilisation and Embryology Authority*, has also said that ‘About one in six couples suffer from problems of infertility at some time in their lives’. See, also, (1999) *The Times*, February 23rd.

⁴ *Dickens, B. Reproduction Law and Medical Consent* (1985) 35 U. Tor.LJ 255 (As cited in *Douglas*, op.cit.,p104)

⁵ op.cit., p104.

months, and 80% will conceive by the end of one year. A failure to conceive within a year may therefore indicate a potential problem ... But the *World Health Organisation* takes *two years* as the cut-off point, and demographers may take *five years* as significant.”

The *Advanced Fertility Center of Chicago*, which provides infertility treatment on a commercial basis, defines infertility as ‘12 months of unprotected intercourse without pregnancy’. Clearly, the shorter the term associated with ‘unprotected intercourse without pregnancy’ (i.e., one year as opposed to five years) the easier it is to associate it with a ‘problem’ and, consequently, to offer and commercialise the practice of its alleviation.

Methods of Overcoming Infertility and Enlarging / or Starting a Family

Methods of overcoming the many possible causes of infertility include: artificial insemination of the woman by donor sperm (sometimes abbreviated as A.I.D. or, even, DI) where her male partner is infertile or carries an inherited disease which may be passed on to a child of the couple; or inseminating her with her partner’s sperm if he has erectile dysfunctional problems or a low sperm count (when the ICSI procedure – intracytoplasmic sperm injection – the introduction by injection of a single sperm into an ovum may be used); and, with regard to the woman, *in vitro* fertilisation, (IVF) a procedure which has developed since the mid 1970s. In this procedure, an ovum is fertilised outside the woman’s body and thereafter transferred into the uterus of the recipient woman. IVF may be performed using the woman’s own ova – the procedure being adopted because the woman has, perhaps, blocked fallopian tubes (‘tubal infertility’) – or donated ova so as to avoid the transmission of a genetic defect. “IVF therefore open[ed] up the possibility for the first time, that the woman who gives birth to a child may not be its genetic mother.”⁶

Although IVF “opened up new horizons in the alleviation of infertility [to the extent that] It [became] possible to observe the very earliest stages of human development, and [brought about] the hope of remedying defects at this very early stage”⁷, it became apparent that:

“Society’s views on the new techniques were divided between pride in the technological achievement, pleasure at the new-found means to relieve, at least for some, the unhappiness of infertility, and unease at the apparently uncontrolled advance of science, bringing with it new possibilities for manipulating the early stages of human development.”⁸

In response to such concerns, four years after the birth in England in 1978 of *Louise Brown*, the world’s first ‘test-tube baby’ (i.e., the first baby born via the IVF procedure developed by *Steptoe* and *Edwards*) the Government established in July 1982 the *Warnock Committee* with the terms of reference:

“To consider recent and potential developments in medicine and science related to human fertilisation and embryology; to consider what policies and safeguards should be applied, including consideration of the social, ethical and legal implications of these developments; and to make recommendations.

⁶ *Douglas, G*, op.cit., p108; and see: “Woman gives birth to her own grandchildren” (2004) *The Times*, January 30th, p17.

⁷ *Warnock Committee, Report of the Committee of Inquiry into Human Fertilisation and Embryology*, Cmnd 9314, 1984. London: HMSO, 1.1

⁸ *ibid.*

Thus, it was the development and the *possibility of manipulating the development* [of human fertilisation and embryology via IVF] that brought about the perceived need for ‘policies and safeguards [and consideration of] ethical and legal implications’. The issue of paternity apart, the long history of AID which, it appears, was first used in human reproduction over 200 years ago (1776) with the first birth being recorded in 1790, has not had the same dramatic impact.

Legal Regulation of Modern Reproductive Processes

The *Warnock Committee* reported in July 1984, two years after it was set up. Many of the recommendations were subsequently enacted in the *Human Fertilisation and Embryology Act 1990 (HFEA 1990)*⁹. One of its recommendations, to establish a regulatory authority to oversee continuing developments in human fertilisation and embryology, came to fruition in the *Human Fertilisation and Embryology Authority (HuFEAu)* as provided for in s.5 of the *1990 Act*.

The *HuFEAu* is a body of 22 persons¹⁰ of which no more than about half are medical practitioners, the others being ‘non-professionals’ and include *Anna Carragher, retired Controller of BBC Northern Ireland*, and *Sally Cheshire* (until November 2009), *Director of Deloitte & Touche*. Appointments made in accordance with the guidance from the *Commissioner of Public Appointments* (the ‘Nolan’ Guidelines) and are for renewable periods of three years.

The Authority has the power to grant or withhold licences for procedures that involve the creation of an embryo *ex vivo* (i.e., outside the woman’s body) or use gametes (sperm or ova) that are donated or stored. Moreover, s.11 *HFEA 1990* provides that the *HuFEAu* may grant any one of **three types of licence**¹¹, and no other, to authorise:

- Activities in the course of providing treatment services: ss.11(1)a (and 13 and sch.2, para 1);
- The storage of gametes and embryos: ss.11(1)(b) (and 14 and sch.3);
- Activities for the purpose of a project or research: ss.11(1)(c) (and 15 and sch.2, para.3).

It is important to note that it is not merely licensed activities that are lawful, however. Artificial insemination of a woman with sperm freshly obtained from her husband / partner; Gamete Intra-Fallopian Transfer (GIFT); and the use of fertility drugs to stimulate ovulation come within this category.

Where applicable, licences are granted under s.12 in respect of authorised activities on specified premises that are carried out under the supervision of the person responsible for the licensed activities. Procedures that cannot be licensed – such as cloning and placing a human embryo in an animal – are specified in s.3(3) *HFEA 1990*.

⁹ N.B. Many provisions of the 1990 Act have been amended by the 2008 Act. Note, in particular, the change of wording in s.13(5) which has substituted the words: “including the need of that child for supportive parenting” for “including the need of that child for a father”.

¹⁰ The current Chairman is *Professor Lisa Jardine CBE*.

¹¹ N.B. This is not strictly true, since s.11 was amended by the *Human Fertilisation and Embryology (Quality and Safety) Regulations 2007/1522* to insert s.11(1)(aa) – but that will not be discussed here.

S.20 of the *Act* provides that an appeal against the refusal to grant a licence for an activity must be made to the HuFEAu and be heard by members of the Authority that do not include those who made the ruling that is now being appealed. Appeal beyond the HuFEAu is on a point of law, only: *s.21 HFEA 1990*. Whilst it is difficult to challenge the Authority's discretion, such a challenge was successful in *Diane Blood's* case. (*infra*)

For a practitioner's view of the *Human Fertilisation and Embryology Authority*, see: 'Fertility expert says regulator is ineffective and should be scrapped' – the views of *Professor Lord Robert Winston* – (2004) *The Times* December 11th.

Developing Issues

A significant function of the Authority is to produce and maintain in force a *Code of Practice* to give guidance about the proper conduct of licensed activities and of the welfare of children born following treatment services: see *ss.25, 26(2)* and *13(5) HFEA 1990*. As to what *you* think may be termed 'proper conduct', consider:

Eligibility for Fertility Treatment

Issues to be borne in mind include:

- IVF involves the allocation of scarce medical resources to what some would contend is the unnatural alleviation of what is not an illness or a disease. Money/resources involve: medical staff; beds; the involvement of altruistic donors, some of whom will have to undergo invasive treatment – particularly when there are "potentially serious 'unknown long-term' risks for women who donate their eggs to allow another woman to have a baby". (See (1998) *Sunday Telegraph*, August 2nd; (1998) *Sunday Times*, November 22nd; and (1998) *The Times*, November 23rd; and the use of expensive drugs (perhaps £1,600/month).
- Should IVF be offered on a "no baby, no fee" treatment deal"? (See (1998) *The Times*, September 10th).
- "Granny" / "retirement" pregnancies: on what basis can or should there be no discrimination solely on the basis of a woman's age?
- Should treatment be confined to married women / widows of a maximum age given that: "One of Britain's foremost fertility specialists has been officially reprimanded for treating older women, lesbians and single mothers" (See (1998) *Sunday Times*, March 1st).
- From the last two points, should an unmarried woman of 66 be given 'hormone treatment for nine years to delay her menopause' and be artificially inseminated so as to give birth at an age when many other women are great-grandmothers? See: 'When this new baby is 16, her mother will be 82', (2005) *The Times*, January 17th, the story of *Adriana Iliescu*, the retired 66-year-old university professor who gave birth to a daughter in Bucharest, Romania, on 16th Jan 2005.
- What degree of counselling should a woman be given prior to undergoing IVF treatment given that doctors have cited 60 studies 'which represent hundreds of cases of cancer that may be linked to fertility drugs'? (See (1998) *Sunday Times*, March 15th).

The Limits of Acceptability of Sources of Donated Gametes

- Has the ‘limit’ been reached / exceeded in respect of a man, from whom sperm is extracted, when he is comatose and has not provided written consent for his wife to be impregnated in the event of his death? (The *Diane Blood* case);
- A man from whom sperm was taken *after his death*? (See (1998) *The Times*, July 16th);
- “High quality” donor sperm from a commercial sperm bank? (See (1998) *The Sunday Times* July 26th); (See also (1999) *The Times*, February 7th);
- “Warning: don’t buy sperm on the internet”: (1998) *The Times*, January 1st;
- Eggs from an aborted foetus? (See (1994) *The Sunday Times*, January 2nd; (1994) *The Times*, January 3rd; (1994) *Sunday Express*, January 9th and February 13th);
- A woman who ‘had her eggs harvested and fertilised by an anonymous sperm donor shortly after she began treatment for leukaemia, which she knew would make her sterile. But [who] in her dying weeks gave her blessing to [her parents for them to find] a host mother for her baby after her death? (See (1997) *Sunday Telegraph*, October 12th and November 30th – the American story relating to the parents of *Julie Garber* who were accused “of trying to ‘duplicate’ their dead daughter by paying £10,000 to a surrogate to have her baby);
- Nuclear transfer – in which the nucleus of an egg of an older woman is transferred to the fertile egg of a younger woman from which the nucleus has been removed? (See the articles: ‘The baby that would have two mothers’ and ‘Baby race that may be too fast for safety’, (1998) *The Times*, October 10th); & see: *ex parte Quintavalle* [2003] UKHL 13.
- Should cloning be permitted? “Top scientists want ‘cowboy’ cloning banned” (2004) *The Times*, January 21st ;
- A child conceived by a 59-year-old widow from an egg from an anonymous donor and sperm from a deceased husband? (See (1998) *Sunday Times*, September 20th).
- “Asian women seek white donor eggs for light-skin babies” – “British fertility clinics are providing infertile Asian women with donor eggs from white women to produce white and mixed-race babies” – (2003) *The Sunday Times*, November 16th .

Issues of Parenthood, Legitimacy and of the Welfare of a Child Resulting From Fertility Treatment

- First, see: *ss.13(5)* [following its amendment by the 2008 Act], *25(2)* and *27-30(1)* *HFEA 1990*;
- ‘When a couple are treated “together” to include the “use” and storage of their embryos but later separate, with the woman seeking implantation of the frozen embryos that have been kept in storage whereas the man had withdrawn his consent, it had to be determined whose wishes would prevail. In *Evans v Amicus Healthcare* [2005] Fam 1; and *Evans v UK* (6339/05) 1 FCR 585, it was Held Natalie Evans’ wish to become a mother was overridden by her former partner’s right not to be a “father”. **N.B.:** Read this case – and see *Sch.3 para.4A* of the 1990 Act as amended (re. The one year “cooling off period”)!’
- “Multiple births a mixed blessing for IVF parents” (2003) *The Times*, October 16th – ‘Women who have twins or triplets after undergoing IVF are suffering depression, stress and marital problems as a result, a study [at the Harvard Medical School in Boston] says. [paragraph 1 of the news item]. Then, [in paragraph 8] it reported that: “In

Britain, the Human Fertilisation and Embryology Authority plans to ban the transfer of more than two embryos in all but exceptional circumstances, and some European countries, notably Denmark, insist on single transfers. In *America*, however, the transfer of up to five embryos is routine".

- (2003) The Sunday Times, March 9th – ‘IVF mothers abort ‘spare’ babies’ – ‘Women who find they are expecting twins or triplets after receiving treatment for infertility are choosing to have one or more babies aborted ... 49 babies were destroyed in the womb by lethal injection in one year, usually to spare their mothers the additional burden of raising them. ... Although some of the babies might have had defects, many would have been healthy and were chosen at random.’ (From the article by **Lois Rogers**, Medical Correspondent).
- Should children born as a result of sperm and egg donations have a right to trace their genetic parents? (See, for example: “Donor children win right to find biological parents” (2004) The Times, January 22nd - and the potential consequence: “Egg shortage threatens baby hopes of thousands” (2004) The Times, January 22nd. The article claims that: “Thousands of infertile couples will be denied their only chance of having children by government plans to strip egg and sperm donors of their anonymity, leading doctors said. Legislation allowing donors to be identified by their genetic offspring would cut off the major source of eggs used in fertility treatment, ending the hopes of women who cannot otherwise conceive a child”. (See now ss.31ZA and ZB of the **1990 Act** as amended and the **Human Fertilisation and Embryology Authority (Disclosure of Donor Information) Regulations 2004, SI 2004/1511**, in force as from 1st July 2004).
- The issue of gender selection: see the Masterton case and **Sch.2 paras,1ZA and 1ZB** of the **1990 Act** as amended; And note:
- (2003) The Times October 17th – “Sex selected babies ‘just as healthy’”: the article claiming that: “Babies born after a controversial sex-selection procedure appear to be just as healthy as those conceived in natural circumstances, according to new [data]. The rate of birth defects in children born after **MicroSort** treatment is between 3 and 4 per cent, a similar incidence to the general population, scientists behind the technique said”.
- (2004) The Times, August 18th – ‘Embryo checks found safe for designer babies’: ‘Embryo screening that is used to create “designer babies” does not threaten their health, the largest ever study of the procedure has found.’ (First paragraph of the article by **Mark Henderson**, Science Correspondent).
- (2004) The Times, November 1st – “Cancer-free ‘designer babies’ get approval”. ‘The ruling by the Human Fertilisation and Embryology Authority deepens the controversy over designer babies. It sets a precedent that will allow doctor’s to ‘cherry-pick’ embryos for a much wider range of traits than at present’. (From the fourth paragraph of the article by **Mark Henderson**, Science Correspondent)
- With regard to the responsibility for a ‘Defective Product’, see, *inter alia*, **s.1A Congenital Disabilities (Civil Liability) Act 1976**.
- See (1998) The Sunday Telegraph, February 1st: “Test-tube baby who is ‘nobody’s child” – the story of a “blue-eyed infant who, a Californian court sa[id] has no parents because she was born in an infertility clinic and born to a surrogate mother.”
- (2004) The Times, September 12th – ‘Court lets couple keep the twins who have five parents’ (donor couple – infertile / adoptive couple – carrying ‘mother’; carrying ‘mother’ was the mother of the infertile woman in the infertile / adoptive couple)

- “Rent-a-womb ‘addict’ plans baby No.9” – “Britain’s most prolific surrogate mother is about to become pregnant for the ninth time and says she will only ‘retire’ after producing 10 children for infertile couples”: (2003) *The Sunday Times*, June 29th.
- How, if at all, would you amend the *Warnock* recommendation that there should be a limit of 10 children fathered by one sperm donor?
- When, if ever, is it permissible to participate in IVF treatment for the purpose of producing a baby that would be free of a specific disease *and* whose blood type would match its older sibling who suffers from that disease, the intention being that the new-born would be a source of stem cells that might save the life of the older child? See: “Couple win right to create life-saving baby” (2002) *The Times*, February 23rd. (The article referred to the Hashmi family. Mrs Hashmi eventually conceived, but it was reported on the 10th December 2003 that she had miscarried. She was said to be ‘devastated’ but that she would ‘try again’). See also: ‘Embryology authority entitled to license tissue-typing tests’, the report of: *R (Quintavalle) v. HuFEA*, (2003) *The Times*, May 20th – the Court of Appeal decision allowing the appeal by the HuFEA in response to *Josephine Quintavalle’s* claim on behalf of CORE (Comment on Reproductive Ethics) that the initial decision of the HuFEA to permit the tests that the Hashmi’s wanted was unlawful. Contrast the Hashmi case with that of the *Whitakers* see: ‘Designer baby to save our sick son’, (2004) *Daily Mirror* September 7th – the essential difference between this case (involving the Fletcher family) and the Hashmi’s case being that the Hashmi’s had to seek permission for the tissue typing whereas, after the HuFEA relaxed their restrictive rules in July 2004, the Fletcher’s were granted permission for tissue typing at the time they received permission for PGD. See also: ‘Curbs on embryo-testing scrapped’ (2005) *The Times* January 20th - in essence, once PGD was licensed at one clinic, other clinics may be licensed ‘so long as their technical proficiency has been approved’. See now *Sch.3, para.1ZA(d)* of the 1990 Act as amended which expressly permits embryo testing for the purpose of tissue typing.

Excusal from assisting in the provision of fertility treatment via Conscientious Objection

s.38 HFEA 1990 provides that:

- (1) No person who has a conscientious objection to participating in any activity governed by this Act shall be under a duty, however arising, to do so.
- (2) In any legal proceedings the burden of conscientious objection shall rest on the person claiming to rely on it.

References

- Brazier, M & Cave, E.** *Medicine, Patients and the Law*, 4th edn., 2007. London: Penguin, Ch.13
- Douglas, G.** *Law, Fertility and Reproduction*. London: Sweet & Maxwell, 1991.
- Downie, S.** *Babymaking: The Technology and Ethics*. London: The Bodley Head, 1988.
- Herring, J.** *Medical Law and Ethics*, 2nd edn., 2008. Oxford: OUP, Ch.6.
- Jackson, E.** *Medical Law Text, Cases, & Materials*, 2nd edn., 2009.. Oxford: OUP, Ch.15;
- Mason & Laurie.** *Mason & McCall Smith's Law & Medical Ethics*, 7th edn., 2005, Oxford: OUP, Ch.4;
- Pattinson, D.** *Medical Law and Ethics*, 2nd edn., 2009. London: Sweet & Maxwell, Ch.8;

Some Concluding Comments on the Modern Reproductive Processes

1. ***The 'post-code' lottery*** – the treatment, if any, that might be available on the NHS has been shown to be dependent on where one seeks treatment. Moreover, see: 'Britain is worst in Europe at helping infertile couples', (2003) *The Times*, July 3rd.
2. ***Acceptance on a Programme of IVF Treatment is Arbitrary, Discriminatory and Requires the Breach of Confidentiality.***
Who is treated? 'Yes' to 'granny' pregnancies but 'No' to homosexual couples even though gay couples have lawfully adopted a child? Should it be permissible for a black woman to undergo IVF with eggs harvested from a white woman? Are the couple to be treated suitable parents – how detailed should questioning be in order for someone (who?) to determine the suitability of a couple for parenthood?
3. ***It is selective.***
Not all reproductive techniques are employed. Who, if anyone outside the doctor-patient relationship should determine what is acceptable and what isn't when medical science continues to extend the range of potentially viable options – e.g., what is "wrong" with eggs from the dead (aborted fetuses); cloning and parthenogenesis? (With regard to cloning, see: ***Human Reproductive Cloning Act 2001***; *R v. Secretary of State for Health ex parte Quintavalle* [2003] UKHL 13; and (2004) *The Times*, June 17th - 'Stem cell researchers to get first embryo cloning licence'.)