

Report of The Commission on Assisted Human Reproduction

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Additional Work Group Members

The Commission invited a number of additional experts with complementary expertise in specific areas to join one of its work groups. These experts joined members of the Commission for Work Group meetings that were held separately from plenary meetings of the Commission.

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Foreword

Infertility can be a devastating experience that causes enormous emotional pain. It can impact on every aspect of an individual's life affecting his/her self-esteem and relationships with others. There are few statistics in Ireland about the prevalence of infertility nor is it known how many couples deliberately choose not to have children. Attempts to alleviate infertility and the deep human feelings associated with it are as old as medical science. For years no reliable treatment was available to alleviate the condition and couples who were childless might be advised to adopt a child. Besides the social pressure to have children, there is frequently a deep and unspoken wish to continue a genetic line through a new generation and this need is not fulfilled by adoption. Science has naturally progressed and reproductive technologies are constantly being improved and developed in tandem with enhanced public awareness of the need for assisted human reproduction (AHR) technologies.

The Commission on Assisted Human Reproduction was set up to report on possible approaches to the regulation of all aspects of assisted human reproduction and the social, ethical and legal factors to be taken into account in determining public policy, in this area. The phrase **assisted human reproduction** was understood by the Commission to refer to any procedure that involves the handling of gametes or embryos. Where feasible the Commission has avoided the excessive use of medical and scientific language in the report.

It is generally recognised that the achievement of *in vitro* fertilisation raises an ethical question not raised by reproductive technologies that attempt to achieve fertilisation within the female body (*in vivo* fertilisation). The fundamental dilemma resides in the possibility that the number of *in vitro* embryos that may safely be transferred to the uterus of a patient is often less than the number of embryos generated. This presents the medical profession, and through them society as a whole, with the dilemma created by the existence of human embryos which will not be used for their intended purpose. And by extension, IVF forces society to face the question whether, for the first time in the history of mankind, human embryos may be used for purposes other than human reproduction. People are also uncomfortably aware of the possibilities inherent in IVF for the commercialisation of the human reproductive process. There is a view that not every person's desire in life should be gratified and that procedures that interfere with nature should not be allowed. However, infertility can be seen as a dysfunction of an individual's body and a case can be made for corrective action.

The Commission took careful note of its terms of reference (see Appendix I) and of a number of key issues identified by the Minister in a note accompanying his letter establishing the Commission. It was clear to the members of the Commission that assisted human reproduction deals with fundamental issues affecting the origins and dignity of personal human life. Accordingly, the Commission decided at an early stage of its deliberations to canvass as broad a range as possible of Irish opinion on the issue. With this in mind a notice was placed in the national press giving the Commission's terms of reference and inviting submissions. In addition, a telephone survey of 1003 adults living in Ireland was carried out. Many respondents counselled extreme caution but there was support for a more pragmatic approach. The Commission investigated the current levels of provision of AHR services in Ireland.

The first element of the task assigned to the Commission was to report on possible approaches to the **regulation** of all aspects of assisted human reproduction. The fact that there is no Irish legislation dealing specifically with the issue left the Commission free to consider the question *ab initio*. Having examined the current legislative position in a number of other countries it reached the conclusion that regulation by statute was desirable.

The second element of the Commission's task was to attempt to identify the social, ethical and legal factors to be taken into account in determining public policy in this area. Ongoing developments in AHR medical technology dictate that it is an area of public concern.

In being asked to advise on the social, ethical and legal factors, the Commission did not attempt to act as the arbiter of public morals. The members were conscious of the strongly held and diverse feelings in the public at large. A broad interdisciplinary approach was taken that allowed recommendations to evolve as a result of informed open debate. It was evident that there exists a broad spectrum of cultural and ethical positions.

The Commission was keenly aware of the fact that assisted human reproduction is an international phenomenon where developments in a particular country may affect and be affected by developments in other parts of the world. Accordingly, cognisance was taken of the social, ethical and legal considerations being applied to the research and delivery of assisted reproduction services in many other jurisdictions. A number of procedures emerging in the wake of *in vitro* fertilisation such as cryopreservation, embryo research, preimplantation genetic diagnosis (PGD), regenerative medicine and reproductive cloning raise new ethical issues in society and for traditional attitudes towards human dignity.

I felt very privileged to have worked with my fellow Commission members and I should like to acknowledge the breadth of knowledge and professional expertise that the members of the Commission, acting in a personal capacity, brought to the exploration of the matters referred to them. I wish to record my appreciation of the expert advice the Commission received from the international scientists, medical doctors, lawyers and especially those people who generously agreed to help the Commission through its specialised work groups. Together these were invaluable in alerting us to the possible repercussions of technological advance for long-established legal and medical practice as well as for values and beliefs that are widely held in Irish society. I learnt a great deal from our discussions and I am deeply grateful for the openness and honesty manifested during the whole process.

The report is intended to reflect the richness and variety of the debates that took place both in the Commission itself and in the work groups. If I may presume to attribute an overall philosophical position to the Commission I think it could be encapsulated in the form of a question: should science do everything that science can do? There was widespread recognition of the benefits of advances in this specialised area of medical science but this was tempered by a note of caution, that society as a whole and not only scientists, must take responsibility for the management of major scientific change, especially in areas that are concerned with the dignity of human life. In our emerging multicultural society it is unlikely that any one set of ethical/moral principles could be completely

acceptable to all. In making its recommendations the Commission sought to put forward a framework broad enough to be generally acceptable to all individuals and groups in society.

The Commission is confident that public debate will play a role in reducing many of the anxieties that people may have and clarify the choices available to individual members of society.

A spirit of genuine enquiry pervaded all the deliberations and I am pleased to be able to record that all members of the Commission felt able to give their assent to the majority of our recommendations.

*Dervilla M.X. Donnelly
Chairperson
March 2005*

Glossary

Blastocyst:	The hollow sphere of cells that develops on day 4/5 from the solid mass of cells produced by the first divisions of a fertilised egg which may implant in the wall of the uterus.
Cloning – Reproductive:	Production of a human being that is genetically identical to another (by the nuclear substitution from a human adult somatic cell or child cell, or by artificial embryo splitting)
Cryopreservation:	Procedure used to preserve and store embryos, sperm and or ova by freezing to very low temperatures.
Cytoplasm:	All of the living part of a cell within the membrane
Diploid cell:	A cell in which the nucleus contains two sets of chromosomes, one derived from each parent.
Embryogenesis:	Term used to describe the early stages of human development, from fertilisation to the eighth week of pregnancy
Embryonic Stem (ES) Cells:	Embryonic stem cell – cultured embryonic cells that can proliferate indefinitely and differentiate into many different cell types and tissues.
Gametes:	Male and female reproductive cells: spermatozoa and ova.
Implantation:	The process in which the embryo penetrates and embeds itself in the lining of the uterine walls in the early stages of prenatal development.
Morula:	A four day old embryo containing 16-32 cells.
Multipotent Stem cells:	Cells that can give rise to differentiated cell types constituting a specific tissue or organ.
Ovum (egg):	Female reproductive cell.
Pluripotent Stem cells:	Cells that can generate all cell types in a foetus and in the adult that are capable of self renewal. Pluripotent stem cells are not capable of developing into an entire organism.
Primitive Streak:	A band of thickening which develops on the embryo at the beginning of the third week of development. The future nervous system will develop in association with this streak
Regenerative medicine:	Regenerative medicine (also known as therapeutic cloning) involves the creation of a cloned embryo using non-diseased donor cells from a patient with a degenerative disease or disorder. The objective is to use the cloned embryo to generate a stem cell line (immortalising those cells) that, in turn, can be used to generate a particular tissue for treatment of the disease in question.
Somatic cells:	All body cells that are not part of the germ line.
Spermatozoa (Sperm):	Gametes produced by the male gonads.
Spermatogenesis:	Production and maturation of sperm within the testes.
Stem cells:	Cells that have the ability to divide indefinitely and to give rise to specialised cells as well as to new stem cells with identical potential.
Surrogacy:	The process where a woman agrees to carry a child for another person(s).
Syngamy:	The process by which the maternal and paternal chromosomes mix in the fertilised egg to form the first diploid cell of an embryo with its own unique genetic makeup.
Totipotent Stem cells:	Cells that have unlimited capacity and can become any tissue of the final organism. Totipotent cells contribute to every cell type of the adult organism.
Zygote:	The first (primordial) diploid cell of the embryo. It is the first cell to result from the fusion of the haploid ovum and spermatozoon

Abbreviations

AHR:	Assisted Human Reproduction
AI:	Assisted Insemination – partner or donor sperm is deposited at the entrance of the cervix or directly into the uterus
AID:	Assisted Insemination by Donor
AIH:	Assisted Insemination by Husband
DNA:	Deoxyribonucleic acid – a nucleic acid that is the main constituent of the chromosomes of all organisms
GIFT:	Gamete Intra-Fallopian Transfer - Assisted reproduction technique where, following stimulation with drugs, mature ova are obtained from the ovary, mixed with sperm and transferred directly to the fallopian tubes where fertilisation may take place
HFEA:	Human Fertilisation and Embryology Authority (UK)
HLA:	Human Leukocyte Antigen (HLA) tissue typing is an additional step to determine the tissue type of an embryo
ICM:	Inner cell mass. These are the cells found on the inside of the blastocyst embryo that may go on to form the foetus
ICSI:	Intra-cytoplasmic Sperm Injection - Method of microinjection of a single sperm directly into the cytoplasm of an ovum
IFFS:	International Federation of Fertility Societies
IUI:	Intra-uterine insemination
IUID:	Intra-uterine insemination by donor
IVF:	<i>In Vitro</i> Fertilisation – a method of assisted human reproduction that surgically removes an ovum from the ovary and combines it with sperm in a laboratory. If the ovum is fertilised the resulting embryo is subsequently placed in the woman's uterus where implantation may take place
IVFDS:	<i>In vitro</i> fertilisation using donor sperm
IVFDE:	<i>In vitro</i> fertilisation using donor egg (ovum)
NISIG:	National Infertility Support and Information Group
OHSS:	Ovarian Hyperstimulation Syndrome - Symptoms may include ovarian enlargement, ascites, hypoproteinemia, hypovolemia, thrombosis, pulmonary oedema, and renal failure
PGD:	Pre-Implantation Genetic Diagnosis
PSS:	Preconception Sex Selection
SCNT:	Somatic cell nuclear transfer
WHO:	World Health Organisation
ZIFT:	Zygote Intra-Fallopian Transfer - Mature ova obtained following stimulation are retrieved from the ovary and mixed with sperm. When fertilisation has occurred, zygotes are placed in one of the fallopian tubes

Executive Summary

This summary provides a brief overview of the contents of the Report, followed by a list of the Commission's recommendations

Establishment and Working Methods of the Commission

The Commission was established in March 2000 by Mr Micheál Martin, TD, Minister for Health and Children with the following terms of reference: *to prepare a report on the possible approaches to the regulation of all aspects of assisted human reproduction and the social, ethical and legal factors to be taken into account in determining public policy in the area.*

The Commission held 23 plenary meetings. It also established a number of work groups comprising Commission members and other participants invited for their expert knowledge of particular aspects of assisted human reproduction (AHR). The work groups met on a number of occasions to consider a range of topics referred to them and they prepared a series of reports that were taken into account by the Commission in preparing its report.

Infertility

Definition and causes

The Commission agreed to adopt the definition of infertility formulated by the World Health Organisation (WHO), namely “lack of conception following one year of unprotected sexual intercourse” (WHO 1993). A number of conditions - some congenital, some occurring in post-pubertal life - are known to affect the capacity of the female to ovulate and of the male to produce sperm of sufficient quantity or quality to achieve a pregnancy, but for about one-third of infertile couples the cause of infertility cannot be found. The infertile member of a couple is as likely to be male as female.

Treatment

The Commission decided that the term assisted human reproduction (AHR) should be used in its report to refer only to procedures that involve the handling of gametes and embryos. Two main types of intervention are comprehended by this definition: assisted insemination (AI) **and** *in vitro* fertilisation (IVF). The essential difference between them is that AI involves the handling of male gametes only and fertilisation takes place within the female body (*in vivo*), while IVF involves the handling of both male and female gametes and fertilisation takes place outside the body (*in vitro*).

Information/Counselling/Consent

Adequate factual information should be provided before treatment commences so as to ensure that patients fully understand the treatment options available to them. Counselling should also be available from appropriately qualified counsellors before, during and after treatment as an integral part of the service offered by recognised clinics. The full and free consent of patients should be obtained before a service provider commences treatment. Moreover, patients who are not successful may need considerable psychological support to enable them to come to terms with the fact that technology cannot help them. This support should be available to people who need it from appropriately qualified counsellors.

Benefits/Risks/Success Rates

The Commission recognised that infertility, and its treatment, can be an extremely traumatic experience for people affected by it. Accordingly, AHR patients, prior to deciding on a course of treatment, should be made fully aware of the potential benefits and risks inherent in such a decision. The benefit of AHR is the obvious one that it makes it possible for people who cannot conceive in the normal way to have children of their own. But patients should also be made aware of the available evidence on the risks of AHR for the health of women and children and of the evidence relating to success rates in AHR treatment.

Commercialisation

Commercialisation arises in medical practice if commercial considerations get priority over patient welfare in arriving at treatment decisions. Since AHR is thought to be especially vulnerable to the risks of commercialisation, the Commission took the view that all necessary steps should be taken to ensure that AHR services in Ireland are completely free from any suspicion of commercialisation.

***In vitro* Fertilisation, Superovulation, Cryopreservation**

In vitro fertilisation, literally “fertilisation in a glass”, was first successfully used in England in 1978 and a number of modifications, including superovulation and cryopreservation, have been introduced since then. Superovulation involves the use of drugs to stimulate a woman’s ovaries leading to the production of multiple ova. Superovulation has become standard international practice in AHR. It is also standard practice to attempt to fertilise all ova, on average about eight, retrieved following superovulation. However, the normal practice in IVF centres in Europe and Australia is to transfer not more than two embryos to the uterus in the course of a single treatment cycle.

The surplus embryos not used for immediate transfer may be preserved in a frozen state (cryopreservation) for further use by the couple who produced them, thereby avoiding the necessity of repeating the risky and uncomfortable procedure of ovarian stimulation. (Sperm may also be preserved in a frozen state. At present ova are not routinely frozen). If frozen embryos still remain after the couple has completed their treatment, the available options include: donation to another couple, donation for research and being allowed to perish.

The Practice of AHR in Ireland

Provision of AHR services

With a view to establishing the level of provision of AHR services in Ireland, the Commission carried out three surveys, one of general practitioners (GPs) and two of consultant obstetricians/gynaecologists. The survey of GPs suggests that they are the first point of contact for most infertile people, that they provide essential diagnostic and referral services but that they do not, in general, provide artificial insemination or *in vitro* fertilisation. At consultant level a relatively small proportion of obstetricians/gynaecologists are infertility specialists who provide AHR services in separate clinics. There were nine such clinics in Ireland when the Commission updated its survey and they were all located in or near large centres of population.

Funding of AHR

AHR is not at present funded directly by the General Medical Service and the Commission was asked not to make recommendations with respect to funding. Some financial assistance is however provided by the State for AHR patients. For example, they can offset the cost of private treatment against their income tax liability, and the cost of prescribed AHR medicines is an allowable expense under the Drugs Refund Scheme. Moreover, some clinics provide subsidised treatment at their own expense for selected couples.

Users of AHR services

In trying to estimate the level of use of AHR services the Commission was assisted by the National Infertility Support and Information Group (NISIG). The group was represented on the Commission by its Chairperson who made available the anonymised results of a survey of its members carried out by the group. The comments of respondents to the survey regarding their experience of AHR were generally positive.

Legal Considerations

Article 40.3.3 of the Irish Constitution provides constitutional protection for the ‘unborn’. It is not clear whether protection applies from fertilisation or from some subsequent point in the process. This lack of clarity has implications for the provision of AHR services in Ireland. Clarification can only be sought in two ways: either from the Supreme Court or by way of constitutional referendum. Moreover, the further issue of whether a gamete provider has ownership or property rights in respect of his/her gametes has not been decided by any Irish court to date. Further legal considerations arise in the context of donor programmes and surrogacy.

Ethical/Social Factors in AHR

The Commission recognised that AHR is a relatively new development and that it raises important ethical and social issues for society. It agreed that the general public has a legitimate interest in the provision of AHR services in Ireland on the grounds that society as a whole is affected by technical intervention in human reproduction and its broadening effect on the meaning and role of the family. It noted recent legislation in Ireland on such ethical issues as abortion, contraception and divorce and felt that the debates on these issues provide an indication of the evolution of ethical attitudes in Irish society over the last thirty years.

There was little information in the public domain regarding public attitudes towards AHR prior to the establishment of the Commission. Accordingly, the Commission sought to canvass public opinion on AHR in Ireland by means of a public conference, a newspaper advertisement and a telephone survey. The evidence from the surveys indicates that public opinion ranges from total opposition to all forms of AHR on the one hand to uncritical acceptance of any assistance that science can give to infertile people on the other. Two main intermediate positions on that continuum were identified. One accepts the principle of technical intervention in human reproduction subject to the condition that the *in vitro* embryo attracts legal protection from the point of fertilisation; the other also supports the principle but holds that the *in vitro* embryo does not attract legal protection until some subsequent point. The evidence also indicates that the treatment of the *in vitro* embryo is a complex issue on which public opinion is divided. The Commission itself was unable to reach unanimity on this point; one member holding the view that legal protection should apply to the *in*

vitro embryo once the process of fertilisation is complete and all other members holding that legal protection should not apply until the point of transfer to the uterus.

Another ethical issue examined by the Commission was whether AHR should be available only to married people or to any adult who requests it regardless of relationship status, social position or sexual orientation. Attitudes among providers and the public in general appear to be sharply divided on this question. Following lengthy consideration the Commission felt that any relevant legislation on the provision of AHR should reflect the general principles of the Equal Status Acts 2000-4 subject to derogations in relation to the upper age of patients and to circumstances where the welfare of the child might be held to be at risk.

The Commission took the view that the welfare of the child should be a primary consideration in the provision of AHR services. In fact, the welfare of the child was a major factor in the Commission's thinking on the need for statutory regulation of AHR services.

Donor Programmes and Surrogacy

The involvement of third parties as donors of gametes/embryos to assist infertile people to conceive raises a range of ethical, legal and social issues. All necessary steps must be taken in the selection of donors so as to ensure that donated sperm/ova are free from the risk of transmitting disease. Appropriate counselling should be provided for all donors as a pre-requisite of informed consent but, in general, donors should not be allowed to lay down conditions for the use of their gametes nor should they be paid for donations. Children born through donated gametes should be entitled to know the identity of their genetic parents. Parental rights and responsibilities should be conferred on the recipient(s) of donations rather than on the donor(s).

The Commission gave lengthy consideration to the arguments for and against surrogacy and concluded, with one member dissenting, that surrogacy should be permitted subject to regulation. The majority of the Commission also considered that the child born through surrogacy should be presumed to be the child of the commissioning couple.

Other Issues

Embryo Research

The Commission considered the arguments for and against embryo research and recognised that there are three basic positions: (i) research should not be permitted; (ii) research should be permitted but only on surplus embryos and (iii) research should be permitted on surplus embryos and on embryos specifically generated for research. The Commission members, with one exception, were in favour in principle of the second position. The generation of IVF embryos specifically for research purposes should, in the Commission's view, be prohibited.

Reproductive Cloning

Reproductive cloning aims to create a human person who is genetically identical to another. The Commission considered the arguments for and against human reproductive cloning and took the view that it should be prohibited.

Regenerative Medicine

Regenerative medicine, also known as therapeutic cloning, aims to use nuclear transfer technology to generate embryonic stem cells for the treatment of genetically determined disease. The Commission distinguished regenerative medicine from reproductive cloning on a number of grounds, including the fact that it is not IVF technology. While recognising that it constitutes an exception to the Commission's general prohibition on the generation of *in vitro* embryos specifically for research purposes, it recommends, with one member dissenting, that regenerative medicine should be allowed.

Pre-conception sex selection (PSS)

The Commission also considered the technique of sperm manipulation leading to pre-conception sex selection (PSS) and felt that it should be permitted for the reliable prevention of serious sex-linked disorders.

Pre-implantation genetic diagnosis (PGD)

Pre-implantation genetic diagnosis (PGD) is a procedure that is used to identify embryos with specific genetic alterations prior to transfer of the embryo to the uterus. Only embryos without the specific genetic alteration are placed in the uterus. The Commission considered, with one member dissenting, that PGD should be permitted under licence to reduce the risk of serious genetic disorders in children born through IVF technology. PGD should also be allowed for tissue typing but only for serious diseases that cannot otherwise be treated.

Regulation of AHR in Ireland

The specific question on regulation addressed to the Commission was whether legislation was necessary to regulate AHR or whether society should continue to rely on voluntary regulation by the Medical Council. For a number of reasons, including the welfare of the child, the Commission decided that a new Act of the Oireachtas should be passed to establish a regulatory body to regulate AHR services in Ireland. Among the body's executive functions would be the issuing of licences to service providers. It would be mandatory for any provider of AHR services to obtain a licence from the statutory body in respect of the provision of any of the clinical and laboratory services specified in the legislation.

List of Recommendations

All recommendations, except those marked with an asterisk, were unanimous.

1. A regulatory body should be established by an Act of the Oireachtas to regulate AHR services in Ireland.
2. National statistics on the outcome of AHR techniques in Ireland should be compiled and made available to the public.
3. Longitudinal studies of children born as a result of AHR should be established, in accordance with standard ethical/legal requirements and with the consent of families, in order to facilitate long-term monitoring.
4. Appropriate guidelines should be put in place to govern the freezing and storage of gametes and the use of frozen gametes. The regulatory body should, in accordance with statutory guidelines, have power to address cases where gametes are abandoned, where the commissioning couple cannot agree on a course of action, where couples separate or where one or both partner(s) dies or becomes incapacitated.
5. Superovulation should be allowed according to well established clinical protocols. Appropriate guidelines should be put in place by the regulatory body to govern superovulation and the harvesting of ova following ovarian stimulation.
6. Service providers should facilitate users who wish to avoid any treatment that might result in the production of 'surplus' embryos.
7. Appropriate guidelines should be put in place by the regulatory body to govern the fertilisation of ova.
8. Appropriate guidelines should be put in place by the regulatory body to govern the number of embryos to be transferred in any one treatment cycle and when to transfer embryos.
9. Appropriate guidelines should be put in place by the regulatory body to govern the freezing of excess healthy embryos.
10. *Appropriate guidelines should be put in place by the regulatory body to govern the options available for excess frozen embryos. These would include voluntary donation of excess healthy embryos to other recipients, voluntary donation for research or allowing them to perish.
11. The regulatory body should, in accordance with statutory guidelines, have power to address cases where embryos are abandoned, where the commissioning couple cannot agree on a course of action, where the couple separates or where one or both partner(s) dies or becomes incapacitated.

12. Counselling should be provided before, during and after treatment to those considering AHR treatment so that they are adequately informed of the risks involved, the potential benefits that may be obtained, and the possibility of success in their particular situation. Suitably qualified professionals should adequately convey the complex medical and scientific ramifications of different treatment approaches in verbal and written form.
13. It should be obligatory for all recognised providers of AHR services in Ireland to obtain written informed consent for all the services they provide. Each stage of the AHR process should be covered by comprehensive consent procedures. A set of guidelines should be drawn up setting out the specific types of consent that need to be obtained and it should be obligatory for all service providers to observe the terms of these guidelines.
14. Best practice infertility treatment guidelines should be developed for general practitioners and gynaecologists working outside specialist clinics. These guidelines should be reviewed on a regular basis.
15. Centres that collect and store gametes and that generate and store embryos should be regulated and licensed by the regulatory body. The regulatory body should lay down quality assurance standards for such centres. Information on the range of services provided by the specialist clinics should be available to the general public.
16. *The embryo formed by IVF should not attract legal protection until placed in the human body, at which stage it should attract the same level of protection as the embryo formed *in vivo*.
17. Services should be available without discrimination on the grounds of gender, marital status or sexual orientation subject to consideration of the best interests of any children that may be born. Any relevant legislation on the provision of AHR services should reflect the general principles of the Equal Status Acts 2000-4 subject to the qualifications set out in section 4.8.
18. Where there is objective evidence of a risk of harm to any child that may be conceived through AHR, there should be a presumption against treatment.
19. Donation of sperm, ova and embryos should be permitted and should be subject to regulation by the regulatory body.
20. Suitably qualified professionals should provide appropriate counselling in advance to all donors of gametes and embryos. Such counselling should be a pre-condition for informed consent by donors.
21. Appropriate guidelines should be put in place to govern the selection of donors; to screen for genetic disorders and infectious disease; to set age limits for donors and to set an appropriate limit on the number of children to be born by the use of sperm or ova from a single donor.
22. Any child born through use of donated gametes or embryos should, on maturity, be able to identify the donor(s) involved in his/her conception.

23. Donors should not be paid nor should recipients be charged for donations *per se*. This does not preclude payment of reasonable expenses and payment for AHR services.
24. In donor programmes, the intent of all parties involved - that the donor will not have any legal relationship with the child and that the woman who gives birth to the child will be the child's mother - should be used as the basis for the assignment of legal parentage.
25. In cases involving sperm donation, there should be a requirement that the partner, if any, of the sperm recipient also give a legal commitment to be recognised as the child's parent.
26. In the case of a child born through ovum donation and in the case of a child resulting from an embryo donation, the gestational mother should be recognised as the legal mother of the child and her partner, if any, should be recognised as the child's second legal parent.
27. Donors should not be able to access the identity of children born through use of their gametes or embryos.
28. Donors should, if they wish, be told if a child is born through use of their gametes.
29. In general, donors should not be permitted to attach conditions to donation, except in situations of intra-familial donation or the use of donated gametes/embryos for research.
30. *Surrogacy should be permitted and should be subject to regulation by the regulatory body.
31. Women who decide to participate as surrogate mothers should be entitled to receive reimbursement of expenses directly related to such participation.
32. The child born through surrogacy, on reaching maturity, should be entitled to access the identity of the surrogate mother and, where relevant, the genetic parents.
33. *The child born through surrogacy should be presumed to be that of the commissioning couple.
34. *Embryo research, including embryonic stem cell research, for specific purposes only and under stringently controlled conditions, should be permitted on surplus embryos that are donated specifically for research. This should be permitted up to fourteen days following fertilisation. The regulatory body should stipulate under what conditions and for what purposes embryo research is permitted. Those donating embryos for research must receive pre-donation information and counselling and they must give informed consent for the use of donated embryos for research. No inducement, financial or otherwise, should be offered/accepted for the donation of embryos for research. Once embryos are used for research their subsequent use for reproductive purposes should be prohibited. The generation of embryos through IVF specifically for research purposes should be prohibited.

35. Human reproductive cloning should be prohibited.
36. *Regenerative medicine should be permitted under regulation.
37. The generation and use of interspecies human embryos should be prohibited.
38. Preconception sex selection should be permitted only for the reliable prevention of serious sex linked genetic disorders but not for social reasons.
39. Research on gametes should be permitted provided it is governed by strict conditions set out by the regulatory body and subject to informed consent from donors. Specific consent should be required from the regulatory body for specific valid research.
40. *Pre-implantation genetic diagnosis (PGD) should be allowed, under regulation, to reduce the risk of serious genetic disorders. PGD should also be allowed for tissue typing only for serious diseases that cannot otherwise be treated. Each licence issued for PGD should specify the proposed procedure. The regulatory body should oversee and monitor developments in PGD.

A number of specific recommendations for the regulation of AHR services in Ireland are contained in Chapter 9.

CHAPTER 1

The Commission's Approach to its Task

This Chapter describes the background to the Commission and its terms of reference, and it gives a brief description of the working methods of the Commission.

1.1 Introduction

Mr. Micheál Martin, TD, Minister for Health and Children, established the Commission on Assisted Human Reproduction in March 2000. The Minister acknowledged that major advances had been taking place in recent years in the capacity of medical science to intervene in the process of human reproduction. Techniques such as *in vitro* fertilisation (IVF), the freezing (cryopreservation) and storage of sperm, ova, embryos and the use of donor gametes are available in Ireland and have enabled many couples to conceive children despite impaired fertility.

The ability of science to intervene in, control or even alter the natural process of human reproduction poses fundamental ethical questions for the medical profession, for Governments and for society as a whole.

Many countries have legislated in recent years to set down the parameters within which such interventions may take place, while recognising that scientific development can often outpace the legislative controls. However, there is no such legislation in Ireland. Medical practice in this area is governed by (Irish) Medical Council Guidelines. These apply only to registered medical practitioners and would be ineffective in the case of any service operated by other persons.

Conscious of the growing public concern that such complex and potentially controversial Assisted Human Reproduction (AHR) procedures are being practised in Ireland in the absence of any legislative controls, the Minister decided to establish the Commission. In his letter, the Minister said that the establishment of the Commission was an essential first step before any policy proposals would be brought forward and that it would serve two purposes: - (i) to provide the medical, scientific and legal expertise necessary for a detailed examination of the possible approaches to regulation and (ii) to prepare a report that would serve as the basis for informed public debate before the finalisation of any policy proposals.

The Commission was provided with a permanent staff and headquarters in July 2001. This facilitated the work of the Commission by providing a permanent venue for meetings and a fixed point of contact for Commission members with the secretariat.

The terms of reference approved by Government for the Commission were: *to prepare a report on the possible approaches to the regulation of all aspects of assisted human reproduction and the social, ethical and legal factors to be taken into account in determining public policy in this area.* They are contained in a letter, dated 23 March 2000, from the then Minister for Health and Children to the Chairperson of the Commission.

The letter also directed the Commission to seek submissions from the public, to consult appropriately to establish the views of service providers, consumers and any adoption issues and to consult with philosophical and theological experts. Consultation with relevant experts in Northern Ireland and in the UK was also expected of the Commission. The Commission was specifically asked not to recommend on the question of public funding. A copy of the letter is attached as Appendix I.

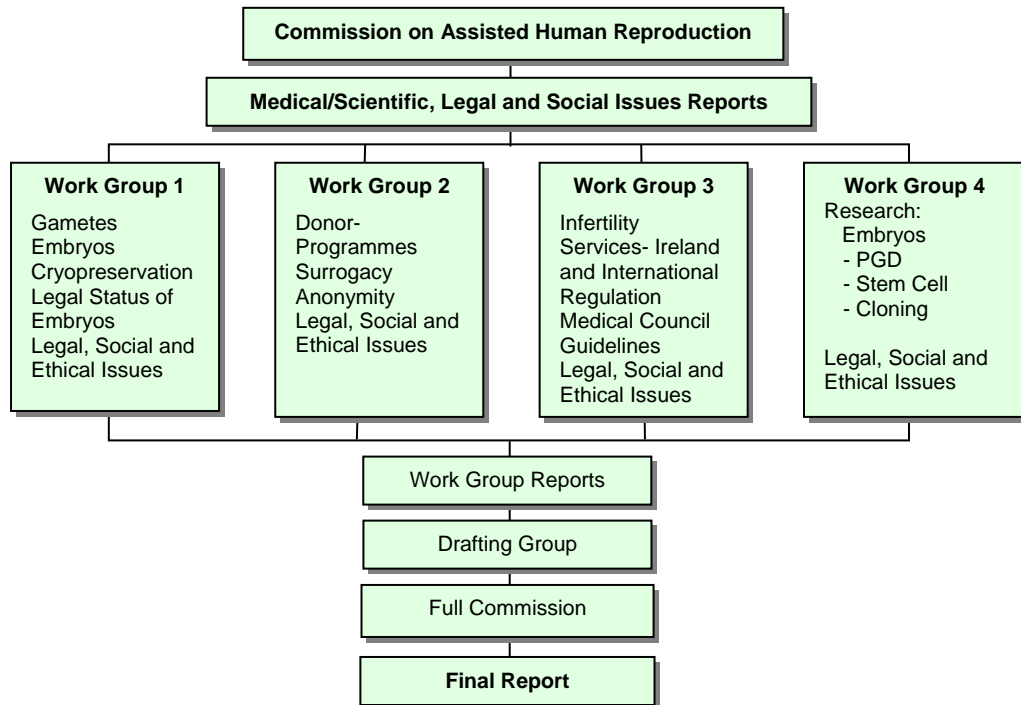
In essence then the Commission's task was to examine the current state of Assisted Human Reproduction (AHR) in Ireland and abroad. The expression AHR as used in this report refers only to procedures that involve the handling of gametes and embryos. This examination would serve as the basis for a report on the options for regulation available to Government that would take account of the social, ethical and legal issues that arise in this sensitive area of medical practice. The report, in its turn, would provide the background for a public debate that would lead to policy proposals. The membership of the Commission provided the medical, scientific, social and legal expertise necessary for a detailed examination of the relevant issues. A number of additional experts with specialised knowledge accepted the Chairperson's invitation to join work groups set up to explore particular aspects of AHR.

1.2 Activities of the Commission

Working Methods of the Commission and the *ad hoc* Work Groups

The Commission met a total of 23 times. The early meetings were devoted to an exchange of information between Commission members and each discipline - medical, scientific, legal and social - prepared a report outlining the current position within that discipline in relation to AHR. This process led to the identification of a substantial list of relevant issues that required investigation.

These issues were grouped under three broad headings: (i) gametes and embryos; (ii) donor programmes and (iii) infertility services and information. A group of issues was assigned to each of three *ad hoc* work groups consisting of Commission members and other invited experts under the chairmanship of a member of the Commission. A fourth work group was given the task of assessing current and future developments in AHR. The task of each work group was to prepare a report for the Commission on the issues assigned to it.



This approach was predicated on the assumption that a small interdisciplinary group was an effective mechanism for the exploration of new developments in reproductive medicine, taking relevant social, ethical and legal factors into account. The work groups met on the mornings of the Commission meetings and held additional meetings as circumstances dictated.

The work group reports were circulated to all members of the Commission and to the invited experts for any comments they wished to make. A special meeting of all contributors was held to discuss these reports. These reports were then used as the basic material for the Commission's report.

Public Consultation and Surveys of Users and Service Providers

Conferences

The Commission held two conferences. The first was held in Dublin Castle in September 2001 and it dealt with the social, ethical and legal factors inherent in AHR. It provided an opportunity for an exchange of views between the Commission members and a small number of invited Irish and international experts.

The second was a large public conference held in February 2003, also in Dublin Castle, for an audience of over 250 people who responded to the Commission's public invitation to attend. The purpose of the conference was to examine the current state of AHR in Ireland and abroad on the basis of presentations from acknowledged experts in the field. It also explored the legal and ethical issues surrounding the *in vitro* embryo and the possible contribution of AHR to the creation of families as distinct from individual children.

Public Advertisement

A public advertisement was placed in the national press in October 2001 inviting members of the public and interested organisations to send in written submissions. The responses, which are summarised briefly in Chapter 6, reflected a wide divergence of opinion in Irish society on AHR.

Telephone Poll

The Commission also recruited a market research organisation to carry out a survey of a quota sample of people over the age of 15 living in Ireland, classified by gender, age, socio-economic status and location. Interviewees were asked a range of questions about fertility treatments and associated support services and research procedures. The responses are summarised in Chapter 6.

Survey of Users

The National Infertility Support and Information Group (NISIG), a voluntary organisation for infertile couples, made available through its Chairperson, a member of the Commission, the anonymised results of a survey of its members carried out to establish the level of satisfaction with services of couples who had sought fertility treatment in Ireland. Further details of the survey are provided in Chapter 4.

Survey of Service Providers

In order to establish the range of services provided for infertile people in Ireland, the Commission entered into consultation with the College of General Practitioners in Ireland and the Institute of Obstetricians and Gynaecologists of the Royal College of Physicians of Ireland. It was agreed that the Commission would conduct three surveys: one of general practitioners, one of consultant obstetricians/gynaecologists working in maternity hospitals/units and one of consultant obstetricians/gynaecologists working in specialist fertility clinics. The first two surveys were conducted by means of written questionnaire and the third by means of a written questionnaire and in some cases an additional interview carried out by Commission staff with the Director of the clinic.

The Commission is satisfied that the responses provide a representative picture of the current provision of fertility services in Ireland and it is very grateful to the people who took the trouble to return completed questionnaires or agreed to be interviewed.

For a detailed account of the outcome of these surveys see Chapter 4.

A member of the Commission carried out an independent survey of general practitioners in the Southern Health Board area and the results of this survey were made available to the Commission.

The Chairperson of the Commission wrote to the Chief Executives of Health Boards in order to establish the number of AHR centres in each Board area and the involvement, if any, of the Boards in the provision of AHR services. The replies received indicate that the Boards are aware of the location of AHR centres in their area but that they have no operational connection with them.

The Chairperson of the Commission had a meeting with the Chairman and Secretary of the All-Party Oireachtas Committee on the Constitution following the publication of the Committee's fifth progress report on Abortion.

The International Perspective

Consultation with the U.K. Human Fertilisation and Embryology Authority took place in February 2001 and the Chairperson attended a meeting of the Authority. The Commission was also represented at meetings of the British Fertility Society. Individual members of the Commission were able to elicit relevant information on AHR through personal contacts with various international experts. One member of the Commission was a professional member of the staff of the Department of Health, Social Services and Public Safety in Northern Ireland. Another member of the Commission was in a position to arrange for (i) a “Comparative Survey of National Legal Régimes Governing Donor Programmes” (carried out in December 2001) and (ii) “Surrogacy – A Comparative Survey of National Régimes” (carried out in May 2002) to be undertaken. (see Appendices II and XII.)

The Commission took note of comparative surveys carried out by the International Federation of Fertility Societies (IFFS) of the provision of fertility services in a large number of countries. The Federation is an international democratic body whose first objective is to create links among countries, peoples and cultures in the field of human reproduction. This aims at stimulating the quality of care and the spread of knowledge in the field. At present 54 national fertility societies are affiliated. The IFFS has carried out surveys of assisted reproductive technologies in a number of countries. The results of the most recent survey, conducted in 49 countries (52 jurisdictions), were published in May 2004 under the title *Surveillance 04*. These comparative surveys were of particular assistance in enabling the Commission to get an understanding of Ireland’s position in the matter of the provision of fertility services compared to other European countries and non-European countries, such as the USA, Canada and Australia.

CHAPTER 2

Infertility – its Causes and Treatment

This chapter describes infertility, its causes, treatments and associated technologies considered by practitioners to constitute an integral part of AHR as currently practised. The benefits and risks of AHR are also discussed.

2.1 Introduction

Fertility is a normal human expectation and its expression in the birth of a child is a matter for celebration in every human society. It is recognised that many people choose not to have children. The majority of adults are naturally fertile but unfortunately, a significant minority of both men and women are not naturally fertile. The growing realisation of the existence of a condition of infertility can be a source of great psychological distress. In some societies a person's standing is defined through parenthood and in these circumstances the suffering of the infertile is aggravated. For those who wish to have children, the desire to give birth to a healthy child is similar whether they are fertile or infertile.

Confronted in a wide variety of social contexts by the centrality of children in the lives of the fertile, the involuntarily childless can experience their own lives as comparatively impoverished and unfulfilled. Their negative feelings are often compounded by the perceived indifference of the fertile population. The options available to the infertile include: remaining childless; fostering; adoption and assisted reproduction.

Medical science, from earliest times, has sought to develop means of assisting couples who were unable to conceive through their own efforts. Accordingly, treatment for infertile couples has a very long tradition in medical practice. However, the phrase AHR in its current technical sense came into use only in the second half of the twentieth century. It is commonly understood to apply to a range of technical procedures that involve the handling of gametes and embryos for the purpose of achieving a pregnancy. These procedures fall under two main headings: (i) *in vivo* fertilisation (more commonly known as assisted insemination) involving the handling of male gametes only and (ii) *in vitro* fertilisation (IVF) involving the handling of both male and female gametes.

2.2 Definition of infertility

The World Health Organisation (WHO) defines infertility as **lack of conception following one year of unprotected sexual intercourse**. The definition implicitly recognises that conception is a natural occurrence that may be expected to supervene within a year of regular sexual intercourse between a male and a female. To allow ample opportunity for conception to take place spontaneously, health professionals do not normally initiate assistive action until a period of at least a year has elapsed. It is estimated that one in six or seven Irish couples is infertile within the terms of the WHO definition of infertility. The Commission acknowledged that some people prefer to apply the term “subfertility” to describe difficulty in conceiving but for the purposes of this report the more commonly used term “infertility” is preferred.

2.3 Causes of Infertility

The cause of infertility is as likely to be found in the male as in the female member of a couple.

Male Infertility

The causes of male infertility are to be found either in the quality or quantity of sperm produced. A small number of males are congenitally unable to produce a sufficient quantity of sperm, or indeed any sperm at all, to achieve fertilisation by natural means. Other factors can also contribute to infertility. For example, mumps in post pubertal life or injury to the testes may result in failure to produce sperm or in the production of poor quality sperm. Inflammation of the prostate gland may reduce the inherent capacity of sperm for spontaneous movement (motility). Male infertility can also be caused by genetic disorders. However, in many cases an actual cause of the sperm abnormality may not be found.

Female Infertility

Known causes of female infertility are: (a) physical, e.g. following tubal disease that results in blockage or damage to the fallopian tubes such that the passage of the ovum down the tubes is impeded or stopped, thus preventing fertilisation; (b) hormonal and genetic abnormalities, e.g. polycystic ovarian syndrome, a condition where many small cysts form on the ovary and hormonal imbalances result which can cause infertility and (c) secondary to an ongoing or past pathology, e.g. endometriosis, a condition where the tissue that normally only lines the uterus is present in other areas of the reproductive system. In many cases of female infertility no cause may be found.

Sexual Dysfunction

Conditions such as erectile dysfunction or premature ejaculation may also render a male unable to father children. Similarly, a small number of women are unable, for physical and/or psychological reasons, to have sexual intercourse. Although such conditions do not fall within the terms of the WHO definition, they account for approximately 5% of referrals to fertility specialists.

Life style issues

Life style factors, such as excessive use of tobacco, drugs and alcohol, may contribute to infertility in both males and females. Infections, including those transmitted sexually, are a growing cause of infertility, particularly where they cause damage to the fallopian tubes in females. Current trends towards later first pregnancies, a higher incidence of second and later relationships and the growing availability of new reproductive technologies are likely to lead to an increased demand for fertility services in the future.

2.4 Treatment of infertility

Three main approaches to the treatment of infertility may be identified:

- (i) An approach designed to overcome the condition that is causing the couple to be infertile, thus enabling fertilisation to take place in the normal way;
- (ii) Introduction of sperm into the female reproductive tract by assisted means (assisted insemination) and
- (iii) The *in vitro* fertilisation of an ovum in the laboratory for subsequent transfer to the uterus - *in vitro* fertilisation (IVF).

The expression AHR as used in this report refers only to procedures that involve the handling of gametes and embryos. The approach to treatment implicit in (i) above does not therefore come within the definition of AHR adopted by the Commission.

Assisted Insemination (AI)

In essence, assisted insemination involves the placing of sperm in the vagina close to the cervix or in the uterus so that fertilisation can take place *in vivo* (in the body). The technology was developed in the context of animal reproduction in the last century and refined for use with humans. The term ‘assisted’ is applied to the procedures involved because they do not depend for their effect on sexual intercourse between the partners.

There are two main variants of this approach:

- (i) Assisted insemination. This involves the placing of sperm into a woman’s vagina, allowing them to negotiate the cervical canal and to reach the fallopian tube so that fertilisation can take place in the normal way.
- (ii) Intrauterine insemination (IUI). This is essentially the same as AI except that the sperm is specially prepared in the laboratory and then introduced into the uterus rather than the vagina as in AI.

With both of these procedures, the woman may, in addition, be treated with fertility drugs to induce or augment ovulation.

***In Vitro* Fertilisation (IVF)**

In the 1970s a dramatic new treatment of infertility known as *in vitro* fertilisation was developed. The essential point about *in vitro* fertilisation is that fertilisation takes place outside the female body and the phrase *in vitro* (literally “in a glass”) is intended to distinguish fertilisation that takes place outside the body from *in vivo* (literally “in the body”) fertilisation.

In IVF, the woman’s ovaries are stimulated to produce additional ova (in an unstimulated menstrual cycle the ovaries would normally produce only one ovum). This is achieved by the injection of follicle stimulating hormones (gonadotrophins) and the resulting ova are ‘harvested’. They are mixed with the male’s sperm in the laboratory, where fertilisation of some ova should occur. After an interval of some days, a number of embryos – usually one or two - that develop and are considered viable by an embryologist are then transferred to the woman’s uterus.

The birth of the first IVF baby in July 1978 generated a great deal of public interest and fledgling services were started in many countries, including Ireland. The main reason for its dramatic impact on society at large was that it was the first time in human history that a live birth resulted from human fertilisation that had taken place outside the female body. *In vitro* fertilisation is discussed in more detail in Chapter 3.

There are a number of recognised adaptations of basic IVF treatment:

- Gamete intra-fallopian transfer (GIFT) involves the handling of both male and female gametes and the transfer of sperm and ova to the fallopian tube by means of laparoscopic guidance
- Zygote intra-fallopian transfer (ZIFT) differs from basic IVF only to the extent that the zygote (embryo) is transferred to the fallopian tube as opposed to the uterus
- Intracytoplasmic sperm injection (ICSI) is a form of IVF that involves the injection of a single sperm directly into the cytoplasm of the ovum.

Donor Programmes

It should be noted that in all of the above treatments, donated gametes may be used instead of gametes provided by the patient(s) undergoing treatment. In fact where one or other member of the 'treatment' couple is unable to produce any or an adequate amount of gametes, treatment can be provided only through the use of donated gametes. Thus assisted insemination can be provided using husband's or partner's sperm (AIH) or by using donor sperm (DI). Intrauterine insemination can also be provided using donated sperm (IUID). Similarly IVF treatment can be carried out using the commissioning persons' gametes (by far the most common form), or by using the commissioning person's ova and donated sperm (IVFDS), or using the commissioning person's sperm and donated ovum (egg) (IVFDE). IVF embryo donation is also a successful medical procedure. The current position in relation to AHR services in Ireland is described in Chapter 4.

- 1. The Commission recommends that a regulatory body should be established by an Act of the Oireachtas to regulate AHR services in Ireland. (The regulatory body is described in detail in Chapter 9).**

2.5 Storage, Handling and Research on Gametes/Embryos

Cryopreservation is the term used to describe the process of reducing organic material to a very low temperature and maintaining it at that temperature. In the context of AHR, the process can be applied to sperm, ova and embryos. It is not yet routinely applied to ova, as the process of ovum freezing is not well developed. There have also been recent developments in the freezing of ovarian tissue containing immature ova and testicular tissue containing immature sperm. These procedures are relatively new and their aim is to produce mature ova and sperm in the laboratory for potential use in AHR. A report from the American Society for Reproductive Medicine (ASRM) in October 2004 states that research advances that enable women's ova and ovarian tissue to be frozen for later use in assisted reproduction are not yet suitable for widespread adoption. The report agrees that the techniques should be offered under strict supervision to cancer patients or other women who will be rendered infertile by medical treatment and who have few other options if they want children.

Some of the advantages of cryopreservation of sperm are that it offers the possibility of deferred fatherhood to male patients undergoing chemotherapy treatment and that it greatly expands the possibilities of using donated sperm in AHR. The purpose of embryo cryopreservation programmes is to give a couple the best chance to achieve a pregnancy with a maximum of safety. It has been found that transferring more than two embryos carries a significant risk of multiple pregnancy while

it does not increase the singleton pregnancy rate proportionately. The advantage of freezing is that there may be an increased chance of pregnancy without the necessity of multiple stimulation cycles and ova retrievals. There are other advantages to embryo freezing. For example, if a woman were acutely ill following ova retrieval, frozen embryos would still be available on her recovery. Additionally, if ovarian hyperstimulation syndrome (OHSS) seems likely to occur, all of the embryos may be frozen to prevent exacerbation of the condition that, if severe, may require hospitalisation. This is discussed in more detail in Chapter 3.

The cryopreservation of embryos is an established practice in the treatment of infertility in many countries. The reality has to be faced, however, that inherent in the practice of the cryopreservation of embryos is the likelihood that surplus embryos may remain at the end of the treatment. The legal aspects of the cryopreservation of embryos merit special attention in Ireland because of the constitutional position of the ‘unborn’ under Article 40.3.3 of the Constitution. The implications of this reality are addressed in Chapter 6 and in Appendix III.

One of the consequences of IVF is that scientists can observe human life in its earliest stages. This has led to the discovery that gametes/embryos can be handled in ways that enable scientists to get new insights into early human life and to diagnose genetic disorders in the embryo. IVF has presented scientists with the opportunity to carry out research on embryos. The use of embryos as a source of stem cells is an issue of much ethical and scientific debate at present.

Directive 2004/23/EC

The Commission took note of Directive 2004/23/EC of the European Parliament and of the Council. The purpose of the Directive is to lay down standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells. The tissues and cells include, *inter alia*, reproductive cells (eggs, sperm), foetal tissues and cells and embryonic stem cells. The standards of quality and safety laid down in the Directive relate only to those cells and tissues that are applied in clinical trials to the human body: they do not relate to human tissues and cells used for purposes other than application to the human body, e.g. *in vitro* research or in animal models. Member States are required to make the arrangements necessary to comply with the provisions of the Directive by 7 April 2006. One such provision is the designation by the Member State of the competent authority or authorities responsible for implementing the requirements of the Directive.

2.6 Benefits and Risks of AHR

Psychosocial

For those who want to have children, infertility can be an extremely traumatic experience, characterised by feelings of guilt, low self-esteem, depression, and sometimes consequent relationship difficulties and sexual dysfunction. These psychological effects have been compared to those following bereavement. The process of discovery and comprehension involved in the diagnosis and treatment of infertility can be a very isolating period for the individual or couple. There may be social consequences too, as extended families and local communities share bonds through child rearing from which childless individuals and couples feel isolated. They may consequently attempt every possible treatment and continue with a cycle of tests and treatments with attendant psychological and financial difficulties over a prolonged period of time.

The main and ultimate benefit of AHR is that it has enabled many thousands of couples in Ireland and throughout the world to achieve a long-cherished ambition to have their own children. Although in the past many couples would have fulfilled their desire for parenthood through adoption, the reality of the scarcity of children to adopt and the difficulties in foreign adoption has meant that this option is not available to everyone. Some couples undoubtedly feel strongly about having a biological link to their child whether through genetics or gestation, or both. Some women consider the physical bond achieved through childbearing as an important aspect of having a child, and some men may find it difficult to accept a child to whom they are not genetically related. For many couples the satisfaction achieved through the rearing of a child is more important than biological or genetic reproduction. In any event, most infertile individuals simply wish to have a child of their own.

Success rates of AHR

Although AHR has achieved prominence in recent years and offers hope to bypass infertility, unfortunately AHR treatment does not guarantee success. The expectation of ultimate fulfilment has to be balanced by an acceptance of the possibility of corresponding disappointment. The age of the woman whose ova are used in the treatment has a major influence on the outcome.

There are no national statistics available in Ireland on the outcome of IVF treatment cycles. Provisional UK statistics released in August 2003 show that between 1 April 2000 and 31 March 2001, 21.8% of IVF treatment cycles resulted in a birth and for women aged under 38 the success rate per treatment cycle was 25.1%. For this reason it is vitally important that counselling be provided to those considering AHR treatments so that they are adequately informed of the risks involved, the potential benefits that may be obtained, and the possibility of success in their particular situation. Regulated quality assurance standards would also help to ensure that those accessing AHR services make decisions on the basis of the most thorough and reliable information available.

2. The Commission recommends that national statistics on the outcome of AHR techniques in Ireland should be compiled and made available to the public.

Health of women

AHR practitioners draw patients' attention to known health risks associated with the AHR procedures themselves. For example, the drugs used to stimulate the ovaries may result in side effects, e.g., ovarian hyperstimulation syndrome (OHSS), in a woman. In such cases, transfer of embryos to her uterus would exacerbate the condition, possibly leading to death and so a decision may be made not to transfer any embryos at that time. There is also an increased risk of ectopic pregnancy and a higher than average incidence of multiple pregnancies associated with AHR.

Health of children born through AHR

Over one million children have been born worldwide through AHR with the vast majority being healthy. However, the higher than average incidence of multiple pregnancies and accordingly of pre-term births represents a risk for the children conceived through AHR.

There is no clear evidence that children conceived and born through IVF are at greater risk of congenital anomalies, allowing for the increase in congenital anomalies that can occur in any multiple pregnancy. In 2002 and 2003 there have been a number of reports suggesting a higher than expected number of children with disorders of genetic imprinting conceived by ICSI. These reports are preliminary and need clarification by larger independent studies. It is also suggested that the male offspring born through ICSI of fathers with low sperm counts may be at a higher risk of being themselves infertile.

Many parents find themselves quite unprepared for the bewildering emotional stresses of relating to two or more newborns at the same time let alone the practical and financial difficulties. Couples frequently express their anxiety about the special difficulties that multiple birth children may face concerning normal growth and development, language acquisition and the need to form an individual identity. This can be a major burden on a family. Multiple births also put additional pressure on the resources of special care baby units.

- 3. The Commission recommends that longitudinal studies of children born as a result of AHR should be established, in accordance with standard ethical/legal requirements and with the consent of families, in order to facilitate long-term monitoring.**

CHAPTER 3

Clinical Practice of Assisted Human Reproduction (AHR)

This chapter describes the clinical and scientific considerations inherent in in vitro fertilisation, including the options for dealing with excess embryos.

3.1 Introduction

In many AHR procedures, embryos are generated outside the body after which they are transferred to the uterus or stored in a frozen state for transfer at a future date. This raises important medical, scientific, legal and ethical/moral questions, not all of which can be answered definitively or in a manner that will receive universal approval.

The technique of IVF, as practised worldwide, is discussed and the rationale behind different aspects of the technique is explored and the pros and cons of the treatment approaches documented. The objective is to provide the scientific background on which to base ethical and legal arguments.

The question of the fate and status of excess healthy embryos is possibly the most difficult of those associated with IVF. There are wide ranging legal, social and ethical implications. These centre particularly on the unresolved questions of what constitutes life or personhood and following on from that when life begins. The process of embryogenesis is described below in section 3.3. Of particular relevance in Ireland is the constitutional guarantee of the right to life of the unborn in Article 40.3.3 and this is discussed in chapter 6, section 6.3.

3.2 Gametes

Males produce sperm (spermatozoa) cells and females produce ova, (oocytes). The term gamete is used to describe sperm and ova. Ova are produced in the female ovary. Sperm are produced in the male testis. Ova and sperm may be obtained from either the genetic parents or gamete donors.

Storage/ freezing

Following collection, ova are stored in physiological conditions, initially without manipulation, for short periods (a number of hours) in an incubator. This is a special cabinet that maintains a very precise temperature and environment. At present ova are not routinely frozen, as the process of ovum freezing is not well developed. The success rates from the use of freeze-thawed ova (unfertilised ova) have not been very high; few babies have been born worldwide.

Sperm that are to be used directly are stored in incubators similar to those used for ova, but unlike the case with ova, the process of sperm freezing works well. Sperm may be frozen for many reasons and most IVF units offer sperm freezing as a back up to males undergoing fertility treatment. Many units also offer this service for male patients about to undergo radiotherapy or chemotherapy or other treatments or procedures, which may interfere with the process of spermatogenesis.

It is also possible to freeze both ovarian tissue containing immature ova and testicular tissue containing immature sperm. The procedure is relatively new. The aim of this procedure is to produce mature ova and sperm in the laboratory for potential use in AHR.

Ownership and use of gametes

There are a number of complex legal issues that need to be considered when dealing with the ownership and use of gametes. These include the use of stored gametes following separation, divorce or death, and the extent to which a person's wishes in respect of their gametes will be taken into account in those circumstances. The issue of whether or not a gamete provider has ownership or property rights in respect of the gametes has not been decided by any Irish court to date. Any dispute in relation to the existence of such rights would raise contractual, constitutional and property law issues and, in the absence of relevant legislation, would be dealt with by the court based on its own facts. In the case of posthumous conception, Irish succession law does not currently deal with the case of a child born more than 10 months after the death of its father. The legal status of such a child is therefore uncertain at this time.

Disposal of gametes

Units that freeze gametes for patients undergoing treatment that may affect gametogenesis usually ask the patients to consent to their disposal on the death of the patient. Gametes are usually allowed to thaw out and are then disposed of by incineration. Such stored gametes are not used for donation, posthumous or otherwise but could be used for research with the consent of the patient(s).

- 4. The Commission recommends that appropriate guidelines should be put in place to govern the freezing and storage of gametes and the use of frozen gametes. The regulatory body should, in accordance with statutory guidelines, have power to address cases where gametes are abandoned, where the commissioning couple cannot agree on a course of action, where couples separate or where one or both partner(s) dies or becomes incapacitated.**

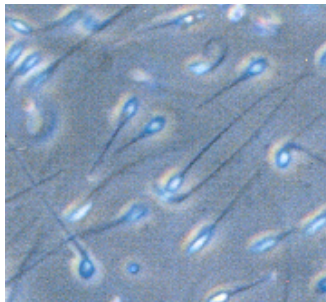
3.3 Fertilisation and Embryogenesis

Fertilisation is not a single event. It is the process by which a single sperm carrying one set of genes (23 chromosomes) fuses with an ovum carrying another set of genes (23 chromosomes). Once the sperm has entered the ovum, the paternal and maternal DNA each forms a pronucleus and the ovum at this stage is called a pro-nuclear ovum or a 2PN ovum. The pronuclei later fuse to form a single nucleus containing 46 chromosomes. Syngamy (fusion) has then occurred with formation of the zygote or one cell embryo.

The term **pre-embryo** has been used to describe the early stages of embryogenesis and also to describe the 2-pro-nuclear stage of fertilisation. The use of the same term to describe two distinct stages lacks clarity and is better avoided. The use of the term pre-embryo is acknowledged, but it is not found to be helpful in distinguishing between scientific and colloquial uses of the term embryo. It is therefore proposed to use the term embryo to describe the stages of development from the completion of fertilisation until the eighth week of pregnancy.

Embryogenesis is a process with specific biological stages. The first cell division takes place approximately one day after fertilisation. The zygote or one cell embryo divides into a 2-cell

embryo; at this stage it is no longer appropriate to call it an ovum or zygote. By the end of this second day it will have reached the 4-cell stage. By day 3, it will have formed an 8-cell embryo. This division, known as cleavage, is under the control of cellular factors from the ooplasm (part of the ovum) and is not influenced by genes from the newly formed nucleus of the embryo. The divided cells are known as blastomeres. Four days after fertilisation, the embryo will consist of a cluster of 16-32 cells (the morula). Between days 4 and 5, spaces begin to form between the cells of the morula. These spaces will coalesce to form a cavity and at this stage the embryo is known as a blastocyst. The cells at the centre of the blastocyst will go on to form the foetus and child. The other cells will go on to form the extraembryonic organs, such as the placenta and the amniotic membranes.



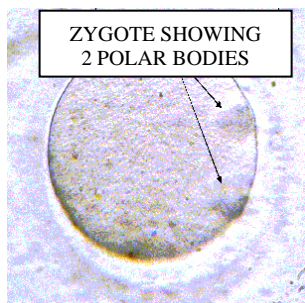
SPERM



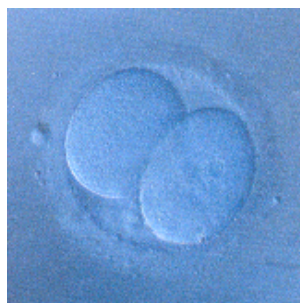
OVULATED OVUM



2PN OVUM



ZYGOTE STAGE



TWO CELL STAGE



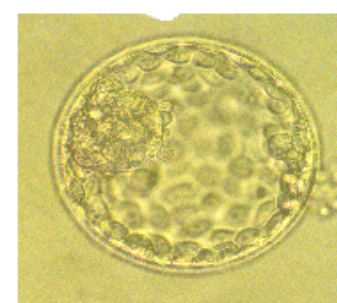
FOUR CELL STAGE



EIGHT CELL STAGE



MORULA STAGE



BLASTOCYST STAGE

The site where the above events take place changes as embryogenesis progresses. As the embryo migrates from the fallopian tube into the body of the uterus, it develops into a blastocyst. When the blastocyst reaches the uterus on day 5-6 it begins to implant and implantation is completed by day 10-11. Implantation is the process whereby the embryo connects to the maternal blood supply and is

able to grow. At implantation the woman becomes pregnant. Prior to implantation the body is unable to differentiate between an unfertilised ovum (which will be shed as part of a menstrual cycle) and a developing embryo. By day 12 it is apparent that a variation in the cell mass (stem cells) is occurring – the process is referred to as ‘cell differentiation’. Eventually cell differentiation leads to the production of different cell types. As the organism develops, all the typical cells are formed e.g. blood cells, liver cells, skin cells etc. Each cell is able to carry out special functions and is able to communicate chemically or electrically with other cells and each occupies its proper place in the growing embryo.

3.4 Clinical Considerations

(a) Basic IVF procedure

In vitro fertilisation (IVF) literally means, “fertilised in glass”. Very simply, ova (eggs) are removed from the woman’s ovary just before ovulation. In the laboratory they are placed with sperm where fertilisation (if it occurs) takes place with the formation of an embryo. This embryo is then placed in the woman’s uterus where it may implant, leading to pregnancy. The original indication for IVF was damaged fallopian tubes (the site of natural or *in vivo* fertilisation). However IVF is now also a successful treatment for a wide range of fertility disorders such as unexplained infertility, endometriosis and sperm abnormalities.

Since first described in 1978, the simple technique of IVF has been modified considerably to enhance safety and success rates. These modifications involve superovulation and embryo freezing and have greatly added to the complexity of the procedure.

(b) Superovulation – Ovarian Stimulation

The initial attempts at IVF involved natural, unstimulated menstrual cycles where usually one, and at most two, ova would develop and be available for fertilisation. It soon became apparent that the success rate of treatment could be greatly improved by first stimulating the woman’s ovaries to produce multiple ova by injecting follicle stimulating hormones (gonadotrophins). This continues to be the case. In two studies which have compared “natural cycle” IVF to “stimulated” cycles, the success rate in natural cycles was 0% and 4% increasing to 17% and 23% in the stimulated cycles.

Apart from increasing the number of available ova, the fertility drugs currently used in IVF practice also suppress the woman’s natural hormones allowing greater control over the treatment cycle, particularly over the timing of removal of the ova. Natural cycles are difficult in that they are less predictable and the woman may ovulate spontaneously before the ova have been removed, thus leading to cancellation of the treatment. The very low success rate and unpredictability of spontaneous ovulation make natural cycle IVF unfeasible for many couples and not a practical option for most clinics. It is standard practice in IVF units to use superovulation (ovarian stimulation) as part of the IVF procedure.

5. **The Commission recommends that superovulation should be allowed according to well established clinical protocols. Appropriate guidelines should be put in place by the regulatory body to govern superovulation and the harvesting of ova following ovarian stimulation.**

- 6. The Commission recommends that service providers should facilitate users who wish to avoid any treatment that might result in the production of 'surplus' embryos.**

(c) Number of ova fertilised

Superovulation, as described above leads to the production of multiple ova (average 8, range 3 to 40). In an ideal world, these ova would be fertilised only as required i.e. one or two would be incubated with sperm and if these fertilised they would be placed in the uterus. If fertilisation did not occur, another two ova could be fertilised and so on. Unfortunately, ova do not survive outside the body and must be used within hours of retrieval. It is not yet possible to consistently identify the best quality ova or the ones that are most likely to be successfully fertilised and the technology is not yet sufficiently advanced to routinely freeze ova. It is therefore necessary to try to fertilise all of the ova once retrieved (i.e. they must all be used immediately or they are wasted). Many IVF treatment cycles therefore produce excess fertilised ova/embryos.

While an option could be to attempt to fertilise a smaller number of ova (e.g.6) and allow the remainder to perish, there is a risk that none might fertilise and the treatment would fail. In most cases approximately 30% of ova do not fertilise and of the 70% that do fertilise some will not be healthy enough to lead to a pregnancy. Most IVF clinicians would regard it as unacceptable to subject the woman to the risks of superovulation treatment if all ova were not then going to be used. It is standard practice in IVF units to attempt to fertilise all ova retrieved.

- 7. The Commission recommends that appropriate guidelines should be put in place by the regulatory body to govern the fertilisation of ova.**

(d) Number of embryos transferred to the uterus.

It is well proven worldwide that the safest pregnancy, for both the mother and child, is a singleton pregnancy. Twin pregnancies are at increased risk of miscarriage, premature delivery, foetal or neonatal death and cerebral palsy. This risk increases dramatically for triplets, quadruplets etc. A question of safety arises and it is therefore medically questionable to transfer more than three embryos to the uterus at any one time.

Much international work in recent years has focussed on reducing the incidence of multiple pregnancies associated with AHR. Studies in particular from Scandinavia, the UK and Australia suggest that the optimal number of embryos to transfer to the uterus at any one time is one or two. It is standard practice in most European and Australian IVF centres to transfer a maximum of two embryos to the uterus at any one time.

Some women may not be able to have any embryos transferred during the treatment cycle. This occurs when the woman develops severe ovarian hyperstimulation syndrome (OHSS). In such cases, transfer of embryos to her uterus would exacerbate the condition, possibly leading to death and so a decision may be made not to transfer any embryos during the treatment cycle. The embryos are frozen for transfer to the uterus at a later stage.

- 8. The Commission recommends that appropriate guidelines should be put in place by the regulatory body to govern the number of embryos to be transferred in any one treatment cycle and when to transfer embryos.**

(e) Freezing of excess embryos

Inherent in the practices outlined above is the production in many cases of more embryos than can safely be used during one treatment cycle. Some of these embryos will be of very poor quality or may show severe abnormalities. Many of these embryos are incompatible with survival and their transfer to the uterus is not in the best interests of the prospective parents as it is likely to give a less successful pregnancy rate and a higher incidence of miscarriage. These poor quality embryos are therefore not usually used in AHR treatments. Despite this, conventional IVF will produce excess healthy embryos for between 10% and 40% of couples undergoing treatment. These embryos can be frozen for subsequent use.

The purpose of all embryo freezing programmes is to give a couple the best chance to achieve a pregnancy with a maximum of safety. If the woman does not conceive following her first embryo transfer, frozen embryos may be thawed and transferred to her uterus, without the need for further superovulation and ovum retrieval. Similarly, for women with OHSS all the embryos may be frozen and subsequently transferred to her uterus when the OHSS has resolved. For couples who conceive with their first embryo transfer, they may achieve a second pregnancy a few years later using previously frozen embryos.

All IVF units in Ireland currently offer embryo freezing for excess healthy embryos and for all healthy embryos when the woman is at risk of severe OHSS. Freezing is carried out in a special cryoprotectant medium and the embryos are frozen in a computer controlled slow rate freezer down to -196°C . At this temperature, all metabolic activity within the cells is arrested and they are essentially in a state of suspended animation. At the end of the freezing procedure they may be stored in tanks filled with liquid nitrogen for several years.

- 9. The Commission recommends that appropriate guidelines should be put in place by the regulatory body to govern the freezing of excess healthy embryos.**

Most couples will use their frozen embryos as described above in an attempt to achieve one or more pregnancies. However, when a couple has decided that their family is complete or that they no longer wish to continue with AHR cycles, embryos may still remain in the frozen state. Decisions on the fate of these embryos can be very difficult and consequently the embryos may remain frozen for a prolonged time while the couple deliberates.

The options available for these embryos include:

- (i) Donate to another person(s) for transfer
- (ii) Donate for research
- (iii) Allow to perish

(i) *Donate to another person(s) for transfer*

Some couples who have excess healthy embryos may choose to donate these embryos to another person(s). The most recent edition of the Medical Council Guidelines (March 2004) indicates that the voluntary donation of fertilised ova to other recipients may be considered. The complexities of this practice e.g. the legal parentage of any children born and the rights of those children to know their biological parents are discussed further in chapter 7.

(ii) *Donate for research*

In other jurisdictions, couples may elect to donate their healthy excess embryos for research purposes. Embryo research is discussed further in chapter 8.

(iii) *Allow the embryos to perish*

In this scenario, if the commissioning couples so wish, surplus embryos should be allowed to perish.

In some cases, embryos may be abandoned or the gamete providers may not be able to agree on a course of action and a mechanism to deal with such cases should be put in place in advance of treatment.

10. The Commission recommends that appropriate guidelines should be put in place by the regulatory body to govern the options available for excess frozen embryos. These would include voluntary donation of excess healthy embryos to other recipients, voluntary donation for research or allowing them to perish.

11. The regulatory body should, in accordance with statutory guidelines, have power to address cases where embryos are abandoned, where the commissioning couple cannot agree on a course of action, where the couple separates or where one or both partner(s) dies or becomes incapacitated.

(f) *Stages at which embryos can be frozen*

The different stages of fertilisation and embryogenesis have been described in section 3.3. Embryos selected for freezing can be frozen at the zygote stage or from day two (the 2-4 cell stage) up to day five, when the embryo will have reached the blastocyst stage.

The processes of fertilisation and embryogenesis are complicated ones and, being biological events, one stage merges into the next. Also, some ova will show fertilisation and some embryos cleavage at an earlier stage than others in the same cohort. It is therefore not always possible to definitively state at which stage freezing will take place as different ova/embryos may be at different points in the process of embryogenesis.

Most IVF units generally transfer embryos to the uterus between day two and day five post ovum retrieval. The two healthiest appearing embryos are transferred to the uterus and any remaining embryos may be frozen if they are of sufficient quality. Most IVF clinicians and scientists would expect to be allowed to use their clinical judgement when deciding on which day to transfer or freeze embryos.

Some ethicists argue that freezing should take place at the pronuclear ovum stage, the argument being that these are still ova and not embryos. However, while ova can be frozen at this stage, it is too early for ova/embryos to implant in the uterus and so any that are to be transferred during that cycle must be allowed to grow in the laboratory until at least day two, at which stage they can be transferred. As stated above, not all fertilised ova will survive until day two and so if only two are allowed to grow on (the remainder having been frozen at the 2PN stage) the couple runs a high chance of having no suitable embryo to transfer on day two. For this reason, most units that preferentially freeze at the 2PN stage actually allow 6 or 8 ova to grow on beyond the pronuclear stage and only freeze at the pronuclear stage those that are in excess of this. Six to eight are allowed to grow on in the hope that at least two of them will produce high quality embryos that are then transferred to the uterus on day two. Any remaining healthy embryos are either frozen at that stage or allowed to perish.

Another disadvantage of freezing at the 2PN stage is that it leads to freezing many more fertilised ova than is the case when embryos are frozen at a later stage. This is because, as stated above, only the healthier embryos will survive for longer periods in the laboratory. Couples who have their ova frozen at the 2PN stage will have higher numbers of ova of uncertain potential and are therefore likely to have to undergo repeated attempts at thawing and subsequent transfer before they will achieve pregnancy.

Legislation in some countries e.g. Germany stipulates that all embryos must be transferred to the uterus and freezing of excess embryos is not allowed but freezing of ova at the pronuclear stage is allowed. A maximum of three embryos may be transferred and only as many ova can be allowed to go beyond the pronuclear ovum stage as the number of embryos planned to be used for transfer. This has led to a lower overall pregnancy rate (13% per cycle) than other centres and a high multiple birth rate (34% twins and 4% triplets). What in effect happens is that some couples achieve three high quality embryos which must then all be transferred, leading to unacceptably high twin and triplet pregnancy rates, while other couples do not achieve any high quality embryo among the three allowed to develop, giving these couples an unacceptably low pregnancy rate.

The ethical viewpoints concerning the status of the embryo are discussed in Chapter 5.

3.5 Other Considerations in AHR practice

Information/Counselling

The Commission took the view that the psychological and emotional needs of AHR patients should get special attention from service providers. Adequate factual information should be provided before treatment commences in order to enable patients to understand the treatment options most appropriate for them. Counselling by appropriately qualified counsellors should also be provided as an integral part of the treatment. It is considered that counselling gives infertile people the opportunity to discuss their thoughts, feelings and anxieties with an individual who is trained in exploring the relevant concerns. For most people there are likely to be potential benefits in discussing matters with a trained counsellor before, during and after treatment. They may then cope better with the difficulties associated with the treatment. Where a number of cycles of treatment have been undertaken without success particular difficulties may arise for patients in accepting the opinion

of the service provider that treatment should be discontinued. Counselling may be of considerable assistance in helping them to come to terms with the service provider's advice.

The Commission agreed that access to information on recognised support groups such as the National Infertility Support and Information Group could be of immense benefit to AHR patients.

- 12. The Commission recommends that counselling should be provided before, during and after treatment to those considering AHR treatment so that they are adequately informed of the risks involved, the potential benefits that may be obtained, and the possibility of success in their particular situation. Suitably qualified professionals should adequately convey the complex medical and scientific ramifications of different treatment approaches in verbal and written form.**

Consent

A decision to embark on a course of AHR treatment is likely to be made only after lengthy consultation with a service provider. The Commission believes that, as in other areas of medical treatment, AHR treatment should not commence until the consent of the patient(s) has been fully and freely given. To be valid, consent must be voluntarily given, based on the requisite information concerning risks, side-effects and alternatives, such that the patient is able to make an informed decision as to whether or not to proceed with treatment.

- 13. The Commission recommends that it should be obligatory for all recognised providers of AHR services in Ireland to obtain written informed consent from patients for all the services they provide. Each stage of the AHR process should be covered by comprehensive consent procedures. A set of guidelines should be drawn up setting out the specific types of consent that need to be obtained and it should be obligatory for all service providers to observe the terms of these guidelines.**

The specific issues that might be addressed in the guidelines include: the use and storage of gametes and embryos; different types of treatment; the future use, including use for research, of stored gametes/embryos surplus to the requirements of the patient(s); the conditions under which treatment may be discontinued; a procedure to deal with a situation where the parties to the consent are no longer available for consultation or where *post factum* differences of opinion have arisen between them etc.

Commercialisation

The possibility that AHR services might be open to the risk of commercialisation was discussed at length by the Commission and by one of its work groups. Commercialisation is said to occur in medical practice if commercial considerations are given priority over patient welfare in arriving at treatment decisions. AHR is open to the danger of commercialisation in a number of ways. First, an infertile person (couple) may, in theory, receive an indefinite number of treatment cycles from more than one service provider. Secondly, the production of *in vitro* embryos for experimental purposes could conceivably be undertaken for commercial reasons. And thirdly, financial considerations could become a factor in the context of recruiting donors of gametes or surrogate mothers. The Commission would like to see AHR services in Ireland develop in a way that would avoid the risk of commercialisation.

CHAPTER 4

Assisted Human Reproduction Services in Ireland

This chapter summarises the results of surveys carried out by the Commission of the provision of AHR services in Ireland at General Practitioner and Consultant level. It notes the results of a survey of users of AHR services carried out by the National Infertility Support and Information Group (NISIG) and it describes the guidelines on reproductive medicine laid down by the (Irish) Medical Council.

4.1 Introduction

At present fertility services, like other medical services in Ireland, are provided at general practitioner and consultant level. The Commission conducted three separate surveys of medical practitioners. The overall position on the basis of the information gathered in the surveys is that general practitioners limit themselves on the whole to providing a diagnostic and referral service, most consultant obstetricians/gynaecologists concentrate on the treatment of fertile couples and a relatively small number of consultants are infertility specialists who provide AHR services in separate clinics.

There are no statistics available on the number of patients that attend general practitioners or consultants in Ireland with a fertility problem. A Public Consultation Document on the future of Fertility Services in Northern Ireland (population 1.7million) published in October 2003 by the Department of Health, Social Services and Public Safety states “a recent local survey of General Practitioners (GPs) indicates that about 5,500 couples in Northern Ireland attend GPs annually with a fertility problem. A local survey of gynaecologists indicates that there are over 2,500 new referrals for infertility made annually in Northern Ireland.”

4.2 Survey of General Practitioners

A questionnaire seeking information on the services provided by general practitioners (GPs) for infertile couples was sent to 1163 GPs selected at random from all Health Board areas. Four hundred and ninety (42%) completed responses were received, a high enough percentage to give an accurate picture of the views of GPs in general on the practice of AHR at the level of primary care. The standard practice among general practitioners, as indicated in their responses to the questionnaire, is to seek to establish whether or not a condition of infertility exists and, where possible, to identify the cause. Eighty per cent of respondents at present appear to limit themselves to diagnostic and referral procedures, leaving the question of treatment in the hands of their consultant colleagues. The other twenty per cent of GPs initiate treatment in appropriate circumstances by administering a drug to stimulate ovulation. The survey reveals that GPs would not in general provide AHR services as defined in this report. They are however the first point of contact for most infertile couples who decide to seek professional assistance with their infertility, and the diagnostic and referral services provided by GPs are an integral part of the overall service to infertile couples.

4.3 Survey of Obstetricians/Gynaecologists working in Maternity Hospitals/Units

A questionnaire was sent to 114 obstetricians/gynaecologists working in maternity hospitals/units in Ireland. Forty-seven (41%) completed responses were received. The survey of consultants reveals that more than half the respondents devote a very small proportion of their time to the treatment of infertility.

One item in this questionnaire sought information on a matter that called for the exercise of ethical rather than medical judgement. That was whether the respondents took account of the relationship status of the patient(s) in coming to a decision as to whether or not to provide treatment. Forty-five (96%) out of forty-seven respondents would provide treatment for unmarried couples. The number of respondents who would provide treatment for single people is twenty-five (53%) and the number who would provide treatment for same sex couples is six (13%). Twenty-eight (60%) respondents would provide treatment for people with a history of psychiatric disorders; thirty-five (74%) for people with physical disabilities and twenty (43%) for people with intellectual disabilities.

- 14. The Commission recommends that best practice infertility treatment guidelines should be developed for general practitioners and gynaecologists working outside specialist clinics. These guidelines should be reviewed on a regular basis.**

4.4 Survey of Obstetricians/Gynaecologists working in Specialist Clinics

At the time of the Commission's initial survey of specialist fertility clinics (October 2001-March 2002) there were eight clinics providing AHR services in Ireland, seven responded to the questionnaire. They are all located in or near large centres of population. Two respondent clinics are specific entities within a large maternity hospital and their activities are subject to the governance of the hospital; the other respondent clinics are not subject to external control. Four of the respondent clinics were providing assisted insemination by husband (AIH) and three of them by donor (DI) as well. One clinic was providing *in vitro* fertilisation using own gametes only. Two were providing both assisted insemination and *in vitro* fertilisation (including donor programmes with the exception of donor ova (egg) (IVFDE).

In November 2004 the Commission decided to update some of the information obtained from the survey. There were nine specialist clinics operating in Ireland at this time and eight of them responded to the survey. The clinic that did not respond to the first survey did not respond to the second survey either.

The summary in the tables that follow is drawn from the responses made by the directors of the eight clinics that agreed to participate in the Commission's survey.

Table 4.1 Survey of Treatments and Services provided by respondent AHR clinics in Ireland

Timeframe of survey: November 2004-January 2005.

CLINIC	A	B	C	D	E	F	G	H
TREATMENT/SERVICE								
Follicle tracking/Clomid and ultrasound	✓	✓		✓	✓	✓	✓	✓
Ovulation Induction	✓	✓		✓	✓	✓	✓	✓
Assisted Insemination by Husband/Partner (AIH)			✓	✓	✓	✓	✓	✓
Intra-Uterine Insemination (IUI)	✓	✓	✓	✓	✓	✓	✓	✓
In Vitro Fertilisation by Husband/Partner (IVFH)	✓	✓		✓	✓	✓		✓
Intra-Cytoplasmic Sperm Injection (ICSI)	✓	✓		✓	✓	✓		✓
Gamete Intra-Fallopian Tube Transfer (GIFT)					✓			
Zygote Intra-Fallopian Tube Transfer (ZIFT)				✓	✓			
In Vitro Fertilisation by Donor Sperm (IVFDS)		✓			✓	✓		✓
In Vitro Fertilisation by Donor Ovum (Egg) (IVFDE)		✓						
Ovum Donation		✓						
Embryo Donation								
Donor Insemination (DI)			✓		✓	✓		✓
Intra-Uterine Insemination by Donor (IUID)		✓	✓		✓	✓		✓
Testicular Biopsy with cooperation of Urology Unit	✓	✓		✓	✓	✓		✓
Epididymal sperm aspiration				✓	✓	✓		✓
Pre-implantation genetic diagnosis								
Surrogacy								

Table 4.2 Practice in relation to cryopreservation in respondent AHR clinics in Ireland

Timeframe of survey: November 2004-January 2005.

Clinic	Cryopreservation								Cryopreservation Period		Policy on Posthumous Use
	Sperm	Ova	2 ProNucleate (PN) ova/embryos					Ovarian Tissue	Sperm	2/PN ova/embryos	
			PN Stage	2-4 cell	8 cell	Morula	Blastocyst				
A	Yes	No	Yes	Yes*	No	No	No	No	1yr IVF, 10yrs cancer	5yrs	Yes (not used)
B	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Unlimited	Unlimited	Yes
C	No	No	No	No	No	No	No	No			
D	Yes	Yes	No	Yes	Yes*	No	No	No	10yrs	Review after 5 yrs	Yes (not to be used)
E	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	10 yrs**	5 yrs	Yes (thawed)***
F	Yes	No	No	Yes	Yes	Yes	Yes	No	Up to 55 th birthday of patient	5yrs	Yes
G	No	No	No	No	No	No	No	No			
H	Yes	No	Yes	Yes	Yes	No	No	No	5 yrs	5 yrs	Yes (not used)

* only in selected cases

** sperm frozen pre-chemo/radiotherapy is stored indefinitely

*** 2PN ova/embryos may be offered to female partner only

All donated sperm used in the respondent clinics is imported.

- 15. The Commission recommends that centres that collect and store gametes and that generate and store embryos should be regulated and licensed by the regulatory body. The regulatory body should lay down quality assurance standards for centres. Information on the range of services provided by the specialist clinics should be available to the general public.**

4.5 Health Boards Survey

As already pointed out in Chapter 1, the Chairperson of the Commission wrote to the Chief Executives of all eleven Health Boards asking them to state the number of AHR centres in their area and whether the Boards had any involvement in the provision of AHR services. She also enquired as to any future plans the Boards might have. The replies received indicate that the Boards are aware of the location of AHR centres in their area but that they have no operational connection with them.

The Commission is aware that some clinics provide services to public patients but they are not obliged to do so. It is also aware that the State makes an indirect contribution to the extent that the benefits of state-subsidised schemes for the purchase of drugs and medicines are equally available to recipients of AHR services, and expenditure on treatment is an allowable charge against pre-tax income.

4.6 The National Infertility Support and Information Group (NISIG) Survey

For a number of reasons the Commission came to the conclusion that it would not be feasible to conduct an independent survey of user attitudes towards AHR. It did however have the assistance in this regard of the National Infertility Support and Information Group (NISIG), a national organisation dedicated to the provision of information and support to users of AHR. The Chairperson of NISIG was a member of the Commission. The Commission is grateful to her for making available the anonymised results of a survey carried out by NISIG with a view to establishing the level of satisfaction of its members with their experience of AHR in Ireland. A copy of the questionnaire used in the survey is attached as Appendix IV. It was sent to 270 couples - all members of NISIG - and 129 (47.7%) completed replies were received. The average age of respondents was 31 (female) and 33 (male) and they had sought medical assistance an average of one to two years after infertility became an issue in their lives.

Seventy eight per cent of respondents found their GP helpful and 56% felt that their infertility had been promptly diagnosed at obstetrician/gynaecological level. Fifteen per cent became pregnant following treatment. The main complaints centred on the distance of clinic from home; the limited choice of clinics; insufficient factual information and a relative lack of counselling. However, 75% of couples who had received counselling found it beneficial. IVF was the most common form of treatment. Fifty-eight per cent of respondents received at least one IVF treatment cycle as against 23% of respondents that received IUI (the next most common treatment procedure).

The survey contained some questions on the socio-personal issues that can arise for infertile people and the responses to these questions are briefly summarised here. The emotions reported when the possibility of infertility first arose were: isolation; anger; bitterness; guilt and denial. Eighty seven per cent of respondents reported feeling that society put them under pressure because they had no children and 63% found it difficult to discuss infertility with their family. While 80% of people felt that the problem brought them closer to their partner, 53% reported that infertility had negatively affected their sexual relationship. Among respondents who had had children with donor assistance, 25% had decided to tell their children about the circumstances of their conception; 20% had decided not to do so and over a half had made no decision. When asked to whom should the

sperm/ova/embryos produced during IVF treatment belong, 90% of couples felt that they should belong to the couple, 3% felt that they should belong to the clinic and the remainder had no opinion.

4.7 Guidelines for AHR in Ireland

Medicine is practised in Ireland subject to guidelines issued periodically by the Medical Council. The Council is a statutory body set up under the Medical Practitioners Act 1978 with responsibility for registering medical practitioners in Ireland and setting standards for medical practice. The guidelines are contained in a booklet entitled: “A Guide to Ethical Conduct and Behaviour” issued to all registered medical practitioners in Ireland which sets out to describe “...a set of principles which doctors must apply in each situation, together with their judgement, experience, knowledge and skills”.

The Commission took note of the fact that in the case of all the Irish specialist clinics, the Director is a consultant obstetrician/gynaecologist on the register of Medical Practitioners of the Medical Council. The representative body of Obstetrics and Gynaecology in the Republic of Ireland is the Institute of Obstetricians and Gynaecologists of the Royal College of Physicians of Ireland. The Institute issued guidelines to its members in 1993 that accepted the therapeutic application of *in vitro* fertilisation. These guidelines were approved in the 1994 Edition of the Medical Council Guidelines, the first edition of the guidelines to refer to Reproductive Medicine.

In 1996 the Institute re-convened its Assisted Reproduction Sub-Committee and requested it “to review the 1993 guidelines in relation to assisted reproduction and to consider other matters related to assisted reproduction”. The sub-committee furnished its report in 1999 and the section of the report entitled “Matters Considered by the Assisted Reproduction Sub-Committee” is attached as Appendix V.

The Medical Council published a further edition of the guidelines in 1998.

The most recent edition of the guidelines was published in March 2004 and the following is the text of Section F - Genetic Testing and Reproductive Medicine:

“24.1 In a rapidly evolving and complex area, doctors are reminded of their obligation to preserve life and to promote health. The creation of new forms of life for experimental purposes or the deliberate and intentional destruction of in-vitro human life already formed is professional misconduct

24.2 Gene Therapy

It is ethical to use gene therapy to modify the genome of human somatic cells provided that the risk is not disproportionate to the benefit. Gene therapy of gametes (sperm or ova) though not yet considered safe for use in humans, may become so with advancing technology. If it then has as its aim the improvement of health it may be ethical.

24.3 Genetic Testing

Genetic testing may be of benefit in diagnosing an illness or predicting its development in the future. Individuals who undergo such testing should be counselled regarding the consequences of their actions and testing should not be done without their informed consent.

24.4 Frozen Sperm and Ova:

Artificial Insemination by Donor (A.I.D.)

There is no objection to the preservation of sperm or ova to be used subsequently on behalf of those from whom they were originally taken. Doctors who consider assisting with donation to a third party must have regard to the biological difficulties involved, and pay meticulous attention to the source of the donated material. Doctors who fail to advise both donor and recipient about the potential implications of such measures and the possible consequences for the would-be parents and their baby could face disciplinary proceedings.

24.5 In-Vitro Fertilisation (I.V.F)

Techniques such as I.V.F. should only be used after thorough investigation has failed to reveal a treatable cause for the infertility. Prior to fertilisation of an ovum, extensive discussion and counselling is essential. Any fertilised ovum must be used for normal implantation and must not be deliberately destroyed.

If couples have validly decided they do not wish to make use of their own fertilised ova, the potential for voluntary donation to other recipients may be considered.

24.6 The Child in Utero

The Council recognises that termination of pregnancy can occur when there is real and substantial risk to the life of the mother and subscribes to the views expressed in Part 2 of the written submission of the Institute of Obstetricians and Gynaecologists to the All-Party Oireachtas Committee on the Constitution as contained in its Fifth Progress Report, Appendix IV, page A407.

24.7 Adoption

Adoption must occur only through the auspices of registered adoption agencies. Pregnant women who are considering adoption must be offered contact with a registered adoption agency (details of these may be obtained from the Adoption Board)."

The section on Reproductive Medicine in the 1998 Medical Council Guidelines contained some changes from the 1994 edition. The limitation of the application of IVF to married couples only in the 1994 edition was no longer included, and the technique of donor insemination was discussed and not considered professional misconduct.

While the text of the relevant section in the 2004 edition differs in places from that of the 1998 edition, in effect there is very little change to the substance. Paragraph "24.3 Genetic Testing" of the 2004 edition is new as is the second paragraph in 24.5 on the voluntary donation of fertilised ova.

4.8 AHR and Equality Considerations

An important issue for consideration is to what extent the provision of AHR services should be subject to general principles of equality. Such services are currently subject to the provisions of the Equal Status Acts 2000-4 (discussed in Appendix IX). However, as section 14(a)(i) of the Equal Status Act 2000 provides that nothing in that Act prohibits the taking of any action required under any enactment, a new statutory code regulating AHR would not be subject to the terms of that Act (though it would have to comply with EC Directive 2000/43/EC on racial discrimination). Nonetheless the Commission recommends that any such legislation should reflect the general principles of the Equal Status Acts 2000-4, subject to the following qualifications:

- a) such legislation may prescribe an upper age limit beyond which individuals would not be entitled to avail of AHR. This affords some protection to the interest of the child in having a parent into his or her maturity and also to society's interest in protecting the health of its citizens;
- b) such legislation may, in the interests of the welfare of the child, confer on the providers of AHR services a discretion to deny AHR services to a person where there are serious concerns, supported by objective evidence, that the welfare of any resultant child could otherwise be at risk.

4.9 Conclusion

It is clear that a comprehensive range of high quality AHR services is currently available in Ireland and the Commission fully expects this to continue. The Commission is of the opinion that the Medical Council Guidelines alone are not sufficient to ensure appropriate regulation of these services throughout Ireland. Furthermore, there is currently no mechanism by which service users have access to information on clinic activities and success rates. The Commission wishes to see a more rigorous framework within which AHR services are provided in Ireland.

The Commission acknowledges that the production and manipulation of embryos produced by AHR treatments raise serious ethical and legal concerns for society. In making its recommendations, the Commission also acknowledges that individuals will have varying general, ethical and religious beliefs regarding AHR techniques.

Attention must also be paid to the complex medical issues involved. The Commission is of the opinion that the recommendations reflect current best practice. It is however cognizant of the fact that medical science is rapidly evolving and that future advances will necessitate regular review of these recommendations.

CHAPTER 5

Ethical Issues

This chapter describes a number of aspects of AHR that would command widespread assent in Irish society and a number of aspects on which public attitudes would diverge sharply. It goes on to outline an ethical continuum extending from total opposition to all forms of AHR to general acceptance of any assistance that science can give to infertile people. Two major intermediate points relating to the treatment of human embryos are identified within the continuum. The ethical issues inherent in decisions to provide treatment for infertile people who are not married and the welfare of children born through AHR are also considered. The current practice of AHR in Ireland is considered against that ethical background and the chapter ends with some conclusions and recommendations.

5.1 Introduction

The Commission acknowledges that the use of technology to assist human reproduction raises important ethical issues for society. Some of the most basic ethical issues relate to the welfare of children born through AHR and to the involvement of donors in the reproductive process. The relationship status of some potential recipients of AHR treatment raises ethical issues for many people. Fundamental issues also arise in the application of certain procedures to embryos generated through IVF.

A position paper prepared by Commission and Work Group members pointed to the importance of identifying ethical values that would command as great a consensus as possible among the people of Ireland in accordance with sound democratic principles. It also stated that a number of ethical positions, with their possible consequences, should be identified in order to ensure that the Commission's report reflected a range of differing views that would serve as a basis for the kind of informed public debate that the report is intended to generate.

The paper went on to argue that any society, whatever its diversity, is founded upon a common ground of ethical value and purpose. For this reason it is appropriate to articulate some broad areas of ethical agreement, as well as disagreement, concerning AHR that may provide parameters for the evaluation of different positions. These areas of agreement and disagreement may help to identify the often unarticulated ethical values that people bring to the debates associated with new reproductive technologies. Acceptance of these values is the core of moral identity both for individuals and for society. Making them explicit and promoting public debate about them will facilitate a broader societal understanding of these values.

Areas of Agreement

The Commission identified the following aspects of AHR about which it believes there is a large measure of public agreement:

- infertility can be deeply distressing for those affected by it and involuntarily infertile couples should have access to appropriate assistance from health professionals to overcome their infertility;

- the autonomy of infertile couples should be respected as far as possible but this autonomy is not absolute;
- recognition of the right of service providers to exercise clinical judgement with regard to the provision of treatment in certain circumstances;
- all AHR treatments should be demonstrably safe for the recipients and for any children born through AHR and in this context safety includes not only physical health but psychological and emotional welfare as well;
- the welfare of children born as a result of AHR in terms of their personal identity and their experience of family relationships should not be compromised by the circumstances of their conception;
- the capacity to overcome infertility should not deflect medical research from further investigation of the basic causes of and treatments for infertility.

Areas of Disagreement

The Commission identified the following broad areas where it feels that there would be a substantial divergence in public attitudes in Irish society:

- whether or not the basic act of human procreation is sacrosanct;
- whether or not the welfare of the child is best served within the traditional institution of the marital family;
- whether or not the *in vitro* embryo has absolute value from the moment of fertilisation and is entitled to legal protection from that stage.

5.2 Ethical Perspectives in AHR

Having considered the above broad areas of agreement and disagreement the Commission identified some key issues to be considered when formulating policies to regulate AHR.

The first issue is the ethical value of the *in vitro* human embryo, both as an embryo prior to being placed in the uterus, and the value of the embryo after implantation.

A second issue is whether or not AHR should be provided exclusively to married couples, or whether other alternative family arrangements, including unmarried heterosexual couples, same-sex couples and single people should be able to avail of AHR services.

Ethical perspectives on the status of the human embryo

It is obvious that opinions about the ethics of AHR range from forbidding any kind of intervention to alleviate infertility to allowing every innovation that medical science has produced. It is understood that most people's individual values, for whatever reason, will fall somewhere along this continuum. The reference points below are illustrative and are selected purely to facilitate the debate.

1. At one end of the continuum is the ethical judgement that there is an intrinsic and irreplaceable link between the union of husband and wife in sexual intercourse and the generation of new life and that, therefore, procreation by natural means is an absolute value in human society. This judgement would exclude all procedures that involve the handling of gametes and embryos (AI and IVF) for the purpose of human reproduction.
2. Further along the continuum, some accept AI and IVF as procedures that could be used under certain circumstances. These procedures would be carried out in circumstances that respected the life and physical integrity of all newly generated *in vitro* embryos. The essential difference between this ethical position and the previous one is that it accepts the intervention of technology in human reproduction and therefore does not see procreation by natural means as an absolute value. This ethical viewpoint would hold that a human life in its complete form is present from the moment of fertilisation onwards, and has an intrinsic or ultimate value based on its humanity or potential for personhood. The embryo is a human life and has the potential to become a mature adult. Procedures that do not respect embryos as human life are in breach of such an ethical code. Research on embryos would not be acceptable to this ethical position, nor would the disposal of surplus embryos produced by IVF.
3. A further ethical position is the judgement that newly generated human embryos would not be entitled to absolute protection from the moment of fertilisation, but would achieve absolute value at some subsequent stage of their development. This approach sees a human life as starting at some defined point subsequent to fertilisation, but not at the point of fertilisation itself. Several distinct stages of embryo development are put forward as the point at which personhood begins.

Some would propose that implantation of the embryo is the beginning of human life. Implantation is an essential step for foetal development, without which a pregnancy will not be sustained. Large numbers of embryos produced at fertilisation both *in vivo* and *in vitro* will not implant, either by chance or because of abnormality in the embryo. By the completion of implantation, the division of a single embryo into identical twin embryos will or will not have taken place.

Some people have proposed a further stage of foetal development, the appearance of the primitive streak at approximately 14 days after fertilisation, as the stage at which human life begins. The primitive streak is the stage at which cells that will become human brain and nerve cells appear. As brain activity, in particular that which controls breathing and the

heartbeat, is necessary for human existence, this ethical position defines basic brain activity as necessary to define human life. This position argues that prior to the appearance of the primitive streak, there is no brain activity, and thus no human life.

Some who hold these positions would propose that the embryo has no intrinsic value but has a symbolic value based on the fact that it is of human origin. Where research is considered, this relative value of the embryo would be weighed against the potential therapeutic benefit of carrying out research on it. This view would allow research when necessary to pursue a good scientific or medical end that cannot be pursued by other means. However, simply because embryos lack moral status in their own right, the symbolic value of embryos would restrict some approaches to embryos. Scientists may not do just anything at all with them. Embryos are not ‘means’ in this sense; for example, they may not be bought or sold.

Others who hold the position that human life is present at some defined point after fertilisation would also hold that the embryo has neither symbolic nor moral value. Embryos are simply a means to several ends and can be used as any other commodity, and have simply a commercial value.

This broad ethical position of an embryo acquiring human life at some stage subsequent to fertilisation would permit preimplantation genetic diagnosis of embryos and embryo research and would not exclude the possibility of stem cell research and other forms of research that might result in the destruction of embryos.

4. Another viewpoint describes the process of fertilisation, embryonic and foetal development as part of a continuous process, with no qualitatively distinct stages. Human personhood is acquired with the developmental process, and there is no single point in embryo development at which human personhood starts. The gradual acquisition of personhood in this process is therefore also paralleled by the gradual acquisition of respect and rights due to that embryo. As with position 3, this position would permit preimplantation genetic diagnosis of embryos and embryo research and would not exclude the possibility of stem cell research and other forms of research that might result in the destruction of embryos.
5. At the other end of the continuum is an ethical position that would see termination of pregnancy as an ethically acceptable expression of an individual’s right to choose. This position would permit preimplantation genetic diagnosis, research on embryos, and the testing and termination of pregnancies affected by a genetic disorder. Those who put forward this position propose the viability of the foetus outside the uterus as the stage at which human life can be considered to exist. Independent existence is necessary for human life and prior to the ability to exist independently human life is not present. This position could also hold that the embryo has neither intrinsic nor symbolic value – it is simply cellular material – and is not worthy of respect or protection. Where the embryo is considered to have neither intrinsic nor symbolic value, the sole instrumental use of

embryos as a means to other goods is permitted and there are no restrictions on what those other goods might be.

The above is a brief summary of the most frequently held ethical positions on the status of the embryo. Most are based on differing interpretations of commonly agreed biological facts. However, biological facts will not resolve the differences between the various ethical positions. It is increasingly clear, at least from available literature, that moral theologians, church leaders and members of religious groups within different religions differ on issues of the status of the embryo and on AHR technologies. Cultural and religious diversity is a developing social reality in Ireland. People have different views on these issues and it must be accepted that everyone is entitled to their point of view.

Ethical perspectives on who may be treated with AHR.

The various technologies involved in AHR are aimed at assisting people to reproduce, and can theoretically be offered to any person, regardless of their social circumstances. There is a wide continuum of ethical positions that try to define to which people AHR services may or may not be offered, looking at factors such as marital status, sexual orientation, and the use of gametes or embryos from unrelated donors.

1. As outlined above, one end of a continuum would not permit any AHR practice whatsoever, holding that there is an intrinsic and irreplaceable link between the union of husband and wife in sexual intercourse and the generation of new life and that, therefore, procreation by natural means is an absolute value in human society. This view is derived as much from a social ethic, as from a religious ethic.
2. A second ethical approach would be to permit AHR, but only to provide AHR to married couples. The use of donated gametes from a third party within this relationship may or may not be permitted.
3. A third ethical approach would be that AHR services can only be provided to heterosexual couples who are in a long-term relationship, however defined, without the expectation that the couples must be married. The use of donated gametes from a third party within this relationship may or may not be permitted.
4. A fourth ethical approach would be that AHR services can be provided as in section 3 above, but also to single people. A single woman who sought AHR to conceive would require the use of donated sperm. A single man would require a female surrogate who may or may not be the ovum donor.
5. A fifth ethical approach would be that AHR services could be provided as in section 4 above, but also to same-sex couples. Same-sex female couples would require the use of donated sperm and same sex male couples would require a female surrogate who may or may not be the ovum donor.

Based on its review of regulatory arrangements in different jurisdictions, the Commission is satisfied that the most commonly held ethical positions are accommodated somewhere along the two major continua outlined above. It is acknowledged that some people will choose a reference point in response to their explicitly articulated commitments to certain ethical views and principles when making a decision on AHR, as outlined in the positions above. Others may find that they will take up a position in terms of their prior commitment to the practices and services they would wish to use or see available and will only then attend to the ethical views and principles which would be implicit in their choice.

5.3 The current practice of AHR in Ireland from an ethical perspective

The principle of AHR

The inclusion of a section on Reproductive Medicine in the Medical Council Guidelines (see Chapter 4) is taken as evidence that the Council accepts the principle of technical intervention in human reproduction. This is reflected in the fact that a number of consultant obstetricians/gynaecologists provide a range of AHR services in Ireland.

The evidence from the telephone survey described in chapter 6 leads the Commission to believe that a substantial majority of the Irish population supports the principle of AHR subject to certain conditions.

The welfare of children

It was noted at the beginning of this chapter that some of the most basic ethical issues in AHR relate to the welfare of children. There is unanimous agreement that all AHR treatments should be demonstrably safe for any children born through AHR and, in this context, safety includes not only physical health but psychological and emotional welfare as well. It is also agreed that the welfare of children born through AHR in terms of their personal identity and their experience of family relationships should not be compromised by the circumstances of their conception. It has also been noted that significant disagreement exists between those who believe that the best interests of children are served within the natural institution of the marital family of husband and wife, and those who believe that alternative patterns of family life can be equally conducive to their integral development. As indicated earlier, many who would accept the principle of technical intervention in human reproduction would confine AHR to married couples because of the judgement that all children should ideally be born to a stable marital family in order to maximise their emotional and social welfare. Many others however, would allow access to AHR for single people and same sex couples. The only reference to children in the Medical Council Guidelines is in the context of warning practitioners that *“doctors who fail to advise both donor and recipient about the potential implications of such measures and the possible consequences for the would-be parents and their baby could face disciplinary proceedings”*.

Relationship status of Recipients

The 1994 edition of the Medical Council Guidelines limited the availability of AHR to married couples but this limitation is not included in subsequent editions. The guidelines make no comment on the provision of services to single people or same-sex couples. The practice as indicated in the responses to the Commission’s survey of consultants seems to be that, in coming to a decision on treatment, Irish obstetricians/gynaecologists would not discriminate between married couples and

unmarried couples in a long-term relationship. Fifty three per cent of respondents would offer services to single people while one in seven would offer services to same-sex couples. In summary, consultants in Ireland seem to be willing to provide treatment for infertile heterosexual couples whether or not they are married. Consultants are divided in their approach to single people and relatively few are prepared to treat same-sex couples.

It is obvious that attitudes among the general population vary widely in respect of the relationship status of people seeking access to AHR. For people who are opposed to AHR in principle the question does not even arise. It has to be recognised however that the relationship status of potential recipients arises in a very acute form for people who accept the principle of AHR only for married couples for whom AHR is the last remaining possibility of having children. These people would have reservations about unmarried people having children either by natural or assisted means and they would probably be unwilling to concede that single people or same-sex couples should have access to AHR under any circumstances.

The Commission does not have any objective information on the proportion of the population that would limit access to AHR exclusively to couples that have met one of the medical criteria of infertility, i.e. regular sexual intercourse over a period of at least a year. It may be that support for the alternative view, namely that an individual's relationship status should not be a relevant factor in determining eligibility for treatment, is increasing, even if it is still a minority view in society as a whole. The Commission also took account of the Equal Status Acts 2000-4 (see Chapter 4, section 4.8 and Appendix IX) that may be interpreted as establishing a legal right to AHR services regardless of relationship status.

Donor assisted reproduction

Complex social, ethical, medical and legal issues arise in the context of donor programmes. The Medical Council Guidelines accept the principle of donor-assisted reproduction. In practice, four of the respondent specialist clinics in Ireland provide donor insemination (DI) and *in vitro* fertilisation by donor sperm (IVFDS), and only one provides *in vitro* fertilisation by donor ovum (egg) (IVFDE). Forty-five per cent of respondents to the telephone survey agreed with the participation of third party donors in human reproduction with 35% being opposed to such participation. A number of issues that arise in donor programmes are dealt with in Chapter 7 and in Appendix VIII.

Associated Procedures

The fact that surplus embryos sometimes remain following the completion of IVF treatment has led to the practice of freezing (cryopreservation) of such embryos for possible future use. The availability of *in vitro* embryos has also promoted research on embryos including stem cell research, cloning and preimplantation genetic diagnosis (PGD).

To the extent that these procedures carry the risk of destruction for some human embryos, none of them would be acceptable to people who take the ethical position that a new human being comes into existence at fertilisation, whereas all of them would be, at least in theory, acceptable to people who believe that an embryo acquires moral status and independent value at some stage subsequent to fertilisation. The Medical Council Guidelines state that there is no objection to the freezing of sperm or ova but make no reference to the freezing of embryos. The responses to the survey of the

specialist clinics indicate that cryopreservation of embryos is practised (*see table 4.2*). The question of research on embryos is discussed in Chapter 8.

5.4 Conclusion and recommendations

In relation to the status of the embryo the Commission agrees with the authors of the position paper referred to in section 5.1 that individual opinions on AHR range from forbidding any kind of intervention to alleviate infertility to allowing every innovation that medical science has produced. It also accepts the analysis in the paper that divides that continuum into three more or less self-contained ethical areas that may be broadly denominated as follows: complete non-acceptance of AHR; acceptance of AHR subject to protection for the *in vitro* embryo from the point of fertilisation and acceptance of AHR subject to protection for the *in vitro* embryo from some subsequent point. The paper points out that the three areas effectively cover the entire spectrum of opinion on AHR and that every individual will find his/her personal views accommodated within one or other of the areas.

It was clear to the Commission that the adoption of the ethical position that procreation by natural means is an absolute value would exclude the use of technical intervention in human reproduction. The *de facto* position is that AHR services are already available in Ireland and their provision is acceptable under the current edition of the Medical Council Guidelines. There is obviously a demand for these services in Ireland and a number of AHR service providers cater for this demand. The Commission accepts that the overwhelming weight of professional and lay opinion in Ireland regards the principle of technical intervention in human reproduction as acceptable from an ethical point of view.

16. The Commission, with the exception of one member, recommends that the embryo formed by IVF should not attract legal protection until placed in the human body, at which stage it should attract the same level of protection as the embryo formed *in vivo*.

17. The Commission recommends that services should be available without discrimination on the grounds of gender, marital status or sexual orientation subject to consideration of the best interests of any children that may be born. The Commission recommends that any relevant legislation on the provision of AHR services should reflect the general principles of the Equal Status Acts 2000-4 subject to the qualifications set out in section 4.8.

The best interests of the child are discussed further in Appendix VII.

CHAPTER 6

Social Attitudes in Ireland to Assisted Human Reproduction

The purpose of this chapter is to assess the overall response of Irish society to the ethical questions raised by AHR and some of its applications. A brief description is given of the scientific and political environment in which AHR developed. Evidence available to the Commission on public opinion on AHR in Ireland is analysed and some recommendations regarding the provision of services are made. The legal issues that arise from the provisions of Article 40.3.3 of the Constitution are also examined.

6.1 Introduction

The Commission was required by its terms of reference to report on the social factors in AHR. After some discussion the Commission considered that the social factors consisted mainly of the overall response of Irish society to the ethical dilemmas inherent in the use of technology to assist human reproduction and in some of its applications. Chapter 5 sets out a continuum that could be seen to accommodate the ethical views of a majority of the Irish population and it identifies a number of theoretical positions that may be taken up in relation to the treatment of the *in vitro* embryo and to the relationship status of potential users of AHR. The purpose of this chapter is to assess, on the basis of available evidence, where the balance of public opinion lies in practice in relation to the same issues, taking account of the relatively short time that has elapsed since AHR has been introduced into this country.

The Commission accepted that ethical questions in AHR arise in the first instance for the people who seek and who provide treatment but that they do not end with them, that society in general has an interest in the provision of AHR services. It argued for this society-wide interest in AHR on the grounds that society as a whole is affected by infertility and by the emerging applications of IVF technology and that AHR has a possible broadening effect on the meaning and role of the 'family'. It further argued that these considerations give society in general a voice in the regulation of AHR services. In reaching that important conclusion, the Commission was fortified by the knowledge that in a large and growing majority of parliamentary democracies examined by the Commission, AHR services are subject to some form of voluntary or statutory regulation.

6.2 The Background to AHR

The second half of the twentieth century was a period of rapid progress in many fields of scientific research. In the field of medical research, in particular, the achievement of *in vitro* fertilisation was probably the most controversial of a wide range of developments. The worldwide publicity that IVF received in the general media generated intense debate on the merits and demerits of the ability of science to initiate human life *in vitro*. The significance of the scientific achievement was recognised, as were the potential benefits of the new technology for infertile couples. A note of concern as to what the further implications of this new departure in human reproduction might be also marked the debate. Soon after the initial success, there was a demand for IVF treatment from infertile couples in many countries, including Ireland, and a willingness on the part of fertility clinics to provide it. As

time went on the effectiveness of IVF treatment was improved by including superovulation as an integral part of the treatment thus raising further ethical issues relating to the treatment of ‘surplus’ embryos.

6.3 AHR in Irish Society

The Commission found it relatively easy to agree that the ethical issues arising in AHR amounted to an arguable case for a society-wide interest in the provision of AHR services within a jurisdiction. Reaching agreement on how that interest should be given expression in practical terms in this jurisdiction proved considerably more difficult. Before turning to public attitudes towards AHR, the Commission considered it relevant to advert to the fact that there has been much public debate in Ireland in recent years on three issues that have major ethical implications: abortion, contraception and divorce. The Commission felt that an analysis of this debate provides an indication of the evolution of ethical attitudes in Irish society over the last thirty years.

Abortion

A referendum to amend Article 40 of the Constitution was held in 1983 and the people approved the insertion of the following as Article 40.3.3: *The State acknowledges the right to life of the unborn and, with due regard to the equal right to life of the mother, guarantees in its laws to respect, and as far as practicable, by its laws to defend and vindicate that right.* The outcome of the referendum demonstrated strong public support for the right to life of the unborn with due regard to the equal right to life of the mother. However, three further amendments on abortion were put to a referendum in 1992. The first was designed to remove the threat of suicide as a ground for abortion. This was rejected. In the course of the same referendum the people approved amendments designed to allow individual citizens the freedom to travel between one State and another and the freedom to obtain or make available, in the State, information relating to services lawfully made available in another state. An amendment in 2001 proposing that “unborn human life after implantation in the womb” should be protected from “intentional destruction” by a restated criminal offence of abortion was defeated.

Contraception

A number of legislative measures have been passed into law over the past quarter of a century designed to regulate contraception. The Health (Family Planning) Act 1979 was passed with a view to ensuring that ‘contraceptives’, which had previously been banned, should become available for the purpose of family planning. Subsequent amendments to the Act ensure almost unrestricted access to contraception.

Divorce

Perhaps the clearest indication of evolving public opinion on ethical issues in Ireland is provided by the two referendums on divorce held in 1986 and 1995. The proposal to remove the constitutional ban on divorce was rejected by almost two thirds of voters in 1986, whereas a similar proposal was accepted in 1995 albeit by a very slim majority.

Political Change

The Commission also felt it relevant to comment on the degree of political change that Ireland has experienced in recent years and to express an opinion on the extent to which that may have affected public attitudes towards ethical issues. One of the most significant events in Ireland’s recent history

was the country's accession, simultaneously with Denmark and the United Kingdom, to the European Union, then the European Economic Community (EEC), in 1973. It is beyond dispute that membership of the EU has conferred rich economic benefits on the country. Moreover, the EU has had a direct effect on Irish law to the extent that many European directives have been incorporated into national legislation. What is also likely is that public attitudes have been affected by long experience of the Union's social programme. For example, proposals made in 2003 regarding stem cell research provide a clear indication of the potential of initiatives at Union level to generate debate on ethical issues within individual Member States.

Scientific Change

Science and technology have been major instruments of change in the lives of ordinary people throughout the second half of the twentieth century. Fast and affordable air travel has increased people's mobility. Television, the computer and the internet have effectively eliminated time and distance as barriers to the transmission of information and images around the globe. Developments in the micro-technologies have greatly increased the ability of scientists to extend the boundaries of knowledge and to discover new applications of existing knowledge.

Inevitably the question arose whether scientific advance *ipso facto* contributes to the betterment of society as a whole. As pointed out in this report, the achievement of *in vitro* fertilisation raised the question whether some of the technologies associated with IVF were necessarily consistent with the level of protection traditionally afforded to embryonic human life. And the production of a sheep from a cloned embryo raised the possibility that the technique of cloning could be applied to human reproduction.

The issue facing society is not whether limits should be set to scientific enquiry but whether society in its collective wisdom can decide that certain outcomes of such enquiry are ethically unacceptable to the point where they should not be allowed to become standard practice. That debate continues in society at large and in national parliaments around the world. One of the objectives of this report is to shed some light on current thinking in Irish society on the main issues involved.

Legal considerations

In the course of its deliberations the Commission took note of the terms of Article 40.3.3 of the Constitution. While it was conscious of the fact that the article was introduced with the unborn conceived by natural means in mind, it recognised that it could also have implications for the unborn conceived through assisted means.

The Commission noted that Article 40.3.3 of the Constitution did not explicitly define the term 'unborn'. This matter is discussed further in Appendix III. The uncertainty relates to the point in the process of fertilisation at which the 'unborn' enjoys constitutional protection. There is general agreement that the term 'unborn' does not apply to any point prior to the fertilisation of the ovum by the sperm. What is not clear is whether Article 40.3.3 applies at that precise point or at some subsequent point during the process of fertilisation and development of the embryo. This uncertainty has important implications for AHR, for if Article 40.3.3 applies to an *in vitro* embryo once fertilisation is complete, one could not allow such embryos to perish. Thus one could not engage in embryonic stem cell research or allow an embryo diagnosed with a genetic disorder to perish following PGD (see Chapter 8). If, on the other hand, Article 40.3.3 does not apply to an *in vitro*

embryo from fertilisation, there would be no constitutional impediment to conventional IVF or to other associated procedures such as embryo (including embryonic stem cell) research and the disposal of embryos diagnosed with genetic disorders.

Unfortunately the law currently lacks clarity on this important point. Clarification can only be sought in one of two ways, either an authoritative pronouncement from the Supreme Court on the meaning of the term 'unborn' for the purposes of Article 40.3.3 or by way of constitutional amendment.

6.4 Information on AHR generated by the Commission

In trying to estimate prevailing public attitudes in Ireland towards AHR, the Commission was faced with the practical problem that there was little relevant information already available in the public domain. The Commission was assisted in its task of generating relevant evidence by its own members and by invited experts who produced a number of research papers on specific topics. It also took a number of new initiatives to collect information on AHR services from three main sources: providers of services; users of services and the general public and the findings are summarised below under those headings.

As reported in Chapter 4, the Commission carried out surveys of the providers of AHR services in Ireland and the results of those surveys are presented there.

As also reported in Chapter 4, the National Infertility Support and Information Group (NISIG) carried out a survey of its members to which 129 couples, all of whom had had personal experience of infertility, responded.

Canvass of Public Attitudes

The Commission took three main initiatives with a view to ascertaining the balance of public opinion in relation to AHR in Ireland. It invited the views of members of the public and interested organisations by means of a public advertisement; it organised a public conference that was attended by over 250 people and it commissioned a market research organisation to conduct a telephone survey of a sample of adults living in Ireland. The results are briefly summarised below.

Public Advertisement

The Commission received over 1700 responses to the public advertisement that appeared in the national press in October 2001. A number of the responses received by the Commission were of common authorship where a memorandum had been drawn up, by for example, a lobby/pressure group, and distributed to a large number of people for signature and transfer to the Commission. Two such submissions accounted for over 900 responses received i.e. over 50% of the total. All of the responses were made available to the Commission members for consideration. The opinions expressed informed the discussions of the Commission and were of benefit to the Commission in finalising its report.

Public Conference

The Commission organised a public conference on AHR in Dublin Castle on 6 February 2003. Three topics were addressed at the Conference: the regulation of AHR, the *in vitro* embryo - legal and

ethical issues - and creating families through AHR. A keynote speaker presented each topic and presentations were followed by an exchange of views between participants and a panel of experts.

The Telephone Survey

In December 2002 the Commission recruited a market research organisation to carry out a survey of a quota sample of people over the age of 15 living in Ireland, classified by gender, age, socio-economic status and location. The survey consisted of a telephone interview in which 1003 participants were asked to respond to a questionnaire (see Appendix VI) designed to measure public attitudes towards AHR.

There were four main sections in the questionnaire:

- Section 1: sought information on the acceptability of AHR as a solution to infertility; on the kinds of people to whom it should be provided; on the most suitable method of regulating AHR and on whether AHR should be available as part of the general health service
- Section 2: dealt with the participation of donors in human reproduction; with the acceptability of providing donor sperm for single women; with the rights of children to information on their genetic parents and with the provision of surrogacy as a service to infertile couples
- Section 3: sought to assess public attitudes to the treatment of surplus embryos and
- Section 4: dealt with embryo research.

The survey population was selected so as to give equal representation to:

- men and women in five age groups: 15 to 24; 25 to 34; 35 to 44; 45 to 54 and 55+
- distributed over five socio-economic groupings: AB (upper middle class and middle class), C1 (lower middle class), C2 (skilled working class), DE (unskilled - no formal training) and F (farming community) and
- living in four regions: Dublin; rest of Leinster; Munster and Connacht/Ulster.

The Commission drew up the questionnaire. It was decided to include four categories of responses: 'yes'; 'no'; 'don't know' and 'in some cases'. The final category was included to cater for those who wished to record qualified support for a particular AHR procedure, e.g. a respondent might wish to indicate support for the involvement of donors in human reproduction but only if any resultant children could be guaranteed access to information about their genetic origins. The questionnaire was administered by telephone by the market research organisation that prepared a report of its findings and presented them to a full meeting of the Commission. The Commission is aware of the limitations of surveys of this kind. The survey was limited to just over 1000 people and the sample excluded by definition people who did not have telephones. Moreover, no advance information was available about the attitudes and knowledge of those who agreed to participate.

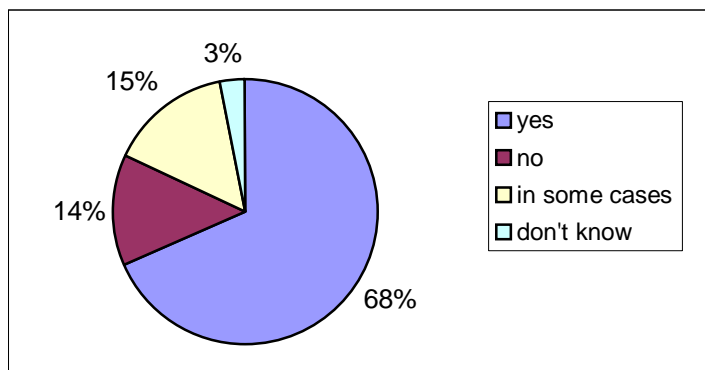
Nevertheless, a summary of the responses to the main areas of enquiry contained in the questionnaire is given below on the grounds that it provides a picture of public attitudes towards AHR, including

the acceptability of AHR services, among the people surveyed and highlights the divergence of opinions regarding embryo manipulation and the use of donor gametes.

(i) The principle of using technology to assist human reproduction

Sixty-eight per cent of respondents found AHR to be an acceptable approach to the solution of infertility and only 14% found it completely unacceptable. Fifteen per cent found it acceptable in some cases and 3% had no opinion. (see Figure 6.1)

Figure 6.1 Agreement with use of AHR



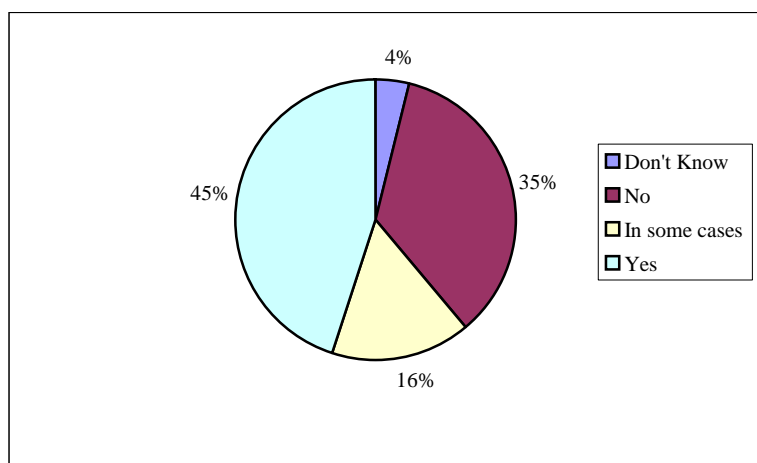
(ii) The Relationship Status of Recipients

Eighty-five per cent agreed with the provision of AHR to married couples and 63% to couples in a stable relationship. Support was higher among younger people, the more affluent socio-economic groups and in urban areas. Almost half of respondents disagreed with the provision of AHR to single women, whilst 60% did not feel that AHR should be made available to same gender couples, single men or post-menopausal women. The situation regarding people with disabilities is the least clear-cut. Over 40% agreed with the provision of AHR to people with disabilities, with a further 28% agreeing that AHR should be provided for people with disabilities in some cases.

(iii) The involvement of donors in AHR

Forty-five per cent of respondents agreed with the participation of third parties in AHR with a significant proportion, 35%, opposed to such participation. (see figure 6.2)

Figure 6.2 Agreement with the Participation of Third Party Donors in AHR



Seventy-five per cent supported the proposition that children born through donor programmes should have access to information about their genetic parents although it should be noted that 42% of respondents felt that donors should be entitled to anonymity except where the life/health of the child is at risk.

(iv) Treatment of surplus embryos

Forty-five per cent were opposed to the production of surplus embryos in the course of IVF treatment and 48% were opposed to the freezing of surplus embryos. Opinions were divided as to how surplus embryos should be dealt with if they remain after IVF treatment has been completed. Twenty-nine per cent felt that the decision should lie with those who produced the embryo, 27% felt that surplus embryos should be disposed of and 23% felt that they should be donated to another couple.

Fifty-seven per cent of respondents disagreed with the manipulation of embryos to enhance success rates when transferred to the uterus, while, conversely, 60% agreed with selection of only healthy embryos for transfer during IVF treatment. Forty-five per cent agreed that medical research on embryos should be allowed if the research could lead to advances in the treatment of genetic diseases, whereas only 16% agreed with the more general proposition that surplus embryos should be donated for research once IVF treatment is complete. Fifty-eight per cent of respondents were opposed to the proposition that scientists should be allowed to generate embryos solely for research purposes while 29% were in favour of it.

(v) Surrogacy

Forty-five per cent of respondents felt that surrogacy should be allowed in Ireland, with 34% of respondents opposed to the suggestion.

(vi) Regulation

The question asked in this section of the survey instrument was: Do you think that AHR should be regulated by:

- (i) the medical profession alone?
- (ii) the medical profession and the law of the land?
- (iii) the law of the land only?

Fifty-eight per cent felt that regulation should lie jointly with the medical profession and the law of the land. Twenty-seven per cent felt that it should lie with the medical profession only and 9% with the law of the land only.

6.5 Conclusions and Recommendations

As pointed out at the beginning of the chapter, the Commission interpreted the phrase ‘social factors’ in its terms of reference as referring mainly to the overall response of Irish society to the ethical dilemmas inherent in the use of technology to assist human reproduction and in some of its applications. The potential for conflict between the treatments that providers/users might expect to be approved and those that society as a whole might be willing to approve was obvious to the Commission and the areas listed below are the areas where that conflict is most likely to arise.

The Ethical Acceptability of AHR

The first issue was the extent to which technical intervention in human reproduction is ethically acceptable in Irish society. The Commission noted the strong opposition to the principle of AHR expressed by a number of participants at the public conference. A number of respondents to the public advertisement and 14% of respondents to the telephone survey espoused the same position. On the other hand, there was considerable support for AHR both at the conference and among the respondents to the advertisement. Eighty three per cent of respondents to the telephone survey expressed support in principle. The Commission also noted that AHR services are being provided by registered medical practitioners in Ireland in accordance with guidelines laid down by the Medical Council and that there is a wide demand for these services.

The Welfare of the Child

At an early stage of its deliberations, the Commission agreed that the welfare of the child was the primary consideration in all matters relating to AHR. However, it also noted that the welfare test is susceptible to very wide interpretation. The test was established in Irish law in the context of choices or decisions that affect children who already exist and who therefore already have interests that can be weighed in the balance. Applying such a test in AHR purports to make a child's best interests relevant to a decision to be made prior to that child's conception. Given that the welfare of children depends largely on parental warmth, sensitivity and responsiveness, the application of the welfare principle will demand that clinicians attempt to anticipate the quality of the relationship that is likely to develop between this couple /individual and any child that they might conceive. The Commission was concerned as to how this might be achieved in a fair, transparent and consistent manner.

Two separate aspects of the matter were considered: first, the safety, from the perspective of the child, of any procedure used in the course of treatment designed to bring a child into existence, and second, the suitability of the environment into which the child would be born from the point of view of the developmental needs of the child.

In relation to the second aspect, the Commission agreed that the environment into which a child would be born should be suitable from the point of view of the physical, psychological and socio-emotional development of the child, particularly in its formative years. However, the Commission was also concerned to avoid the possibility of excessive restriction in the absence of evidence-based ethical justifications. It was also cognisant of the fact that clinics generally rely on information provided by prospective parents themselves and therefore their ability to identify potentially problematic cases may be severely limited.

- 18. The Commission recommends that where there is objective evidence of a risk of harm to any child that may be conceived through AHR, there should be a presumption against treatment.**

***In Vitro* Embryos**

The Commission considered the evidence available to it regarding public attitudes in Ireland towards the *in vitro* embryo and, in particular, the measure of care and protection due to it. A full session of the public conference was devoted to the topic and the presentations were followed by vigorous, sometimes impassioned, debate. The obvious conclusion is that participants at the conference were

divided on the question of whether or not the *in vitro* embryo is entitled to absolute protection from the time of fertilisation.

The overall conclusion reached by the Commission is that Irish society is divided on the question of the action that may be taken with respect to the *in vitro* embryo. The Commission noted that it is unclear whether the *in vitro* embryo is entitled to legal protection under the terms of Article 40.3.3 of the Constitution. The Commission believes that the relevant steps should be taken to obtain the necessary clarification. However, as already stated in Chapter 5, the Commission, with the exception of one member, recommends that the embryo formed by IVF should not attract legal protection until placed in the human body, at which stage it should attract the same level of protection as the embryo formed *in vivo*.

Relationship Status of Users

The Commission was dependent mainly on the telephone survey for evidence of public attitudes towards the relationship status of users of AHR. Eighty-five per cent of respondents agreed with the provision of AHR to married couples. It will be recalled that 83% of respondents to the telephone survey found AHR acceptable in principle. It is logical to assume that anybody who accepts the principle of AHR would agree that it should be available to heterosexual couples who are married. Similarly the 63% of respondents who agreed with the provision of AHR to heterosexual couples in a stable relationship may be assumed to represent almost three-quarters of all those who agree with AHR in principle.

Fifty-four per cent of telephone respondents agreed with the provision of AHR services for single women, while 41% agreed that they should be available to same gender couples, single men and post-menopausal women.

In summary, the evidence suggests that there is virtually unqualified professional and lay support for the provision of services to married couples among Irish people who support AHR in principle and a very high level of support for the provision of services to heterosexual couples in a stable relationship. Professional and lay opinion appears to be sharply divided on the provision of AHR services to people who do not satisfy either of the above criteria.

The Involvement of Donors in AHR

The percentage (45%) of telephone respondents in favour of donor involvement in AHR was higher than the percentage (35%) that was opposed to it. Forty-five per cent were in favour of and 34% were opposed to surrogacy. The Commission also noted that assisted insemination by donor sperm (AID) is acceptable under the current edition of the Medical Council Guidelines. The guidelines also accept the donation of embryos by couples who have decided that they do not wish to make use of their own surplus fertilised ova. Donor programmes and surrogacy are considered in more detail in Chapter 7.

Regulation

In considering the question of regulation, the Commission took the following points into account:

- There appears to be an international consensus that the delivery of AHR services should be subject to standards and norms that command broad support in the society where the services are provided

- The conclusion following the session devoted to the topic at the public conference was that the matter was of such general interest to society that some form of social regulation was not only desirable but also necessary
- There is support for statutory regulation among professional groups representing service providers and
- There was strong support for external regulation among the respondents to the telephone survey.

The Commission felt that the question to be addressed was not whether AHR services should be subject to regulation but rather what form that regulation should take. The main options were either to accept the *status quo* of voluntary regulation by means of Medical Council Guidelines or to regulate AHR by means of an Act of the Oireachtas (see recommendation 1).

CHAPTER 7

Donor Programmes and Surrogacy

This chapter recognises the feasibility of using donated gametes in the process of assisted human reproduction. It describes the different kinds of donor programmes and discusses some of the clinical, legal and ethical issues that arise in them. It devotes a separate section to the question of surrogacy. The chapter concludes with a detailed set of recommendations.

Donor Programmes

7.1 Introduction

When a couple cannot achieve fertilisation through the use of their own gametes, fertilisation may be achieved through the use of gametes donated by third parties (donors). The Commission acknowledged that the involvement of donors in AHR presents a number of ethical, social and legal dilemmas.

The general principle was recognised that AHR gives individuals a degree of control in procreation that is characterised by deliberate choices and plans. This applies also to the role of third parties who may become involved in the procreative process through gamete donation. The intent with which each party becomes involved should be respected as a critical and inherent part of the process.

In making recommendations in this area, the Commission's primary concern is the interests of the child born through donor programmes. The best interests of the child in AHR are discussed in detail in Appendix VII. The Commission also took account of Section 24.4 of the Irish Medical Council's Guide to Ethical Conduct and Behaviour (6th ed. 2004) - Frozen Sperm and Ova: Artificial Insemination by Donor (AID).

7.2 Gamete/Embryo Donation

The question of sperm donation arises when the male partner is unable to produce suitable or sufficient sperm to achieve fertilisation by natural means (see Chapter 2). Donor sperm can be used in assisted insemination (DI) or in *in vitro* fertilisation (IVF).

Similarly, the question of ovum donation arises when a woman is unable to produce suitable or sufficient ova to conceive by natural means (see Chapter 2). For obvious reasons, donated ova have to be fertilised *in vitro*. Ovum donation is much more complex and time-consuming than sperm donation and is accompanied by personal discomfort for the donor and the risk of medical complications. Potential ovum donors include: women who agree to an ovum-sharing arrangement (where a woman undergoing fertility treatment receives subsidised treatment in return for sharing her ova with another woman undergoing treatment); women undergoing gynaecological procedures; relatives/friends of recipients and other altruistic donors.

If both partners are infertile, a pregnancy may be achieved through the transfer of an embryo to the uterus of the woman. The embryo would be generated using donor gametes. Although infrequently

practised, embryo donation has been shown to be a medically successful procedure. There are two possible sources of embryos for donation. The first would be where those who have successfully borne a child/children through AHR and do not require use of any remaining frozen embryos themselves may donate spare embryos for use by other person(s). The second would be the specific generation of embryos for donation using donor gametes. Following discussion about the ethical distinction that may be drawn between different means by which embryos might become available for donation purposes, the Commission felt that safeguards should be put in place to avoid the commercial production of embryos.

- 19. The Commission recommends that donation of sperm, ova and embryos should be permitted and should be subject to regulation by the regulatory body.**

7.3 Practical Issues in Donor Programmes

Clinics should adopt current best practice in the conduct of donor programmes. The Commission recognises that at present only imported donor sperm is used in the specialist clinics in Ireland and as such is subject to legislation/regulation on donor identification in the country of origin.

Selection of Donors

In the selection of donors, account should be taken of their medical, genetic, and reproductive history, physical examinations should be carried out and testing for transmissible diseases should be conducted. Sperm samples should be screened and appropriate guidelines should be put in place to enable regulation.

- 20. The Commission recommends that suitably qualified professionals should provide appropriate counselling in advance to all donors of gametes and embryos. Such counselling should be a pre-condition for informed consent by donors.**

Sperm should be frozen and not used for at least six months, and then only when further viral tests on the donor of sperm prove negative. This is to avoid the risk of transmitting any diseases that require an incubation period prior to detection. Donors should be asked whether they wish to receive the results of such tests and appropriate counselling should also be available in that context.

The mixing of sperm from the recipient's partner with that of a donor is not a desirable practice. It is used as a way of leaving the identification of the genetic father of a resulting child intentionally ambiguous. Intentional ambiguity is not in the best interest of the resulting child and should therefore not be allowed.

- 21. The Commission recommends that appropriate guidelines should be put in place to govern the selection of donors; to screen for genetic disorders and infectious disease; to set age limits for donors and to set an appropriate limit on the number of children to be born by the use of sperm or ova from a single donor.**

Best interests of children

One of the main questions to be decided in relation to donor programmes is whether the identity of the donor should be withheld from, or disclosed to, children born through donor programmes. Anonymity in AHR is discussed in detail in Appendix VIII. The main argument in favour of withholding information centres on the fear that there would be no supply of sperm donors were identification to be adopted. However, countries where donor identification is permitted have found that reduced supply does not continue beyond a relatively brief period.

The arguments in favour of disclosing information include the value of openness and honesty and the avoidance of identity confusion. In addition, the need of children to discover their genetic heritage is met. Having access to genetic origins is potentially of profound importance for people's understanding of their identity in a psychological, genetic and historical context. The Commission considered and discussed the arguments for and against anonymity and concluded that the safeguarding of the best interests of the child born through AHR necessitates access for all children to information that would enable them to identify their genetic origins.

- 22. The Commission recommends that any child born through use of donated gametes or embryos should, on maturity, be able to identify the donor(s) involved in his/her conception.**

The process of consent given by donors should include the information that their identity would be kept on record and that a resulting child may be given access to that record on request. Legislation should provide that no legal responsibilities would arise for donors from such access.

Payment for donations

The Commission is of the opinion that financial inducements in AHR are not acceptable. They would subject reproduction to the taint of commercialisation and might put unreasonable pressure on those who are undergoing AHR treatments. Reduction of costs for fertility services and/or freezing services in return for ova and/or embryo donation should not be permitted since such inducement to donate could nullify voluntary informed consent.

- 23. The Commission recommends that donors should not be paid nor should recipients be charged for donations *per se*. This does not preclude payment of reasonable expenses and payment for AHR services.**

Legal Parentage

The issue of the legal parentage in Ireland of children born through donor programmes is complicated by the absence of legislation and the lack of any judicial precedents.

- 24. The Commission recommends that in donor programmes, the intent of all parties involved - that the donor will not have any legal relationship with the child and that the woman who gives birth to the child will be the child's mother - should be used as the basis for the assignment of legal parentage.**

The application of the principle of intent will necessitate the broadening of traditional family structures to encompass the social family, as opposed to the biological one that has determined the shape of our laws to date.

- 25. The Commission recommends that in cases involving sperm donation, there should be a requirement that the partner, if any, of the sperm recipient also give a legal commitment to be recognised as the child's parent.**

This will protect the interest of both the child and the social parents. In the case of the recipient being a single woman there is no second legal parent.

In relation to ova donations, the question arises as to whether the legal mother of a child should be the genetic mother who donated her ova or the gestational mother who carried the child to term and gave birth to it. Legal maternity is important for birth registration, domicile and citizenship provisions, succession, childcare provisions, adoption, social welfare and educational provisions as many of these services and rights depend on the consent of the legal mother.

However, the intent of all parties involved should be the same as that of those involved in sperm donation, i.e., that the ovum donor would not have any legal relationship with the child. It is intended that the woman who gives birth to the child would be the child's mother and that her partner, if any, should be the child's second parent.

- 26. The Commission recommends that in the case of a child born through ovum donation and in the case of a child resulting from an embryo donation, the gestational mother should be recognised as the legal mother of the child and her partner, if any, should be recognised as the child's second legal parent.**

It is acknowledged that these recommendations would necessitate a change in the current law relating to parentage.

Rights and Obligations of Donor and Recipient

The Commission considered the rights to be accorded to donors of sperm, ova and embryos.

- 27. The Commission recommends that donors should not be able to access the identity of children born through use of their gametes or embryos.**

In the Commission's view it is important for psychological and emotional reasons for donors to know whether children have been born through their donations.

- 28. The Commission recommends that donors should, if they wish, be told if a child is born through use of their gametes.**

Although the Commission wishes to encourage those who have children through donor programmes to tell their children of the circumstances of their conception, the Commission also recognises that to

try to enforce this would be impracticable and possibly an unjustifiable interference with the constitutional rights of the family.

The Commission also considered whether donors should be permitted to attach conditions to their donations in terms of the socio-economic status, religious belief, race and so on of the recipient. This was felt to be unnecessarily discriminatory and contrary to the spirit of donation. However, the Commission acknowledges that there may be situations in which donors may wish to donate only to a particular person such as a family member or close friend, or may specifically direct that the donated material should not be available for research purposes.

29. The Commission recommends that in general, donors should not be permitted to attach conditions to donation, except in situations of intra-familial donation or the use of donated gametes/embryos for research.

7.4 Surrogacy

Surrogacy offers opportunities to some people to have children in circumstances where it would otherwise not be possible. For example, it may enable a woman who has ova but no uterus to have her fertilised ova carried to term by another woman (referred to as 'the surrogate mother') with the joint intention and understanding that the woman who intends to rear the child (referred to as 'the commissioning mother') will be the legal parent. The medical indications for surrogacy are (i) absence of uterus capable of carrying a pregnancy to viability and (ii) a medical condition causing serious risk to the health/life of a woman were she to become pregnant e.g. serious heart disease. The types of surrogacy potentially available are surrogacy using any of the following: the commissioning couple's gametes; the commissioning mother's ova and donor sperm; the surrogate's ova and the commissioning father's sperm; the surrogate's ova and donor sperm; donor ova and the commissioning father's sperm; and donor ova and donor sperm/ donor embryo. It should be noted that none of the clinics that responded to the Commission's survey was providing surrogacy treatment at that time.

Surrogacy arrangements can take place using IVF or AI techniques, but may also be carried out without any medical intervention. Where surrogacy is carried out privately and without medical intervention, the arrangement would be impossible to regulate.

The arguments considered during the Commission's discussions include the following:

Arguments in favour of surrogacy

- Given the shortage of children available for adoption, surrogacy might be the only option for some people to have a family, especially in cases of non-traditional families where adoption poses particular problems.
- The right to procreate should extend to surrogacy arrangements made by fully autonomous adults, once no harm to children is expected as a result.
- Surrogacy may be understood as an expression of altruism.

- The use of the human body for surrogacy is ethically indistinguishable from other accepted practices that separate genetic, gestational and social parenting, such as donor insemination, adoption and wet nursing. It is also indistinguishable from other practices whereby the human body may be seen as being utilised for profit, such as professional athletics and modelling.
- Although some people may find the practice of surrogacy inherently objectionable, the State should not enforce one set of values against those who do not share those values and, in the absence of demonstrable harm to children or others involved in surrogacy, should remain neutral.
- Although much research needs to be done on the follow-up of children born through surrogacy, the most recent research carried out (on very young children) indicates that commissioning parents are more attentive than average to children and the well-being indicators for the children are very positive at this stage.

Arguments against surrogacy

- Surrogacy represents the incursion of market values into gestation and traditional values of reproduction.
- Commercial surrogacy involves the use of contractual models whereby those who agree to become surrogate mothers are vulnerable to exploitation. Respect and consideration for women demands that this potential for exploitation be prohibited by the prevention of surrogacy contracts.
- The commercialisation of gestation places a monetary value on children which conflicts with their fundamental rights to be loved unconditionally as individuals and not as commodities.
- Surrogacy is unnatural because it separates the genetic, gestational and social roles of motherhood. Society should not interfere with the laws of nature by adjusting the natural or standard physiology of reproduction.
- Respect for human beings demands that no person should ever be used as a means to an end. The involvement of a third party as gestator for the child treats her as an object by which the achievement of the birth of a child can be attained. The commissioning party hires her in order to satisfy their own desires, rather than to give life to a child.
- A woman cannot possibly know before becoming pregnant and carrying the child for the duration of the pregnancy how she will feel on having to relinquish that child at birth. Her perceptions about attachment to the child may be very different at the time of her agreement to become a surrogate mother from when she gives birth and it is unreasonable to expect her to contract out of her right to retain custody of the child.

The Commission considered how best to address the ethical and legal concerns in relation to surrogacy and whether it was preferable to regulate or prohibit surrogacy.

The majority of members were in favour of regulating surrogacy, and all members were strongly of the view that commercialisation of the practice should not be permitted by the regulatory authority.

One member was strongly opposed to regulation and took the view that surrogacy ought to be prohibited. Such opposition was based on the opinion that surrogacy inherently entails risks of exploitation of women and commodification of children. On this view, public policy dictates taking a strong stance against such arrangements and should prohibit commercial agencies from seeking to make a profit from surrogacy. It was also argued that the recognition by the State of the legitimacy of surrogacy, even in tightly regulated circumstances, would give rise to a growth of such arrangements on a commercialised basis.

30. The Commission recommends, with one member dissenting, that surrogacy should be permitted and should be subject to regulation by the regulatory body.

However, in view of the complex issues that can arise in surrogacy arrangements, the Commission considered that great care should be taken with setting out the conditions under which such arrangements may be entered into. As far as possible, regulations should be introduced that would protect the various interests of all parties to a surrogacy arrangement, with particular reference to the interests of any resulting children.

The Commission was concerned with the possibility of commercial interests being involved in reproduction and, in keeping with its views on payments in donor programmes, felt that participants in surrogacy should not profit from such an arrangement. The prohibition on commercialisation reflects a concern that by placing a monetary value on a woman's reproductive capacity, the inherent value of women and children is implicitly undermined. Surrogate mothers should not suffer financial loss, but there should be no element of profit involved in the arrangement.

31. The Commission recommends that women who decide to participate as surrogate mothers should be entitled to receive reimbursement of expenses directly related to such participation.

7.5 Practical Issues in Surrogacy

Surrogate Mothers

In order to protect the health and well being of both the surrogate mother and the future child, the surrogate mother should be over the age of 18 and within the normal reproductive age range. Potential surrogate mothers should be rigorously screened both from a medical and a psychological point of view, bearing in mind the importance of consent to the relinquishment of the child at birth.

The Commission considered whether, as is the case in the legislation of some other countries, there should be any requirements that a surrogate mother should be married, be resident in the state or have previously given birth and have living with her at least one child of her own.

In relation to the requirement that the surrogate mother be married, the Commission could find no medical, legal or ethical justification for such a requirement. In relation to residency, similarly the Commission found no compelling justification. The Commission considered arguments that a surrogate mother who had a child previously might be better able to predict the effect of the pregnancy and birth experiences on her but maintain that this should not be made a requirement. While it might be easier for the surrogate mother to relinquish the child if she had another child living with her on whom to focus, it was also felt that if the surrogate mother had other children it could be psychologically damaging to them to see her give up a sibling. On balance, it was decided not to make it a condition that the surrogate mother have an existing child living with her.

Commissioning Person(s)

In keeping with the child's need for a parent until it reaches maturity and principles of anti-discrimination law, the age limit of the commissioning person(s) should be within the normal parenting range. The commissioning person(s) should be screened from a medical and psychological point of view to ensure, as far as possible, full understanding of the arrangement and commitment to the future child.

There should be no prohibitions regarding marital status, gender or sexual orientation of the commissioning person(s). Each clinic should have discretion whether to treat the prospective parent(s), keeping in mind the paramount importance of the welfare of the child and taking into account anti-discrimination law.

Identification of parentage

32. The Commission recommends that the child born through surrogacy, on reaching maturity, should be entitled to access the identity of the surrogate mother and, where relevant, the genetic parents.

This is consistent with recommendations regarding the identification of genetic parentage in donor programmes. The surrogate mother and/or the genetic parent/s should be informed that the child has the right to access to their identity but that no legal responsibilities will ensue from such access

Problems regarding adoption law

As the law currently stands, it is likely that the surrogate or birth mother would be considered to be the legal mother of the child. Consequently, it would be necessary for the commissioning person(s) to adopt the child in order to have a legal relationship with it. Alternatively, a commissioning man may apply for guardianship of the child under the Status of Children Act 1987 if he is the biological father of the child, but his partner would not have any right to make such an application.

Section 41(1) of the Adoption Act 1952 makes it illegal to make or receive any payment or other reward in consideration of an adoption. Contravention of this section is an offence. Therefore, if the surrogacy arrangement involved the payment of money to the surrogate, this may be seen as being in

‘consideration of an adoption’ and thus illegal. This remains a contentious issue and one which either the legislature or a court will have to decide as a matter of policy. However, the Commission is of the view that payment of reasonable and legitimate expenses to the surrogate mother should not be seen as contravening the Adoption Act.

Contractual issues/custody rights

There are different types of surrogacy arrangements that may be entered into and the rules that may be envisaged for one type may not necessarily fit the others. Some may have a contractual basis while others may not. There are commercial surrogacies and altruistic surrogacies, anonymous and intra-familial arrangements, genetic surrogates (who use their own ova) and gestational surrogates (who act as carriers of the commissioning couple’s embryo).

An examination of the custody rights of those who participate in surrogacy raises the difficulty of how to determine parentage in these circumstances. In the case of a surrogate who uses her own ova to conceive the child it is likely (following the example of many other jurisdictions) that, as she is both the genetic and gestational mother, an Irish court would currently hold her to be the legal mother. In the case of a surrogate who carries an embryo generated from the commissioning couple’s gametes, the position is not as clear. Both genetics and gestation play a necessary and equally important role in bringing the child into existence. It is argued that by choosing one over the other, the law is imposing an artificial primacy that is arbitrary and illogical.

The most obvious conflict that can arise in a surrogacy arrangement involves both the surrogate and the commissioning person(s) seeking custody of the child. In most jurisdictions it has been held that the surrogate is the legal mother, irrespective of the lack of genetic relationship between her and the child.

In custody disputes the court is obliged to treat the best interests of the child as paramount. This has involved examinations of financial stability, educational backgrounds and psychological assessments of both sides of the dispute in courts in other jurisdictions.

Constitutional rights

In Ireland the problems inherent in surrogacy arrangements are likely to be further complicated by the impact of the Irish Constitution. Our Constitution both acknowledges the special status of the married family as "the natural primary and fundamental unit group of society" and recognises the natural rights of its members. In a surrogacy arrangement, some particular constitutional issues are likely to be raised:

- Does the right to marital privacy protect surrogacy agreements?
- Could a surrogate mother be said to have a right of privacy (individual or marital, if she entered into the arrangement together with her husband) that would protect a surrogacy agreement?
- On the other hand, does the State’s constitutional obligation to protect the institution of marriage preclude the legislative endorsement of surrogacy arrangements?
- Does the surrogate mother of a child have a right to its custody?
- Does the natural father of a child, born to a surrogate and therefore outside of the marital relationship, have any recognised rights with regard to its care and custody?

- If the surrogate is married, could her husband have any rights to the child as being part of his own family?

These are issues that have unfortunately not yet been clearly addressed, either in the Constitution itself or in the body of case law that has built up around the interpretation of its various provisions.

Assuming, for the sake of argument, that surrogacy is constitutionally permissible, legislative intervention may be necessary to ensure that the resultant child is deemed to be a member of the family of the commissioning couple. A number of situations need to be distinguished. First, where the commissioning father's sperm impregnates the surrogate mother, it is certainly arguable that the surrogate mother would have constitutional rights to the resultant child unless those rights were waived or forfeited. Second, where the surrogate is carrying a fertilised ovum from the commissioning couple, the situation is less clear, given that we currently have no guidance as to the constitutional rights, if any, of the gestational mother and the commissioning couple in respect of the child. Third, where surrogates donate both egg and sperm, the resultant child could only be transferred into the commissioning couple's family through the process of adoption or by virtue of a future, alternative statutory process. In this context, attention would have to be paid to the provisions of ss.41 and 42 of the Adoption Act 1952 dealing with advertising and payment of sums in consideration of the adoption of a child.

To complicate matters further, where the surrogate is married, the law at present would presume the resultant child to be a member of her family, though this presumption may be rebutted. In the event of a custody dispute between the surrogate and commissioning parents, it may be difficult, though not impossible, for the courts to resolve the issue by reference to the best interests of the child if the child is deemed to be a member of a particular married family.

Legal parentage in surrogacy

The Commission is of the opinion that rights based on the 'intent of reproduction', in other words what all parties intended from the outset of the arrangement, should form the basis of recommendations on legal parentage in cases of surrogacy. However, the Commission was aware that this might raise constitutional difficulties that would have to be addressed.

The Commission considered four options in relation to the legal parentage of a child born through surrogacy:

- (i) The child born through surrogacy is presumed to be that of the birth mother.
- (ii) The child born through surrogacy is in general that of the commissioning person(s).
- (iii) The child born through surrogacy is presumed to be that of the commissioning person(s).
- (iv) The child born through surrogacy should be that of the commissioning person(s).

33. The majority of the Commission recommends that the child born through surrogacy should be presumed to be that of the commissioning couple.

It came to this conclusion because the word 'presumed' allowed enough flexibility in relation to the legal parentage of the child in the case of some fundamental change in the circumstances under which the surrogate mother consented to the arrangement. However, there was also a minority view within the Commission that favoured more leeway for the birth mother especially in cases where the

birth mother has a genetic link with the child. For example, some were of the view that where such a genetic link exists, the presumption should be reversed so that the surrogate mother would be presumed to be the legal parent of the child. In this context, the possibility of a “fast track” procedure whereby the commissioning person(s) might seek recognition as the legal parent(s) of the child was mooted.

Options for regulation

The following four options for the regulation of surrogacy were considered.

- (i) A separate licensing body specifically for surrogacy.
The Commission is of the opinion that the expense and administration involved in setting up the appropriate expertise and support structures would not seem justified by the (probably) small numbers of surrogate arrangements.
- (ii) Special supervision by the Department of Health.
This would involve special arrangements to be made between clinics wishing to proceed with surrogacy arrangements and the Department on an individual basis, perhaps following a set code of practice for such arrangements. The Commission was not in favour of this option.
- (iii) Extend the remit of the Adoption Board to include surrogacy.
There are many factors associated with surrogacy that have similarities with those considered in adoption and therefore a case could be made to extend the current remit of the Adoption Board to enable it to regulate surrogacy. The Commission was not in favour of this option.
- (iv) Include in remit of a Regulatory Body for AHR.
This option would involve the independent statutory body regulating surrogacy arrangements.

The Commission considers that option (iv) would be the most appropriate and has recommended that the regulatory body should regulate surrogacy.

CHAPTER 8

Current and Future Developments in Assisted Human Reproduction

In this chapter the Commission examines research as it impacts on AHR and its procedures and the treatments that have emerged or may emerge as a result of IVF. Areas of current research, including embryo research, embryonic stem cell research, human reproductive cloning, regenerative medicine, biological and genetic manipulation of gametes and preimplantation genetic diagnosis are discussed and future developments are considered.

8.1 Introduction

Research might be defined as a systematic investigation to establish facts and principles that is driven by the pursuit of knowledge. Without research to progress developments, many areas of science and medicine would not exist today. However, what is at issue in relation to research in the area of AHR is whether or not the means by which knowledge is pursued, the tools utilised in gaining the knowledge and the process by which the knowledge is attained are ethically acceptable or warranted. Similarly, the Commission is concerned about whether or not the application of such knowledge will enrich and enhance the well being of individuals and society.

It is recognised that IVF was born out of research, has progressed through research and is now accepted as a standard medical practice; however analysis of methods aimed at enhancing IVF success rates may still be considered as research. This chapter provides a brief introduction to the scientific issues involved which impinge on the ethical questions that arise on topics such as embryo research, embryo splitting, embryo cloning, embryonic stem cell research and preimplantation genetic diagnosis (PGD).

The benefits of research in AHR include: the understanding of the biology of human embryonic development; improvement in IVF treatments; expansion of research potential directed at the enhancement of reproductive medicine; improvement in the reliability of PGD testing and an increased diagnostic capability.

8.2 The human embryo and scientific research

The ethical issues arising from the use of *in vitro* embryos in scientific research raise the sensitive question as to whether it should be permitted or not, as it will result in the destruction of the embryo. A question to be answered is whether or not there are benefits to be achieved by embryo research that outweigh the negative consequence for the embryo. Views on the status of the embryo differ.

Many countries have addressed the subject of the status of the embryo and have legislated while others are contemplating legislation. In Ireland, the legal meaning of the word unborn in Article 40.3.3 in the Irish Constitution is unclear. The uncertain nature of the law on this vital point has profound implications for any research programmes. Clarification may wait on either an authoritative pronouncement from the Supreme Court or a constitutional amendment. The availability of a

freezing programme that allows a couple the best chance to achieve a pregnancy with maximum safety, avoiding the need for further ovarian stimulation treatment can result in excess embryos being cryopreserved. The question before the Commission was how should one deal with excess embryos. Should they be available for research?

The Commission noted that Article 2 of the Convention on Human Rights and Biomedicine emphasises the primacy of the interest and welfare of the human being over the sole interest of society or science. Scientists have agreed that a balance must be maintained between protection of fundamental rights and the freedom of research.

Article 15 of the Convention states “Scientific research in the field of Biology and Medicine shall be carried out freely subject to the provisions of the Convention and other legal provisions ensuring the protection of the human being”. Freedom of research is justified but not absolute. The fundamental rights of the individual limit it.

If research on the embryo is not ruled out in principle, then the research to be carried out would be expected to justify the use of the donated embryos. Those countries currently doing research on embryos are carrying out experiments in the field of human reproduction, in particular IVF treatment and procedures, such as studies in prolonged culture, freezing and the viability of the embryo, in the development of embryonic analysis for diagnostic or therapeutic purposes and embryo toxicity/toxicology.

Questions about the acceptability of research, in general, using human embryos have prompted a number of governmental ethical committees throughout Europe and elsewhere to open the subject for discussion. The first concern is the justification/legitimacy of using an embryo for any purpose other than procreation and the second is the ultimate destruction of the embryo. The following summarises moral positions on the status of the embryo *in vitro* and the implications of these positions for the use of such embryos in research.

The continuum of ethical positions on the status of the embryo is outlined in Chapter 5. The first two positions (section 5.2: 1,2) hold that human life is present from the moment of fertilisation, and that the human embryo already has human rights, most specifically, the right to life. This ethical position would mandate a ban on embryo research. The question is whether those holding such a position on the status of the embryo must also refrain from using the benefits of embryo research carried out elsewhere. If they truly believed that a human embryo has intrinsic and unconditional value, then it would be difficult for them to avoid a charge of moral inconsistency and some would say complicity in using the results of embryo research borrowed from elsewhere.

The dominant view of jurisdictions that permit embryo research or are considering doing so is that the embryo has a relative moral value and that, as such, its instrumental use is ethically acceptable. This ethical position would be in line with those outlined in Chapter 5 (section 5.2: 3-5). Once this view is granted, what is at stake is the extent of the use of human embryos: the limits and conditions that must be drawn in the light of the relative value of the embryo coupled with the importance of the goals of embryo research. The fact that embryo research might lead to greater knowledge or that useful applications are conceivable is not sufficient; it has to be clear that the interests served by the research outweigh the human and social costs and are considered to be of greater benefit to society.

One usual stipulation is that research be carried out only on *in vitro* embryos up to fourteen days after fertilisation (prior to the appearance of the primitive streak) and within the terms of strict codes of practice.

The European Society for Human Reproduction and Embryology (ESHRE) Task Force on Ethics and Law states that the pre-implanted embryo is owed respect as a symbol of future human life. Their wish is to establish a code of ethical practice in assisted reproductive technologies. While they acknowledge that the pre-implanted embryo is owed a certain respect and that the welfare of any resultant children is paramount, they also take into account that the embryo cannot reach its potential to become a foetus and a child unless and until it is transferred into a uterus. They feel that there is a case to be made in treating the embryo differently before and after implantation. The ESHRE Task force has divided embryos for research into 2 categories: surplus embryos donated by couples undergoing IVF and embryos generated for the specific purposes of research. The Task Force states that research embryos should not be transferred into a uterus for the purposes of achieving a pregnancy. The ESHRE Task Force also states that embryos should not be generated specifically for research unless supernumerary embryos cannot be used and accepts that research should only be permitted up to day fourteen. It suggests that where possible animal models should be used first.

Embryonic stem cell research

Embryonic stem cells (ES cells) arise from the cells of the inner cell mass of the embryo (blastocyst). These embryonic cells have the capability to form all the different cell types and organs in the body. The cell lines so formed can give rise to new cells indefinitely. These cells can be cryopreserved and cultured again on thawing. The cells (ES cells) are **pluripotent** i.e. they have greater potential for differentiation than **multipotent** adult stem cells.

As ES cells appear to be able to become any kind of tissue, once the mechanisms for differentiation are understood, then provision of banks of skin, bone, liver etc. tissues could be available to replace individual organs. Also, the use of embryonic stem cells for toxicological purposes has great potential and offers scientific advantages over the use of animal cells/tissues, as they are not reliable models for predicting human embryotoxic responses. The potential for use of ES cells in regenerative medicine has yet to be realised but experts believe the scope of stem cell applications is enormous. Stem cell culture banks have been set up in the UK, USA and Germany thus alleviating the constant need to use further embryos to generate stem cells. It should be noted that although German law prohibits the production of embryonic stem cells it does permit their importation. A list of specific examples of potential applications of pluripotent stem cell research is contained in Appendix X.

A high level expert group from the European Science Foundation has considered the subject of stem cell research and has stated in a report dated August 2002 that: *“There are two major considerations concerning this topic. Firstly, the scientific study of human stem cells is at such an early stage that it is necessary to carry out experiments on cells obtained from embryos and adults in parallel. Secondly, the legislative situation governing work in this field differs considerably between countries represented in the European Science Foundation. The medical potential of stem cell therapy is obvious. Therapy using stem cells for diseases that involve the degeneration of defined cell types, such as diabetes, Parkinson’s disease or Huntington’s chorea, could become available within the foreseeable future. Stem cell therapy for diseases that affect whole organs or complex tissues is*

thought to be possible in the future, but in these cases, the potential is much longer term. Although progress in stem cell biology has been rapid, there are many important scientific questions that need to be addressed.”

The Expert Group’s recommendations and a table on the legislative situations in the countries who are members of the European Science Foundation are contained in Appendix XI.

Questions need to be raised about the regulation of embryonic stem cell research to ensure that:

- a) embryo donors who may supply ES cells are not exploited and
- b) donors are fully counselled and informed of the current purposes and procedures of embryo research. A time limit should be placed on the cryopreservation of embryos that are to be used for research purposes.

The issue of donors’ entitlements to any benefits deriving from embryonic stem cell research is beyond the remit of the Commission.

Arguments in favour of embryo research

The arguments in favour of embryo research include:

- The pre-implanted embryo merits respect as early human cellular life. This respect does not require that we ascribe full moral standing to early embryonic life or equal predictability as we do to implanted embryos.
- The fact that there are surplus embryos in most applications of IVF processes presents challenges to IVF providers as to what to do with them e.g. should they be frozen, donated or allowed to perish? The embryos that are not transferred and are to be frozen in perpetuity or allowed to perish must be evaluated against the needs of *third* parties who suffer from various maladies that research on embryos *may* eventually alleviate.
- Embryonic stem cell research promises significant therapeutic benefits. It is this enhancement of prospects for *others plus* the absence of prospects for early embryonic life that makes it possible to justify research for others living and suffering.
- By allowing research with surplus embryos from IVF, fewer will be lost and someone will benefit.

Arguments against embryo research

The arguments against embryo research include:

- The deliberate and direct disposal of embryos is treating them merely as means to other ends and is morally unacceptable.
- Embryonic stem cell research should not be carried out until the potential of adult stem cells has been fully explored.

In summary there are three possible positions that could be taken on embryo research:

- (i) embryo research should not be permitted.
- (ii) research should be permitted only on surplus embryos donated specifically for research
- (iii) research should be permitted not only on surplus embryos donated specifically for research but also on embryos generated specifically for research purposes.

The Commission considered the documentation available regarding public attitudes towards the pre-implanted *in-vitro* embryo and the protection due to it. The recommendations that follow on embryo research were the decisions made at the end of numerous lengthy debates on the status of the embryo. Each of the considered moral positions is not distinct and many riders were added during Commission discussions.

Arguing from a scientific position some believe that at the moment of fertilisation a new unique genetic entity begins to exist and that reference could be made to a human being. Others believe the defining moment is later in the development. Arguments based on the potential of an embryo to be a person lead to the question of whether or not an *in-vitro* embryo should be respected as if it were a person. If so, the process of selection of an embryo for transfer to the uterus (an event that has to happen for an embryo to fulfil its potential to become a person) could be seen as unacceptable. However, a counter argument exists that disputes the equation of potential with actuality, i.e. just because an embryo has the potential to become a human being does not mean that it should be treated as if it were a human being.

The use, creation and disposal of embryos in research has long been justified by its proponents because of the contribution it makes to our understanding of the processes of contraception and reproduction. The question of adequate legislative controls as to what research may be permitted also arises.

Legal Regulation

It is argued that the legal profession is not well equipped to deal with the revolution in biotechnology, particularly one of the proportions indicated by modern genetics. Law has traditionally been reactive rather than proactive, responding to specific developments rather than establishing structures within which flexibility is possible by monitoring advances on the one hand while accommodating changing knowledge and capacity on the other. The pace of change in this area, the need for flexibility and the importance of developing public understanding through education and debate means that any legislative intervention should be passed with as full as possible an appreciation of the consequences, and kept under periodic review.

The advances that have already taken place in genetic technology and those that potentially offer therapeutic benefits in the future have raised discussions in many countries regarding the best means of regulation of this technology. In the European context, national regulation exists in many jurisdictions including Austria, Finland, Germany, the Netherlands, and Norway. Many countries have opted for a two-tier method of ethical review by local research ethics committees, followed by review at national level, often by scientific rather than ethical experts. Another common trend evident in other countries is the utilisation of AHR legislation as a means of regulating genetic

technology. This has been criticised on the basis that such laws were drafted in response to the advent of IVF in the 1980s, the focus of which was to avoid interference with reproductive cell-lines with provisions relating to genetic technology being introduced by way of later amendments.

At an international level, a number of declarations exist dealing with the ethical issues raised by stem cell research and other techniques. The most important of these in this context is the European Convention on Human Rights and Biomedicine, which was agreed in 1996 and signed by five states at the Oviedo meeting in 1997. It was drafted in an attempt to keep pace with biomedical developments and to close legal loopholes that might exist within Europe where scientists could exploit lack of regulation in order to evade the legal restrictions in force in their own countries. The underlying principles contained in the Convention are autonomy and informed consent.

- 34. The Commission recommends that embryo research, including embryonic stem cell research, for specific purposes only and under stringently controlled conditions, should be permitted on surplus embryos that are donated specifically for research. This should be permitted up to fourteen days following fertilisation. The regulatory body should stipulate under what conditions and for what purposes embryo research is permitted. (One member dissented from this recommendation) Those donating embryos for research must receive pre-donation information and counselling and they must give informed consent for the use of donated embryos for research. No inducement, financial or otherwise, should be offered/accepted for the donation of embryos for research. Once embryos are used for research their subsequent use for reproductive purposes should be prohibited. The generation of embryos through IVF specifically for research purposes should be prohibited.**

8.3 Human reproductive cloning and regenerative medicine (therapeutic cloning)

Definition and description of human reproductive cloning

For the purposes of assisted human reproduction, human cloning can potentially be carried out using two different technological methods.

The first form of cloning is the production of two or more genetically identical embryos by *in vitro* splitting of early human embryos (embryo splitting). In embryo splitting (as the term indicates), the early embryo is sectioned into two or more parts each of which can undergo further cell division with the potential to develop into a foetus. Nuclear and mitochondrial genes are identical in cloned individuals produced by embryo splitting. This technique is analogous to the process by which identical twins are generated by normal reproduction. Although embryo splitting has been widely used in bovine reproduction, it has not been used in human reproduction.

The second form of cloning is known as Somatic Cell Nuclear Transfer (SCNT) or cell nuclear replacement (CNR) and is how Dolly the sheep was produced. The nucleus is removed from the unfertilised ovum and replaced by a nucleus from an adult somatic cell. The adult nucleus is placed into the enucleated ovum by microinjection. The resultant ovum has a complete diploid set of chromosomes and has the potential to divide, differentiate and grow to produce an individual identical in genetic make-up to the individual by whom the transferred nucleus was donated.

To date several different species of animals have been cloned from adult differentiated cells by SCNT. The ability to produce cloned human individuals by nuclear transfer is technically challenging at present. Since 1998 there have been a number of groups who have claimed that they have generated human clones, but none has been substantiated. However, in February 2004 a Korean group reported in the journal “Science” the production of human embryonic stem cell lines from cloned embryos. Of the cloned human embryos produced, 25% developed to blastocyst stage. However, the researchers did not place any cloned blastocysts in the uterus, but generated an embryonic stem cell line from the blastocyst. Thus human cloning has been shown to be technically possible, at least to the developmental stage of a blastocyst.

However, there remains a major concern over the outcome for cloned embryos produced by SCNT, assuming that such embryos can develop beyond the blastocyst stage. A significant factor is the question of the health and well being of cloned individuals; in cloned animals the incidence of miscarriage, neonatal death and congenital abnormalities is high.

There are significant concerns about the accuracy of reprogramming of nuclear genes in the transferred adult nucleus that is used to make a clone. There are two principal biological concerns for cloned organisms. The first is the true age of the cloned organism. The question has been posed as to whether the cloned person has the same lifespan as a non-cloned person of a similar age. Currently there is no definitive answer.

The second concern is the fact that a clone only has genes that come from a single cloned person. In higher organisms including humans, some genes have imprints that specifically mark a gene as coming from either a mother or a father. In addition, some imprinted genes may only function when they are derived from a mother, and the paternal copy of the gene is silent. The opposite can also occur. There are often significant differences in imprinting of genes between different species. A number of medical disorders, including birth defects and significant learning disability, can arise as a result of disruption of the normal imprinting process. When a somatic cell nucleus is being prepared for transfer into an enucleated ovum, there may well be significant interference with the accuracy of genetic imprints in the somatic cell nucleus, which may cause major problems in any cloned organism.

The Commission in its deliberations appreciated that human reproductive cloning could be the only reasonable reproductive option for the infertile persons who wished that their own genetic material would play a part in the reproductive process. Counter arguments such as safety, lack of dignity and the attendant social implications that could be attached to the child due to unusual family relations or its affect on genetic diversity were considered. Reproductive cloning would mean that people are repeatable and would immediately diminish the value of personhood. A human being has an intrinsic value. The outcome of the Commission’s discussions is summarised under arguments for and against human cloning.

Arguments in favour of human reproductive cloning

Arguments in favour of human reproductive cloning include:

- Cloning adds to the reproductive options already available and enhances procreative choice for the infertile. It has been argued that principles of self-determination, autonomy and privacy would encompass the right to engage in reproductive cloning.
- The right to procreative liberty entails the right to choose which gametes and embryos to use. This choice then extends naturally to negative selection of the embryos on the basis of genetic characteristics. When a person looks at the most likely application of cloning techniques, to enable infertile couples to procreate genetically related children, cloning shares many features with AHR and genetic selection. The motive behind the cloning should be considered as irrelevant, in the same way as motive is not considered when fertile couples reproduce.
- Cloning may be the only way for some people to have a genetically related child.
- Cloning may be a means of ensuring that a hereditary disease is not transmitted to a future child. This would ease concerns as to the child's potential future health.
- Cloning may be used to replicate a dying or deceased child. This would enable the bereaved family to draw comfort from the existence of a future child who would share many of the same physical characteristics as the child who has died.
- Cloning may be used to replicate a child for purposes of tissue transplantation. This would facilitate life-saving techniques in circumstances where a close tissue match is essential to an existing child's treatment.

Arguments against human reproductive cloning

Arguments against human reproductive cloning include:

- Animal cloning has not yet reached the minimum level of safety and efficacy that is needed before research on human cloning could even begin. Given these concerns, it would be unethical to even consider applying these techniques in humans.
- At the core of human dignity is the idea that every human being has an intrinsic value, that human life is beyond price. Cloning will change our perception of personhood.
- 'Deliberately cloning human beings is a threat to human identity, as it would give up the indispensable protection against the predetermination of the human genetic constitution by a third party. Further ethical reasoning for a prohibition to clone human beings is based first and foremost on human dignity which is endangered by instrumentalisation through artificial human cloning.' (Council of Europe, *Additional Protocol to the Convention on*

Human Rights and Biomedicine on the Prohibition of Cloning Human Beings, Explanatory Report (ETS No. 168) Para.3.)

35. The Commission recommends that human reproductive cloning should be prohibited.

Regenerative medicine (therapeutic cloning)

Regenerative medicine involves the creation of a cloned embryo using non-diseased donor cells from a patient with a degenerative disease or disorder. Although the technology initially is the same as for reproductive cloning, the objective is to use the cloned embryo to generate a stem cell line (immortalising those cells) that, in turn, can be used to generate a particular tissue for treatment of the disease in question. A significant potential advantage of regenerative medicine is that cloned embryonic cells that are genetically identical to the host will not generate an immune response following transplantation. The proposed benefits are based on the pluripotency of embryonic stem cells. Embryonic stem cells have the ability to develop or differentiate in culture into a wide range of different types of tissue, when given the correct stimulus by specific trophic factors. Experiments on animal embryonic stem cells (principally from the mouse) have shown that pluripotent animal embryonic stem cells can differentiate into nerve cells, fat cells, skeletal muscle cells, smooth muscle cells and blood vessels. The exact mechanisms by which such cell differentiation in animal embryonic stem cells takes place are not yet clarified, but the principle has been demonstrated.

The promise put forward by proponents of regenerative medicine is that the differentiation processes shown in principle in animal embryonic stem cells may also be applied to human embryonic stem cells. Specific cell types derived from cloned human embryonic stem cells could therefore be used in theory to replace diseased or damaged cells in whichever organ was diseased. Potentially, human embryonic stem cells could be differentiated into pancreatic insulin producing beta cells to treat diabetes, or cardiac muscle cells to replaced damaged hearts, or even nerve cells to treat disorders such as Parkinson's disease.

Legal Considerations in cloning

Whether it is possible to allow regenerative medicine and prohibit reproductive cloning is a matter of debate. The fear is, that once a cloned embryo is generated in the laboratory for any purpose, there will be no way of policing the use of that embryo to ensure that it is not transferred to a woman's uterus to produce a cloned child. On the one hand, it is argued that it is possible and important to avoid this particular slippery slope by criminalising reproductive cloning while recognising the significant potential offered by continuing efforts in regenerative medicine. However, it must also be recognised that once the scientific feasibility of reproductive cloning exists, although reputable scientists will observe legal prohibitions, a small number of persons might be prepared to violate such a law.

In relation to the question of whether a right to engage in human reproductive cloning might be protected by international human rights law, the basis upon which such a claim could be currently grounded is weak. However, given the relatively recent interest in reproductive rights, there is a possibility of expansion in this field.

The status of the ‘cloned organism’

When a human embryo is generated through sexual reproduction or through AHR, the ovum is fertilised by a sperm. The resulting entity is an embryo. With regenerative medicine, the ovum is not fertilised but has its nucleus replaced by a somatic diploid nucleus. Therefore it is argued that this cloned organism is a new type of biological entity never before seen in nature, has none of the attributes normally seen in embryos and will be disposed of at the blastocyst stage to form a cell line. Many would see this entity not as an embryo, but as an ‘activated ovum’. For those who believe that it is an embryo and that it has a right to life, then its deliberate creation in order to dispose of it would be wrong. Others argue that the benefits of the research and the possible therapies it might produce far outweigh the claims of the activated ova.

Regenerative medicine and reproductive cloning require the use of human ova donated specifically for research, and regenerative medicine of necessity is the production of “an embryo” specifically for research. Although the Commission has recommended that the generation of embryos through IVF specifically for research purposes should be prohibited, it felt that an exception should be made for regenerative medicine. This exception is made on the basis that regenerative medicine is not actually IVF. The objective is to generate a stem cell line that in turn can be used to generate a particular tissue for treatment of a specific disease and one of the main potential advantages of this procedure is that the cloned embryonic stem cells are genetically identical to the host and will not generate an immune response following transplantation.

36. The Commission recommends, with one member dissenting, that regenerative medicine should be permitted under regulation.

Ireland

In the Irish context it is difficult to predict the legal status of the cloned organism and whether it comes within the meaning of ‘unborn’ in the Constitution. There is little guidance to be gained from a perusal of the case law to date, and there are no legislative provisions dealing with the issue.

In the processes of cloning the ovum is not fertilised by sperm and it could be argued that the cloned organism does not come within any interpretation of the ‘unborn’. However, despite the method of its creation, the cloned organism is regarded by many professionals in this field as ‘morphologically indistinguishable’ and ‘functionally indistinguishable’ from the embryo generated by fertilisation. Whether the embryo would then come within the meaning of ‘unborn’ is still open to question.

Interspecies Somatic Nuclear Cell Transfer

Interspecies chimeric embryos, made up of cells and nuclei from different species, have been produced in animal science, although none to date have produced a live animal. There have been reports of successful transfer of IVF produced animal embryos from one species into the uterus of another species, both in cows and goats. These techniques have been proposed in zoology as a method for preserving endangered species by using either IVF embryos, or interspecies chimeric embryos, implanted into the uteruses of recipient animals of another species.

In 2003 a South Korean Agricultural Science group reported the generation of interspecies human-bovine embryos. Cells from human umbilical cord had their nuclei removed, and the nuclei were

placed into enucleated bovine ova. Four to nine per cent of the resultant embryos proceeded to the blastocyst stage, and had evidence of human chromosomes and bovine mitochondrial genes in the cytoplasm. The authors proposed that the use of enucleated bovine ova might potentially solve one of the technical problems of human cloning, which is the shortage of human recipient ova.

However, there are major technical concerns over the outcome of any such interspecies human embryos. In addition, even if the technical problems could be overcome, many have expressed grave doubts over the impact of such a procedure on concepts of human dignity and personhood.

37. The Commission recommends that the generation and use of interspecies human embryos should be prohibited.

8.4 Manipulation of gametes

Genetic manipulation of gametes has been used for some time in veterinary research and a number of techniques have been developed. Application of these techniques to humans is both very restricted and in the preliminary stages of investigation, or remains untested.

Sex selection

There are two reasons why a person might wish to select the sex of a child – one medical and the other social. The ability to select the sex of a child would be of great benefit to couples at risk of sex-linked genetic diseases and would be advantageous to couples who want a family of specific gender composition.

Sex is determined by the sex chromosome carried by the sperm. Sperm bearing an X chromosome, when united with the X chromosome from the ovum (females only produce X chromosome) will result in an XX pregnancy that produces a female. When a sperm bearing a Y chromosome (men have both X and Y chromosome bearing sperm) unites with the X chromosome from the female, an XY pregnancy will result giving rise to a male.

Sperm sorting techniques are now available. The Commission acknowledges that there are difficulties and concerns of various degrees relating to the safety of sex selection using sperm sorting but there is also great potential in avoidance of sex-linked disorders.

The Commission considered arguments in relation to the use of sex selection for non-medical or social reasons to facilitate the achievement of gender balance in a family, or indeed to create a family of a specific gender composition. The main thrust of such arguments is that the decision to have children is an area of private life in which the State should intervene only to prevent the occurrence of harm. In the absence of any evidence that harm might occur to children selected for their sex, the presumption in favour of reproductive liberty should apply to facilitate personal choices in this regard. However, it also noted that there is no widespread agreement as to the nature and scope of such a right to reproductive liberty, and public anxieties regarding slippery slopes towards the creation of children ‘to order’ would also indicate a general disapproval of such techniques.

- 38. The Commission recommends that Preconception Sex Selection should be permitted only for the reliable prevention of serious sex linked genetic disorders but not for social reasons.**

Other Procedures

There are a number of other techniques being developed including the following: - ***In-vitro spermatogenesis*** - the removal of immature sperm followed by maturation of those sperm *in vitro* can result in the production of mature sperm that could be used to overcome infertility. ***In vitro maturation of ova*** - the retrieval of immature ova from the ovary that are matured *in-vitro* and subsequently fertilised using intracytoplasmic sperm injection (ICSI). **Ooplasmic transplantation** - the transfer of donor ooplasm without the donor nucleus that could be used in the treatment of developmentally compromised ova.

- 39. The Commission recommends that research on gametes should be permitted provided it is governed by strict conditions set out by the regulatory body and subject to informed consent from donors. Specific consent should be required from the regulatory body for specific valid research.**

8.5 Preimplantation genetic diagnosis (PGD)

Preimplantation genetic diagnosis (PGD) is a procedure that can be carried out following standard IVF that is intended to identify embryos with specific genetic alterations prior to the stage in IVF of transfer of the embryo to the uterus. Only embryos without the specific genetic alteration are placed in the uterus, and those with the genetic alteration are allowed to perish. It is a complex procedure requiring medical and technical expertise and is available only in a small number of specialist units.

Thorough counselling before and after the procedure is an essential part of PGD to ensure that the person(s) choosing PGD fully understand the complex issues surrounding it. PGD is possible because the four to eight-cell human embryo can continue to develop even after removal of a cell. All the cells at that stage are totipotent, and each cell can develop into a normally formed human person. The removal of a single cell at this early stage does not appear to interfere with normal embryogenesis. This stage is the earliest point at which a cell can be removed and its characteristics determined. Testing of embryos by PGD would also require the use of donated unrelated embryos to ensure the specificity and sensitivity of genetic testing of a single embryo cell.

Uses of PGD

1. The most common use for PGD is to identify gene alterations in embryos, where the gene alteration causes an untreatable serious childhood onset genetic disorder. Embryos found to be unaffected are selected for transfer to the uterus.
2. PGD has also been used not only to implant an embryo without a genetic disorder, but also to select an embryo with a specific Human Leukocyte Antigen (HLA) tissue type. When a baby conceived in this way is born, its cord blood could be used for transplantation into a sibling with the identical HLA tissue type.

3. PGD can be used, and has been used, to detect disorders that may only develop in adult life, such as Huntington's Disease, or a hereditary cancer predisposition.
4. PGD has also been proposed for use in prospective mothers, without any personal or family history of a genetic disorder, but who have an increased chance of a child with a chromosomal disorder due to the mother's age.
5. PGD can clearly also be used to control the sex composition of a family. Sex selection can be done for social reasons, where the parents wish to have a child of a particular sex. As discussed in the context of sperm sorting techniques, there are arguments in favour of and against the use of technology to predetermine the sex of the future child.

Arguments in favour of PGD

The arguments in favour of PGD include:

- PGD presents an alternative to conventional prenatal genetic diagnosis for person(s) at increased risk of a child with a genetic disorder. By diagnosing gene alterations *in vitro* you enable person(s) to avoid having to consider or undergo the clinical termination of a pregnancy found to give rise to a child with a genetic disorder. For some people PGD is considered to be morally more acceptable than termination of pregnancy.
- In the context of a choice between PGD and termination of pregnancy, PGD benefits the health, welfare and safety of the mother. Setting concerns about the status of the embryo aside, PGD is a better option to prenatal testing in the early stages of pregnancy from the point of view of the physical, psychological and emotional well being of the woman concerned.
- Because PGD is a means to avoid the suffering of future children, of mothers and families, it is consistent with the traditional goals of medicine which are to avoid or relieve suffering whenever it is possible to do so.
- Given the goals outlined above, it could be considered to be morally wrong to conceive where there is a known high risk of transmitting a serious disease or defect to a person's offspring. Consistent with this view, the decision to use PGD to prevent implantation of embryos with serious defects is morally praiseworthy.
- PGD offers reassurance to older women and others who are at risk of having a child with a genetic disorder. The availability of PGD can enhance the procreative choices of high-risk people and older women who, for any number of complex reasons did not reproduce earlier in their childbearing years.
- PGD expands the procreative choices of individuals and couples and potentially in the future could enable the selection of other traits that could be considered desirable.

Arguments against PGD

Arguments against PGD include:

- PGD for diagnostic purposes involves embryo selection and may involve embryo disposal; research will inevitably involve disposal.
- There is also concern over the predictive value of the genetic test. A genetically abnormal fertilised ovum, if allowed to mature and produce a live born infant, might not necessarily generate a disorder or disease in the individual.
- Some genetically caused diseases such as Huntington's Disease only develop symptoms when the person is in their 30s or 40s. Some argue that people with these diseases may live for many decades unimpaired. It is further argued that, by the time children conceived c.2002 reach their 30s or 40s, it is likely that a cure for these diseases may have been found.
- It could be argued that the application of PGD departs from the goals of preventive medicine and marks the start of the 'slippery slope' to more eugenic objectives. There is a concern that therapeutic PGD that selects for 'clinically' healthy embryos (disease free) may lead to enhancement PGD that selects for 'socially' healthy embryos.
- There is an emerging disability rights movement built on the shared belief that many problems experienced by persons with disabilities, problems which seriously interfere with the quality of their lives are caused, not solely or even most importantly by the impairment, but by the ignorance of other people, the fear of difference and the institutional and legal barriers in society.
- There are concerns that the availability of PGD and its promotion as a component part of responsible parenting will marginalise those parents who did not choose it and whose children have, subsequently, inherited diseases.
- The technology of PGD is not completely accurate.

PGD for Tissue Typing

PGD may be used to conceive a child who would be able to provide a tissue donation for an ill sibling. This would typically be medically recommended only where all other attempts to save the life of the existing child have been unsuccessful and the prognosis is poor without a suitable tissue donation. The use of PGD in these circumstances does not disadvantage the embryo/ resulting child.

There is ongoing debate surrounding the use of PGD for such purposes as it may be argued that it is unethical to bring a child into existence to save the life of another. Those who are opposed to such a practice argue that it is objectionable to conceive a child as a means to an end, rather than as an end in itself, and that conditional procreation is contrary to the dignity and worth of the child. On the other hand, proponents argue that children may be conceived for many different reasons other than for their own sakes, such as to be a companion to an existing child, or to provide security for parents

in old age, or to run a family business and these reasons are not deemed objectionable. The conception of a child to help save the life of a sibling does not mean that the child will not be loved and valued for itself.

In the United Kingdom a number of applications have been made to the licensing authority by couples who wished to use PGD for tissue typing. The Authority (HFEA) originally drew a distinction between the applications based on whether or not the procedure was being used to benefit the embryo or only the existing child. Therefore, if PGD was being used to avoid serious disease in the embryo, the same cell used for the genetic test could also be tested for a tissue match. In cases where the disease was not caused by a genetic abnormality, or where no test existed for the disease in question, PGD for tissue typing alone was deemed unacceptable. However the Authority has recently changed its policy and no longer draws such a distinction.

The Commission considered these arguments and agreed that PGD should be permitted for tissue typing for serious diseases that cannot otherwise be treated. Each application for use of PGD for tissue typing should be considered on its merits.

Legal Issues

PGD has been available for over ten years in some jurisdictions, although not yet in Ireland. The protection given by the Irish Constitution to the right to life of the unborn may, depending on the interpretation of the word ‘unborn’ in Article 40.3.3 of the Constitution, prohibit the use of PGD on the basis that affected embryos would be allowed to perish.

The European Convention on Human Rights and Biomedicine (Oviedo Convention 1997) provides in Article 12 that tests that are predictive of genetic diseases may be performed only for health purposes or for scientific research linked to health purposes and subject to appropriate genetic counselling. Article 14 provides that techniques for sex selection should not be used except to avoid serious sex-linked diseases. Article 18 provides that where the law of a member state allows embryo research, the embryo must be adequately protected, and that the creation of the embryo for research purposes is prohibited. The meaning of these articles and the expressions used such as ‘adequate protection’ is as yet unclear. It is argued, for example, that if PGD is to develop further in order to screen for other diseases, research is needed to refine the scientific approaches. Ireland has not signed the Oviedo Convention.

- 40. The Commission recommends, with one member dissenting, that PGD should be allowed, under regulation, to reduce the risk of serious genetic disorders. PGD should also be allowed for tissue typing only for serious diseases that cannot otherwise be treated. Each licence issued for PGD should specify the proposed procedure. The regulatory body should oversee and monitor developments in PGD.**

CHAPTER 9

Regulation

This chapter outlines briefly the current system through which AHR is regulated in Ireland. It goes on to examine the approach to regulation adopted in a number of other jurisdictions and it concludes by recommending a new system of regulation for AHR in this country.

9.1 Introduction

In considering its recommendations the Commission took account of the fact that technical intervention in human reproduction is acceptable under the Medical Council Guidelines and that a number of registered medical practitioners are already providing a range of AHR services in Ireland under guidelines laid down by the Medical Council. However, the Commission believes that, in view of the major social, ethical and legal implications of AHR for society in general as well as for the providers and users of services, the guidelines **on their own** do not constitute a sufficient form of regulation. Accordingly, the Commission recommends a legislative framework for the regulation of AHR and makes detailed recommendations under a number of headings in relation to those aspects of AHR services that should, in the Commission's view, be subject to regulation

9.2 Approaches of Other Jurisdictions

The Department of Foreign Affairs prepared a background research paper for the Commission on relevant legislation in other countries in December 2001 and at that time it found that AHR was governed primarily by either 1) legislation, 2) a combination of legislation and professional guidelines or 3) professional guidelines. The variety of approaches to regulation reflects the complexity involved in developing a statutory régime to cover all aspects of AHR. In addition, the establishment of a licensing or similar régime is a characteristic of the legislative approaches surveyed.

An extract from this paper is contained in Appendix XII.

The International Federation of Fertility Societies (IFFS) surveys

The Commission also took note of reports published by the International Federation of Fertility Societies (IFFS). The IFFS is a federation consisting of fertility societies drawn from some fifty-four different countries. It carries out surveys of assisted reproduction technologies in affiliated countries and it holds occasional conferences to disseminate information among its members on recent developments in AHR.

As reported in Chapter 1, the results of the most recent IFFS survey, conducted in 49 countries (52 jurisdictions), were published under the title *Surveillance 04* dated May 2004.

The purpose of the survey was: To tabulate practice with respect to the adoption of guidelines/regulations relating to AHR services; to tabulate methods of surveillance, if any, of such

guidelines/regulations and to tabulate similarities and differences between the guidelines/regulations concerning the various procedures under the umbrella of AHR.

The report describes the then current approach to the regulation of AHR in each jurisdiction and gives details of the specific position adopted in relation to the practical and ethical questions that arise in the delivery of AHR services. The report provided a very useful source of comparative reference for the Commission. Table 9.1 below is an extract from *Surveillance 04*.

Table 9.1 Legislation and Guidelines

Country	Legislation	Guidelines	Neither
Argentina		✓	
Australia (West)	✓		
Australia (South)	✓		
Australia (Victoria)	✓		
Australia (Remainder)		✓	
Austria	✓		
Bangladesh			✓
Belgium	✓		
Brazil	✓		
Bulgaria			✓
Canada			✓*
Chile			✓
China		✓	
Czech Republic	✓		
Denmark	✓		
Ecuador			✓
Egypt		✓	
El Salvador			✓
Finland			✓
France	✓		
Germany	✓		
Greece	✓		
Hong Kong	✓		
Hungary	✓		
Iran			✓
Ireland		✓	
Israel	✓		
Italy		✓	
Japan		✓	
Jordan			✓
Korea		✓	
Mexico			✓
Morocco		✓	
The Netherlands	✓		
Norway	✓		
Poland		✓	
Portugal		✓	
Romania			✓
Saudi Arabia		✓	
Singapore	✓		
Slovenia	✓		
South Africa		✓	
Spain	✓		
Sweden	✓		
Switzerland	✓		
Taiwan	✓		
Tunisia	✓		
Turkey	✓		
United Kingdom	✓		
Uruguay			✓
United States of America		✓	
Venezuela			✓

* Bill is before parliament

(The Assisted Human Reproduction Act came into force in Canada in April 2004).

EU Directives

The providers of AHR services in Ireland will be subject to the provisions of any relevant EU Directives. For example, Directive 2004/23/04/EC (see section 2.5) which was published in the Official Journal of the European Union on 7 April 2004, sets out standards of safety and quality for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells. The provisions of the Directive will have important implications for AHR clinics and centres that store gametes. Ireland is required to make the necessary statutory and administrative arrangements to comply with the Directive not later than 7 April 2006.

9.3 Options for Regulation

The Commission discussed the possible approaches to the regulation of AHR Services in Ireland and considered the various options available. A number of different approaches were considered: -

- (i) guidelines and a code of practice should be drawn up by each recognised clinic/unit acting independently;
- (ii) a common set of guidelines and a code of practice should be agreed by all recognised clinics/units and applied by each individual clinic/unit;
- (iii) the Medical Council Guidelines should be used as the basis for regulation;

The above approaches would not require legislation.

- (iv) legislation based on the UK Human Fertilisation and Embryology Act 1990 adopting its code of practice, and
- (v) legislation to establish an independent regulatory body appointed by the Government.

9.4 The Case for Statutory Regulation

The Commission recommends option (v) above i.e. that new legislation should be introduced to establish an independent regulatory body to regulate the provision of AHR services in this jurisdiction. This recommendation is based on a number of considerations. First of all, there is widespread acceptance of the fact that reproductive medicine has ethical implications that affect not only the providers and users of the service but society in general. There is recognition of the special position of reproductive medicine in the fact that it is given more significance than other areas of medical practice in the guidelines issued periodically by the Medical Council. The guidelines are a set of ethical principles that registered medical practitioners must apply to the clinical situations in which they work. While practitioners will continue to apply these principles, the Commission felt that the guidelines on their own do not provide a strong enough platform on which to base future practice in the area of AHR.

Secondly, a substantial majority of the jurisdictions examined by the Commission either already have statutory regulation or they are in the process of preparing relevant legislation. In recommending statutory regulation the Commission believes that it is following best international practice. Thirdly, legislation offers the opportunity to make specific provision for the expression of views of potential users in the on-going development of AHR services. Present arrangements do not make explicit provision for a user input into the development of services. Fourthly, the terms of statutory regulation would apply to all service providers and users. A perceived limitation of voluntary regulation is that the guidelines apply only to registered medical practitioners and not to other professionals working in the field. Finally, statutory regulation is the preferred option of the Institute of Obstetricians and Gynaecologists in Ireland.

9.5 Proposals for Statutory Regulation

The Commission makes the following recommendations for the regulation of AHR services in Ireland.

Legislative Framework

The Commission recommends that:

- A regulatory body should be established by an Act of the Oireachtas to regulate AHR services in Ireland
- The regulatory body should:
 - act independently and be publicly accountable to government through the Department of Health and Children
 - have the function of advising the government on all matters relating to AHR and associated procedures including research
 - have the authority to issue guidelines in relation to the provision of AHR services and associated procedures including research within the jurisdiction
 - be authorised to issue licences for AHR procedures (clinical, laboratory and storage and research)
 - have power to suspend or revoke a licence for stated reasons
- Provision should be made for regular review of the legislation in order to accommodate medical, scientific and social developments

Licensing Arrangements

The Commission recommends that the regulatory body should issue separate licences for clinical, laboratory and storage, and research services. The licence should be for a specified period and be subject to regular review. It should be illegal for a service provider to provide any of the above services without a licence authorising the provision of the service specified in the licence.

Clinical treatments

The Commission recommends that the regulatory body should have power to issue a licence to service providers authorising them to provide a range of clinical treatments including the following:

- intra-uterine insemination (IUI)
- *in vitro* fertilisation by husband/partner (IVFH)
- intra-cytoplasmic sperm injection (ICSI)

- gamete intra-fallopian tube transfer (GIFT)
- zygote intra-fallopian tube transfer (ZIFT)
- donor insemination (DI)
- intra-uterine insemination by donor (IUID)
- *in vitro* fertilisation by donor sperm (IVFD)
- *in vitro* fertilisation by donor egg (IVFDE)
- surrogacy (one member dissented from this recommendation).

Associated procedures

The Commission recommends that the regulatory body should have power to approve a range of clinical procedures associated with AHR including the following:

- Sperm donation
- Ovum donation
- Embryo donation
- Epididymal sperm aspiration and testicular biopsy for AHR
- Superovulation by the injection of follicle stimulating hormones (gonadotrophins)
- Pre-implantation genetic diagnosis (PGD) to reduce the risk of serious genetic disorders and for tissue typing. (one member dissented from this recommendation).
- Cryopreservation

Prohibition

The Commission recommends that the legislation should prohibit specific procedures including the following:

- reproductive cloning
- the creation of embryos through IVF specifically for research purposes
- sex selection for social reasons
- the generation and use of interspecies human embryos

Laboratory and Storage services

The Commission recommends that:

- Licensing should deal with such broad issues as the laboratory conditions under which gametes/embryos may be stored, the treatment of embryos following their retrieval and the nature of the consent required of users of storage services
- The licensing should also involve assessments of biological storage systems; standards of biological care; assessments of governance, record keeping, information dissemination; levels of specific consents; criteria for storage; duration of storage and contingency planning
- The regulatory body should draw up the detail of licensing provisions in terms of specific standards, assessments, and review procedures for each centre

Research services

The Commission recommends that the regulatory body should have power to issue a licence to service providers authorising them to engage in the following:

- Research on gametes

- Research on surplus embryos that are donated specifically for research for purposes specified in the licence and under stringently controlled conditions. This research should be permitted up to fourteen days following fertilisation (one member dissented from this recommendation).

Providers of AHR

The Commission recommends that:

- Service providers that collect and store gametes and that generate and store embryos should be regulated and licensed by the regulatory body
- Service providers must hold a current, valid licence for the AHR services (clinical, laboratory and storage and research) that they provide
- The regulatory body should have power to prohibit any practice that could be deemed to constitute commercialisation of AHR.
- Service providers should provide information to the general public on the range of services they offer

Conclusion

The Commission approached its task from the standpoint that AHR is a positive development in reproductive medicine that offers the possibility of parenthood to involuntarily infertile people. It came to the conclusion in the course of its work that there is widespread support for the current range of clinical and laboratory services provided by recognised AHR centres in Ireland.

The Commission's main recommendation is that a system of regulation for AHR should be introduced by an Act of the Oireachtas. The main effect of this recommendation would be that the AHR services specified in the Act could be provided only on foot of a licence issued to recognised service providers by a regulatory body to be set up under the Act.

The Commission also recommends, with one member dissenting, that the regulatory body should have authority to issue licences permitting the testing of *in vitro* embryos for genetic alteration and tissue typing and the use of surplus *in vitro* embryos for research purposes but it recognises that these recommendations would require clarification of the meaning of the word 'unborn' in Article 40.3.3 of the Irish Constitution.

The Commission ventures to express the hope that these and other recommendations will provide the stimulus for a national debate on a matter that is of major importance to current and future society.

Expressions of Dissent

1. RESERVATION IN RELATION TO RECOMMENDATIONS CONCERNING THE EMBRYO

While I am in agreement with the other recommendations of the Commission, I am unable to support those recommendations that envisage the deliberate destruction of the embryo and so take this opportunity to outline my position on the crucial issue of when human life should begin to enjoy the benefit of legal protection.

By way of a preliminary comment, it is important to note that the issue with which we are concerned here is not whether life exists, but rather whether the right to life is restricted by reference to the developmental stage of human beings. It is indisputable that new human life exists once the process of fertilisation is complete. The issue is whether that life is deserving of the fullest protection of the law. The debate, therefore, is concerned with values relating to human rights rather than with matters of natural science, on which there is no disagreement between the majority and myself.

Turning to my own position on this issue, this is informed by the belief that the individual must be treated as an end in himself/herself and cannot be regarded as a means to an end. Thus I do not subscribe to a utilitarian approach to this issue that would permit the use of a human life for the benefit of others, no matter how needful or deserving those others might be.

Broadly speaking, opinion on when life should be legally protected falls into two schools of thought. One school (to which I subscribe) holds that legal protection should commence once the ovum (egg) has been fertilised; the other school would withhold legal protection until some later stage in the process that commences with fertilisation, though within this school there are differing views as to what that stage should be, with some deferring legal protection until twinning has either occurred or is no longer possible, others taking the view that implantation of the embryo in the womb is the critical point, others basing legal protection on the commencement of neurological function, and still others arguing for incremental increase in the protection afforded to the foetus as it develops.

As I have already indicated, I believe that legal protection should apply once the process of fertilisation is complete. We now have in place, for the first time, human life with a genetic programme that, in an appropriate environment, will result in a unique person or (very occasionally) two or more such persons. This is also the start of a developmental process that continues throughout the rest of the resultant life, continually altering that life's relationship with others. In this very important sense, the embryo is more than simply a cluster of cells or matter for, once destroyed, it is impossible to recreate that particular life with its unique genetic programme and its unique, ever developing relationship with the rest of humanity. In my opinion, respect for this life and for its ability to relate, in an absolutely unique manner, to the rest of humanity demands that we should do nothing deliberately to destroy the embryo and that, where possible, we should facilitate its development.

In some situations, it may be possible to predict that the implantation of a particular embryo will result in miscarriage. In such circumstances, I consider that it is not necessary or appropriate that the embryo should be transferred to the uterus. However respect for the human nature of that embryo

would require that it be allowed to die naturally and would preclude its deliberate destruction or exploitation.

The alternative approach to the status of the embryo, whereby the application of legal protection to the embryo/foetus is postponed to some point after fertilisation, suffers from the difficulty that the selection of this point inevitably becomes an arbitrary exercise. This point is illustrated by the fact that there is no consensus among those who reject fertilisation as the critical point for the application of legal protection to human life as to when this protection should commence. While I accept that positive rights may sometimes be based on arbitrary distinctions - a person aged 17 years and 364 days may not vote in an election but a person one day older may - I do not accept that the right to life, which is the absolute pre-requisite for the enjoyment of all rights, should be restricted in an arbitrary manner. This position would appear to be widely shared for the protracted and complex debate about the moral and legal status of the embryo is itself evidence of a deep unease at the selection of an arbitrary basis for protecting unborn life.

Turning to consider the specific alternatives offered to fertilisation as a starting point for legal protection for the embryo/foetus, it is, of course, true that in nature, most fertilised ova do not lead on to successful pregnancies and this fact is sometimes cited as a reason for withholding legal protection from life until some point after fertilisation. However, this is a naturalistic fallacy and, as such, unpersuasive. No one would suggest that a society with an infant mortality rate of, say, 50% for children under the age of twelve months should be permitted to kill any child under that age. By the same token, I do not see how the fact that most embryos fail to develop successfully in nature can justify the deliberate destruction of an embryo.

It is also true that occasionally an individual embryo may result in the development of two or more foetuses and this fact is sometimes cited as a reason for withholding legal protection from the embryo until that point in its development (usually the ninth day) where the possibility of twinning may be ruled out. The contention here is that, prior to that point, it is not clear that we are dealing with an individual human life. Again, I am not persuaded by this argument. If I oppose the destruction of an embryo because this prevents the development of a unique, irreplaceable individual, I can hardly condone its destruction where this may prevent the development of two or more such individuals. Indeed, the possibility that destruction of the embryo may deprive us of the unique contribution that two or more individuals may make to human experience strengthens, rather than undermines, my view that legal protection should apply to the embryo once fertilisation is complete.

For some, the implantation of the embryo in the womb is the point at which life should secure legal protection. My difficulty with this position is that it makes the moral status of the embryo conditional on its physical location rather than on its essential nature. Moreover, in the case of *in vitro* embryos, this position also makes the legal protection afforded to the embryo conditional on the decision of another party to transfer the embryo, rather than inherent in its nature as human life. The pre-implanted embryo is, in essence, the same as the post-implanted embryo insofar as its genetic blueprint is already in place. Inasmuch as I consider that respect for the life contained therein precludes the deliberate destruction of the embryo, the issue that arises for me with regard to the pre-implanted embryo is whether or not that respect also requires that each embryo be transferred to the uterus. I re-iterate the point made above that where it is clear that an embryo, if implanted, will not

develop into a successful pregnancy, it is neither necessary nor appropriate to proceed with transfer and such an embryo should be permitted to die naturally. I do consider that all viable embryos should be transferred to the uterus so as to respect fully their right to life. This position, however, is not without its difficulty. Current AHR practice entails the cryopreservation of embryos in order to increase the chance of pregnancy without requiring the woman to undergo multiple potentially hazardous stimulation cycles and ova retrievals. Moreover, if the woman is acutely ill following ova retrieval, cryopreservation would enable frozen embryos to be available to her on her recovery. In addition, cryopreservation of embryos would prevent exacerbation of ovarian hyperstimulation syndrome if such syndrome were present in the woman. In principle, I do not object to the cryopreservation of embryos, provided such cryopreservation does not preclude the subsequent implantation of the embryo. However, it would appear that current practice with regard to cryopreservation entails the production of surplus embryos, not all of which can be transferred to the uterus and some of which will eventually have to be destroyed. I consider that this outcome violates the embryo's right to life and so I recommend that the number of ova to be fertilised in any treatment be limited in number so as to enable all to be transferred to the uterus. It follows that I am also opposed to research on surplus embryos or to their use as a source of embryonic stem cells. I consider that, notwithstanding the benefits that flow from the freezing of surplus embryos and notwithstanding the potential good that might follow from research on embryos or the use of embryonic stem cells, such a course of action objectifies the embryo in a manner that is inconsistent with the value that each human should be treated as an end in him or herself, rather than as a means to an end. For the same reason, I am also opposed to therapeutic cloning (regenerative medicine).

It is sometimes suggested that we should await the start of neurological function before providing legal protection to the embryo. This argument is based on the analogy with death, where cessation of such brain function is taken as conclusive evidence that an individual has died. The analogy, however, is a false one. In the case of death, the absence of brain function is irreversible. This is patently not so in the case of the embryo and so the start of brain function does not appear to be a significant moral marker for the purposes of this debate.

Finally there is the more open-ended argument that respect for the embryo/foetus should increase incrementally as that life develops. In my opinion, this principle is too imprecise to ensure proper respect for human life. Taken to its logical conclusion, it even deprives the fact of birth of any significance in this context for a premature baby born at 30 weeks is clearly less developed than a foetus at a later stage in pregnancy. Indeed, the principle also permits the argument that a new born infant with severe physical and/or intellectual abnormalities is not deserving of full legal protection.

In conclusion, therefore, for all these reasons, I consider that human life should be protected once fertilisation has occurred. The continuum that exists from this point on may be illustrated by comparing the consequence that follows from destroying an embryo with the consequence that follows from destroying a foetus at some later stage in its development. In both cases, the act of destruction interrupts a process that could eventually have resulted in a unique person, with his or her own unique, distinctive personality, appearance and relationship to others.

The view that legal protection should apply to life once fertilisation has taken place does have certain serious implications for AHR. I have already considered the implications of my position for cryopreservation and for embryonic research but additionally my view clearly precludes the

destruction of an embryo following PGD. Directly as a result of my membership of the Commission, I have become more aware of the great anguish experienced by infertile couples. I am also acutely aware of the argument that scientific research using embryonic stem cells might eventually yield significant benefits, perhaps even cures, for the sufferers of various grave illnesses. Yet however earnestly one would wish for an end to the suffering endured by infertile couples and the victims of devastating illnesses such as Alzheimer's, Parkinson's Disease, etc., that cannot be at the expense of the principle that each human life should be regarded as an end in itself, rather than as a means to an end. If this principle is sacrificed, we alter our own attitude to human life by categorising some human life as worthy of full legal protection and other human life as mere 'human material', destined to be used for the benefit of those in the privileged category. Thus, inevitably, we have to confront the question of when this principle should apply.

The issue of when legal protection should be provided for life is one to which, over the years and in particular during the currency of this Commission, I have given considerable thought and I cannot convince myself of any view other than that the embryo, as an inchoate unique and irreplaceable individual or individuals, is deserving of such respect as to preclude its deliberate destruction. My inability to see a significant moral marker between the zygote and the embryo/foetus at any later stage of development means, moreover, that I consider that the embryo comes within the principle that the individual can never be treated as a means to an end, no matter how desirable that end might be. Accordingly I cannot support the recommendations in the Commission's Report that entail the deliberate destruction of the embryo.

G.F. Whyte

2. RESERVATION IN RELATION TO RECOMMENDATIONS ON SURROGACY

In the following paragraphs, I express my dissent from the recommendations of the Commission on the matter of surrogacy. While I acknowledge that surrogacy has the capacity to be of benefit to some infertile couples, assisting them to have much longed for children, I believe that the risks of exploitation and commodification that accompany it clearly outweigh these benefits, and that surrogacy should be prohibited by law. This prohibition should be directed towards persons assisting in the establishment of a surrogate pregnancy, and commercial agencies, rather than commissioning couples, since the birth of a child should not be tainted with criminality.

I would also like to make some observations about the enforcement of the custody contract where the surrogacy agreement breaks down.

Traditionally, the view in this jurisdiction has been that surrogacy contracts would be unenforceable as being against public policy. Within the EU, there is no jurisdiction in which surrogacy contracts are enforceable against the surrogate mother, and even in the US, where a number of jurisdictions regulate surrogacy, most statutes stipulate that surrogacy contracts are unenforceable.

The Commission's recommendations are, against this background, extraordinarily far-reaching. They envisage that custody, following the birth of the child, would follow the "intent of reproduction" and that the commissioning couple would be presumed to be the legal parents of the child. While this presumption could be rebutted at a later stage by the surrogate, this would require her to initiate

proceedings against the commissioning couple, who would take custody of the child at the time of birth.

The corollary of this recommendation is that, where a surrogate mother formed an attachment to the child she was carrying and wished to keep it, she would nevertheless be forced to relinquish the child to the commissioning couple. Since the commissioning couple would be regarded as its legal parents, no legal process would be required to establish their rights and they would be entitled to remove the baby at birth. If the surrogate mother resisted, reasonable force could be used to effect the removal.

There are a number of points to note about this proposal.

As our Report points out, in all but a tiny handful of legal systems around the world, the woman who gives birth to the child is regarded as the legal mother of the child until some other event, such as adoption, displaces the presumption. This is uniformly the case within the European Union.

There are two principal reasons for this. Firstly, it is regarded as essential, in the interests of the child, for there to be absolute clarity, from the moment of birth, as to the child's legal parentage.

Secondly, there is a broad cultural consensus that a woman who has just given birth may be uniquely vulnerable and the removal of her baby against her will is repugnant, unless she poses a threat of immediate harm to the child. This social norm is reflected in Article 10(2) of the United Nations International Covenant on Economic, Social and Cultural Rights (ICESCR), which obliges Contracting States to accord special protection to women who have just given birth. It is also reflected in the jurisprudence of the Irish Supreme Court, which has held, in a strong line of case law, that a mother has a constitutional right to the guardianship and custody of her child from the moment of birth.

Against this, it could be argued that a surrogate mother who has contracted with a commissioning couple after careful counselling should not be permitted to resile from the contract she made as a responsible and autonomous adult.

The way in which the Courts would respond to this argument can, I believe, be gleaned from existing jurisprudence in the area of adoption. In our system of adoption, a mother may not consent to an adoption before the birth of the child, even if she wishes to do so. Although the legislation does not articulate the reason for this policy choice, it is reasonable to suppose that it is in response to strong statements from the Supreme Court to the effect that a mother cannot legally consent to waiving her constitutional rights until it is absolutely clear that she has a full understanding of what she is giving up.

This is a proposition which is firmly grounded in the emotional reality of pregnancy, labour and childbirth. For most women, especially those pregnant for the first time, these experiences are life-altering. The power of the emotion which may accompany them is, for many – perhaps most – women, unexpected and revelatory, and the sense of connection with the developing baby, profound. The law allows for these realities by providing that a woman cannot make an irrevocable decision to give up her rights to custody of her child until she has been through these experiences, so that there can be no doubt that her consent is fully informed.

Given the care with which our courts have sought to protect the rights of birth mothers in the adoption context, it seems very likely that the courts would consider that a legal regime which compelled a surrogate mother to surrender custody of her genetic offspring at birth, on foot of a private agreement made before the pregnancy had been embarked upon, was unconstitutional.

Where the child was not the surrogate's genetic offspring the situation is perhaps less clear, but ultimately, it seems unlikely that the Courts would countenance the compulsory removal of a newborn infant, without legal process and backed up by threat of force, from the woman who has undergone pregnancy and childbirth, with their attendant risks and discomfort, in order to bring it into the world.

Christine O'Rourke

Appendix I

Letter from Minister of Health and Children, Mr. Micheál Martin, T.D.

Letter from Minister

March 2000

Professor Dervilla Donnelly
Chairman
Dublin Institute for Advanced Studies
10 Burlington Road
Dublin 4

Dear Professor Donnelly

I would like to thank you most sincerely for agreeing to chair the Commission on Assisted Human Reproduction.

The terms of reference which have been approved by Government are

to prepare a report on the possible approaches to the regulation of all aspects of assisted human reproduction and the social, ethical and legal factors to be taken into account in determining public policy in this area.

The membership of the Commission is outlined in the enclosure with this letter. I am of course happy to consider the appointment of additional experts to the Commission if the need arises.

Also enclosed with this letter is a short brief on the key issues which need to be considered and which I hope you will find useful. Alternatives to legislation, such as reliance on medical ethics, should be included in the Commission's examination; the examination of the legislative option should look in detail at the individual provisions which might be included; and the consideration of each approach should take into particular account the need to be able to respond to future technological advances.

The Commission is also required to seek submissions from the public. In addition the Commission is expected to consult appropriately to establish the views of service providers, consumers and any adoption issues. The Commission will also be expected to consult with philosophical and theological experts to ensure that their perspectives are considered and reflected as appropriate in the Commission's report. Consultation with the relevant people in Northern Ireland and in the UK is also expected of the Commission. I am of the view that given the difficult nature of the issues to be examined, the Commission would need at least a year to report.

The establishment of the Commission is an essential first step before any policy proposals are brought forward. It will serve two purposes:

- firstly, it will provide the medical, scientific and legal expertise necessary for a detailed examination of the possible approaches;
- secondly, the publication of its report will provide the basis for informed public debate before the finalisation of any policy proposals.

The Commission is not being asked to recommend on the question of public funding.

The Commission will be provided with a secretariat. This issue is currently being addressed together with the question of office accommodation. Pending finalisation of the accommodation arrangements, meetings can be held in the Department or other meeting venues.

Finally, I would like to repeat my appreciation of your willingness to chair the Commission and to wish you well in your deliberations. If I or my officials can assist in any way or clarify any issue please do not hesitate to contact us.

Yours sincerely

Micheál Martin
Minister for Health and Children

Appendix II

Executive Summary of Comparative Surveys of National Legal Regimes Governing Donor Programmes and Surrogacy

***(i) Executive Summary of Comparative Survey of National Legal Regimes
Governing Donor Programmes (December 2001)***

PART I: General Issues

Section 1. Framework for Assisted Human Reproduction

AHR is governed primarily by either 1) legislation (*e.g.* in the *United Kingdom*), 2) a combination of legislation and professional guidelines (*e.g.* in the *Netherlands* and *Canada* under existing law), or 3) professional guidelines (*e.g.* in the *USA*). The second approach appears to be the most common, reflecting the complexity involved in developing a statutory régime to cover all aspects of AHR. In addition, the establishment of a licensing or similar régime is a characteristic of the legislative approaches surveyed. Some of the legislation considered, especially older legislation, relates to AI specifically rather than to AHR generally.

Section 2. Basic Concepts

(i) Definition of Donor

The trend among the jurisdictions surveyed appears to be not to define ‘donor’. *France*, *Australia (Victoria)*, *South Africa* and the *State of New Hampshire* in the *USA* are exceptions. Generally, the term appears to be employed in the context of third party donations, rather than donation from the husband/partner.

(ii) Definition of Recipient

In general, the jurisdictions considered do not provide a definition of the term ‘recipient’ where it is used in their legislation. Most countries do not use the term at all. However, it appears that different parties may be treated as a ‘recipient’. A ‘recipient’ may be an individual woman receiving treatment, a couple or a woman in conjunction with her partner in certain situations. The term may, in so far as it is used and by implication, be qualified where legislation sets out categories of people who may not receive AHR treatment.

(iii) Definition of Partner

The legislation considered does not generally use the term ‘partner’, and where it is used it is generally not directly defined. Any definition given is generally provided in the context of recipients. Legislation frequently treats partners as part of a married couple or heterosexual cohabiting couple, although a number of national statutes are silent on the question of same-sex partners and do not preclude the possibility.

Section 3. Legal Basis of Relationships

In general, the jurisdictions considered do not expressly state the legal basis of the relationships between the parties (exceptionally, *Spain* explicitly places the relationship between the donor and the clinic on a contractual basis). Nonetheless, a contractual basis may be implied in certain situations in conjunction with written consent agreements provided for in the legislation. Such contracts may include a duty of care on the part of the clinic in relation to the treatment of the donor and recipient and are re-enforced in legislative provisions. Moreover, principles of the law of tort or negligence may apply.

Section 4. Status of Gametes

In the jurisdictions considered, the legal status of gametes is not specifically dealt with in the legislation on AHR. Certain jurisdictions provide that although human body parts are not property in the conventional sense, they may be transferred for specific purposes on death, *e.g.* organ donation for transplant or research. The sale of body parts is often prohibited. It seems that parties to AHR treatment often act as if the sperm ‘belongs’ to the man from whose body it came, and likewise to the woman in respect of an egg donation. If a donor is in a position to decide how his/her donation is to be used, s/he essentially has a *quasi* property right: a donor can decide who can use the donation, and what is to be done with it on their death. In different countries, a donor may exercise different levels of control over what happens to the donation following the donor’s death. The *USA* appears to be exceptional among Western countries in its express recognition (in a judicial decision) of a limited property right in gametes. On this authority, the donor’s ‘rights’ in relation to the donation may be considered an interest in the nature of ownership to the extent of decision-making rights with respect to the gametes.

Section 5. What Genetic Material May be Donated

(i) Donation of Egg and Sperm

In general, the jurisdictions considered permit the donation of both sperm and eggs. The donation of eggs may be subject to conditions or limitations in some jurisdictions, *e.g.* limitations on storage, which may make egg donation less common. In a small number of countries, egg donation is forbidden.

(ii) Numerical Limits

Some of the jurisdictions studied set a limit to the number of donations permissible in law. The limit is generally set by reference to the number of live births. In the *United Kingdom*, the Human Fertilisation and Embryology Code of Practice sets the limit, while in *France*, *Spain*, *Austria* and *South Africa* the number of possible donations is limited by legislation. Furthermore, *Switzerland* and *Austria* confine donations to the one clinic.

Section 6. Limitations on Participation in Donor Programmes

(i) Participation by Donor

(a) Medical requirements and age

In the jurisdictions examined, conditions on who may donate, where they are set out in legislation, generally include a requirement of medical acceptability, including both physical and mental health, and in particular, healthy sperm. Age is usually linked to the medical requirements and upper and/or lower limits are set in a number of the jurisdictions studied. Several jurisdictions have legislated for an exclusion of donations by minors. In a number of jurisdictions, more detailed criteria may be laid down in secondary legislation or regulatory/professional codes of practice.

(b) Other considerations

In the jurisdictions considered, access to donor programmes is not generally decided on the bases of nationality, race, ethnicity, marital status, gender or sexual orientation. It may be that restrictions in relation to such matters are precluded in the light of non-discrimination requirements in general law.

(c) Intra-family donation

Legislation in other jurisdictions does not generally deal with the issue of intra-family donation. In countries where the donor has no control over who may be the recipient, intra-family donation is not likely to occur. Some countries do not allow egg donation at all, ruling out intra-family egg donation. In other jurisdictions, the donor herself must be undergoing fertility treatment, a condition which would considerably reduce the incidence of intra-family donation. In addition, it may be that existing common law and legislative provisions relating to incest, applied by analogy, cover intra-family donation.

(d) Application appeals

In general, the jurisdictions studied do not provide a legal means of appealing a decision to refuse a donation. However, the *United Kingdom* Human Fertilisation and Embryology Authority Code and *Spanish* legislation specifically state that the reasons for a refusal must be clearly explained to the person concerned. Provision for an appeal may be governed by other health legislation or by the general law. In addition, the decisions of licensing authorities in common law countries will generally be subject to the usual principle of judicial review of public bodies, and the equivalent principles of administrative law in civil law countries may apply.

(ii) Participation by Recipient

(a) Medical requirements and age

Most of the countries studied place medical restrictions on access to treatment: recipients must be infertile or seeking to avoid the transmission of serious genetic disease. Upper and lower age limits are set down in some of the jurisdictions considered.

(b) Discrimination and parenting

In laying down requirements as to access to AHR, the jurisdictions studied generally require that the recipients be married or in a cohabiting, stable relationship with a partner of the opposite sex. However, AHR is available to women without a partner in certain jurisdictions. Assisted conception raises questions of public order and morality and where states offer AHR treatment to single women, particular consideration is frequently given in the statutory or regulatory scheme to the provision of a suitable environment for the upbringing of the child, taking account of his/her needs.

(c) Other considerations

The source of the infertility or the fact that the recipients may already have children is not usually relevant in the jurisdictions examined. *France* and *Switzerland* are the only countries that specifically lay down a reflection period before persons applying for AHR may be accepted. Concerns that are addressed by requiring a period of reflection prior to treatment may also be addressed by counselling and the provision of information.

(d) Application appeals

In general, the jurisdictions considered do not make legal provision for an appeal against a decision to refuse the potential recipient treatment. *Sweden* is an exception in this regard. An appeal procedure may be provided under general health legislation. In addition, the decisions of licensing authorities in common law jurisdictions will

generally be subject to the principle of judicial review of public bodies, and the equivalent principles of administrative law in civil law countries may apply.

PART II: Role of Clinics with regard to Artificial Human Reproduction

Section 1. Licensing

Most of the jurisdictions surveyed provide that AHR may only be carried out by a physician or a person licensed for that purpose in a licensed/authorised centre, while a minority (chiefly, *Germany* and the *USA*) do not.

Section 2. General Obligations of Clinics

In most of the jurisdictions surveyed, some express provisions are made as to the standard of facilities and treatment that are to be used in AHR treatment. Typically, these relate to the type of equipment used and the level of experience and training of the personnel employed. Apart from the express provisions, general principles of contract and tort law may be applicable. For example, in common law countries the general principles of negligence and the concept of a duty of care will generally be applicable. Moreover, implied contractual terms concerning the provision of services may also be applicable. In Ireland, section 39 of the Sale of Goods and Supply of Services Act, 1980 provides that in every contract for the supply of a service where the supplier is acting in the course of business, there is an implied term that the supplier has the necessary skill to render the service; that s/he will supply the service with due skill, care and diligence; that, where materials are used, they will be sound and reasonably fit for the purpose for which they are required; and that, where goods are supplied under the contract, they will be of merchantable quality. Similar legal provisions may exist in other countries.

Section 3. Screening

In the countries surveyed, provision is frequently made as to screening requirements that must be met before a donation can be accepted. Quarantine of the donation for a minimum period to avoid the transmission of the HIV virus or other diseases is also common. It is usual for the relevant law to include penal provisions for the breach of an obligation to screen donors. It is unusual for the legislation of the jurisdictions considered to provide an express right to take proceedings against the donor if the child is born with a disability or an inherited disease.

Section 4. Matching of Donor and Recipient for Non-medical Reasons

Some of the countries surveyed allow for the matching of donor and recipient by reference to non-medical criteria. One issue not addressed in the legislation considered is the potential consequences of mismatching. General principles of liability may be applicable, but it is unclear if any other particular consequences may follow from mismatching, e.g. whether or not a couple could ever refuse to accept a child born as a result of mismatching.

Section 5. Mixing Gametes

The mixing of donor gametes from two or more different sperm or egg donors is expressly prohibited in many of the countries considered.

Section 6. Provision of Information and Counselling

(i) Information and Counselling for Donor

The approach taken by other jurisdictions indicates that the provision of information is usually mandatory before any donation may be given. The type of information to be

imparted is not always stated, but generally concerns parentage, possible implications of the procedure and disclosure of the identity and other personal details of the donor. Only the *United Kingdom, Australia (Victoria), Western Australia* and the proposed *Dutch* legislation specifically require counselling for donors. In other jurisdictions, the provision of information to the donor may be encompassed by more general requirements as to freedom of information or a duty of care. The requirement of counselling for members of a family affected by genetic testing is not included in the legislation considered.

(ii) Information and Counselling for Recipient

The provision of information to recipients and their partners is, generally, a legal prerequisite to receiving treatment in the jurisdictions considered. Information to be given typically includes details on the treatment procedure and the implications and risks involved. In some jurisdictions, it also includes information on adoption. Clinics are usually the party obliged by law to provide information and counselling. Although the word ‘counselling’ is not always used, the obligation to provide information commonly encompasses the idea of transmitting to the participant a full awareness of the implications of the treatment undertaken. Whether or not there is an obligation to provide genetic counselling is not generally addressed in the legislation considered.

Section 7. Consent

(i) Consent of Donor

On the basis of the countries surveyed, it appears that, as the providers of donor programmes, clinics are generally under an obligation to ensure that effective written consent is received from donors in relation to the use or storage of gametes and the procedures involved in obtaining the donation. Not all the countries considered require separate consent for the storage of gametes by law. The issue of consent to genetic testing of the donor is not generally addressed.

(ii) Consent of Donor Spouse/Partner

The law is generally silent on the issue of the consent of a donor’s spouse/partner. However, consent of the spouse/partner is required by law in a small number of the jurisdictions surveyed - in *France, Australia (Victoria)* and *South Africa*.

(iii) Consent of Recipient

Effective written consent to AHR treatment by the recipient is an essential legal requirement in most of the jurisdictions considered in this paper. The clinic is under an obligation in some instances to ensure that consent is received for each cycle of the treatment. Some jurisdictions expressly require that the consent be recorded on file and also make express provision for the revocation of consent.

(iv) Consent of Recipient Spouse/Partner

In the jurisdictions considered, the law generally requires the consent of the recipient spouse/partner. In some jurisdictions, it must be verified that this consent is still valid at the time the treatment commences.

Section 8. Record-Keeping and Confidentiality

(i) Obligation to Keep Records

In almost all of the countries examined, there is a legal obligation to keep records. Some jurisdictions set down in law the exact information that is to be recorded. The

countries considered commonly require that those records or part thereof be supplied to a central registry or authority. One distinctive requirement in the legislation surveyed is that information on the recipient couple must be cross-referenced with information on the donor (*South Australia*).

(ii) Disclosure of Records and Confidentiality

(a) Confidentiality in relation to general information

In general, the legislation examined allows for disclosure of general information in certain circumstances, *e.g.* where general information is to be made available to any resulting child. Some jurisdictions provide additional data protection for the parties involved in the treatment procedure, the donors and any resultant children. The legislation does not generally set out what steps may be taken by recipients/donors to remedy a breach of confidentiality. It is uncommon in the jurisdictions examined for the legislation on AHR specifically to provide for the donor/recipient to receive the results of any examinations undertaken in the course of the donation or treatment.

(b) Anonymity of donor and recipient

Although there is a general prohibition on the disclosure of the identity of donors in the legislation relating to AHR, in certain circumstances, set down in law, disclosure of identity is permitted, *e.g.* where any resulting child is entitled to learn the identity of the donor, where the party to be identified consents or where disclosure is for the purpose of criminal proceedings. The need for specific protection of the identity of the recipient is less commonly dealt with in the legislation in the jurisdictions considered.

(c) Authority to release information

In those jurisdictions in which the issue of who should disclose information is addressed, an outside agency may have responsibility for the disclosure where the law does not expressly provide that disclosure is by the clinic.

Section 9. Remuneration

In most of the jurisdictions considered, payment for the donation of gametes is prohibited. The *USA* and the *United Kingdom* do allow donor remuneration. In general, travel and other expenses may be reimbursed to a donor. No country provides for an actual right to receive remuneration, while certain jurisdictions go so far as to criminalise any form of remuneration for the transfer of gametes.

Section 10. Importation of Gametes

In those jurisdictions where the issue of the importation of gametes is addressed, states tend to allow for importation subject to approval and directions by a specific agency or regulatory body or the Ministry of Health.

Section 11. Storage of Gametes

Most of the jurisdictions studied permit the storage of both eggs and sperm. In general, the approach taken by other jurisdictions has been to set time limits on the storage of eggs and sperm and to attach conditions to such storage.

Section 12. Posthumous Conception

In the countries considered, the general trend appears to be against posthumously conceived children in all but the most exceptional circumstances. Most of the legislation that deals with the subject prohibits the use of the sperm of a deceased man, and where considered, some

countries also prohibit the use of the eggs of a deceased woman. Spain is exceptional in making express provision for posthumous conception, and the Netherlands proposes to adopt a similar position. Posthumous conception is also possible under legislation in the United Kingdom.

A distinction is made between posthumously conceived children and posthumously born children, with whom there is less difficulty. The latter can be accommodated under existing law as akin to a naturally conceived child whose father dies before birth.

For a male recipient who receives the eggs of his dead wife/partner, the situation is essentially one of surrogacy and not the subject of this paper.

Part III. Rights and Obligations of Other Parties

Section 1. Rights and Obligations of Donor

- (i) **Disclosure of Medical History**
In the legislation surveyed, provision is usually made for the disclosure of a prospective donor's medical history. The legislation does not however, generally, contain provisions as to the liability of the donor for failure to disclose fully all relevant information. Similarly, the legislation does not attach any liability to the clinic for the donor's failure to disclose. In this case, general principles of tort law may be relevant in that a duty of care may be owed by participants to anyone who could reasonably be foreseen as likely to be affected by their conduct. However, it may be that liability in tort would not attach to the clinic unless the clinic itself was negligent in some way; vicarious liability of the clinic for the donor's failure would not apply unless this was provided for in legislation.
- (ii) **Attaching Conditions to a Donation**
Donors have varying degrees of control over the genetic material they donate. Some of the jurisdictions considered emphasise the need to obtain from donors consent as to the exact uses to which their donations may be put, while others do not deal directly with the issue at all. In general, states allow donors a degree of control over who may receive the donation. In some jurisdictions, donors may attach a condition designating a specific person as the recipient of their donation. The legislation considered does not generally proscribe certain conditions on the basis that they are unjustly discriminatory with reference to such considerations as nationality, race, or sexual orientation. However, general laws on non-discrimination may limit the extent to which a donor may set conditions relating to such matters.

Section 2. Rights of Medical Personnel

Only a small number of the jurisdictions considered expressly provide for medical personnel to opt out of AHR procedures in the legislation governing AHR. This matter may however be addressed in the general law relating to medical practice or in professional guidelines.

Part IV. Liability

Section 1. Introductory Comments

- (i) **Civil and Criminal Liability**
Liability in civil law and in criminal law are fundamentally different. Although various rationales have been put forward for the existence of the criminal law, one basic feature

distinguishing criminal from civil liability is that the former is punitive, while the latter can be regarded as coercive. Both types of liability may apply in the case of AHR, with criminal liability in general being more precisely elaborated and confined to the more serious contraventions of the law. In Ireland, a breach of a statutory requirement will generally give rise to a statutory tort or civil wrong, whether or not a specific sanction for breach is laid down in the relevant legislation. In other jurisdictions, equivalent principles of liability may apply.

(ii) **Corporate and Individual Criminal Liability**

Both an individual and a corporate entity – in this context, a clinic or licensed provider of AHR treatment – may be civilly and criminally liable. Clearly, a corporate entity cannot be imprisoned in the way that an individual can, but a corporation can be subject to punitive criminal sanctions, such as fines. A number of countries specifically provide for the latter in respect of licensees that have breached certain provisions of AHR law.

Section 2. Criminal Liability and Sanctions

A clear trend in the legislation surveyed is the inclusion of a régime of criminal sanctions for certain breaches of the legislation. These sanctions encompass both fines and terms of imprisonment for natural persons. For bodies corporate, offences are punishable by heavy fines.

***(ii) Executive Summary of Comparative Survey of National Legal
Regimes Governing Surrogacy (May 2002)***

Introduction

Surrogacy can be divided into two main types: 1) Full/host/gestational surrogacy, whereby the surrogate mother receives an embryo that does not belong to her - this type of surrogacy would seem dependent on more modern forms of assisted human reproduction (AHR); 2) Partial/straight/traditional surrogacy, whereby the surrogate mother contributes her own eggs and accepts the sperm of the father (either coitally or through artificial insemination (AI)). In so far as surrogacy involves modern techniques of AHR, such as AI or *in vitro* fertilisation (IVF), national legal régimes on AHR generally will also be relevant and applicable to the surrogacy process.

Part 1: Legal Framework and General Issues

Section 1. Definition of Surrogacy

Some of the jurisdictions surveyed, especially common law jurisdictions, have defined ‘surrogacy’ or a related term, such as ‘surrogate contract’, in the legislation considered. Most of the definitions encompass surrogacy where the contract or agreement is made prior to the beginning of pregnancy and that where the contract or agreement is made following the commencement of a pregnancy (although the latter situation is less likely to arise in practice, since surrogacy usually involves an existing couple who wish to have a child planning the surrogacy in advance and often with a surrogate mother who was previously unknown to them). Generally, the language used encompasses both traditional and gestational surrogacy.

Section 2. National Legal Régimes

(i) Introduction

In most of the jurisdictions surveyed, surrogacy is governed by legislation. In a number of countries, especially common law jurisdictions, a legislative vacuum has been addressed by the courts in deciding surrogacy cases with reference to parenthood and adoption legislation and to the courts’ perception of the demands of public policy. A number of these cases indicate that the courts will treat traditional and gestational surrogacy somewhat differently; in the case of traditional surrogacy, the courts tend to look more favourably on the interests of the surrogate mother as against those of the commissioning or parenting couple. Most jurisdictions with legislation in the area have expressly addressed surrogacy either in a dedicated piece of legislation or in particular provisions in AHR legislation. A number of jurisdictions surveyed have general legislation on AHR that is also applicable to surrogacy, though not expressly addressed to regulating its practice.

(ii) The Making and Enforceability of Surrogacy Contracts - The Child’s Best Interests?

In most of the jurisdictions surveyed, surrogacy contracts are not enforceable. In a number of these jurisdictions, this is provided for in statute, while in others the courts have determined, in the absence of any statutory rule, that surrogacy contracts are unenforceable for public policy reasons. In that regard, the most frequently cited reason is that the best interests of children must be the paramount factor in determining custody, rather than the intent of the parties to a surrogacy arrangement, as would be the case if contracts were to be enforceable. A small minority of jurisdictions ban surrogacy arrangements outright, rather than simply making the contract unenforceable

in the event of a dispute between the parties. Conversely, *Arkansas (U.S.A.)* is exceptional in creating a statutory presumption that the intended parents are the parents in law of the child. Two other states in the *U.S.A.*, *Virginia* and *New Hampshire*, are exceptional in providing for prior judicial authorisation of surrogacy arrangements and, more generally, for enacting a detailed statutory régime in relation to surrogacy.

(iii) Commercial Surrogacy

A clear trend among the jurisdictions surveyed was the outlawing of commercialised surrogacy involving the remuneration of (a) intermediaries and (b) the surrogate mother for their participation in the surrogacy arrangement. In a number of jurisdictions, however, a surrogate mother may be remunerated for out of-pocket expenses incurred by her as a result of her participation in a surrogacy arrangement. The general prohibition on commercialisation reflects a concern that by placing a monetary value on a woman's reproductive capacity, the inherent value of women and children is implicitly undermined.

Section 3. Exclusions and Non-Medical Restrictions on Participation

(i) Surrogate Mother

In general, the jurisdictions considered do not address the issues of exclusions and non-medical restrictions on who may be a surrogate mother. *Virginia* is exceptional in excluding non-married women from being a surrogate mother. Where non-medical restrictions are imposed, they relate to age, residency requirements, and general suitability and fitness to be a parent.

(ii) Commissioning Party

In general, the jurisdictions considered do not address the issues of exclusions and non-medical restrictions on who may be intended parents. In relation to family status, where the issue is addressed, legislation makes restrictions concerning marital status and genetic relationship to the child. The question of same-sex intended parents is not expressly addressed in the legislation considered. However, same-sex parents are indirectly excluded where the intended parents are required to be married. In relation to non-medical restrictions, where the issue is addressed, the legislation considered contains provisions relating to age, general suitability and fitness to be a parent, and financial capacity to be a parent.

Section 4. Medical Screening for Surrogacy

(i) Surrogate Mother

In general, the jurisdictions considered do not make any legal provision as to medical restrictions on who may be a surrogate mother. Where such restrictions are provided for, they relate to the general fitness of the surrogate mother to carry through a pregnancy, in terms of both physical and psychological health. A formal screening process is generally provided where there are such requirements. Further, some jurisdictions make reference to professional codes and guidelines as reference points in determining medical fitness and suitability.

(ii) Commissioning Party

In general, the jurisdictions considered do not address the issue of medical restrictions on the intended parents in a surrogacy arrangement. Where the issue is addressed, restrictions entail a requirement that the intended mother be infertile or unable safely to undergo a pregnancy and that the commissioning party enjoy the general physical and

psychological fitness and suitability for the parenting of a child. A formal screening process is generally provided where there are such requirements. Further, some jurisdictions make reference to professional codes and guidelines or other regulations as reference points in determining medical fitness and suitability.

Section 5. Advertising

Roughly half of the jurisdictions surveyed address the issue of advertising, and those that address the issue prohibit advertising in relation to surrogacy. This prohibition is generally expressed in broad terms to cover all parties to the contract – intermediaries (such as medical personnel), the surrogate mother, and the intended parents.

Section 6. Licensing and Registration

In general, the jurisdictions surveyed have not enacted any provisions concerning registration and licensing requirements as to professionals involved in the surrogacy process. However, in so far as surrogacy involves AHR techniques and other medical procedures, rules governing licensing and registration in AHR and medicine generally will apply.

Section 7. Counselling and Information

Two of the jurisdictions surveyed stipulate that participants in the surrogacy process shall undergo counselling. Of these jurisdictions, *New Hampshire* specifies that this requirement only applies to participants over the age of 35 and relates to genetic counselling. Generally, in so far as surrogacy involves AHR techniques, general requirements as to counselling and the provision of information in the context of the former will also be applicable to surrogacy. The professional guidelines in the *Netherlands* are unusual in emphasising the long-term need for the provision of counselling and advice and the coordination of data on the surrogate mother and parents.

Section 8. Consent

In general, the legislation considered does not make specific provision for the consent of participants in a surrogacy arrangement. Where provision is made, the tendency is to require that the consent be voluntary and in writing. In so far as surrogacy involves AHR techniques, the provisions in the legislation on consent to the latter will also apply to surrogacy. However, in *Ireland* and other common law jurisdictions where there is no specific legislation regulating AHR, general legal principles as to consent to surgical procedures and general principles of contract may be relevant. Where surrogacy involves a surgical procedure on the surrogate mother, consent will be required as a general rule of medical (and criminal) law.

Part II: Rights and Obligations of Parties

Section 1. Rights and Obligations of Surrogate Mother

In general, the jurisdictions considered do not express in legislation the entitlements and rights of the surrogate mother in relation to the surrogacy process. However, such rights may be implicit in the legislative scheme. For example, in so far as the contract of surrogacy is not enforceable, the surrogate mother is entitled to keep the child and raise it as her own. Moreover, general principles of law - for example, relating to medical standards of care or contractual rights - may be applicable. None of the jurisdictions considered have enacted provisions expressly directed at preserving the confidentiality of the surrogate mother's identity. However, in *New Zealand*, under adoption legislation, the birth parent of an

adopted child may prevent identifying information as to parenthood from being given to the child.

Section 2. Rights and Obligations of Commissioning Party

In general, the jurisdictions considered do not grant the intended parents specific rights in the context of surrogacy arrangements. However, in so far as their role entails contact with professional services and other such parties, the normal principle of a professional standard and duty of care will apply to them. *Virginia (U.S.A.)* (where contracts are enforceable) is unusual in expressly emphasising the responsibilities of the intended parents to the child (as well as the custody rights of the parents) regardless of the child's health, physical appearance, and any mental or physical handicap, and regardless of whether the child is born alive. In other jurisdictions, the legislation does not set out specific obligations of the parents. However, in terms of obligations toward the child, general principles of family law will generally apply.

Section 3. Rights of the Child

In general, the legislation considered does not address the question of children's rights in the specific context of surrogacy. However, it is a general principle of family law in many jurisdictions that custody of a child is to be determined by reference to the best interests of the child. By rendering this consideration paramount, any entitlement of the parties to a surrogacy contract to have a dispute determined with reference to their interests, e.g. in having a contract enforced or in terms of their biological role in the pregnancy is negated. Moreover, in *Ireland*, the duty of parents to care for their children, which can conversely be presented as a right of the child to be cared for by its parents or guardians, is a principle of constitutional law.

Part III: Liability

Section 1. Introduction

The distinction between, and nature of, civil and criminal liability was briefly surveyed in the main AHR paper and is not discussed here in any detail. A breach of any statutory requirement is a civil wrong (or statutory tort in common law jurisdictions). Some statutory provisions in relation to surrogacy are specifically made subject to criminal liability in the event of their breach.

Section 2. Civil Liability

In general, the legislation considered does not address the issue of civil liability of the parties in a surrogacy arrangement. Where the issue is addressed, in *Virginia (U.S.A.)* and *New Hampshire (U.S.A.)*, provision is made for the liability of the intended parents to the surrogate mother where the former terminate or breach the contract of surrogacy. In *Virginia*, the intended parents will be liable for a portion of the expenses of the surrogate mother even where it is the surrogate mother who terminates the contract of surrogacy. Neither jurisdiction addresses the general issue of liability for breach of any of the statutory provisions. As in other jurisdictions, civil liability in this instance will fall under general principles of law. In common law jurisdictions, for example, breach of a statutory provision constitutes a statutory tort or wrong and a court may impose civil sanctions in consequence.

Section 3. Criminal Liability

In most of the jurisdictions surveyed, criminal sanctions are prescribed for certain breaches of surrogacy laws. Typically, criminal sanctions are applicable to breaches relating to

commercial surrogacy, advertising of surrogacy, and acting as an intermediary. *New Hampshire (U.S.A.)* imposes criminal sanctions in relation to breaches of consent, counselling, and medical evaluation requirements. The sanctions prescribed encompass both fines and imprisonment. The *United Kingdom* makes express provision for corporate criminal liability. The sanctions prescribed encompass both fines and imprisonment.

Appendix III

Ascertaining the meaning of the word ‘unborn’ for the purposes of Article 40.3.3 of the Constitution

Ascertaining the meaning of the word 'unborn' for the purposes of Article 40.3.3 of the Constitution

Article 40.3.3 of the Constitution provides, in Irish:

"Admhaíonn an Stát ceart na mbeo gan breith chun a mbeatha agus, ag féachaint go cuí do chomhceart na máthar chun a beatha, ráthaíonn sé gan cur isteach lena dlíthe ar an gceart sin agus ráthaíonn fós an ceart sin a chosaint is a shuíomh lena dhlíthe sa mhéid gur féidir é."

The English language version reads:

"The State acknowledges the right to life of the unborn and, with due regard to the equal right to life of the mother, guarantees in its laws to respect, and, as far as practicable, by its laws to defend and vindicate that right."

Determining at what stage of human life this guarantee applies is a crucial issue for the Commission, given its implications for assisted human reproduction and, in particular, for the treatment of spare embryos.

The Constitution does not explicitly define the terms, "beo gan breith" or "unborn" and so we have to turn to secondary sources in attempting to ascertain the meaning of these terms.

Dictionary definitions

Ó Dónaill¹ defines the noun "beo" as (1) "Living being" and (2) "Life". "Breith"² is defined by the same author as "birth". In the present context, these terms are too indeterminate to resolve the question of when Art.40.3.3 begins to apply to human life.

The New Shorter Oxford English Dictionary (1993) treats "unborn" as both a noun and adjective. As an adjective, it is defined as "1. Not yet born; *spec.* (of a child) still in the womb; *fig.* Not yet begun or in existence. 2. Not having been born; never to be brought into existence." Its definition as a noun is "Those who or that which is unborn".

Again, these terms are indeterminate in the present context.

Judicial commentary

The Courts have yet to define "beo gan breith"/"unborn" for the purposes of Art.40.3.3. In *McGee v. A.G.*,³ Walsh J. indicated that the right to marital privacy did not extend to the use of family planning methods that would endanger human life⁴ but he offered no view as to

¹ **Foclóir Gaeilge-Béarla** (1977).

² De Bhaldraithe defines "unborn" as "gan bhreith" - **English-Irish Dictionary** (1959) - whereas the Constitution uses the phrase "gan breith" In his magisterial study of the Irish text of the Constitution, Ó Cearúil comments on this point, "By leaving 'breith' unlenited, one anticipates a following phrase, instead of the finality of 'gan bhreith'" - **Bunreacht na hÉireann: A Study of the Irish Text** (Government of Ireland, 1999) at p.549. In similar fashion, the **Report of the Constitution Review Group** (Government of Ireland, 1996) comments (at p.275) in respect of the English language version of Art.40.3.3 that, "There is no definition of 'unborn' which, used as a noun, is at least odd. One would expect 'unborn human' or 'unborn human being'".

³ [1974] IR 284.

⁴ "[It is] a fundamental point ... that the rights of a married couple to decide how many children, if any, they will have are matters outside the reach of positive law where the means employed to implement such decisions do not impinge upon the common good or destroy or endanger human life." - [1974] IR 284 at p.313. See also the view of Griffin J. in the same case that the right of married couples to use contraception did not extend to a

how to distinguish contraception from other methods of family planning that have an abortifacient effect.⁵

It should be noted, that in *Attorney General (SPUC) v. Open Door Counselling Ltd.*,⁶ Hamilton P. took the view that the statutory protection of the right to life of the unborn applied from the moment of conception.

"Ss. 58 and 59 of the Offences Against the Person Act 1861⁷ protected and protect the foetus in the womb and having regard to the omission of the words 'Quick with child' which were contained in the 1803 Statute, that protection dates from conception. Consequently, the right to life of the foetus, the unborn, is afforded statutory protection from the date of its conception."⁸

The **Green Paper on Abortion**⁹ appears to equate this with fertilisation¹⁰ but Charleton, McDermott and Bolger take the view that it is not clear whether Hamilton P. is referring to the "moment" of fertilisation or implantation.¹¹

Parliamentary debates

It would appear from the Parliamentary Debates on the Eighth Amendment of the Constitution Bill 1982, which led to the enactment of Art.40.3.3, that the sponsors of the Amendment deliberately decided not to define the terms, "beo gan breith" or "unborn". Thus Dr. Michael Woods, T.D., who, as Minister for Health in the previous administration had responsibility for introducing the Bill providing for the current wording of Art.40.3.3, said,

"Despite what would undoubtedly have been the wish of the promoters of this amendment and the majority church in this island, there is no attempt in the wording of the amendment to define the moment at which the life of the unborn begins. The amendment does not attempt to make this definition. Most, of course, would argue that it begins at the time of conception, but this is a matter of theological and scientific argument and in preparing the wording of the amendment we felt it was not appropriate to the Constitution to have such definitions."¹²

Certainly one of the grounds given for opposing the Bill was that the terms "beo gan breith" and "unborn" were ambiguous and that the Amendment could apply from the moment of

right to use abortifacients "as in the case of abortifacients entirely different considerations may arise" - p.335. Again, the judge did not attempt to define abortifacient.

⁵ The meaning of abortion was discussed by the All-Party Oireachtas Committee on the Constitution in its Fifth Progress Report on Abortion (Government of Ireland, 2000). See below, 000.

⁶ [1988] IR 593.

⁷ Sections 58 and 59 of the 1861 Act deal with the supply and administration of 'any poison or noxious thing' to a pregnant woman with intent to procure a miscarriage. They are not applicable to AHR practices but clearly have some bearing on the question of when life begins.

⁸ [1988] IR 593 at p.598.

⁹ Government of Ireland, 1999.

¹⁰ See para.7.08, set out below. Keown also contends that ss.58 and 59 apply from the moment of fertilisation - see "Miscarriage: A Medico-Legal Analysis" [1984] Crim. L. R. 604.

¹¹ See **Criminal Law** (Butterworths, 1999) at para.7.63. **The New Shorter Oxford English Dictionary** (1993) defines "conception" as "the action of conceiving, or the fact of being conceived, in the womb", implicitly linking conception with implantation, and in 1983, the then U.K. Attorney General, Sir Michael Havers, stated in the House of Commons that no prosecution under the 1861 Act would be taken against those who supplied women with the 'morning after' pill or against women who used it.

¹² See Dáil Debates for 9 February 1983, at col.1386.

fertilisation, thus calling into question certain forms of family planning such as the use of IUDs and the morning after pill. Thus Mr. Dick Spring, T.D., the then Tánaiste, said,

*"It is clear that the word 'unborn' is likely to be interpreted by the Supreme Court as the moment at which the human ovum is penetrated by a sperm - the moment when human life commences."*¹³

The legal advice to the Government of the then Attorney General, Mr. Peter Sutherland, (read into the record by Barry Desmond, T.D., a Minister in that Government) was to the effect that the word 'unborn' was unclear in its meaning.

*"In particular it is not clear as to what life is being protected, as to whether 'the unborn' is protected from the moment of fertilisation or alternatively is left unprotected until an independently viable human being exists at 25 to 28 weeks."*¹⁴

It is worth noting that an attempt at the Report Stage of the Bill in the Seanad to preclude the application of Art.40.3.3 prior to implantation was defeated.¹⁵ The amendment in question, put down in the name of Senator McGuinness, provided for the insertion of the following phrases after "breith" and "unborn" in the Irish and English versions of Art.40.3.3 -

"gan an t-ubhán toirchithe roimh iomphlandú don ubhán toirchithe sin i gcneas na broinne a áireamh",

"which shall not include the fertilised ovum prior to the time at which such fertilised ovum becomes implanted in the wall of the uterus".

Academic and other commentary

In common with judicial commentary on the meaning of the word "unborn", non-judicial commentary on this term has largely taken place in the context of abortion, rather than assisted reproduction.

In the leading text on Irish abortion law, Kingston, Whelan and Bacik, **Abortion and the Law**,¹⁶ the authors express the view that

*"it cannot be said with certainty whether the protection afforded by Article 40.3.3 to the 'unborn' applies from the moment of fertilisation, the moment of the implantation, or from some later date."*¹⁷

In **The Report of the Constitution Review Group**¹⁸ the absence of a definition of the word "unborn" is identified as a difficulty in the current state of the law.

¹³ See Dáil Debates for 27 April 1983, at col.2197.

¹⁴ See Dáil Debates for 17 February 1983, at col.474. In my opinion, the term 'unborn' does apply to the foetus prior to viability, a position also taken by the authors of the **Green Paper on Abortion** (Government of Ireland, 1999) at para.7.12.

¹⁵ See Seanad Debates for 25 May 1983, at cols.1091-1151.

¹⁶ Round Hall/Sweet and Maxwell, 1997.

¹⁷ At p.32.

¹⁸ (May, 1996).

"There is no definition of 'unborn' which, used as a noun, is at least odd. One would expect 'unborn human' or 'unborn human being'. Presumably, the term 'unborn child' was not chosen because of uncertainty as to when a foetus might properly be so described.

Definition is needed as to when 'unborn' acquires the protection of the law. Philosophers and scientists may continue to debate when human life begins but the law must define what it intends to protect.

'Unborn' seems to imply 'on the way to being born' or 'capable of being born'. Whether this condition obtains as from fertilisation of the ovum, implantation of the fertilised ovum in the womb, or some other point, has not been defined.

In the context of abortion law, which deals with the termination of pregnancy, a definition is essential as to when pregnancy is considered to begin; the law should also specify in what circumstances a pregnancy may legitimately be terminated and by whom.

If the definition of 'pregnancy' did not fully cover what is envisaged by 'unborn', the deficiency would need to be remedied by separate legal provisions which could deal also with other complex issues, such as those associated with the treatment of infertility and in vitro fertilisation.

At present, all these difficulties are left to the Supreme Court to resolve without explicit guidance."¹⁹

The Review Group ultimately recommended the introduction of legislation dealing with, *inter alia*, the definition of 'unborn', while recognising that such legislation would have to comply with Art.40.3.3 generally.

This issue is also addressed in the **Green Paper on Abortion**²⁰ which sets out certain options for dealing with the issue of abortion but without making any recommendations. Dealing with how one might define the term 'unborn' in the context of possible further change in the law on abortion, the Green Paper said the following (at paras.7.07 - 7.13):

"The issue of whether the term 'unborn' should be or can be defined may again arise in any option involving the retention of Article 40.3.3 or in any amendment of the article which uses that term. If it is decided therefore that 'the unborn' should be defined, at least four types of definition are possible, as follows: (i) the time of fertilisation, (ii) implantation, (iii) some other specified time after fertilisation, or (iv) viability.

From an analysis of the campaign surrounding the 1983 amendment it would appear that supporters of the amendment were satisfied that the term 'unborn' provided constitutional protection from the time of conception/fertilisation, although the actual timing of this cannot be precisely defined. Although the issue has never directly arisen for consideration by the Courts there is some judicial support for this interpretation (Attorney General (SPUC) v. Open Door Counselling [1988] IR 593 at 598). Were such an interpretation to be formally confirmed, it would appear to cast some doubt over the legality of the use of post-coital contraception (the 'morning after' pill and post-coital IUD) but neither have been subjected to legal challenge since the passing of the 1983

¹⁹ *Op. cit.* at pp.275-6.

²⁰ Government of Ireland, 1999.

constitutional amendment and do not appear currently to cause any difficulties for the medical profession. However, a formal definition of the 'unborn' in the Constitution or in legislation might alter this situation.

While not of direct relevance to this Green Paper the implications of defining the term 'unborn' in this way for in vitro fertilisation (IVF) and the freezing of embryos must be considered. If it were specified within a definition that the protection of Article 40.3.3 extended to in vitro fertilisation, legal problems could arise in relation to some practices in this area. If, as an alternative it was decided to specifically exclude in vitro fertilisation from the protection of Article 40.3.3, the result could appear anomalous.

The second approach, i.e., defining the term 'unborn' as commencing from 'implantation' could be imprecise and would probably require some further definition. If a definition of 'implantation' was considered feasible, the difficulties regarding post-coital contraception and IVF treatment would not arise, although legislative regulation of the latter would still be required.

The third approach, i.e. defining the term 'unborn' as commencing from a specified time after fertilisation (for example "ten days after fertilisation") would not interfere with current practice regarding the use of post-coital contraception (provided the specified time chosen was not so early as to render such a practice unconstitutional). However it could be expected that there would be significant opposition to a definition along these lines.

With regard to the final approach, 'viability', it must be said that this definition does not reflect current medical practice or the accepted current constitutional and legal position, nor was it proposed in any of the submissions received. It would permit abortion on grounds wider than those specified in the X case judgement. Such a definition would require a constitutional amendment.

Finally, the option of continuing to operate without a definition of the 'unborn' must also be given consideration. Although the difficulties associated with the term 'unborn' cannot be dismissed, they have not troubled the Courts or the medical profession to date. It is significant that in the debate over an amendment to the Constitution in 1992 the issue of defining the term 'unborn' did not feature to a significant extent. It is arguable that much of the difficulty relates to the implications of possible definitions for the whole area of IVF treatment, which, in itself, is not of direct relevance to the Green Paper."

Penultimately, the whole question of abortion was recently examined by the All-Party Oireachtas Committee on the Constitution in its **Fifth Progress Report on Abortion**.²¹ While the Report has a somewhat inclusive discussion of the term 'abortion',²² it does not consider in detail the difficulties attaching to the definition of the term 'unborn', though it does advert to this question in the context of its discussion of the legality of the morning after-pill.²³ Addressing the question of whether the morning-after pill is an abortifacient, the All-Party Committee states,

²¹ Government of Ireland, 2000.

²² At pp.19-23.

²³ See pp.101-2.

The problem centres on when the unborn comes into being. Some would argue it is when an ovum is fertilised. However, great numbers of fertilised ova are lost in the natural course of things and never become implanted in the uterine wall. As a result some argue that implantation is the decisive event in the development of unborn life...

The Family Planning Act 1979 specifically prohibits the importation, sale and distribution of abortifacients. In as much as the morning after pill is available and prescribed the legal presumption must be that it is not regarded as an abortifacient.

While the foregoing comments have been made largely in the context of the debate on abortion, two commentators have considered the meaning of the term 'unborn' in the context of assisted human reproduction. Writing in 1989, Sherlock²⁴ records that many of those involved in the parliamentary debates considered that the term referred to the foetus from the moment of conception²⁵ and she concludes that the law is uncertain with regard to the legality of interceptive methods of birth control. More significantly in the present context, she comments,

*"[I]t is likely that the courts would hold the in vitro embryo to come within the protection of [Art.40.3.3], and if this is the case, it would appear to rule out embryo research in Ireland, certainly in cases involving the destruction of the embryo. It would also have implications for infertility treatments involving in vitro fertilisation (IVF) as it would undoubtedly require that all embryos produced would have to be placed in the woman's uterus. Presumably, this would have to include the placing in the uterus of embryos even if they were known to be defective."*²⁶

A contrary view is offered by Madden who argues:

*"If the 'unborn' means 'not yet born' or 'with the potential to be born' then, in the light of the biological development of the early embryo and the absence of potential in the pre-implantation embryo, it is likely that the embryo in the laboratory does not qualify for this constitutional protection."*²⁷

Conclusion

Having reviewed the above material, the only obvious conclusion one can draw about the meaning of the word 'unborn' in Article 40.3.3 is that the meaning is uncertain. That

²⁴ "The Right to Life of the Unborn and the Irish Constitution" (1989) XXIV *Ir. Jur. (n.s.)* 13, at pp.21-5.

²⁵ Though, as she also points out, a number of deputies taking this view also managed to indicate support for post-coital interception in the case of rape, without indicating the basis on which they reconciled these two positions.

²⁶ At p.24 (footnote omitted).

²⁷ Madden, *Medicine, Ethics and the Law*, (Butterworths (Ireland) Ltd., 2002), para.6.116. As we have already noted, however, the Green Paper on Abortion commented, at para.7.9, that the exclusion of *in vitro* fertilisation from the protection of Article 40.3.3 could appear anomalous.

Art.40.3.3 applies from the start of, or at some point during, the process of fertilisation cannot be ruled out.

Clearly the uncertain nature of the law on this vital point has significant implications for AHR. Clarification can only be obtained in one of two ways, either an authoritative pronouncement from the Supreme Court on the meaning of the term 'unborn' for the purposes of Art.40.3.3 or by way of constitutional amendment. (Any legislative clarification of the term would always be subject to legal challenge).

Appendix IV
National Infertility Support & Information Group
(NISIG) Survey

**National Infertility Support & Information Group
(NISIG) Survey**

Q1: How many years are you married / in your present relationship?

Q2: What is your current age? (Please tick)

	20-25	26-30	31-35	36-40	41-45	46+
Female						
Male						

Q3: How many years were you trying to conceive before seeking medical advice?
(please tick)

1-2	3-4	5-6	7-8	9+

Q4: In relation to question 3, what age were you when you sought medical advice?
(Please tick)

Female	
Male	

Q5: Was your infertility caused by; (Please tick)

A male problem	A female Problem	Both male & female	Unknown

General Practitioner;

The following questions refer to your G.P. (Please tick the appropriate answer to the following questions)

Q6: Is your GP; (Please tick)

Male	Female

	Yes	No	Don't know
Q7: When seeking medical advice, was your GP Helpful?			
Q8: Did your GP understand your infertility?			
Q9: Did your GP arrange hormone analysis for the female?			
Q10: Did your GP arrange hormone analysis for the male?			
Q11: Did your GP organise a semen analysis for the male?			
Q12: Did your GP prescribe clomid for you?			

Q13: How long were you taking Clomid? _____

	Yes	No	Don't know
Q14: Did your GP organise a scan while on this medication?			
Q15: Was your GP's treatment/intervention successful?			
Q16: If yes, was your pregnancy single birth? multiple births?			

Q17: If multiple birth, how many children did you have? _____

Q18: Did your GP refer you to any of the following? (please tick)

Obstetrician/Gynaecologist (Obgyn)	Urologist	Endocrinologist	IVF Clinic	IUI Clinic

Obstetrician and Gynaecologist (OBGYN)

The following questions refer to OBGYN (Please tick the appropriate answer to the following questions)

Q19: How long after initial consultation with your G.P. were you referred to an OBGYN? _____ years and _____ months.

	Yes	No	Don't know
Q20: Did your OBGYN diagnose your infertility promptly?			
Q21: Was the OBGYN referral to IVF specialist prompt?			
Q22: Did OBGYN intervention result in a pregnancy? (Clomid)			
Q23: If yes, was your pregnancy single birth? multiple births?			
Q24: If multiple births, how many children did you have? _____			
Q25: Did OBGYN surgical intervention result in a pregnancy?			

Q26: What infertility treatment did you receive? (Please tick)

Clomid	
Clomid/profassi	
IUI	
IUI/Donor sperm	
IVF	
IVF/ICSI	
IVF/Donor sperm	
IVF/Donor egg	
IVF/Egg sharing	
Surrogacy	
Other	

If further treatment was needed, please complete next section

Please State

Q27: Which clinic did you attend? City/Town _____ Country _____

Q28: How long does it take to travel from your home to the Clinic? _____

	Yes	No	Don't know
Q29: Is there a waiting list in the clinic you attend/attended?			
Q30: Are you aware of all the services available at the Clinic?			
Q31: Are you aware of the success rate at your clinic?			
Q32: Are you aware of how many couples are treated yearly in the clinic?			
Q33: Are you happy with your choice of clinic?			

If not, why?

	Yes	No	Don't know
Q34: Do you stay in rented accommodation?			
Q35: If so, how much did it cost? _____			

For the male partner;

	Yes	No	Don't know
Q36: Is the accommodation provided acceptable to you when giving a sample?			
Q37: Did you have a physical examination?			

Counselling;

	Yes	No	Don't know
Q38: Does your clinic hold educational meetings?			
Q39: Is attendance compulsory?			
Q40: Do you agree with compulsory attendance?			
Q41: If attended, was it beneficial to you?			
Q42: Is/was counselling mandatory prior to treatment at your clinic?			
Q43: Does your clinic provide qualified counselling service?			
Q44: Would you find counselling beneficial prior to treatment?			
during treatment?			
post treatment?			
Q45: Do you feel that more counselling should be mandatory prior to treatment?			
Q46: Have you got a medical card?			
Q47: Are you a private patient?			

Q48: How much did your treatment cost to date? _____

Q49: How many times did you have treatment?

IUI	IUI/D	IVF	IVF/D

(D = donor)

	Yes	No	Don't know
Q50: Do you intend having more treatment?			
Q51: On reflection, would you have committed yourself to as much treatment as you did?			

Q52: Who gave/gives your injections? (please tick)

Self	
Partner	
Friend	
GP	

Feelings/Emotions;

Q53: Describe your feelings/emotions when you realised you had problems conceiving.

Please use the following scale for all or the emotions listed below.

(1 = strong feelings, 2 = mild feelings, 3 = no feelings)

Anger	
Bitterness	
Isolation	
Guilt	
Denial	

	Yes	No	Don't know
Q54: Do you feel society puts pressure on you because you do not have a child?			
Q55: Are you included in social events involving children?			
Q56: Are you happy to attend social events involving children?			
Q57: Do you enjoy Christmas with your extended family?			
Q58: Would you prefer to be alone at Christmas?			
Q59: How are your feelings on Mother's/Father's Day?			

Q60: As a couple, do you find it difficult to discuss the topic of infertility?			
Q61: As a couple, do you find it difficult to discuss the topic of infertility with your family?			
Q62: As a couple, do you find it difficult to discuss the topic of infertility with your friends?			

Q63: Are you getting the emotional support from your partner?			
(Female)			
(Male)			

Q64: If not, whom do you turn to? (please tick)

Family	Friends	Clinic	Counsellor	NISIG	Other

	Yes	No	Don't know
Q65: Has infertility affected your sexual relationship?			
Q66: If yes, did you seek professional help/advice?			
Q67: Are you as a couple closer?			
Q68: Are you as a couple further apart?			
Q69: Have you as a couple attended counselling outside of the Clinic?			

Q70: If only one of you attended, which one?
Q71: How long did you attend counselling?

Male	Female

Q72: Did you have to pay for counselling?
Q73: How much was the cost of counselling in total?

Yes	No	Don't know

Q74: Do you attend NISIG meetings?
Q75: Are you separated?
Q76: If so, was infertility a contributing factor?

Donor Conception;

Q77: If you have a donor conceived baby/babies, do you intend telling your child of its conception?
Q78: If not, did you seek advice coming to this decision?
Q79: Was advice/counselling available to help you come to this decision?
Q80: If you intend telling your child, is there advice available to you?
Q81: If yes, from whom?

Yes	No	Don't know

The following questions refer to **embryos**. (Please tick the appropriate answer to the following questions).

Q82: Do you wish for your spare embryos to be frozen?

Yes	No	Don't know

Should spare embryos be:

- Q83: Placed in your womb when not ovulating?
 Q84: Buried by you?
 Q85: Donated?
 Q86: Research (within 14 days of defrosting) under
 medial/ethical/legislative guidelines/regulations?

Yes	No	Don't know

Donor sperm/eggs;

- Q87: Should donor sperm be available?
 Q88: Should donor eggs be available?
 Q89: Should egg sharing be available?
 Q90: Should donor embryos be available?
 Q91: Do you / did you need this service?
 Q92: Should donor sperm/eggs come from an anonymous
 source?

Yes	No	Don't know

Embryo Transfer;

- Q93: When do you think that embryo transfer should occur (please tick)

Day 2	Day 3	Day 4	Beyond day 4

(Please note, egg collection day 0, insemination 8 hours, fertilisation 18 hours,
 zygote 45-48 hours day 2)

- Q94: Should 3 embryos rather than 2 embryos be transferred, if
 the female is over 40 years, for optimal chance of
 conceiving?

Yes	No	Don't know

Surrogacy;

- Q95: Should surrogacy be available?
 Q96: Did you / do you need this service?
 Q97: Should wife's eggs, husband's sperm, host womb
 surrogacy be available?
 Q98: Should donor eggs, husband's sperm, host womb
 surrogacy be available?
 Q99: Should wife's eggs, donor sperm, host womb surrogacy be
 available?
 Q100: Who should the growing foetus be the property of?

Yes	No	Don't know

The couple seeking surrogacy	The host mother

Q101: Who should the sperm/ova/embryos produced during treatment be the property of?

The couple	The clinic

Q102: Where did you hear of NISIG? (please tick)

G.P.	Gynaecologist	Infertility Clinic	Media	Other

Q103: Please circle if past / present member.

Appendix V

Report of Assisted Reproduction Sub-committee of the Executive Council of the Institute of Obstetricians & Gynaecologists

Report of Assisted Reproduction Sub-committee of the Executive Council of the Institute of Obstetricians & Gynaecologists

Membership of committee

Dr. Dermot MacDonald, MAO, FRCPI, FRCOG, FACOG (Hon), Chairman, Consultant Obstetrician/Gynaecologist, National Maternity Hospital, Holles Street.

Prof. Tom Clarke, FRCPI, FAAP, DCH, Consultant Neonatologist, Rotunda Hospital, Dublin, Associate Professor of Neonatal Paediatrics, Royal College of Surgeons in Ireland.

Dr. Denis A. Cusack, FRCPI, Barrister at Law, Director and Senior Lecturer, Division of Legal Medicine, University College Dublin.

Dr. Declan Egan, FRCOG, Consultant Obstetrician/Gynaecologist, University College Hospital, Galway.

Prof. Andrew Green, MB, PhD, FRCPI, Professor of Medical Genetics, University College Dublin, Our Lady's Hospital for Sick Children, Crumlin.

Prof. Robert Harrison, MA, MD, FRCP, FRCOG, FRCS, Professor of Obstetrics & Gynaecology, Royal College of Surgeons, Dublin.

Dr. Maureen Junker-Kenny, MA, FTCD, Head of School of Hebrew Biblical and Theological Studies, Lecturer in Practical Theology/Christian Ethics. University of Dublin, Trinity College.

Ms. Deirdre Madden, B.C.L., LL.M., BL, Lecturer in Law, University College Cork.

Prof. William Thompson, BSc, MD, FRCOG, Professor of Obstetrics & Gynaecology, Queen's University, Royal Maternity Hospital, Belfast.

Prof. T.J. McKenna, MD., FRCP (Lon), FRCP (Ed), FACP., FRCPI., (Resigned because of inability to attend).

Dr. Susan McManus, MB, FRCP, Consultant Geneticist, (Resigned because of inability to attend – May 1997).

Dr. Adrienne Pope, B.Sc., Hons., PhD., Embryologist, Rotunda Hospital, Dublin 1 (Resigned to return to Australia in November 1997).

Note from Chairman of the Institute

The Institute of Obstetricians and Gynaecologists is very grateful to Dr. Dermot MacDonald and his team for working hard to produce the report on Assisted Reproduction. The report has been debated at the Executive Council meetings of the Institute on more than one occasion and at the last Executive Council on 24th April 1999, it was accepted.

However, it is important that I should state here, that there are some members of the Institute who are not happy with either all or part of the contents of this report. However, the majority have accepted it and I have agreed to have this note inserted at the front of the report.

The next step will be to try and set up a regulatory body on Assisted Reproduction. We are in discussion regarding this with the Chief Medical Officer of the Department of Health and Children.

Dr. Harith Lamki

Chairman
7/5/99

Foreword

The Institute of Obstetricians & Gynaecologists of the Royal College of Physicians of Ireland is the representative body of Obstetrics & Gynaecology in the Republic of Ireland. It draws some of its membership from Northern Ireland.

The Executive of the Institute in June 1996 invited Dr. MacDonald to accept the Chairmanship of the Assisted Reproduction Sub-Committee following the resignation of Dr. Edwin Lillie. Dr. Edwin Lillie had chaired this sub-committee since its establishment in 1985.

The re-convened sub-committee was requested by the Executive to review the “1993 Guidelines and to consider other matters related to assisted reproduction”. The members of the sub-committee were proposed by the Executive of the Institute. Others were invited by the Chairman to join and were subsequently confirmed as members by the Executive. The Chairman in recommending members was aware of the complexity of the matters being reviewed and the need for particular expertise.

The sub-committee met on 14 occasions. The members of the sub-committee, set out to have a report issued to the Executive Council of the Institute by early 1998.

The sub-committee received submissions from the National Infertility and Support Group as well as from individuals from within and outside of the medical profession.

The Chairman wishes to express his gratitude to all members of the committee, to those who made submissions and to those who replied to our letters seeking guidance on particular matters. The Chairman in particular appreciates that many members travelled long distances and all gave generously of their time to attend the meetings.

The Medical and Scientific facts of the process In Vitro Fertilisation

1. It is accepted that the methods of in vitro fertilisation (IVF) and intra cytoplasmic sperm injection (ICSI) are significant advances for the treatment of certain causes of human infertility.
2. IVF is a most suitable treatment for women who have a normal uterus and produce healthy eggs, but have damaged, diseased or absent fallopian tubes. The latter conditions may prevent eggs from passing from the ovary to the uterus. Without IVF, the possibility of achieving a pregnancy in such cases with severe tubal problems is remote.
3. IVF may be used to treat other causes of infertility such as impaired sperm function and unexplained infertility. This has led to the use of IVF in a larger percentage of cases of infertility. ICSI is most appropriate for severe male factor infertility.

4. In IVF human eggs are obtained from the ovary. The eggs are incubated with sperm so that fertilisation can occur outside the woman's body (in vitro). In cases of ICSI a single sperm is injected into a single egg.
5. The zygote* is then transferred to the uterus.
6. In practice, the obtaining of the eggs, the culture outside the woman's body and the transfer of the zygote to the uterus, must be carried out by appropriately qualified clinical and laboratory personnel under carefully controlled conditions.
7. It has been common and accepted practice to transfer more than one zygote to the uterus as this enhances the successful pregnancy rate.
8. Drugs are usually given to the woman to stimulate the ovaries to produce several eggs per cycle.
9. When multiple zygotes are transferred, multiple pregnancies may result. In order to address this issue no more than 3 zygotes, and if feasible no more than 2, should be transferred to the uterus in any treatment cycle.
10. Overall IVF and related procedures may result in up to 15-20 per cent live births per treatment cycle.
11. There is no conclusive evidence that IVF per se results in an increased risk of abnormalities in babies. Further studies are required in relation to ICSI.
12. In IVF pregnancies there is an increased risk of complications including miscarriage, ectopic pregnancy and premature labour.

(Zygote usually at 2 to 4 Cell Stage – See Appendix 1)

Guidelines for doctors practising Assisted Reproduction Techniques

1. Couples must be appropriately counselled, should understand the method and its complications and must give informed consent prior to embarking on IVF.
2. The service should be available to married couples or to couples in a stable relationship. All children born following assisted reproduction procedures have the right to identify their genetic parents.
3. Relevant records must be maintained to allow all children born following assisted reproduction procedures to identify their genetic parents.
4. Assisted Reproduction Techniques are clinical practices used for the treatment of selected causes of human infertility. In no circumstances should they be used to produce or store human embryos for research purposes.

Ref: A Guide to Ethical Conduct and Behaviour and to Fitness to Practice – 4th Edition – Medical Council.

Initial Report

Aware of a certain urgency the sub-committee of the Institute of Obstetricians and Gynaecologists of the Royal College of Physicians of Ireland after its second meeting made a brief report to the Executive suggesting that no alterations be made in the 1993 guidelines. This was primarily to enable the sub-committee to continue with its considerations without the pressure of the Executive awaiting a report.

Matters considered by the Assisted Reproduction Sub-Committee

The instruction given by the Executive to the Sub-Committee was to review the 1993 guidelines in relation to assisted reproduction and to consider other matters related to assisted reproduction.

The Chairman anticipated that it was unlikely that there would be unanimity on aspects of the matters under discussion. As an aid in formulating the report 8 key questions were identified and the replies form the basis of this report. Replies were received from all members of the sub-committee.

The Chairman in formulating the report has attempted to give a balance to the views expressed by the members of the sub-committee.

Finally the committee was very conscious in all its deliberations of the rapid developments in many aspects of assisted reproduction and the medical, scientific, legal and ethical problems which exist.

The Committee's paramount concerns throughout its deliberations were for the welfare and interest of the unborn child and of the children born through assisted reproduction techniques and for the couples treated by these techniques.

Question 1: Is legislation necessary in the field of assisted reproduction?

The majority view was that legislation is necessary for the following reasons:

to lay down the boundaries of what our society consider acceptable in the field of assisted reproduction; to give guidance to the practitioners; to establish the legal status of children born as a result of treatment. As many controversial practices may develop such as cloning and experimentation on embryos, the general view was that legislation will be necessary.

Extensive research in the medical, legal and ethical considerations should be carried out first to ensure that the legislation be appropriately drafted. This work should be funded by the Department of Health.

The opposing view was based on the fact that it is unusual to legislate the practice of any medical procedure and that the public do not appreciate being denied the best medical treatment available due to legislative limitations. Those opposing felt that the guidelines were adequate for practitioners.

Question 2 : Should either a voluntary body or a statutory licensing authority be established to regulate assisted reproduction (including research)?

The committee favoured a licensing authority, which would be initially voluntary but eventually statutory.

The risk of unscrupulous practitioners setting up practice to possibly exploit the need of infertile couples was stressed. Recognition was given to the fact that the Medical Council must also maintain professional and ethical standards in the field of assisted reproduction.

Question 3 : Should Freezing of Sperm be part of Assisted Reproduction?

The overall view was in favour of freezing of sperm. Recognition was expressed of the complex legal issues that remain to be addressed. It was felt that such a service should be available in IVF units rather than in urological units. The practice of sperm freezing for storage should be within the framework of legislation. Particular recognition was given to those men who would wish to have children following cancer treatment. The posthumous use of sperm was not approved.

Question 4 – Should freezing be available?

The committee unanimously agreed that freezing should be introduced as part of the techniques of assisted reproduction. By its introduction the woman might only have to undergo the strain of ovarian stimulation and egg retrieval once. It was also recognised that there was the possibility of improved results from the second and third cycles. The risk of multiple pregnancy with its complications might be reduced.

In relation to freezing as in other matters, the Committee recognised the need for informed consent based on clear exposition of the ethical and legal issues of each method, their success and failure rates, to be acquired from each couple.

(1) At what stage in the fertilisation process do you suggest freezing be introduced?

(a) the pronuclear (see Appendix 1)

A small majority (5 of 9) was in favour of freezing at the pronuclear phase (See Appendix 1) based on the conviction that this entity did not come within the definition of the term zygote and accordingly embryo destruction would not arise. The chief reason was that this procedure gave a balance of benefit to patients without the possible need for embryo destruction.

Those opposing freezing at this stage and favouring freezing at the zygote stage of development based their views on the benefit to patients. This benefit arises from the ability of the embryologist to be reasonably certain that a zygote was present at freezing. Such certainty is not present at the pronuclear phase.

(b) the zygote (see Appendix 1)

Four favoured freezing at this stage of development, basing their views on the benefits to patients. Three were opposed, acknowledging the possibility of embryo destruction following this procedure; two were undecided.

Concern was expressed that the current practice of insertion of spare embryos into the uterine cervix might result in the risk of cervical pregnancy for mother and embryo. However, no cervical pregnancies have been reported despite extensive clinical experience of this practice.

(2) How do you address the issue of the unwanted frozen pronucleus or zygote?

Those who favoured freezing at the pro-nuclear phase i.e. before syngamy, (that is before the genetic material from both gametes combines to form the “new genetic unit”) in general, did not see any ethical problem in unfreezing at this stage.

Those favouring freezing of the zygote (after syngamy) expressed views which included unfreezing at various times up to 10 years. One member suggested donation to research; donation to another couple was suggested by three members. It is essential that decisions must be based on the consent previously acquired by the couple at the onset of treatment.

Question 5 – Should Donor Insemination be Available?

It is recognised that assisted donor insemination (DI) is readily available at present in Ireland without legislation or control.

Majority View:

Donor Insemination (DI) can be regarded as a separate issue from invitro fertilisation. The majority support the view that donor insemination be part of assisted reproduction techniques. ICSI has reduced its utilisation in male infertility. It is also seen as an option in special cases where both parents are carriers of the same genetic disorder. The legal aspects of donor insemination require deeper consideration to ensure a workable framework. The majority accepted the need of ensuring that identifiable information is available to the child on reaching maturity. This contrasts with the opposing view in that the donor should remain anonymous. Difficulties are seen in relation to donor insemination, include the duration of storage of sperm, the liability of the donor and the keeping of confidential records by an authority.

Question 6 – Should Egg Donation be Available?

The committee divided equally on this issue with one failing to reply. Those in favour saw it as raising the same issues as donor insemination (DI). The number of patients requiring such a procedure would be small.

Those opposed based their views on the legal and ethical difficulties which arise from multiple parentage for the identity of the child. These concerns were also expressed by those in favour. The need for a register to be maintained as in donor insemination for those who wish egg donation was recognised.

All were against any commercial business being practised in relation to egg or sperm donation. It also is the majority view that identifiable information of the genetic mother should be available to the child. In addition, the medical risks for the donating women through hyper-stimulation and egg harvesting were recognised.

Question 7 – Should embryo donation be available?

The majority view was opposed to the creation of embryos from donor sperm and egg being available for transfer to a third party.

The minority view accepted the very small need for such in clinical practice.

However, the majority view supported the altruistic and non-commercial donation of “spare” embryos with the consent of the donating couple. Another minority opposed in all circumstances this practice because of difficulties in relation to the identity of the child.

Question 8 – Should surrogacy be part of the programme to assist the infertile?

The majority of the committee agreed that there was no support for a surrogacy programme. The committee recognised that the ethical and legal problems raised by surrogacy outweighed any possible benefit. The committee recognised the commercial risks associated with this practice and the need for legal clarification of the issues involved. The committee recognised that future legislation may clarify the overall position in regard to surrogacy.

Support for surrogacy was expressed by one committee member provided the practice was closely monitored.

Appendix 1

The process of human fertilisation and embryogenesis (“development of embryo”) has several defined stages.

For the purposes of this report the following is an explanation of the terms used.

A. PRONUCLEAR STAGE

This is when the sperm nucleus containing the paternal chromosomes is present in the egg cytoplasm but has yet to fuse with the egg nucleus containing the maternal chromosomes i.e. before syngamy.

B. ZYGOTE

This is when the paternal and maternal chromosomes have fused and begun to divide into 2 cell, 4 cell, 8 cell stage (i.e. after syngamy) eventually onto morula and subsequent blastocyst.

Appendix 2

Further enquiries in relation to the original Question 4 of the draft report of the Assisted Reproduction Sub-Committee of the Institute of Obstetricians & Gynaecologists

Question 1:

Do you support freezing of the unifying/unified sperm and egg?

Question 2:

At what stage in the fertilisation process do you suggest freezing be introduced?

Question 3:

How do you address the issue of the unused frozen zygotes or (pre-embryos/embryos)?

Appendix 3

Clarifying enquiries in relation to previous question 4

Question 1:

Do you support freezing of sperm and eggs?

Question 2:

At what stage in the fertilisation process do you suggest freezing be introduced

- A) The pronuclear (i.e. when the sperm nucleus containing the paternal chromosomes is present in the egg cytoplasm, but has yet to fuse with the egg nucleus containing the maternal chromosomes i.e. before syngamy)
- B) Zygote (i.e. when the paternal and maternal chromosomes have fused and begun to divide into 2 cell, 4 cell, 8 cell stage (i.e. after syngamy) eventually onto morula and subsequent blastocyst)

Question 3:

How do you address the issue of the unwanted frozen pronucleus or zygote?

Appendix VI

**Telephone Questionnaire administered
by the Market Research Bureau of Ireland (MRBI)**

Telephone Questionnaire administered by the Market Research Bureau of Ireland (MRBI)

MRBI/6301/03

**COMMISSION ON ASSISTED HUMAN
REPRODUCTION
FINAL QUESTIONNAIRE**

ASK ALL RESPONDENTS

**I would now like to ask you a series of questions on medical procedures such as artificial insemination and 'in-vitro' fertilisation, used to assist human reproduction
.....**

Q.1 Artificial insemination and 'in-vitro' fertilisation, also known as IVF, are medical procedures that can enable couples to have children if one or both partners are infertile. Overall, do you agree with the use of these technologies or not? Please answer yes, no or in some cases. **SINGLE CODE.**

Yes	1
No	2
In some cases	3
Don't know	4

Q.2 Do you think that artificial insemination and IVF should be available to people in the following situations or not? Please answer yes, no or in some cases. **READ OUT AND ROTATE ORDER BETWEEN INTERVIEWS**

READ OUT ↓	YES	NO	IN SOME CASES	DON'T KNOW
Married couples	1	2	3	4
Unmarried couples in a stable relationship	1	2	3	4
Same gender couples	1	2	3	4
Single women	1	2	3	4
Single men	1	2	3	4
People with disabilities	1	2	3	4
Post-menopausal women i.e. women over 50 years	1	2	3	4

Q.3 Who do you feel should be responsible for the regulation of assisted human reproduction? **READ OUT. FLIP ORDER BETWEEN INTERVIEWS**

- The medical profession 1
- The law of the land 2
- The medical profession and the law of the land 3
- Other (please specify) 4
- Don't know (DNRO) 5

Q.4 Do you think that artificial insemination and IVF should be available to medical card holders or not? Please answer yes, no or in some cases. **SINGLE CODE.**

- Yes 1
- No 2
- In some cases 3
- Don't know 4

Assisted human reproduction makes it possible to involve third parties in the reproductive process. For example, artificial insemination can enable women to become pregnant with sperm donated by another male. IVF can enable infertile women to become pregnant using eggs donated by another female and surrogacy is an arrangement where a woman agrees to have a child either by artificial insemination or IVF for an infertile couple or individual.

Q.5 In general, do you agree with the participation of third party donors in the process of human reproduction or not? Please answer yes, no or in some cases. **SINGLE CODE.**

- Yes 1
- No 2
- In some cases 3
- Don't know 4

Q.6 Are you in favour of donor sperm being made available to the following? Please answer yes, no or in some cases. **READ OUT AND ROTATE ORDER BETWEEN INTERVIEWS**

READ OUT ↓	YES	NO	IN SOME CASES	DON'T KNOW
Single women	1	2	3	4
Two women in a relationship	1	2	3	4

- Q.7** Do you think that children born through the involvement of third party donors have a right to....? Please answer yes, no or in some cases. **READ OUT AND ROTATE ORDER BETWEEN INTERVIEWS**

READ OUT ↓	YES	NO	IN SOME CASES	DON'T KNOW
Know the identity of their genetic parents	1	2	3	4
Access genetic information from both biological parents for example information on the parents' medical history or inherited illnesses	1	2	3	4

- Q.8** Do you think the practice of surrogacy - that is where a woman agrees to have a child either by artificial insemination or IVF for an infertile couple or individual - should be allowed in Ireland or not? Please answer yes, no or in some cases. **SINGLE CODE.**

Yes 1
 No 2
 In some cases 3
 Don't know 4

- Q.9** Do you think that some form of payment should be made available to? Please answer yes, no or in some cases. **READ OUT AND ROTATE ORDER BETWEEN INTERVIEWS**

READ OUT ↓	YES	NO	IN SOME CASES	DON'T KNOW
Donors of sperm or eggs	1	2	3	4
Surrogate mothers	1	2	3	4

- Q.10** Do you think that donors and surrogate mothers have the right to? **READ OUT AND FLIP ORDER BETWEEN INTERVIEWS**

Remain anonymous in all circumstances 1
 Remain anonymous in all circumstances except
 where the life or health of a child is at risk 2
 Should not be anonymous in any circumstances 3
 Don't know (DNRO) 4

Embryo is the term used for a human organism in the period immediately following fertilisation. Embryos generated outside the female body are known as 'in-vitro' embryos. In a single cycle of IVF (in-vitro fertilisation) treatment, not more than three 'in-vitro' embryos may be transferred to the womb. Where more 'in-vitro' embryos are produced than can be used, they are described as 'surplus embryos' and may be stored in a frozen state for future use.

Q.11 Do you agree with the production of surplus embryos during IVF treatment or not? Please answer yes, no or in some cases. **SINGLE CODE.**

Yes	1
No	2
In some cases	3
Don't know	4

Q.12 Do you agree with the freezing of surplus embryos or not? Please answer yes, no or in some cases. **SINGLE CODE.**

Yes	1
No	2
In some cases	3
Don't know	4

Q.13 Once a couple or individual has completed their IVF treatment, do you think that surplus embryos should be? **READ OUT AND ROTATE ORDER BETWEEN INTERVIEWS**

Donated to another couple	1
Donated to another individual	2
Used in medical research	3
Disposed of	4
Should be the decision of the people who produced the embryos (DNRO)	5
None of these (DNRO)	6
Don't know . (DNRO)	7

Medical scientists have the ability to treat 'in-vitro' embryos in a way that will enhance the embryo's chance of survival following transfer to the womb. In order to achieve this, some other embryos may have to be experimented upon and could be injured or destroyed in the process.

Q.14 Do you think this type of embryo treatment should be allowed or not? Please answer yes, no or in some cases. **SINGLE CODE.**

Yes	1
No	2
In some cases	3
Don't know	4

Medical scientists also have the ability to screen 'in-vitro' embryos for the presence of some genetic diseases such as cystic fibrosis. 'In-vitro' embryos that are discovered to be affected by a genetic disease are not normally transferred to the womb.

Q.15 Do you think that medical scientists should be allowed to select only healthy embryos in this way? Please answer yes, no or in some cases. **SINGLE CODE.**

Yes	1
No	2
In some cases	3
Don't know	4

Research on 'in-vitro' embryos may lead to advances in the treatment of some diseases such as heart disease, Parkinsons, leukemia and so on. However, in the process of conducting this research, embryos would be destroyed.

Q.16 Do you think medical research of this kind should be allowed on embryos or not?
Please answer yes, no or in some cases. **SINGLE CODE.**

Yes	1
No	2
In some cases	3
Don't know	4

Q.17 Do you think that medical scientists should be allowed to generate embryos for
research purposes only? Please answer yes, no or in some cases. **SINGLE CODE.**

Yes	1
No	2
In some cases	3
Don't know	4

Appendix VII

The Best Interests of the Child in Assisted Human Reproduction

The Best Interests of the Child in AHR

Introduction:

Assisted human reproduction raises complex issues in many legal contexts ranging from family and constitutional law, to human rights, contract and property law. In addressing these issues the Commission sought to prioritise some fundamental underlying themes such as autonomy, privacy and informed consent, respect for human life and dignity, and the welfare of individuals born by or otherwise affected by AHR.

In reaching its recommendations on the many diverse practices in AHR the Commission frequently returned to the question of the welfare and best interests of the child or children to be born from or otherwise likely to be affected by AHR. [The term ‘offspring’ may be a preferable term to use, as children become teenagers and then adults, at which stages the psychosocial ramifications of having been conceived by AHR will have their greatest impact. Reference to the welfare of implicitly dependant children fails to acknowledge this reality. (Daniels et al. 2000)] The terminology used here is also important with words such as interests, welfare, needs and rights often being used in the literature interchangeably. It may be that a tighter set of definitions would be more useful as follows: ‘interests’ are issues relevant to individuals; ‘needs’ are those interests manifested in the real world; ‘rights’ are needs that can be claimed against other parties. (Freeman, 1996, 1998)

The welfare issue will inevitably play a large part in any debate on whether and how to legislate for the provision of AHR treatment services in Ireland. However, while everyone might agree on the fundamental importance of the interests of the child, it may be more difficult to find a societal consensus on what this means. While the absence of definition may be seen in a positive light as enabling the judiciary (in whose hands relevant decisions often have to be taken) to be creative and flexible in its interpretation of the principle over time, it may also be criticised as indeterminate and subjective. There may also be those who see the right of the prospective adults to procreate as taking precedence to the interests of a hypothetical future child. In addition, there are no reliable criteria for adequate parenting and, thus, no criteria which can be used to guarantee the best interests of the child. (Harris 1990) If we cannot reach a consensus on minimum parental capabilities, how can we exclude potential candidates for parenthood? (Lafollette 1980). It is significant that often where judgments or recommendations are made for the sake of the child, it is difficult to support these by factual evidence. In fact, we may be ‘surreptitiously making moral judgments’. (Warnock 1987)

Another difficulty relates to the weight to be given to children’s welfare. In relation to child placement and custody issues it is common in most jurisdictions to include in relevant legislation a statement that the welfare or best interests of the child are to be the *paramount* consideration. This is understood to mean that ‘children’s welfare trumps and outweighs all other considerations; no other interests or values may affect the decision; children’s interests are the only ones that count.’ (Reece) In some jurisdictions the child’s welfare is to be the ‘*first* or *primary* consideration’, or alternatively ‘a factor to be taken in to account’. The weight to be accorded to welfare (however it is defined) in this context obviously depends upon the legislative language used.

The welfare principle:

The welfare principle enjoys almost universal endorsement and has been described as the 'cornerstone' of current family law. There is however a distinction to be drawn in language here too, between 'welfare' and 'best interests'. A traditional interpretation of 'welfare', which has found favour in Irish courts for some time, would take into account parental rights in the context of the child's welfare. A more progressive view of 'best interests' would focus on the rights of the child and reflect notions of autonomy and respect for the child's wishes. The UN Convention on the Rights of the Child places a 'best interests' standard at the heart of international children's rights law and puts the child at the centre of the process of informing state action in all areas related to children. It provides in Art. 3(1): 'In all actions concerning children, whether undertaken by public or private social welfare institutions, courts of law, administrative authorities or legislative bodies, the best interests of the child shall be a primary consideration.' It is noteworthy that the best interests of children are only 'a' primary consideration and not 'the' primary consideration, thus providing for other concerns to be accorded equal, or even greater, weight. (Daniels et al 2000)

Problems exist in applying the paramountcy principle in that 'while everybody agrees that children's welfare should be paramount, nobody knows what children's welfare demands.' (Cretney 1992) It has been argued that 'deciding what is best for a child poses a question no less ultimate than the purposes and values of life itself' (Mnookin 1975). The absence of certainty over what is a good childhood contributes to the ultimate uncertainty of a decision in relation to child custody. It also leads to criticism as to the subjectivity of the judicial decision based on the judges' social background and personal prejudices. (Reece) 'What is or is not in children's interests depends largely on who is asked the question.' (Bainham 1998) In an Australian case in 1992 Brennan J. said 'it must be remembered that, in the absence of legal rules or a hierarchy of values, the best interests approach depends upon the value system of the decision-maker. Absent any rule or guideline, that approach simply creates an unexaminable discretion in the repository of the power...' (*Secretary, Dept. of Health and Community Services v JWB and SMB* FLC 92-3 at 79)

In defence of the paramountcy of the welfare principle it may be argued that children are necessarily vulnerable and dependant, and therefore must be protected from harm, that childhood has a huge psychological importance for the future adult, and that whatever love and security children are given will become part of a future society of strong and independent adults. Brewaeys argues that the paramountcy principle is a positive evolution. The child has no voice in its parents' decision to procreate and its welfare is directly dependent on the quality of the parental care. Its own development history will influence further generations. The inequality between parents and children implies an ethical obligation, for whatever adult party involved, to look carefully at the possible impact of the decision on the future development of the child.

However, there is also possibly a danger in the use of the term 'child' in this context as this expression 'conjures up an image of early years and, with that image, goes vulnerability. Vulnerability leads many people to think in terms of what protective measures need to be put in place to minimise that particular vulnerability.' (Daniels 1999) Children only remain children for a limited period of time and, as adults, may have strong objections to others making decisions on their behalf. For example, couples who sought donor insemination were traditionally advised not to inform their children of the method of their conception, in order to ensure that the child 'fit' in to the family and not be the subject of any negative attention.

However, some of those adults conceived in this way object very strongly to this policy and the fact that decisions were made for them, albeit supposedly in their 'best interests'. Caution should therefore be exercised in legislating or formulating policy to 'protect' children, when such policies may later become a source of vulnerability for them. (Daniels 1999)

Welfare and assisted reproduction:

The lack of a consensus view on what children's welfare demands or of adequate scientific information about what ensures healthy psychological development enables those who take the decisions to impose their own subjective views. (Cretney and Mason 1990) In the specific context of AHR, it may be considered that the 'welfare' test is too artificial to be workable in the context of an unborn child. 'How much *more* speculative and subjective must an assessment be of a *potential*, not actual, child's welfare, when there may well be no evidence on which to assess the *potential* parents' skills in child care and development.' (Douglas)

There are concerns expressed here about laboratory manipulation of embryos, splitting genetic and gestational parenthood, pre-implantation screening and the risks of physical or psychological injury to children born from these techniques. Questions are raised about the impact on children of several sets of genetic and social parents, some of whom the child will never know, which arise in relation to gamete donors and surrogate mothers. A wider concern is expressed in relation to the contribution made by AHR to the breakdown of the traditional nuclear family, although AHR is also a means of building such families. (Robertson 1994)

Concerns about the welfare of offspring are serious and important. 'Genetic and biological ties are so central to our notions of individual identity and family that the possibility of adverse effects from deliberate separation of these elements must be taken seriously. Indeed, participants in these endeavours are often nervously aware that they are engaged in an enterprise for which the psychological, social, and legal rules have not yet been written.' (Robertson 1994).

There are a number of different ways of evaluating welfare here. Firstly we may use the maximum welfare principle, which implies that one should not knowingly and intentionally bring a child into the world in less than ideal circumstances. Research shows that children need a stable home with mature caring adults who themselves have a sound relationship. Of course it is also important to remember that fertile couples often have children in less than ideal circumstances, and it is not possible or even desirable to try to 'control' natural means. However, when technology is used in an attempt to conceive a child, ethical considerations come into play, as we now have a means by which to control conception in order to maximise the child's welfare.

The difficulty with the use of this principle is that every characteristic of those who request medical assistance that does not conform to the 'heterosexual married parents with their genetically related children' pattern is assumed to result in negative consequences for the child. (Golombok 1998). The comparison underlying the moral assessment of the child's welfare is that the expected happiness of the child would have been greater if it had been born in ideal circumstances. (Pennings 1999). However, this comparison is strictly speaking impossible since the same child could not have been born in other settings, to other parents and at a different time. If we apply this standard, we are comparing the quality of life of different children born in different settings, which, if applied consistently, would exclude the overwhelming majority of the population from procreation. 'People who are poor,

unemployed, handicapped, obese, workaholics and/or old should all be rejected as potential parents since the child they will have would have had a better life had it been born to other parents. (Pennings). It would mean that all prospective parents should consider all possible circumstances which might contribute to the welfare of their child during the whole period of their reproductive lifespan in order to try and figure out at what time and in which circumstances (such as timing, reproductive partner, economic situation and so on) procreation would result in the child with the highest possible welfare. This unrealistic undertaking would exclude many of us from procreation and would severely impinge upon autonomy.

The second measure of evaluation of welfare could be referred to as the minimum threshold principle. As we are unable to discover adequate criteria of what it means to be a good parent, we simply set a minimum threshold below which prospective parents must not fall in order to be given access to reproductive technologies. It is likely that a reasonable consensus could be reached on which circumstances would be considered unacceptable, such as previous criminal convictions for child abuse, serious mental illness, drug abuse and severe marital strife. This standard takes the view that child should not be brought into the world only if it would have been better for that child never to have been born. (Robertson 1994). The UK and Irish courts would be unlikely to ever countenance the notion that it might be worse to be alive than never to have been born, and on that basis all AHR would have to be allowed. This accords maximal priority to procreational autonomy, and may be unconvincing in the context of the importance of the welfare of the child.

A middle ground between these two alternatives may be considered: the reasonable welfare principle, which does not aim to ensure that the child is perfectly happy, but is reasonably happy. Given that no parents are perfect and no one is completely happy, we do not generally criticise parents for making decisions that might negatively impact upon their children, such as moving house, changing schools, working outside the home and so on. We only criticise parents when the pursuit of their own goals has disastrous consequences for their children. So this test would apply to render AHR acceptable when the child conceived as a result of treatment will have a reasonably happy life. What we mean by reasonably happy is difficult to define, but would be taken to include having a normal range of opportunities, and the abilities to realise goals which in general make human lives happy. (Pennings). So, for example, if it was shown by research that children born to single women by DI were seriously disadvantaged in their ability to form relationships, or that children born to lesbian couples had difficulties in relation to gender or sexuality, this may constitute a good reason to deny access to those groups. (None of these disadvantages has been evidenced by research to date). Similarly with regard to access by DI offspring to the identity of their genetic parents, if the lack of this information leads to disruption of a reasonably happy life, then it may be sufficient reason to prohibit anonymous donation.

The true determining factors for the child's well-being (strong desire for parenthood, warm and supportive relationships etc.) do not coincide with and are not (mainly) determined by the sexual orientation, the number of parents or the genetic relatedness. (Golombok 1998). If we have the welfare of the child in mind, we ought to select on those characteristics and conditions which have a proven influence on the well-being and happiness of children, and not on ideologically or religiously based features. (Pennings)

The interests of children/offspring born through AHR may be seen in four categories: psychosocial, medical, material and legal. 'Psychosocial interests are manifested as the need

of each individual to develop a sense of identity in combination with other prerequisites for personal security and stability. The quest for identity is the process by which offspring become aware of who and what they are and where they “belong” both socially and culturally.’ (Daniels et al. 2000) This ‘need’ for identity may or may not become a ‘right’ depending on whether it becomes enforceable.

In relation to medical interests, AHR offspring’s interests can be seen in terms of ‘being the product of effective and safe medical procedures’ (Daniels et al 2000), and a need to be exposed to no greater quantum of risk than other offspring. Material interests are no different for AHR offspring than any others in terms of food, clothing, shelter and education. Their legal interests lie in defining parental responsibilities, succession rights, and other status provisions.

The combination of these rights is a concept referred to as ‘looking after their welfare’, described generically as claims on behalf of all children to develop in a normal and healthy manner, the right to protection from abuse and inadequate care, and the right to social justice. (Freeman 1996). Judge (later Governor-General) Sir Michael Hardie-Boys of New Zealand, (often quoted during the parliamentary debates in the UK at the time of passing of the HFE Act) described children’s welfare as follows:

‘Welfare is an all encompassing word. It includes material welfare, both in the sense of adequacy of resources to provide a pleasant home and comfortable standards of living and in the sense of adequacy of care to ensure that good health and due personal pride are maintained. However, while material considerations have their place, they are secondary matters. More important are the stability and security, the loving and understanding, care and guidance, the warm compassionate relationships, that are essential for the full development of the child’s own character, personality and talents.’ (Hardie-Boys 1981)

The UK model:

The Warnock Report in the UK (1984), which was set up to examine the implications of developments in AHR, addressed the issue of scarcity of resources and felt that some individuals seeking treatment would have a more compelling case than others. In such circumstances ‘medical practitioners will, clearly, use their clinical judgement as to the priority of the individual case bearing in mind such considerations as the patient’s age, the duration of infertility and the likelihood that treatment will be successful.’ As regards the question of eligibility for treatment the Report recommended that hard and fast rules should not be applied, but recognised that this would place ‘a heavy burden of responsibility on the individual consultant who must make social judgments that go beyond the purely medical.’

In furtherance of this recommendation the HFE Act 1990 obliges clinics ‘to take account of the welfare of any child who may be born as a result of the treatment (including the need of that child for a father) and of any other child who may be affected by the birth’ (s.13(5)). This has been criticised as extremely vague and at the risk of becoming meaningless (Brewaeys). Although it may be of symbolic value in reminding us that children must be protected from harm, what does it precisely mean to say that ‘account has been taken’ of the future child’s welfare? Which criteria must be used to prove parental fitness? Who will take that into account? What if there is disagreement between the parties involved about the best interest of the child? How should we balance the interests of prospective parents and children-to-be? What sorts of families should we encourage and assist? Under which

circumstances is it appropriate to deny someone access to AHR? It has been argued that the compromise encompassed within section 13(5) 'does not so much reflect a well-considered concern for the best interests of the offspring, but rather advances a negative view of lesbian and single-mother lifestyles.' (Blyth 1995)

The Code of Practice of the HFEA has further developed the statutory obligation by specifying the importance certain factors in the provision of a stable and supportive environment for the child. Where people seek licensed treatment, centres should bear in mind the following factors:

- a. their commitment to having and bringing up a child or children;
- b. their ability to provide a stable and supportive environment for any child produced as a result of treatment;
- c. their medical histories and the medical histories of their families;
- d. their health and consequent future ability to look after or provide for a child's needs;
- e. their ages and likely future ability to look after or provide for a child's needs;
- f. their ability to meet the needs of any child or children who may be born as a result of treatment, including the implications of any possible multiple births;
- g. any risk of harm to the child or children who may be born, including the risk of inherited disorders or transmissible diseases, problems during pregnancy and of neglect or abuse; and
- h. the effect of a new baby or babies upon any existing child of the family.

Where people seek treatment using donated gametes, centres should also take into account:

- a. a child's potential need to know about their origins and whether or not the prospective parents are prepared for the questions which may arise while the child is growing up;
- b. the possible attitudes of other members of the family towards the child, and towards their status in the family;
- c. the implications for the welfare of the child if the person providing the gametes for donation is personally known within the child's family and social circle; and any possibility known to the centre of a dispute about the legal fatherhood of the child.

Further factors require consideration where the child will have no legal father, in which case the centre should consider the prospective mother's ability to meet the child's needs, and whether there is anyone else within the mother's family and social circle willing and able to share the responsibility for meeting those needs and for bringing up and caring for the child. In circumstances where it is intended that the child will not be brought up by the carrying mother, centres should bear in mind the provisions with regard to legal parentage, and should consider whether there is any risk of disruption to the child's early care and upbringing if any dispute arises between the parties involved in the conception of the child, and the effect of the arrangement on any child of the commissioning parents' or carrying mother's family. This section in the Act is the first time in the UK that doctors have been directed by statute to consider a prospective patient's fitness to care for a child when deciding whether to offer treatment. 'It therefore overtly requires a social judgement to be made in which would otherwise be assumed to be a medical decision. By so doing, it begins to open up to scrutiny the fact that values and prejudices may colour clinicians' choices of whom to treat and how to treat.' (Douglas) It may be seen as having two elements: firstly, what is the justification for treatment? This may be because a woman or her partner is infertile or is at risk of passing on a defective gene to the child, or to relieve childlessness brought about by lifestyle choice. The clinician's view of the justification for treatment may be coloured by whether the person seeking treatment is 'infertile' (e.g. through premature menopause at age 30) or 'childless'

(e.g. having concentrated on her career and then reached menopause at 45). Whether this is acceptable or not depends, perhaps, upon whether we believe that AHR is a clinical treatment for infertility, or an alternative method of building families for childless couples or individuals.

The second element is to consider whether the person is qualified to receive treatment. This could be done by operating a checklist of factors considered appropriate, such as age, sexuality, marital status; or it could be done by relating qualification to the likelihood of the patient's parenting being such as to safeguard or jeopardise the child's welfare. (Douglas). It has been suggested that this provision in the UK legislation enables centres to justify turning away those whom they would have turned away anyway, but under the guise of concern for the prospective child's welfare. 'Provided a couple appear 'normal', they will be subject to no real scrutiny, and thus their privacy and their autonomy are respected. (Douglas) It may be argued that this in effect provides legislative sanction for what amounts to discrimination.

There is a vast difference between deciding not to treat a person after having investigated their circumstances and concluding that the child would be at risk of harm, and ruling out a group of people on the basis of a subjective view of 'normality'. The latter is based on social acceptability or stereotypical views of appropriate family life, and would be contrary to equality legislation in many jurisdictions. In the Glover Report on Reproductive Technologies to the European Commission (1989) it was said that 'no doubt people should be discouraged from taking high risks of major family disasters. And it goes without saying that new forms of family life must only be tried voluntarily. But, subject to these qualifications, we prefer a society predisposed in favour of 'experiments in living' to one in which they are stifled. We may find that *not* all happy families are alike.'

Centres in the UK have expressed concern about their ability to gather the information required to reach an equitable judgement of 'risk' in this context (Lieberman 1994), and Baroness Warnock has also noted that it may involve 'guessing about the good of the child' (Warnock 1996). This lack of a collective approach and a common standard detracts from the effectiveness of the welfare of the child test (Blyth). Although the statutory test was designed to ensure that treatment services are withheld where there is thought to be risk of harm to the child, in practice, provisions made for the welfare of the child may be ineffective and permit less legitimate and discriminatory activities, such as the exclusion of certain social groups. (Blyth)

Quality of parenting:

From a psychological perspective, the quality of children's relationships with their parents, and particularly how securely attached they are to their parents, is considered to be central to their emotional well-being throughout childhood and into adult life. (Golombok) Studies of difference in children's attachments have shown that the involvement of a person (usually but not necessarily a parent) who is warm and responsive to the child, and who is sensitive to the child's needs, is associated with the development of a secure attachment relationship. From this perspective it is parental responsiveness rather than biological relatedness that is considered to be important for the development of secure attachment relationships. This is also demonstrated by the lack of difference between adopted and non-adopted infants in relation to those securely attached to their mother. Another aspect of parent-child relationships that has been shown to shape children's development is parental style, with an authoritative style combining warmth and discipline, having the most positive outcome in

terms of helping children to develop self-reliance, social responsibility and co-operation. Another important feature is the quality of the relationship between the parents themselves as exposure to marital conflict and hostility can lead to psychological problems for children.

In considering the welfare of children born through AHR, one of the important concerns is the danger that children will be reared by a person who is not their genetic mother or father, and that they may never know who their 'true' father or mother is. There is a fear that the unrelated parent may subtly reject the child, leading to the child experiencing a sense of abandonment by the parent. However, research on children conceived by ovum or sperm donation shows not only that these children are functioning well (bearing in mind that the average age of the children studied was 6 years), but also that they have better relationships with their parents than children who have been naturally conceived. (Golombok). This suggests that a strong desire for parenthood seems to be more important than genetic relatedness for fostering positive family relationships, and that conception by gamete donation does not appear to have an adverse effect on the socio-economic development of the child.

Another related concern here is the suggested association between secrecy regarding genetic parentage and negative outcomes for children. This suggestion is based on adoption research and family therapy literature. It has been demonstrated that adopted children benefit from knowledge about their biological parents, and that children who are not given such information may become confused about their identity and at risk for emotional problems. Secrets are believed to be detrimental to family functioning because they create boundaries between those who know and those who do not, and cause anxiety when topics related to the secret are discussed. Children who discover the secret later in life are sometimes angry at their parents for having kept it secret, and may be frustrated at not being able to obtain more information about their missing donor father. But they typically do not feel rejected or abandoned as adopted children often do, and many express gratitude for the gift that made their existence possible. The negative outcomes that may pertain in this situation may be overcome by a policy of discouraging secrecy and encouraging families to be open with children regarding the method of their conception.

The welfare of children born through IVF has been studied by one of the leading research centres in this field (Family and Child Psychology Research Centre, City University, London). In its most recent findings some differences were found between families who had undergone IVF and those whose children had been naturally conceived. However, these differences were also found in relation to families with adopted children, suggesting that the experience of infertility, rather than the lack of a genetic relationship between mother and child, is associated with differences in parent-child relationships. These differences were both negative and positive. The children themselves did not differ according to family type for any assessments of socioemotional functioning. The study concludes that conceiving a child by IVF does not have a deleterious effect on parenting or on the psychological development of the child. On the contrary, families with a child conceived by IVF obtained significantly higher ratings than families with a naturally conceived child on measures of mother's warmth to the child, mother's emotional involvement with the child, mother-child interaction and father-child interaction. In line with these findings, mothers and fathers of naturally conceived children reported significantly higher levels of stress associated with parenting. (Golombok, McCallum and Goodman 2001)

Other studies carried out by the same research centre focussed on families who were recipients of ovum donation, and families who had a child through surrogacy. In the most recent study carried out while the children were less than one year old, these families were compared with families with a naturally conceived child in relation to measures of expressed warmth, mother-and father –child interaction, emotional involvement and sensitive responding. The results were positive with both surrogacy and ovum donation mothers showing significantly higher expressed warmth towards their child, and significantly higher quality of mother-child interaction than the natural means mothers. The same was true of father-child interaction and emotional involvement of mothers with their children. Assessments of the child's temperament were made and no differences were found between the three family types rated on fussiness of mood, adaptability to new situations, general activity and predictability of reaction. The study concluded that the surrogacy families seem to be characterised by warm relationships and good parent-child interaction, reflecting exceptionally high quality parenting 'which may be due to the strong desire of these couples to have a child and the effort they have put into trying to conceive....There is no evidence so far to support the concerns that have been voiced about the practice of surrogacy.' (McCallum 2002)

In relation to single parenthood, whether children born in such circumstances do less well than those from two-parent homes seems to depend on their financial situation and the extent to which their mother has an active network of family and friends to offer social support. From the evidence that exists so far, family circumstances rather than single parenthood per se, appears to be the best predictor of outcomes for children in solo mother homes.

In relation to lesbian parenthood there are concerns that the children will be teased and bullied in school, and that boys will be less masculine, and girls less feminine than their peers from heterosexual homes. There is also concern that they will be confused about their own sexuality. Studies have shown that no differences between children of lesbian and single heterosexual mothers have been identified for emotional well-being, quality of friendships or self-esteem of the children. Sons and daughters of lesbian mothers are no different from sons and daughters of heterosexual mothers in terms of their masculinity or femininity. Lesbian mothers are just as warm and responsive to their children and just as nurturing and confident as heterosexual mothers. Another significant factor to emerge from the studies is that co-mothers in two-parent lesbian families are more involved with their children than are fathers in two-parent heterosexual families.

Irish law:

In the Irish legal context the importance of the welfare principle runs through all of family law. In relation to proceedings under the Guardianship of Infants Act 1964 the court is obliged by Section 3 of that Act to regard the child's welfare as the 'first and paramount consideration' in the resolution of the dispute. However 'the strengthening of parental authority and emphasis on parental rights has given rise to the suggestion that s.3 of the 1964 Act may be unconstitutional in so far as the section requires the courts to regard a legitimate child's welfare as the first and paramount consideration in the determination of custody disputes between parents and third parties. In the main, where there is a clash between the rights of parents and the rights of the child in such cases, it is the parental right that has been accorded a constitutional superiority.' (Shatter 1997). In relation to adoption applications coming before the High Court, the court is obliged under Section 2 of the Adoption Act 1974 to give priority to the welfare of the child. Welfare in relation to an infant is said to comprise its 'religious and moral, intellectual, physical and social welfare'. (S.2 of the 1964 Act, as

substituted by s. 9 of the Status of Children Act 1987). To this has been added 'emotional welfare', by McGuinness J. in *DFO'S v CA* (1999).

There are three aspects of this principle to have been given consideration thus far by Irish courts: the 'blood-link', bonding, and the risk of harm to the child. In *G v An Bord Uchtala* [1980] IR 32, Kenny J. took the view that 'the blood link between the (mother) and her child means that an instinctive understanding will exist between them which will not be there if the child remains with the (prospective adopters)'. Parke J. in the same case said: 'The emotional and physical bonds between a woman and her child which she has borne give to her rights which spring from the law of nature'...and 'a child's parent is the best person to bring it up as the affinity between them leads to a love which cannot exist between adoptive parents and child.' In *PM and GM v An Bord Uchtala* (unrep. 27 Nov. 1984) Finlay P. could not find evidence on the facts of that case to support the importance of the blood-link as a feature in the future welfare of the relevant child. However, in *RC and PC v An Bord Uchtala and St Louise's Adoption Society* (Unrep. 8 Feb. 1985) O'Hanlon J. felt this principle was important and stressed that 'a baby and growing child would always be better off with its natural mother if she is a devoted and concerned parent and can provide in a reasonable manner for the physical as well as the emotional needs of the child.'

These views are typically representative of a legal presumption derived from the Constitution, that, the welfare of a child will be best assured by it being reared by its mother, i.e., that the parental right to custody is itself the best guarantor of child welfare. (O'Halloran 1992)

In relation to 'bonding', the courts have placed much importance on the length of time spent in the environment of the would-be adopters. In *NB and TB v An Bord Uchtala* (unrep. 18 Feb. 1983) the court refused a request to remove a child from prospective adopters on the basis that disruption of the child's routine could lead in the long-term to behavioural problems for the child, possible delinquency, and inability to form lasting personal relationships. Similar judgements have been made in other cases such as *MO'S v MO'S* (Kenny J. unrep. April 1970): 'The main psychological need for children if they are to become happy citizens is a feeling of security, a conviction that people care for them and about them and a feeling of continuity.'

The risk of harm to the child concentrates on physical injury/ neglect from an irresponsible parent, or the psychological harm from being uprooted from its family environment. The case law in the UK concentrates on issues around stability, material prospects, education, happiness and other benefits. The judiciary has tended to take increasing notice of the work of psychiatrists and psychologists as demonstrated in *Re L (An infant)* (1962) 106 Sol Jo 611 where the court took into account the psychological harm that could follow if a child was to be removed from its adoptive home. The concept of a 'psychological parent' has gained approval in many cases of this nature. This concept is defined as follows: '...whether any adult becomes the psychological parent of a child is based on day-to-day interaction, companionship, and shared experiences. The role can be filled by a biological parent or by an adoptive parent or by any other caring adult...but never by an absent, inactive adult, whatever his/her biological or legal relationship to the child may be.' (Goldstein et. al)

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Appendix VIII

Anonymity in Assisted Human Reproduction

Anonymity in Assisted Human Reproduction

1. The use of donor gametes in assisted reproduction raises a fundamental difficulty in relation to the subsequent identification of the donor. While secrecy used to be strongly advocated in such situations in the past, there is now a growing acknowledgement of the interests and rights of the child born through these techniques. It is argued that the child has a right to be told of the circumstances of its conception, and the identity of its genetic father/mother.
2. Separation from genetic parents in the context of adoption has been shown to cause, for some adoptees, identity confusion and other psychological disturbances. This problem has been termed “genealogical bewilderment”.¹ Although the issues are not identical for those born through assisted reproduction, there are sufficient similarities to cause concern. One fear is that the parents themselves will not tell the child of the circumstances of its conception² but will have told other family members or friends at that time.³ Such secrecy may exacerbate disharmony rather than promote family relationships,⁴ as the child overhears partial allusions to his conception and hears half-truths and evasions from his parents in reply.⁵ However, this has not always been supported by studies done of DI families which demonstrate that the problem and reaction varies among families.⁶
3. Apart from the psychological need to trace one’s roots to establish a sense of identity, there may also be a need to discover one’s genetic health for medical reasons. One may be able to preserve one’s health by altering behaviour to prevent problems such as heart disease, alcoholism or breast cancer if one has knowledge of a genetic predisposition in the family.⁷ Not only is it helpful in diagnosing medical problems to know of family

¹ See further, Sants “Genealogical Bewilderment in Children with Substitute Parents” (1964) 37 *Brit.J. of Med. Psychology* 133; Hanley “A reasonable Approach to the Adoptee’s Sealed Records Dilemma” (1975) *Ohio Northern L. Rev.* 542

² Studies done in the UK show that more than 70% of couples do not tell their children of their true biological origins. Kovacs, Mushin, Kane and Baker “A Controlled study of the Psychosocial Development of children conceived with donor semen” (1993) 8 *Human Reproduction* 788-790; Lui, Weaver, Robinson, Debano, Neiland, Killick and Hay, “A Survey of Semen Donor attitudes” (1994) *Human Reproduction*

³ Haimes E. “Secrecy: What can Artificial Reproduction learn from Adoption?” (1988) 2 *Int. J. of Law and the Family* 46-61. Haimes cites unpublished work which discloses a large number of couples counselled for DI who proposed not to tell their children, but intended telling or had told others in the family.

⁴ Baron and Pannor, *Lethal Secrets: The Shocking Consequences and Unsolved Problems of Artificial Insemination*, (New York, Warner Books 1989) at 52

⁵ “The young child’s partial overhearing of mysterious allusions, and his sense of parental lies, half-truths and evasions may incur confusion, suspicion and anxiety for which he needs his parents’ help – instead he feels cut off from them by a conspiracy of silence.” Holland “Adoption and Artificial Insemination: Some Social Implications” (1971) 50 (4) *Soundings* 302 at 305

⁶ The divorce rate among DI couples appears to be lower than non-DI couples of similar ages. Studies show that the vast majority of those who have undergone DI are pleased to have done so. See Amuzu, Laxova and Shapiro “Pregnancy Outcome, Health of Children and Family Adjustment after DI” (1990) 75 *Obstetrics & Gynaecology* 899 at 904.

⁷ Swanson “Donor Anonymity in artificial insemination: is it still necessary?” [1993] 27 *Columbia J. of Law and Social Problems* 151 at 174

history, but certain hereditary diseases such as haemophilia or Huntington's disease, must be of concern to persons planning to have children of their own.⁸

4. The main reason generally given for the reluctance to give identifying information to DI children is the belief that the supply of sperm donors would cease. It is also argued that the donor may have a strong interest in remaining anonymous and may not welcome a potentially traumatic disruption of his family life by the appearance of a child of whose existence he was unaware for eighteen years. He may not have a developed perception of the needs of the child and may simply see it as an unwanted intrusion.⁹ He may fear the imposition of legal responsibility on him for the maintenance of the child. However, this may also depend on social or cultural factors as studies in Australia and New Zealand show greater receptiveness than most European jurisdictions to the giving of identifying information to the child.¹⁰ The surveys suggest that most donors have serious misgivings about their legal responsibility for DI offspring that might cause them to stop donating if their identities were revealed without legal protection. Even in the absence of such legal risks, anonymity remains important to some donors due to the risk that a DI offspring would appear in their later lives. But these reservations might be minimised if social and professional attitudes about DI changed overall.¹¹
5. In most countries in which DI is available, access to identifying information is prohibited or at least restricted. However, some jurisdictions, most notably Sweden, have legislated for the child's right to access the identity of biological parents. Although the supply of sperm donors initially fell after the change in the law in 1984, the number of donors

⁸ O'Donovan "A right to know one's parentage" (1988) 2 *Int'l J. of Law and the Family* 27-45 at 30.

O'Donovan argues that if access to genetic and identifying information is regarded as an important interest in the case of those who have been adopted, then there is no legitimate distinction which may be drawn between those children and children born as a result of reproductive technology. She also points to the inconsistency in the position of the medical profession who, on the one hand encourage a person to be aware of his/her medical history but, on the other hand, make no attempt to record it in the case of adopted children or those born through donor insemination.

⁹ Some studies however show the contrary, that is, that the donor *does* have an interest in his potential children. In a study in New Zealand, 80% of donors wanted to know if children were conceived. See Purdie, Peek, Irwin, Ellis, Graham & Fisher, "Identifiable Semen Donors - Attitudes of Donors and Recipient Couples" (1992) *New Zealand Med. J.* 27-28. This is similar to previous studies in Australia, New Zealand and USA. See Kovacs, Clayton, McGowan "The Attitudes of Semen Donors" (1983) 2 *Clin. Reprod. Fertil.* 73-5; Rowland, "Attitudes and Opinions of Donors on an Artificial Insemination by Donor (AID) Programme" (1983) 2 *Clin. Reprod. Fertil.* 249-59; Daniels, "Semen Donors in New Zealand: Their Characteristics and Attitudes" (1987) 5 *Clin. Reprod. Fertil.* 177-90; Daniels, "Semen Donors: their motivations and attitudes to their offspring" (1989) 7 *J. Reprod. Infant Psychology* 121-7; Handelsman, Dunn, Conway, Boyland, Jansen, "Psychological and Attitudinal profiles in donors for artificial insemination" (1985) 43 *Fertil. Steril.* 95-101; Sauer, Gorrill, Zeffer, Bustillo, "Attitudinal survey of sperm donors to an artificial insemination clinic" (1989) 34 *J. Reprod. Med.* 362-4. Some of these studies show that many donors often think about their DI children. See Daniels *id.*, and Sauer *et. al.*, *id.*

¹⁰ In a New Zealand study in 1992, 53 couples embarking on DI replied to an anonymous questionnaire asking what they wanted to know about the donor should they become pregnant. 51% were definitely and 32% probably going to tell a child of its donor origins. Items most frequently listed for themselves and on behalf of a child were - interests/sports (57%), physical attributes (41%), occupation (37%) and family background (26%). 42% of the women and 28% of the men thought that the child should have access to the identity of the donor eventually. 38 donors were also surveyed - 68% were agreeable to their identity being available to a DI child on maturity. When a new category of identifiable donor was created, 20 of 36 (56%) new donors and donors still donating chose this option. Purdie *et. al.*, *ibid.* at 27

¹¹ Gibson E. "Artificial insemination by donor: information, communication and regulation" (1991-2) 30(1) *J. of Fam. Law* 1 at 32

returned to normal levels after a short period.¹² Current law in the UK provides that a person who knows that s/he has been born through AHR may apply to the licensing authority (HFEA) to access information regarding their genetic health and racial origin. S/he may also seek information as to whether an intended spouse may be genetically related to her/him.

6. With the introduction of the Human Rights Act 1998 in the UK, a number of cases were instigated challenging existing medical practices under the provisions of the ACT, which incorporates the European Convention on Human Rights. The law of human rights may be considered an obvious means through which a child could claim a right to information as to its parentage. Article 8 of the ECHR provides a right to respect for private and family life which, though it does not expressly refer to any aspects of the child's identity, might be said to be violated by denial of access to knowledge as to existence of family members.¹³ In *Rose and another v Secretary for Health, HFEA*¹⁴ an action was taken by two individuals who had been conceived through DI on grounds that denial of access to information relating to their biological fathers was in breach of Article 8. In his judgement, Scott Baker J. said that 'respect for private and family life requires that everyone should be able to establish details of their identity as individual human beings. This includes their origins and the opportunity to understand them. It also embraces their physical and social identity and psychological integrity.' The court held that Article 8 was engaged both in relation to identifying and non-identifying information. The decision as to whether the system in operation in the UK was in breach of the Human Rights Act would fall to be decided on another occasion.
7. Following a consultation process by the Department of Health in the UK, the government announced plans in January 2004 to change the law to enable children born as a result of sperm, eggs or embryos donated after April 2005 to access the identity of their donor when they reach the age of 18. The earliest 18 year olds will be able to do this will be in 2023.
8. At a European level the Commission and Court have been relatively flexible in their approach to the issue of whether the right to identify biological parents exists in the context of modern reproductive technology. The approach taken in the past has been criticised as being adult-centred rather than child-centred with a focus on a traditional perception of the child's best interests rather than the rights of the child.¹⁵ The approach to date also recognises that there is a wide margin of appreciation to be given to member states in determining the steps to be taken to comply with the ECHR while safeguarding the needs and interests of its own community.

¹² See further, Daniels "The Swedish Insemination Act and its Impact" (1994) 34(4) *Australian and New Zealand J. of Obst. & Gyn.* 437-9; Daniels and Lagos "The Swedish Insemination Act and the Availability of Donors" (1995) 10(7) *Human Reproduction* 1871-4 and Daniels, Ericsson and Burn "The views of semen donors regarding the Swedish Insemination Act 1984" (1998) 3 *Medical Law International* 117-134

¹³ Connolly "Problems of interpretation of Article 8 of the ECHR" (1986) 35 *ICLQ* 567-593)

¹⁴ [2002] EWHC 1593

¹⁵ Hale, *From the Test-tube to the Coffin: Choice and Regulation in Private Life* (1996) 29-41

The Disclosure of Information about the participants and children born as a result of AHR procedures.

Country	The donor is anonymous.	The disclosure of the identity of the donor/child born as a result of DI is based on consent.	The donor's identity is disclosed.
Austria			✓
France	✓		
New Zealand			✓
Norway	✓		
Quebec, Canada	✓		
Spain	✓		
Sweden			✓
Switzerland			✓
Southern Australia		✓	
United Kingdom	✓		
Victoria Australia			✓
Western Australia		✓	

Jurisdictions in which the donor is anonymous:

France: Law No. 94-653 of 29th July 1994, Article 16-8 provides no information may be divulged that enables that identification of a person who has donated an element or a product of his body or of the person who has received such an element or a product. The donor may not know the identity of the recipient, nor the recipient that of the donor. In the event of therapeutic necessity, only the physicians of the donor and recipient may have access to information enabling the identification of these persons¹⁶.

Norway: Law No. 56 of 5th August 1994, The Act relating to the application of biotechnology in medicine. Chapter 2, Section 2-7 provides "The medical staff are under an obligation to ensure that the sperm donor's identity is kept secret. The sperm donor shall not be given information concerning the identity of the couple or the child".

Quebec, Canada: Civil Code of Quebec, Book Two: The Family, Title Two: Filiation, Chapter 1: Filiation by blood, Section III: Medically Assisted procreation, Section 542 provides, "Nominative information relating to the medically assisted procreation of a child is confidential. However, where serious injury could be caused to the health of a person born of such procreation or of any of his descendants if he were deprived of the information he requires, the court may allow such information to be transmitted confidentially to the medical authorities concerned. A descendant of such a person may also avail himself of this right if the fact that he is deprived of the information he requires could be the cause of serious injury to his health or the health of any of his close relatives". However there is currently no comprehensive federal or provincial legislation governing human reproductive technologies and related research. In response to this at federal level draft legislation governing assisted human reproduction has been submitted to a Standing Committee on Health for review and further discussion¹⁷. The Standing Committee will issue their report on the legislation in January 2002. In discussions on the draft legislation the provinces and territories, with the exception of Quebec, have acknowledged the need for federal leadership in an area that is rooted in deeply held societal values and have also recognised the need for consistency and coherence across the country to discourage any form of "reproductive tourism"¹⁸. Section 21 (3) of the draft legislation provides that "health reporting information under the control of the Minister that was provided by a donor of human reproductive material, a person who has undergone an assisted reproduction procedure or a person who was conceived by means of such a procedure, shall be disclosed only with the written consent of the donor or that person". Section 21 (4) of the draft legislation provides the Minister may disclose health reporting information relating to a donor to a person undergoing an assisted reproduction procedure or to any person conceived by means of that procedure and to descendants of a person so conceived, but the identity of the donor shall not be disclosed without the donor's consent.

Spain: Law No. 35/1988 of 22nd November 1988 on assisted reproduction procedures. Chapter III **Section 5(1)** provides the donation of gametes and pre-embryos for the purposes

¹⁶ Englert (ed), *Gamete Donation: Current Ethics in the European Union*, Human Reproduction Vol. 13 Supplement 2 1998. Part III Current European Laws on gamete donation p. 105 at p. 110.

¹⁷ see www.hc-sc.gc.ca/english/, Health Canada website containing a copy of draft legislation as well as background reports and documents.

¹⁸ *ibid.* "Reproductive and Genetic Technologies" Feedback Report – Discussions and Written Comments on Proposed Federal RGTs legislation.

authorised by this Law shall form a gratuitous, formal and secret contract entered into between the donor and the authorised centre. Section 5(5) provides the donation shall be anonymous, the particulars of the identity of the donor being kept in strictest secrecy and in coded form in the corresponding bank and in the National Register of Donors. The resultant children shall have the right, either personally or through their legal representatives, to obtain general information concerning the donors, not including their identity. Recipients of gametes shall likewise have this right. Only in exceptional cases, in extraordinary circumstances that entail a verified danger to the life of the child, or under the law of criminal procedure, may the identity of the donor be disclosed; it shall be a condition that such disclosure is indispensable to avert a danger or to attain the legal objective referred to. Disclosure shall be limited in character and shall under no circumstances make public the identity of the donor¹⁹.

United Kingdom: Human Fertilisation and Embryology Act 1990. Section 33 of the Act provides no person who is or has been a member or employee of the Human Fertilisation and Embryology Authority (hereinafter the Authority) shall disclose any information contained in the register of information pursuant to section 31 of the Act. Similarly section 33 prohibits the disclosure of any other information obtained by any member or employee of the Authority on terms or in circumstances requiring it to be held in confidence. Section 33 (3) and (4) lay down the exceptions to the disclosure of information with regard to members or employees of the centre, the Register-general and non-identifying information. Section 35A amends the Data Protection Act 1984 and states “Personal data consisting of information showing that an identifiable individual was, or may have been, born in consequence of treatment services..are exempt from the subject access provisions except so far as their disclosure under those provisions is made in accordance with section 31 of the Act (the Authority’s register of information)”. Section 34 of the Act provides for the disclosure of information held by the Authority in the interests of justice in proceedings before a court to determine whether a person is a parent of the child as defined in sections 27 to 29 of the Act. The court can order the Authority to disclose whether or not any information relevant to the question is contained in the register and if it is to disclose what information is specified in the order. However such an order may not require the Authority to disclose any information in relation to the keeping or use of gametes of any identifiable individual or of any embryo taken from any identifiable woman as defined in section 31 (2)(b) of the Act. In considering an application for the release of information from the Authority the Court must be satisfied it is in the interests of justice taking into account any representations made by any individual who may be affected by the disclosure and the welfare of the child if under 18 years and of any other person under that age who may be affected by the disclosure. Under section 35 where proceedings are instituted under section 1 of the Congenital Disabilities (Civil Liability) Act 1976 and it is necessary to identify a person who would be a parent of the child but for section 27-29 of the Act the Court may make an order requiring the Authority to disclose any information contained on the register identifying that person.

Jurisdictions in which disclosure of information concerning the identity of the donor requires the consent of the participants in the procedure:

Southern Australia: Reproductive Technology Act 1988, Section 18 (1) provides a person must not disclose the identity of a donor of human reproductive material except in the administration of the act, in order to carry out an artificial fertilisation procedure or with the consent of the donor of the material. According to section 31 (2) of the Reproductive

¹⁹ op. cit. n. 1 at p. 127.

Technology (Code of Ethical Clinical Practice) Regulations 1995 a licensee must, on application by a person of or over the age of 16 years who was born in consequence of the use of donor reproductive material, give to the person a copy of all information (other than identifying information) relating to the donor or donors kept by the licensee. However where the licensee has reason to believe that if all or some of the information were disclosed there may be a reasonable likelihood of the donor's identity being readily ascertainable, the licensee must not disclose that information. Section 35 of the Regulations provide a licensee must ensure that the necessary steps are taken to ensure that any confidential information kept by the licensee is disclosed only as is authorised or required by the Act and must investigate and report any suspected disclosure of information in contravention of the act. Section 36 provides where an application is made to a licensee for access to information concerning the personal affairs of a person in relation to whom the licensee keeps a record and the person to whom the information relates has given his or her consent to disclosure, the licensee must give the applicant a copy of that information. However under Section 36 (2) a licensee must not disclose the identity of a donor of reproductive material to a person who was born in consequence of the use of the donor's reproductive material unless the person is of or over the age of 16 years. The Reproductive Technology (Code of Ethical Research Practice) Regulations 1995 provide in section 18 that consent by a person concerning disclosure of information concerning himself or herself must be given in writing and in a manner and form that complies with the Reproductive Technology (Consent Forms) Standard 1995 prepared by the Council. The consent will not be effective unless the person giving the consent has, before signing the consent form, received an information statement that complies with the Reproductive Technology (Information Statements) Standard 1995 prepared by the Council. The consent may be given subject to conditions, may be varied at any time by the signatories or may be revoked at any time by a signatory by notice in writing given to the licensee.

Western Australia: Human Reproductive Technology Act 1991. Section 46 (2) provides a person on payment of the prescribed fee, shall be entitled to be furnished with information in a register if the information supplied relates to that person in their capacity as a participant in an artificial fertilisation procedure. Section 46 (3) provides a person on payment of the prescribed fee may be furnished with information in a register if it does not identify but relates to a biological parent of that person or a child of which that person is a biological parent. Under Section 49 (1) a person is prohibited from divulging any information disclosed or obtained by reason of the Act respecting the identity of a donor of gametes, a participant in a procedure involving reproductive technology or a child born as a result of an artificial fertilisation procedure. However under section 49 (2)(d) the above information may be divulged or communicated "with the consent of each donor, participant or child in question or other person whose identity may be disclosed in so far as it does not identify any person who as a participant in the relevant procedure and who has not given such consent". The Human Reproductive Technology (Licences and Registers) Regulations 1993 do not clarify any further the provisions relating to consent and disclosure of information.

Jurisdictions in which the donor's identity is disclosed:

Austria: Federal Law 1992 (Serial No. 275) The Reproductive Medicine Law, Section 20 deals with access to information concerning third persons who provide sperm, and related matters²⁰.

²⁰ *ibid.* p. 106.

New Zealand: Status of Children Amendment Act 1987 sections 4-15 deal with the status of the child born as a result of assisted human reproduction. The act does not require that the donor be identifiable. However according to Daniels, Ericsson and Burn "most clinics will not now accept donors unless they are willing to be identified"²¹. New Zealand has been said to have taken an "educational rather than a legislative approach" on the issue of information sharing and DI and has fostered an environment of openness²². The report of the Privacy Commissioner to the Minister of Justice in relation to Part 3 of the Assisted Human Reproductive Bill also points out that for several years the providers of AHR services have for ethical and accreditation reasons declined to receive donations on an anonymous basis²³. The Human Reproduction Bill is currently being reviewed by a Standing Committee the report of which is to be published on November 30th 2001. Under the new bill the donors of gametes and recipients of AHR services will be made aware as a precondition to donation and receipt of services that information will be collected and retained so that the children born as a result of donated materials will have access to their genetic origins. Children born as a result of an AHR procedure are entitled to have access to identifying donor information held by the providers of the service and the Register-General upon turning 18 years. Donors will be entitled to find out if a donation has resulted in a birth, but will not have access to identifying information about a donor child until the child turns 25, unless the child expressly consents to donor access after turning 18 years. Donor children and donors will have access to non-identifying information about each other prior to the donor child's attaining the age of 18 years.

Sweden: The Swedish Insemination Law No. 1140/1984. Section 4 provides when a child is conceived through insemination and is sufficiently mature he shall be entitled to be apprised of the information on the sperm donor which is recorded in the hospital's special register. The Health and Welfare Committee shall be under a duty to assist the child in obtaining this information if the child so requests. Under the Regulations and General Recommendations No. 6 of 27th March 1987 of the National Board of Health and welfare on insemination section 2 the physician must inform the donor that the resultant child is entitled to learn who the donor is²⁴.

Switzerland: Article 119 of the Constitution of Switzerland, "Medical Assistance to Procreation and Gene Technology in the Human Field", provides in sub-section (g) "Every Person shall have access to the data concerning his or her ancestry"²⁵.

Victoria Australia: Infertility Treatment Act 1995.

(a) Application by parents for information contained on central register.

Under section 74 the parents of a person born as a result of a donor treatment procedure may apply to the "Authority" for information required to be recorded in the central register about a donor whose gametes were used during the procedure. This application for information which must be in writing may relate to non-identifying information and/or information which may identify the donor. According to section 75 (1) the Authority must provide the parents with non-identifying information if it is satisfied the parents have been offered counselling about the potential consequences of the disclosure of that information. Under section 75 (2)

²¹ Daniels, Ericsson and Burn, "The views of semen donors regarding the Swedish Insemination Act 1984", Medical Law International 1998, Vol. 3 p. 117 at p. 130.

²² *ibid.*

²³ see www.privacy.org.nz/people/assisted.html, provides a summary of the bill.

²⁴ *op. cit.* n. 1 at p. 131.

²⁵ see www.uni-wuerzburg.de/law/sz00000_.html

however the Authority can only release information that identifies the donor with the consent of the donor, if the information is given in accordance with any condition or limitations imposed by the donor, and if the Authority is satisfied that the applicant has received counselling about the potential consequences of the disclosure of that information from a counsellor approved under the act. The Authority make reasonable efforts to find the person whose consent is required and must advise that person that he or she may need counselling and provide him or her with the names of counsellors approved under the act. If a person has already consented to the disclosure of his or her identity before the information is given the Authority must make reasonable efforts to advise that person that the information is about to be given.

(b) Application by donor for information about persons born as a result of donor treatment procedure:

Under section 76 the donor can apply to the Authority for information required to be recorded in the central register about any person born as a result of a treatment procedure in which his or her donation was used in the procedure. The donor is entitled to request non-identifying information about the child born or about the parents of the child, and/or identifying information about the child born or about the parents of the child. According to section 77 and 78 the authority must provide the donor with non-identifying information concerning the child born and parents if it is satisfied that the applicant has been offered counselling about the potential consequences of the disclosure of information. In relation to information that would identify a child under 18 years both parents must consent, in the case of a person over 18 years the person themselves can consent, the information must be given in accordance with the conditions or limitations imposed by each person consenting and the Authority must be satisfied the applicant has received counselling by an approved counsellor. The Authority must make reasonable efforts to locate the person whose consent is required. The Authority must advise the person whose consent is required that he or she may need counselling and provide the person with a list of counsellors approved under the legislation. If a person consents to the giving of information, before the information is given the Authority must make reasonable efforts to advise that person that the information is about to be given.

(c) Application by a person born as a result of a donor treatment procedure or descendant for information about donor.

The child born as a result of a donor treatment or a descendant of such person may apply in writing for non-identifying information about the donor and/or identifying information about the donor. The Authority must give any such information on the central register that does not identify the donor if the Authority is satisfied that the applicant has been offered counselling about the potential consequences of the disclosure of that information. The Authority is authorised to release information identifying the donor if it is satisfied that the applicant has received counselling about the potential consequences of the disclosure of the information from a counsellor approved under the act. Prior to the release of information the authority is under an obligation to make reasonable efforts to advise the donor that the information is about to be given and to advise the donor that he or she may need counselling and provide the donor with the names of counsellors. Where the child requests identifying information about the donor the consent of the donor is not required under the act in contrast to (a) and (b) above. Under section 7 of the Infertility Treatment Regulations 1997

counselling required prior to donation under section 16 of the Act should include the requirements of the Act in relation to the disclosure of the identity of the donor to the Authority and to donor-conceived children if they seek that information.

Appendix IX
**Implications of the Equal Status Acts 2000-4 for Assisted Human
Reproduction**

Implications of the Equal Status Acts 2000-4 for Assisted Human Reproduction

Introduction

The Equal Status Acts 2000-4 prohibit, to varying degrees, direct and indirect discrimination on certain prescribed grounds in relation to, *inter alia*, the provision of services.

Grounds of discrimination

The prohibited grounds of discrimination are (ss.2 and 3):

- gender,
- marital status, (i.e. being single, married, separated, divorced or widowed)
- family status, (i.e. being pregnant or having responsibility as a parent or person *in loco parentis* for a person under the age of 18 or as a parent or primary carer for a person over that age with a disability who requires care or support on a continuing, regular or frequent basis)
- sexual orientation,
- religion, (which includes absence of religious belief)
- age, (*though treating a person who has not attained the age of 18 years less favourably or more favourably than another, whatever that other person's age, is not to be regarded as discrimination on this ground - s.3, sub-s.3*)
- disability,
- race, (including colour, nationality, national or ethnic origins),
- membership of the Travelling Community or
- victimisation (where one has taken or is otherwise involved in proceedings taken under the legislation).

"Disability" is defined in s.2 as

- "(a) the total or partial absence of a person's bodily or mental functions, including the absence of a part of a person's body,
- (b) the presence in the body of organisms causing, or likely to cause, chronic disease or illness,
- (c) the malfunction, malformation or disfigurement of a part of a person's body,
- (d) a condition or malfunction which results in a person learning differently from a person without the condition or malfunction, or
- (e) a condition, disease or illness which affects a person's thought processes, perception of reality, emotions or judgement or which results in disturbed behaviour."

Meaning of discrimination

According to s.3 (as amended by s.48 of the 2004 Act), discrimination on most of the grounds identified in the Act can arise in any of three different ways.

First, it can occur where, on any of the discriminatory grounds listed in the Act (including situations where a ground is incorrectly believed to be applicable or where a ground previously but no longer exists or where a ground may exist in the future), a person is treated less favourably than another person.

Second, it can occur when a person who is associated with another person is treated, by virtue of that association, less favourably than another person and where similar treatment of the other person with whom the first person is associated would constitute discrimination under the Act.

Third, it can arise where an apparently neutral provision puts a person who is able to invoke one of the nine substantive grounds of discrimination targeted by the Act at a particular disadvantage compared with other persons unless the provision is objectively justified by a legitimate aim and the means of achieving that aim are appropriate and necessary.

Specifically in relation to disability, the legislation additionally provides that discrimination includes a failure to do all that is reasonable to accommodate the needs of a person with a disability by providing special treatment or facilities if, without such treatment or facilities, it would be impossible or unduly difficult for the person to avail himself/herself of the service, accommodation, etc. – s.4. However s.4(2) absolves the service provider from this obligation where the cost of providing such special treatment is more than nominal. Sub-section 3 provides a further limit to the obligation by providing that a failure to provide such special treatment or facilities for a person with a disability shall not constitute discrimination if, by virtue of another provision of the proposed legislation, a refusal to provide the service in question to that person would not constitute discrimination. Sub-section 4 further provides that where a person has a disability that could cause harm to that person or to others, treating the person differently to the extent necessary to prevent such harm shall not constitute discrimination. In the present context, this last provision would presumably protect a service provider who refused to provide AHR services to a person with a disability where the disability was such that the person could cause harm to any child conceived as a result of the provision of AHR services. While the legislation does not define "harm", it presumably covers both physical and emotional harm.

Discrimination and the provision of services

Section 5 prohibits discrimination in the provision of goods or services to the public, whether provided for consideration or otherwise. Sub-section 1 provides:

"A person shall not discriminate in disposing of goods to the public generally or a section of the public or in providing a service, whether the disposal or provision is for consideration or otherwise and whether the service provided can be availed of only by a section of the public."

"Person" in this context includes "an organisation, public body or other entity" while "service" means "a service or facility of any nature which is available to the public generally or a section of the public" - s.2. Thus hospitals and clinics providing AHR services are clearly covered by the Act.

Section 5(2) of the Act provides for a number of derogations from the principle of equal treatment in relation to the provision of services, of which the following may have some, albeit perhaps limited, relevance in the present context:

1. differences in the treatment of persons on the gender ground where embarrassment or infringement of privacy can reasonably be expected to result from the presence of a person of another gender;
2. differences in the treatment of persons in a category of persons in respect of services that are provided for the purpose of promoting, for a bona fide purpose and in a bona fide manner, the special interests of persons in that category to the extent that the differences in treatment are reasonably necessary to promote those special interests;

3. differences, not otherwise specifically provided for, in the treatment of persons in respect of the disposal of goods, or the provision of a service, which can reasonably be regarded as goods or a service suitable only to the needs of certain persons.

In addition to these specific derogations from the principle of equal treatment in the context of the provision of services, regard should also be had to s.16(2)(a) which provides that treating a person differently does not constitute discrimination where the person is so treated solely in the exercise of a clinical judgment in connection with the diagnosis of illness or his or her medical treatment. In addition, s.14(b) permits preferential treatment or the taking of positive measures bona fide intended to a) promote equality of opportunity for persons who are, in relation to other persons, disadvantaged or who have been or are likely to be unable to avail themselves of the same opportunities as those other persons or b) cater for the special needs of persons who, because of their circumstances, may require facilities, arrangements, services or assistance not required by persons who do not have those special needs.

These appear to be the only relevant derogations from the principle of equal treatment in the provision of services in the present context. It is not clear whether any of these derogations would allow the providers of AHR services to differentiate on grounds of marital status, sexual orientation, age, family status, religious belief, race or membership of the Traveller Community. This would not appear to present any difficulties in relation to the last four grounds, though it may possibly raise a constitutional issue in relation to the first two grounds and a practical issue in relation to the third.

Taking that practical issue first, to the extent to which current practice discriminates against clients on the grounds of age, because they are too old, such a practice could only be defended on the ground that it is the exercise of a clinical judgment in connection with the medical treatment of the client. (By virtue of s.3, sub-s.3, less favourable treatment of persons under the age of 18 is not to be regarded as discrimination on the age ground.)

Turning to the possible constitutional issue, the question here is whether the Oireachtas can, through the Equal Status Acts 2000-4, require hospitals/clinics to provide AHR services without reference to the marital status of the clients or whether such provision would amount to a disregard of the State's constitutional duty, under Art.41.3.1, "to guard with special care the institution of Marriage, on which the Family is founded, and to protect it against attack."

It is important to note, as a preliminary point, that this constitutional duty is imposed only on the State so that if private bodies, such as hospitals or clinics, decide to offer AHR services to non-marital families, this would not appear to raise any constitutional difficulty. The issue here is whether *the State can oblige clinics to provide a service to non-marital families*, either as a result of the existing provisions of the Equal Status Acts 2000-4 or as part of any possible future legislation regulating AHR.

In order to establish the unconstitutionality of a legislative requirement that AHR services be provided to non-marital families, one would have to argue that such a provision amounted to the promotion of alternative social units to the marital family and that such promotion amounted to a failure by the State to guard with special care the institution of marriage, contrary to Art.41.3.1. While this argument is certainly stateable, it should be noted that in *MhicMhathúna v. Ireland* [1995] 1 IR 484; [1995] 1 ILRM 69 the Supreme Court held that the constitutional duty to protect the institution of Marriage does not preclude the State from offering preferential child-centred financial support to one-parent families, at least where

such support does not constitute an inducement not to marry. Thus any constitutional challenge may also have to establish that such a legislative requirement amounts to an inducement not to marry. It remains to be seen whether the courts would agree that a statutory requirement that AHR services be provided to non-marital families satisfied such a test so as to render the requirement unconstitutional.

Appendix X

Specific examples of potential applications of pluripotent stem cell research

Specific examples of potential applications of pluripotent stem cell research

- 1. Cancer:** Pluripotent stem cells may be used to treat the tissue toxicity brought on by cancer therapy. Because cancer cells have the ability to replicate and therefore resemble stem cells in this way, study of the molecular and cellular biology of stem cells may improve understanding of cancer cell resilience. Some cancers are resistant to chemotherapy; gene transfer may allow this resistance to be overcome.
- 2. Cardiovascular diseases:** Stem cells could potentially be used to repair the failing heart, to treat malformations in children, to repair vascular damage resulting from high blood pressure and atherosclerosis. Preliminary animal work indicates that healthy heart muscle cells, when transplanted into the heart repopulate heart tissue and work with the host cells. Similarly stem cells may be useful in repairing lung tissue following injury.
- 3. Diseases of the gastrointestinal tract and kidney:** Stem cells, differentiated into beta cells of the pancreas, could be used in the treatment of diabetes and eliminate the need for insulin treatment. Stem cells could potentially be used to replace diseased liver tissue. Similar treatments may apply to certain kidney disorders and a number of studies are in progress, which are investigating the possibility of growing bladder cells.
- 4. Diseases of the nervous system:** Loss of nerve cells is a feature of neurodegenerative disorders like Parkinson's Disease, Alzheimer's Disease, Huntington's Disease, amyotrophic lateral sclerosis and others. Similarly cell loss occurs with stroke, brain trauma and spinal cord injury several other disorders that affect adults and young children. Results from foetal tissue transplantation into humans as a treatment for Parkinson's Disease have been encouraging and results from animal experiments using animal models of several disorders, including Parkinson's Disease, have been very successful. Applications for stem cell therapy in stroke, spinal injury, multiple sclerosis, epilepsy, Tay-Sachs disease are possible. Several disorders in children arise as a result of the absence of a single enzyme; the possibility that stem cells may be used as a vector allowing replacement of the enzyme cannot be ruled out.
- 5. Allergy and Infectious Diseases:** Pluripotent stem cells could potentially replace transplantation and could be used in the treatment of autoimmune diseases, like multiple sclerosis and rheumatoid arthritis. Ultimately, human pluripotent stem cells might be used to create transplantable cells, tissues and even organs eliminating the problems associated with shortage of donors and rejection. Human pluripotent stem cells might be used in treatment of immunodeficiency disorders like HIV/AIDS.
- 6. Skin:** Human pluripotent stem cells could make a significant contribution to applied trauma and burn research, such as research devoted to the development of "artificial skin".
- 7. Birth defects:** Pluripotent stem cells could be used to replace organs or tissues that are defective as a consequence of birth defects. One example is biliary atresia which describes a defect in liver development; human embryonic stem cells could potentially be directed to form liver tissue or to replace the damaged organ and save the life of the affected infant.
- 8. Vision:** There are several degenerative disorders of the retina that could be potentially treated by stem cell therapy and results using animal models are promising. Other possible

applications include treatment of corneal ulcers, chemical or thermal injury, bullous keratopathy, and various cicatricial diseases. Transplantation with pluripotent stem cells could facilitate healing of the ocular surface, reducing inflammation, vascularization, and scarring.

9. Environmental Health: Human pluripotent stem cell research also offers a new research approach for assessing the effect of environmental toxins on cell function.

10. Musculoskeletal Diseases: Stem cells can be cultured to generate bone or cartilage cells and could potentially be used in diseases and degenerative conditions in which bone or cartilage cells are deficient in numbers or defective in function, for example osteogenesis imperfecta and chondrodysplasias. Stem cells could be introduced into a joint for treatment of osteoarthritis or into large gaps in bone that can arise from fractures or surgery.

11. Deafness: Stem cell research offers the potential of replacing hair cells in the inner ear that are often lost due to genetic, infectious, traumatic, or pharmacologic causes

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Appendix XI

European Science Foundation High Level Expert Group Recommendations on Human stem cell research

***European Science Foundation High Level Expert Group
Recommendations on Human stem cell research***

- 1.** It is essential to proceed with research on stem cells derived from embryos, foetal tissues and adults, in parallel. Indeed, a key question is to what extent the different types of stem cells in the human embryo, foetus and adult differ. For example, the ease with which they can be made to multiply in culture, their longevity in culture in the laboratory, the range and nature of the mature cell types they can be induced to make, and the molecular signals that bring about these changes.
- 2.** Research is also required to overcome the problem of immunological rejection of cells from donors who are not genetically identical with the recipient.
- 3.** European Science Foundation recognises the major ethical concerns that surround this area of research. It recommends that all work on human stem cells should be properly regulated. In many countries the scientific community is engaged pro-actively in ensuring regulation is put in place.
- 4.** There are major differences in the legislative framework between countries concerning human stem cell research. The European Science Foundation urges all European countries to introduce legislation and regulation to oversee and control the laboratories concerned, the scientists involved and the experiments that can be performed.
- 5.** When therapies from the study of human stem cells become available, patients from all countries will wish to use these results. The European Science Foundation recommends that, in developing their legislative framework for this type of research, European countries take this reality into consideration.
- 6.** Reproductive cloning, that is attempts to create a new human being by any means other than those involving fertilisation of an ovum by a sperm, is forbidden in most European countries. The European Science Foundation and its member organisations endorse this position from the ethical point of view.
- 7.** Therapeutic cloning, in which a nucleus from a somatic cell is transferred into an ovum from which the nucleus has been removed, has potential for therapy of serious and disabling diseases. For this reason, the European Science Foundation suggests that fundamental research involving this technique should be supported, but under strong regulatory control by national bodies.
- 8.** Some scientists wish to study chimaeric embryos, that is embryos created by the fusion of a nucleus from one mammalian species with an ovum from another species. The European Science Foundation suggests that research of this kind should be limited to non-human species when it can be ethically justified, as in the case of endangered species.
- 9.** Much of the research in this area is currently being done in the commercial sector. It is therefore not readily available for the use of nor proper scrutiny by the scientific community. The European Science Foundation believes that it is particularly important that adequate funds are made available from public bodies to the scientific community outside the

commercial sector to keep pace with those developments. It is essential for public confidence that the views of independent scientists are available for development of national policies.

10. Scientific advance is so rapid in this area that regulation and legislation will need to be kept under continual review. The European Science Foundation recognises that the position differs between countries and that there will be continual debates on this sensitive issue. The ESF will ensure that this paper is updated regularly to reflect scientific and regulatory changes in the future.

Regulations on the use of human stem cells in research in European countries*

Country	Reproductive cloning prevented by national law	Research authorised by national law			Ministries in charge	Specific National Committee(s)	Competences of the Committee members	Communication
		Stem cells	Human embryos	Aborted fetuses				
Austria	Yes	No Law	No Law	No Law	Justice And Health	No	-	Yes
Belgium	No	No Law	No Law	No Law	Public Health & Research (W) Justice & Health (F)	National Committee of Bioethics	Biologists, physicians, ethicists, lawyers, lay persons	Yes
Cyprus (x)	Yes	No Law	No Law	No Law	Health & Law Office	No	-	No
Czech Republic (x)	No	No Law	No Law	No Law	Health	Bioethics Committee of R&D Council & Ethical Committee of the Ministry of Health	Biologists, physicians, ethicists, theologians, philosophers, lawyers	Yes
Denmark (x)	Yes	In prep. (end) 2002	In prep. (end) 2002	In prep. (end) 2002	Science, Technology and Innovation	The Central Scientific Ethical Committee	20 members (9 specialists, 11 lay persons)	Yes
Finland (x)	Yes	Yes	Yes	Yes	Social Affairs and Health	Sub-committee on Medical Research Ethics of the National Advisory Board of Health Care Ethics		
France (x)	Yes	Yes (somatic and foetal stem cells) No (embryonic stem cells)	No	Yes	Employment and Solidarity	National Consultative Bioethics Committee for Health and Life Sciences	39 members (5 philosophers and theologians, 15 scientists and physicians, 19 lay persons with competence in bioethics)	No
Germany	Yes	No (embryonic stem cells) No Law (somatic and foetal stem cells)	No	No Law	Federal Ministry of Health	Central Ethics Commission for Stem Cell Research	18 members (biology, ethics, medicine and theology)	Yes
Greece (x)	No	No Law	No Law	No Law	Development and Health	No	-	No
Hungary (x)	In prep.	Yes	No	No	Health	National Scientific and Ethical Committees	24 members (medical doctors, lawyers, priests, journalists, ethicists, members of the Parliament, representatives of the Ministry of Health) and a Chair	Yes
Iceland (x)	Yes	No	No	No	Health and Social Security	National Bioethics Committee	5 members (health, sciences, scientific ethics and human rights)	No
Ireland	No	No Law	No Law	No Law	Dept. of Health and Children	No	-	No

Country	Reproductive cloning prevented by national law	Research authorised by national law			Ministries in charge	Specific National Committee(s)	Competences of the Committee members	Communication
		Stem cells	Human embryos	Aborted foetuses				
Italy (x)	Yes	Yes	No	Yes	Health	National Committee of Bioethics	Clinicians, pharmacologists, ethicists, scientists, lawyers, representatives of patient rights	Yes
Luxembourg (x)	In prep.	No Law	No Law	No Law	Health	National Consultative Bioethics Commission for Health and Life Sciences & Committee for Research Ethics (Min. of Health)	Lawyers, theologians, social workers, teachers, doctors, representatives of social security department	No
Netherlands (x)	Yes	Yes	Yes On left-over embryos	Yes	Health, Welfare and Sport	Central Committee on Research involving Human Subjects	Lawyers, physicians, nurses, methodologists, pharmacologists, psychologists, ethicists & 3 advisors on research on embryos	Yes
Norway (x)	Yes	In prep.	No	Yes	Health	National Committee for Research Ethics	At least 9 members (physicians, geneticists, ethicists, lawyers, lay persons) Yes	
Poland (x)	No	No Law	No Law	No Law	Health and Social Affairs & National Education & Science	No	-	Yes
Portugal (x)	Yes	No Law	No Law	No Law	Health	National Committee for Reproductive Medicine & National Council of Ethics for the Life Sciences	5 members (1 member of Medical Reproduction Society, 1 medical genetics expert, 2 specialised physicians, 1 biologist) & 21 members (Physicians, legal experts, ethicists, philosophers, geneticists, 1 theologian)	Yes
Slovak Republic (x)	Yes	No Law	'Non-therapeutic', 'interventional' research on human embryos prohibited	Yes	Health	Central Ethics Committee of the Ministry of Health	Multidisciplinary (experts and lay persons)	Yes
Slovenia (x)	Yes	Yes (somatic stem cells and embryonic stem cells from spared embryos)	Yes on embryos which are no longer part of a parental project (14 days)	Yes if authorised by the NMEC	Health	The National Committee for Medically Assisted Reproduction (MAR) & the National Medical Ethics Committee	5 members (1 MAR expert, 1 lawyer, 1 ethicist, 1 psychologist and 1 ombudsman's representative) & 13 members (7 physicians, 1 psychologist, 1 social scientist, 1 lawyer, 1 theologian, 1 ethicist, 1 lay	Yes

Country	Reproductive cloning prevented by national law	Research authorised by national law			Ministries in charge	Specific National Committee(s)	Competences of the Committee members	Communication
		Stem cells	Human embryos	Aborted foetuses				
Spain (x)	Yes	No Law	No	Yes	Health	National Commission for Human Assisted Reproduction	person) 22 members (scientists, lawyers, psychologists, social representatives, members of the Department of Health)	Yes (few)
Sweden (x)	Yes	No Law	Yes (14 days)	Yes	Health and Social Affairs & Education	No	-	Yes
Switzerland (x)	Yes	No	Yes	No	Federal Office for Public Health & Federal Office for Justice	National Ethics Committee	18 to 25 members (Ethicists, members of the medical profession, scientists, lawyers, lay persons)	Yes
Turkey (x)	No	No Law	No Law	No Law	Health	Central Ethical Committee	20 members (3 medical pharmacologists, 3 clinicians, 1 pharmaceutical chemist, 1 pharmaceutical technologist, 1 toxicologist, 1 pharmacist, 1 dentist, 4 specialised physicians, 4 representatives of Ministry of Health, 1 lawyer) and a chair (Advisor of the Health Minister)	No
United Kingdom	Yes	Yes	Yes (14 days)	Yes	Department of Health	Human Fertilisation and Embryo Authority (HFEA) & Human Genetics Commission (HGC)	21 members 1/2 medical and scientific expertise, 1/2 lay expertise & 22 members, (the chair of HFEA, scientists, lawyers, ethicists, members of the medical profession, of industry, a journalist, a member of the National Consumer Council	Yes

* The questionnaire was sent to the Heads of ESF Member Organisations. Replies were received from agencies in 25 out of 27 ESF national groups.

(x) Among the 25 respondents' countries, 20 have signed the Convention on Human Rights and Biomedicine (Oviedo, 04/04/97) and the Protocole on the prohibition of cloning human beings. Only 9 have ratified them.

Appendix XII

Extract from Comparative Survey of National Régimes Governing Donor Programmes – Framework for Assisted Human Reproduction

***Extract from Comparative Survey of National Régimes Governing
Donor Programmes (December 2001) – Framework for Assisted Human Reproduction***

In the **United Kingdom**, AHR is governed by legislation, in particular, the Human Fertilisation and Embryology Act, 1990 (HFEA 1990) and a regulatory body set up under that legislation, the Human Fertilisation and Embryology Authority.¹ A licence, which may be granted by the HFEA, is necessary to carry out any of the activities covered by the legislation. The activities authorised by the licence can only be carried on in premises to which the licence relates and under the supervision of the ‘person responsible’.² The HFEA is required by law to publish a Code of Practice.³

In **France**, AHR is governed by legislation inserting provisions into various codes (the Public Health Code, the Civil Code, the Penal Code and the Intellectual Property Code)⁴ and by a consultative body, the National Commission for Medical and Reproductive Biology, which was established by a 1988 Decree.⁵ The National Commission for Medical and Reproductive Biology is consulted on the issue, suspension and withdrawal of licences. Clinics must be authorised to carry out AHR and any related activity. Authorisation is given by the Minister for Health who issues licences under the legislation following consultation with the National Commission for Medical and Reproductive Biology and the National Commission on Health and Welfare Facilities.⁶ Further guidance can be found in a Ministerial Order that sets out the rules of good practice which must be observed.⁷ The law also provides for a National Ethical Consultative Committee for Life and Health Sciences.⁸ The purpose of this Committee is to give opinions on ethical issues raised in the fields of biology, medicine and health and to publish reports on these matters.

¹The Human Fertilisation and Embryology Act, 1990 is supplemented by statutory instruments: the Data Protection (Miscellaneous Subject Access Exemptions) Order (S.I. No. 419 of 2000) and the Human Fertilisation and Embryology (Special Exemptions) Regulations 1991 (S.I. No. 1588 of 1991).

²Human Fertilisation and Embryology Act, 1990, section 12(a). The ‘person responsible’ may be a human person, a body corporate, a partnership or unincorporated association (section 46).

³The *United Kingdom* Human Fertilisation and Embryology Authority Code of Practice, 4th edition July 1998.

⁴Law No. 94-653 of 29 July 1994 on respect for the human body and Law No. 94-654 of 29 July 1994 on the donation and use of bodily substances and parts, AHR and pre-natal diagnosis.

⁵Decree No. 88-328 of 8 April 1988 established the National Commission on Medical and Reproductive Biology in pursuance of certain provisions of Law No. 700-1318 of 31 December 1970 on the reform of the hospital system as amended. See also the Public Health Code (New Legislative Section), Book 1, Title 1, article L. 2113-1, referred to hereinafter as the Public Health Code unless otherwise indicated.

⁶Articles 10, L. 673-5, 11, and L. 184-1 of Law No. 94-654 of 29 July 1994.

⁷Order of 12 January 1999 which includes the Rules of Good Clinical and Biological Practice in the Field of Medically Assisted Procreation. The Rules of Good Clinical and Biological Practice are annexed to the Order, and in this paper reference will be to the Rules rather than the Order. Order of 10 May 2001, dealing with AHR for patients at risk of viral diseases, amends Order of 12 January 1999.

⁸Established by Decree No. 97-555 of 29 May 1997 in pursuance of section 23 of Law No. 94-654 of 29 July 1994.

In *Spain*, AHR is governed by legislation,⁹ and a consultative body, the National Commission on Assisted Reproduction. The National Commission on Assisted Reproduction was established under legislation in 1997 for the purpose of, *inter alia*, giving direction in relation to the use of AHR procedures, collaborating with the public health authorities in relation to those procedures and proposing criteria and norms for the procedures.¹⁰ Similar autonomous commissions may be set up in the Autonomous Communities.¹¹ The role of these commissions is stated to be one of reference and support for the National Commission on Assisted Human Reproduction.¹² All centres or services in which the procedures for AHR are carried out are considered as public or private health centres and are governed accordingly by the provisions of the General Law on Health¹³ and Regulations made for its implementation. The law makes provision for a National Register of Donors of Gametes and Pre-embryos for the purpose of human reproduction.¹⁴ Following applications by clinics, the competent health authorities in the relevant Autonomous Communities may grant licences to those establishments that meet the requirements set down by law.¹⁵ The Autonomous Communities must inform the central state authorities of the centres authorised to carry out AHR.¹⁶

In *Norway*, the Law on the Medical Use of Biotechnology governs AHR.¹⁷ This law provides that biotechnology may only be used for medical purposes in establishments specifically approved for those purposes by the Ministry of Health and Social Affairs.¹⁸ Applications

⁹Law 35/1988 of 22 November 1988; Royal Decree 415/1997 of 21 March 1997 establishing the National Commission on Assisted Human Reproduction; Royal Decree 412/1996 of 1 March establishing obligatory examination records of donors and users in relation to AHR procedures and regulating the creation and organisation of the National Register of Donors of Gametes and Pre-embryos for the purpose of human reproduction; Royal Decree 413/1996 of 1 March 1996 laying down the technical and functional requirements for the authorisation and approval of health centres and services involved in AHR.

¹⁰Law 35/1988 of 22 November 1988, Chapter VII provided that a National Commission on Assisted Reproduction be established to provide guidance in the field of AHR. The National Commission was established by Royal Decree 415/1997 of 1 March 1997.

¹¹ The term 'Autonomous Communities' refers to the regional division of power in *Spain* where the regions or autonomous communities have autonomy in relation to certain areas of governance.

¹²Law 415/1997 of 21 March 1997, section 12 pursuant to the Final Provisions of Law 35/1988 of 22 November 1988.

¹³Law 14/1986 of 25 April 1986.

¹⁴Royal Decree 412/1996 of 1 March 1996 establishing the obligatory study records of donors and users in relation to AHR procedures and regulating the creation and organisation of the National Register of Donors of Gametes and Pre-embryos for the purpose of human reproduction.

¹⁵These requirements are set down by the central state authorities, but may be supplemented by the Autonomous Communities.

¹⁶Royal Decree 413/1996, sections 2 and 3.

¹⁷Law No. 56 of 5 August 1994 on the Medical Use of Biotechnology, as amended by Law No. 29 of 16 May 1997 and Law No. 126 of 21 December 2000. See further the Observations on the individual provisions of the amending legislation on AHR from the Minister for Health and Social Welfare.

¹⁸The Ministry may also lay down more detailed provisions concerning extra-corporeal fertilisation in pursuance of sections 2(10) and 8(1) of Law No. 56 of 5 August 1994.

must be made by clinics to carry out activities covered by the Biotechnology Law.¹⁹ The law also provides that the Crown shall appoint a Biotechnology Board to issue opinions on matters covered by the law in this domain and any other questions concerning biotechnology.²⁰

In **Sweden**, legislation governs activities relating to AHR.²¹ The legislation is supplemented by Regulations of the National Board of Health and Welfare.²² Donor insemination may only take place in public hospitals.²³ Procedures for extra-corporeal fertilisation may be carried out by general (public) hospitals and by private hospitals. However, private hospitals must apply to the National Board of Health and Welfare for permission to carry out extra-corporeal fertilisation.²⁴ At public hospitals the principal care official shall decide whether such services are to be provided.²⁵

In **Denmark**, AHR is governed by legislation and is further regulated by Ministerial Orders, Circulars and Guides and the National Board of Health.²⁶ The law governs what treatment methods may be applied. This is done by means of a series of prohibitions of certain procedures and also by subjecting the use of certain methods to detailed conditions.²⁷ Under the legislation, the Minister for Health and the National Board of Health are empowered to lay down rules concerning the use, donation, implantation and storage of gametes.²⁸ All new methods of treatment and diagnosis in connection with AHR must be approved from ethical and technical standpoints by the Minister for Health. The application for approval is made by

¹⁹Regulations No. 872 of 9 September 1994 set down a deadline for the receipt of application for approvals in respect of activities covered by the Law and which were already in progress when the Biotechnology Law entered into force.

²⁰Law No. 56 of 5 August 1994, section 8(4).

²¹Law No. 711 of 14 June 1988 on fertilisation outside the body and Law No. 1140 of 20 December 1984 on insemination. There is also a law dealing with embryo research: Law No. 115 of 1991.

²²Regulations and General Recommendations No. 6 of 27 March 1987 of the National Board of Health and Welfare on AI; Regulations and General Recommendations No. 35 of 30 November 1989 on *in vitro* fertilisation; and Regulations and General Recommendations No. 15 of 30 September 1992.

²³Law No. 1140 of 20 December 1984, section 3.

²⁴Law No. 711 of 14 June 1988, section 3 and Regulations and General Recommendations No. 35 of 30 November 1989, rubric 7.

²⁵Regulations and General Recommendations No. 35 of 30 November 1989, rubric 7.

²⁶Law No. 460 of 10 June 1997 on AI in connection with medical treatments, diagnosis and research, supplemented by Order No. 728 of 17 September 1997 on AI, the Ministry of Health Circular of 22 September 1997, the National Health Service Order No. 758 of 30 September 1997 on the reporting of IVF treatment and other matters, as well as pre-implantation, and the National Health Service Guide of 30 September 1997, Guidelines for Danish physicians on AI and other treatment to promote reproduction.

²⁷Guidelines for Danish physicians on AI and other treatment to promote reproduction of 30 September 1997.

²⁸Sections 17 and 20 of Law No. 460 of 10 June 1997; Order No. 758 of 30 September 1997 on the reporting of IVF treatments, *etc.* and pre-implantation diagnosis; Circular No. 108 of 13 June 1994 on the notification by physicians of new forms of treatment intended to cause pregnancy; Guidelines No. 109 of 13 June 1994 on the introduction of new methods of treatment in the field of procreative technology.

the physician to the National Board of Health, which prepares a report and submits it with the opinion of the Ethical Council to the Minister for Health.²⁹

In **Austria**, the Reproductive Medicine Law governs AHR and amends the Civil Code and the Marriage Law.³⁰ Authorisation is required from the head of the provincial government to carry out AHR.³¹ The Federal Minister for Health, Sport and Consumer Protection, in agreement with the Minister for Justice, is involved in laying down detailed rules in relation to reporting by clinics and for implementing the Reproductive Medicine Law.³²

In **Germany**, AHR is governed by legislation, the Constitution and provisions of various codes.³³ The Law of 13 December 1990 for the Protection of Embryos sets down requirements for AHR, but does not establish a licensing régime, or a supervisory or consultative authority. This law is supplemented by guidelines of the Federal Physicians' Chambers on the circumstances in which IVF may be offered and indications for IVF and embryo transfer and Regulations for the payment of AHR treatment services.³⁴

In the **Netherlands**, the legislation in force specifically covering the area of AHR comprises a Planning Decision (or Ministerial Decree, analogous to a Statutory Instrument) on In vitro Fertilisation, an amendment to the Decision and a Decision governing sex selection.³⁵ The Decision makes reference to Guidelines issued by the Netherlands Obstetricians and Gynaecologists Association. The Health Council also plays a role in the regulation of AHR, publishing advisory opinions and reports on matters relating to AHR. There are thirteen centres where IVF (within the meaning of the Decision on Special Procedures and Appliances of the Law on Hospital Supplies) is provided and such number is deemed to be sufficient for the next ten years.³⁶ In September 2000, a Bill entitled the Embryo Bill was submitted to the Lower House of the Dutch Parliament and the relevant documentation (an explanatory booklet issued by the Ministry of Health) suggests that it will take several

²⁹Order No. 728 of 17 September 1997, sections 16(1), (3) and 17. Order No. 220 of 4 March 1997 promulgates the Law on the establishment of an Ethical Council to the National Board of Health.

³⁰Federal Law of 1992 (Serial No. 275) regulating Medically Assisted Procreation (Reproductive Medicine Law); Decree of 23 June 1988 of the Federal Chancellery on the testing of semen donors or, as appropriate, of semen for the purposes of AI; and Decree of 9 October 1998 (Serial No. 362) of the Federal Ministry of Labour, Health and Social Affairs on reports with regard to activities and experience in the field of AHR.

³¹Federal Law of 1992 (Serial No. 275), section 5.

³²*Ibid*, section 17. See also Final Provisions, article V, section 8.

³³Law of 13 December 1990 for the Protection of Embryos; the German Civil Code, section 159 ff (Descent - who is the mother); the German Penal Code, sections 27a and 121a (Adoption); and the German Constitution, article 74(1).

³⁴R.G. Lee and D. Morgan, *op cit*, at 279.

³⁵Decision of 26 May 1998 prohibiting sex-selection on non-medical grounds; Planning Decision on In vitro Fertilisation by the Minister for Health, Welfare and Sport 1 April 1998; and Amendment of the Planning Decision on In vitro Fertilisation by the Minister for Health, Welfare and Sport, 12 December 2000. The Decisions are issued having regard to article 5 of the Law on Special Medical Procedures of 28 July 1958, as amended. Clinics are licensed to carry out IVF treatments pursuant to the Law on Special Medical Procedures.

³⁶Planning Decision on In vitro Fertilisation by the Minister for Health, Welfare and Sport, 1 April 1998, Annex, section 1.

months before the Lower House will come to a decision on this Bill. As of June 2001, no such decision had been made. [Note: This Act came into force in September 2002.]

In **Belgium**, a Crown Order governs the standards that must be attained by clinics before authorisation for AHR is given by the Minister for Public Health.³⁷ The law governing this area divides AHR into two types of programme. Programme A encompasses the diagnosis of sterility, the provision of information to the recipient on the procedures available and their cost, treatment involving stimulation of the ovaries, testing necessary for AHR, gathering gametes and their treatment, and counselling recipients as to the implications of the programme. Programme B includes the activities of Programme A but further includes the implantation of embryos and the preservation and freezing of embryos and gametes.³⁸ The legal requirements for Programme A also apply to Programme B with supplementary requirements for Programme B.

In **Italy**, both the Senate and the Chamber of Deputies have produced Bills on matters related to biotechnology.³⁹ These Bills have not become law. Under legislation passed by the Chamber of Deputies (but as of August 2001 yet to be approved by the Senate and enacted by the President), a relatively restrictive régime would apply to AHR.⁴⁰ Clinics would be obliged to apply to the Health Institute for authorisation to carry out AHR. The proposed legislation distinguishes between centres where AHR treatment would be carried out and centres where gametes would be collected and stored. In addition, the proposed legislation states that AHR shall be carried out in public and private establishments authorised by the regions. By decree of the Minister for Health, a National Register of authorised establishments shall be set up at the Health Institute. All authorised centres shall be required to enrol on the Register.⁴¹ The Minister for Health may by decree pursuant to the legislation determine the criteria for allowing donations in clinics where that proves essential for the application of the appropriate AHR procedure.⁴² In the absence of legislation currently in force, AHR would appear to be guided by the Medical Association's Code of Deontology, which sets down certain requirements for such procedures.

³⁷Crown Order of 15 February 1999, establishing the norms to which AHR procedures must conform in order to have official approval. The Civil Code contains provisions governing the paternity of children born as a result of AHR. See also, the Crown Order of 15 February 1999 establishing criteria applicable to health care programmes dealing with AHR.

³⁸Crown Order of 15 February 1999, articles 5 and 15.

³⁹Chamber of Deputies, Report of the XIIth Standing Committee (Social Affairs), submitted to the President on 14 July 1998, Bills No. 414 *et al* on the initiative of the Deputies; Senate Bill No. 217 on the initiative of Senator Salvato, forwarded to the President on 9 May 1996, Rules on Artificial Insemination, *in vitro* fertilisation and the transfer of gametes and embryos; Senate Bill No. 3381 forwarded to the President on 25 June 1998, Rules on medically assisted fertilisation; Senate Bill No. 2963, forwarded to the President on 18 December 1997, Medically assisted fertilisation; Senate Bill, No. 783, forwarded to the President on 26 June 1996, Insertion of article 235-bis into the Civil Code concerning the disownment of paternity in the case of children born following heterologous fertilisation.

⁴⁰Draft Law 4048 (see, *e.g.* discussion in Lee and Morgan, *op cit*, at 281-282).

⁴¹Unified Text of the Commission, Rules Governing Medically Assisted Procreation, articles 12 and 13.

⁴²*Ibid*, Chapter III, article 9(5)(f).

In **Switzerland**, AHR is governed by federal law and further regulated by individual cantons.⁴³ Authorisation must be received from the individual cantons to carry out treatment, to store gametes or to collect sperm.⁴⁴ For example, in *Geneva*, the law provides that IVF may be performed in private medical establishments that have received special authorisation from the *Conseil d'État* for this purpose.⁴⁵ The *Conseil d'État* makes its decision on the basis of the views of the Cantonal Medical Officer, acting on behalf of the Commission for the Surveillance of the Health Profession.⁴⁶ In the canton of *Basel-Land*, a Directive by the Directorate of Public Economy and Health on IVF has been issued that provides that AHR shall be guided by the medico-ethical guidelines of the Swiss Academy of Medical Science.⁴⁷ The Federal Law on Medically Assisted Procreation of 18 December 1998 provides for the establishment of a National Ethics Commission by the *Conseil fédéral*. The Commission is set up, *inter alia*, to follow the development of the techniques of AHR; to give opinions of an ethical nature on social, scientific and technical questions; to draft directives in pursuance of the law of 1998; to advise, on request, the Federal Assembly, the *Conseil fédéral* and the cantons; and to inform the public and promote discussion of the issues posed by AHR.⁴⁸

In **Canada**, the Law Reform Commission considered the subject in its Medically Assisted Procreation Working Paper of 1992.⁴⁹ A Bill was proposed in 1996, based substantially on a draft Bill contained in Appendix B of the Law Reform Commission Working Paper, but was not passed in the Canadian Parliament. As a result, AHR procedures are only partially regulated in Canada by legal provisions developed specifically for that purpose, supplemented by professional guidelines and general principles of law. AHR procedures are governed in part by the Food and Drugs Act: Processing and Distribution of Semen for Assisted Conception Regulations of May 1996,⁵⁰ which make reference to the Guidelines for Therapeutic Donor Insemination 1992:1993, as amended from time to time, published by the Canadian Fertility and Andrology Society, 1993. Currently, a new Bill (Assisted Human Reproduction Bill) is being processed through Parliament, but has yet to be enacted. The Canadian Society of Fertility and Andrology and the Society of Obstetricians and Gynaecologists of Canada have been active in the area and have produced a number of reports on related issues.⁵¹

⁴³Federal Law on Medically Assisted Procreation of 18 December 1998 and Regulation on Medically Assisted Procreation of 4 December 2000. See also article 119 of the Federal Constitution of Switzerland.

⁴⁴Federal Law of 18 December 1998, article 8 and Regulation of 4 December 2000, article 1.

⁴⁵Regulations of 28 May 1986 concerning the conditions governing the practice of *in vitro* fertilisation and embryo transfer in private medical establishments, section 4.

⁴⁶*Ibid*, section 6.

⁴⁷Directive of 2 February 1987 on *in vitro* fertilisation and embryo transfer for the treatment of human infertility, section 1. *Basel-Stadt* also has legislation on AHR - Law of 18 October 1990 on Reproductive Medicine in Humans.

⁴⁸Federal Law of 18 December 1998, article 28.

⁴⁹Law Reform Commission of Canada, *Medically Assisted Procreation, Working Paper No. 65*, Ottawa, 1992.

⁵⁰Statutory Instruments 1996, SOR/96-252 to 265 and SI/96-40 to 42, 1664-1818.

⁵¹Collated in Canadian Fertility and Andrology Society/Society of Obstetricians and Gynaecologists of Canada Report, *Joint Policy Statement: Ethical Issues in Assisted Reproduction*, Montreal and Ottawa, 1999

In **Australia**, AHR is regulated by the individual territories or states. The territories of *Victoria*, *South Australia* and *Western Australia* have legislation governing this area. In the remaining states, AHR is governed by general common law principles and professional guidelines. In addition, the Commonwealth Family Law Act, 1975 (as amended by the Family Law (Amendment) Act, 1987) contains some provisions relevant to the legal relationship of donors and children born of AHR.

In **Australia (Victoria)**, AHR is governed by legislation of 1995 and 1997,⁵² and is regulated by the Infertility Treatment Authority,⁵³ which has the power to grant licences under the legislation.

In **South Australia**, the Reproductive Technology Act, 1988 regulates the use of reproductive technologies and establishes a South Australia Council on Reproductive Technology whose functions include the formulation of a code of ethical practice⁵⁴ and the granting of licences.⁵⁵ In 1995, a detailed Code of Ethical Clinical Practice was issued as a schedule to statutory Regulations.⁵⁶ Furthermore, the Regulations make reference to a Code of Practice drawn up by the Fertility Society of Australia.⁵⁷

In **Western Australia**, AHR is governed primarily by the Human Reproduction Technology Act, 1991. Sections 15-21 of the Act provide a framework for the operation of a Code of Practice to be drawn up by a statutory Council. However, no Code of Practice has yet been issued, although Regulations relating to the Council and to licences and registers have been published⁵⁸ and, in 1997, the Commissioner of Health published Guidelines in the Government Gazette concerning AHR treatment in the form of Directions under section 31 of the Act.⁵⁹

⁵²Infertility Treatment Act, 1995 and the Infertility Treatment (Amendment) Act, 1997.

⁵³*Ibid*, Part 9 establishes an Infertility Treatment Authority.

⁵⁴Reproductive Technology Act, 1988, section 10.

⁵⁵*Ibid*, section 13(1). In *South Australia*, the Reproductive Technology Act, 1988 establishes the Reproductive Technology Council (Part II) and establishes a licensing regime for the provision of AHR treatment (Part III).

⁵⁶Reproductive Technology (Code of Ethical Clinical Practice) Regulations 1995.

⁵⁷Code of Practice for Units Using *In Vitro* Fertilisation and Related Reproductive Technologies prepared by the Reproductive Technology Accreditation Committee of the Fertility Society of Australia, as amended from time to time.

⁵⁸Western Australian Reproductive Technology Council (Nominating Bodies) Regulations 1992 and Human Reproductive Technology (Licences and Registers) Regulations 1993.

⁵⁹Human Reproductive Technology Act Directions, WA Government Gazette, 3 October 1997, 5577. The Introduction to the Directions observes that the Directions are “issued on the advice of the Council and must be complied with by the licensees until revoked or until the Code of Practice, once completed and receiving Parliamentary approval pursuant to S. 16 of the Act, prevails” (*ibid*, at 5579).

In *South Africa*, AHR is governed by legislation and Regulations have been made by Government pursuant to the legislation.⁶⁰ AHR must be performed in accordance with the law and the code of practice for AHR published by the Department of Health and Social Welfare.⁶¹ Authorisation to carry out AHR is granted by the Minister of National Health and Population to any institution that complies with the prescribed conditions, subject to any further conditions prescribed by the Minister.⁶²

In the *USA*, no federal legislation has been enacted governing AHR. Instead, as with Australia, the issue is left to individual states, where the tendency has been to let professional bodies govern AHR practice. One author makes the observation, “It is probably fair to say that the guidelines promulgated by the American Fertility Society represent the only American ethical standards which can guide programmes of assisted reproductive technology in the USA”.⁶³

⁶⁰Human Tissue Act, 1983, as amended by the Human Tissue (Amendment) Act, 1989: Regulations regarding the AI of persons, and related matters (Government Notice No. R. 1182 of 20 June 1986) made by the Minister of National Health and Population Development in pursuance of section 37 of the Human Tissue Act, 1983. A new Health Bill was published in late 2001 and, when promulgated in 2002, will replace the Human Tissue Act and Regulations. In this paper reference is made only to the 1983 Act, as amended, and the Regulations made thereunder.

⁶¹Human Tissue Act, 1983, section 22. In *Bulgaria*, legislation has made provision for AHR in Order No. 12 of 30 May 1987 entitled AI in women. In *Hungary*, legislation governs AHR (Ordinance No. 7 of 22 March 1989 amending Ordinance No. 12 of 29 September 1981).

⁶²Human Tissue Act, 1983, section 24.

⁶³H. Jones, ‘The USA Experience’, in P. Brindsen, (ed.), *A Textbook of In vitro Fertilisation and Assisted Reproduction*, 2nd ed., 1999, at 428, and ‘The Ethics Committee of the American Fertility Society Ethical Considerations of the New Reproductive Technologies’, 46 *Fertility and Sterility* 89S (1986).