REVIEW OF THE HUMAN TISSUE ACT 1983

DISCUSSION PAPER: ASSISTED REPRODUCTIVE TECHNOLOGIES

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FOREWORD

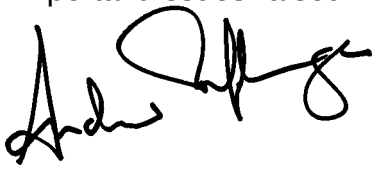
Over the last twenty years there have been dramatic developments in the treatments available to assist infertile couples to have children. These treatments have been both the cause and result of extensive research involving experimentation upon human embryos and human reproductive material.

Both the treatments, and the attendant research, have sparked widespread ethical debate within scientific, medical, sociological and religious circles, and have been the subject of extensive inquiry by Parliaments and law reform bodies both within Australia and overseas. The debate increases as these artificial reproductive technologies push further the scientific and societal bounds governing human reproduction.

In response to community concern the Government has decided to introduce a law to ensure that two procedures do not develop in New South Wales. The Government has announced the banning of human cloning and trans-species fertilisation involving human gametes or embryos. In 1988 the NSW Law Reform Commission described these procedures as so abhorrent that they should be legally prohibited. The National Health and Medical Research Council has similarly expressed its position on the unethical nature of these procedures.

Research and developments in the field of human reproduction are not issues for doctors, scientists, politicians and lawyers alone. They are issues for all of us. The role of science in human reproduction has developed to a stage where it is having a profound effect upon our society and challenging the values that underpin it.

This Discussion Paper is the first stage in a process to obtain the views of the New South Wales community on the interplay between science and human reproduction, and whether laws should be passed to ensure that research and developments in the field of human reproduction are consistent with the community's values and wishes. Over the coming months the Government will be providing other opportunities through various public forums for you to have your say. I encourage everybody to think about and discuss the important issues raised in this discussion paper.



Andrew Refshauge MP
Deputy Premier
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PART I: INTRODUCTION

[1.1] Review of the Human Tissue Act 1983

The Human Tissue Act presently deals with a variety of matters, the common element of which is the use of tissue, including blood, from either a living or dead body for medical, scientific or therapeutic purposes. The origins of the present Act are found in the Corneal and Tissue Grafting Act which was enacted in 1955 to overcome perceived legal difficulties in allowing for corneal grafting, a then relatively new technology. In 1966, the Act became the Tissue Grafting and Processing Act, its terms being widened to accommodate the removal of tissue for “therapeutic” as well as transplant purposes.

In 1977 the Australian Law Reform Commission inquired into the appropriate legislative means of providing laws for the preservation and use of human bodies and of the removal, preservation and use of organs and tissue for the purposes of surgery, medical therapy, transplantation, education and research. The ALRC drafted model legislation, which was the basis for the 1983 Act. The original Act dealt with:

- donations of tissue by living adults and children;
- blood donations;
- removal of tissue after death;
- post mortem examinations; and
- prohibition on trading in tissue.

In 1985, increasing concern over the transmission of contaminants such as HIV led to amendments to the Act to ensure that donors of blood and semen were adequately screened prior to donation. Amendments in 1987 were made to protect suppliers of semen, blood and blood products from litigation in relation to the transmission of contaminants through blood and semen in circumstances where the supplier has taken reasonable care to prevent such transmission. Provisions were also introduced to regulate private suppliers of blood and semen.

Since these amendments, the Act has remained substantially unchanged.

The need for a review of the Human Tissue Act has been apparent for some time. In 1994, the Regulation made under the Act was the subject of review pursuant to the provisions of the Subordinate Legislation Act 1989. In the course of reviewing the Regulation, submissions were received which highlighted issues concerning the

provisions of the Act. Other submissions are received by the Department of Health from time to time.

The advancement in new technologies for treating infertility utilising human reproductive tissue necessitates an examination of the law in that area. Currently, the provisions of the Act dealing with donation of tissue by living persons do not include reproductive material. In 1986, the NSW Law Reform Commission released a report into Human Artificial Insemination. In 1988, the Commission released a report into In Vitro Fertilisation and a report into Surrogate Motherhood. No legislation has yet been enacted in NSW which deals with assisted reproductive technologies. However the Government has announced its intention to introduce legislation to prohibit the practices of trans-species fertilisation and cloning discussed later in this discussion paper.

[1.2] The review process

The Department of Health is issuing this discussion paper which deals with assisted reproductive technologies (presently only dealt with by the Act in terms of semen donation). The paper considers the question of whether any regulation of the provision of assisted reproductive technologies is necessary and, if so, in what form.

[1.3] National Competition Principles Agreement

In April 1995, the Council of Australian Governments agreed to the National Competition Principles Agreement. This commits Commonwealth, State and Territory Governments to consider the potential anti-competitive effect of all legislation. The guiding principle of the Agreement is that legislation should not restrict competition unless it can be demonstrated that:

- the benefits of the restriction to the community as a whole outweigh the cost; and
- the objectives of the legislation can only be achieved by restricting competition (NSW Government Policy Statement of Legislation Review, June 1996 at p 24).

If it were to be proposed that any aspect of assisted reproductive technologies (ART) should be regulated by legislation, the NSW Government will apply the above principles. Throughout the discussion in this paper, the question of whether legislative regulation is necessary to prevent harm, or the risk of harm, to the public (consumers of ART and persons born as a result of ART procedures) will be canvassed. Persons making submissions may also wish to consider the above principles when addressing the issues raised in this paper.

[1.4] Format of this discussion paper

Much valuable work has been done throughout Australia and overseas into the question of the appropriate legislative mechanisms for regulating ART. It is not the intention of this discussion paper to repeat this work. This paper merely seeks to raise, in an accessible manner, the issues which have been raised in NSW and other Australian States. The law and guidelines which apply in relation to those issues are discussed. “Options for discussion” are then raised to structure debate on those issues.

[1.5] Submissions

Written submissions are invited on the options for discussion raised in this paper. There is no special form for submissions. However, a contact name and address for each submission is requested. Submissions should be forwarded to:

ADDRESS Legal and Legislative Services Branch
NSW Department of Health
Locked Mail Bag 961
NORTH SYDNEY NSW 2059

The **closing date** for submissions is 31 July 1998

[1.6] Glossary

AI

Artificial insemination. The procedure of transferring sperm without also transferring an ovum into the reproductive system of a woman. Includes artificial insemination with donor sperm (DI) and with husband's or partner's sperm (AIH).

AIH

Artificial insemination using sperm from the woman's husband. The term "husband" usually includes de facto partner.

AI Report

The NSW Law Reform Commission's Report "Human Artificial Insemination", Report No 49, 1986.

ART

Assisted reproductive technologies. Any medical technology which procures, or attempts to procure, a pregnancy by means other than coitus. Includes AI, IVF and GIFT.

DI

Artificial insemination using sperm from a donor other than the woman's husband/partner.

embryo

The fertilised ovum from the time of the commencement of penetration of the ovum by the sperm until the time of implantation. The use of this definition for the purposes of this paper is discussed at paragraph [5.2].

gamete

Sperm and ova.

GIFT

Gamete Intra-Fallopian Transfer: The placement of ova and sperm in the fallopian tubes to bring about fertilisation.

IVF

In Vitro Fertilisation. Fertilisation of an ovum outside the body and the transfer of the fertilised ovum to the body of a woman. Includes technologies such as ZIFT (Zygote Intra-Fallopian Transfer), PROST (Pro-Nuclear Stage Ovum Transfer) TEST (Tubal Embryo Stage Transfer) and FET (Fallopian Embryo Transfer). Also includes ICSI (Intracytoplasmic Sperm Injection). This is a procedure where the ovum is injected with a single sperm to effect fertilisation before the fertilised ovum is transferred to the body of a woman.

IVF Report

The NSW Law Reform Commission's Report "In Vitro Fertilization" Report No 58, 1988.

LRC
NSW Law Reform Commission.

NHMRC
National Health and Medical Research Council.

NHMRC Guidelines
National Health and Medical Research Council "Ethical Guidelines on Assisted Reproductive Technology 1996".

ovum
The female gamete produced in the ovaries (plural: ova).

parthenogenesis
Cell division in an ovum which only involves the chromosomes of an ovum.

primitive streak
The dense area on the central posterior region of the embryo, formed by a rapidly proliferating mass of cells. It indicates the spinal axis along which the embryo will develop.

South Australian Act
Reproductive Technology Act 1988 (SA).

surrogacy
An arrangement whereby a woman agrees to become pregnant and to bear a child for another person or persons to whom she will transfer custody at or shortly after birth. This definition of surrogacy is discussed at paragraph [10.1].

Surrogacy Report
The NSW Law Reform Commission's Report "Surrogate Motherhood", Report No 60, 1988.

sperm
The male gamete produced in the testicles.

Victorian Act
Infertility Treatment Act 1995 (Vic). It is noted that the bulk of this Act has not yet commenced. However, as commencement is mandated by 1 January 1998, the provisions of this Act are discussed rather than the provisions of the Infertility (Medical Procedures) Act 1984 which is to be repealed by this Act.

Western Australian Act
Human Reproductive Technology Act 1991 (WA).

PART II: ASSISTED REPRODUCTIVE TECHNOLOGIES AND THE LAW

[2.1] Introduction

There has been much debate in the community in the last ten years about whether there is any need for legislation in relation to the provision of assisted reproductive technologies. Undoubtedly, the law already has some influence in the way ART treatments are provided, to whom and on what terms. However, because of the relatively recent development of these technologies, the common law has had little opportunity to develop in this area. Accordingly, there is a great deal of uncertainty as to how the law may respond to disputes which arise in relation to ART, such as those involving the ownership and use of gametes and embryos.

ART has been developed by the medical and scientific community primarily as a treatment for infertility. Thus, it is generally provided and, to some degree regulated, in the same manner as other medical treatments. However, like some other areas of recent scientific and medical technology, it has been argued that ART is in some way qualitatively different from other medical treatments. Rather than simply alleviating the medical condition of an individual through treatment which has consequences only to that individual, ART alleviates infertility by allowing for the birth of another person. Thus, the interests of a third person (the child born as a result of the technology) are affected by the treatment. In some cases, ART is not used as a medical treatment for infertility at all, but as an alternative means of obtaining a pregnancy for fertile persons who cannot, or do not wish to, for a variety of reasons, engage in coitus.

This discussion paper examines the proposal that the provision of ART is different to other kinds of medical treatment. It invites the community to put forwards submissions as to whether it should be treated differently to other medical treatments and if so, how. Is there any harm to the community which arises from the current provision of ART by the medical profession which requires ART to be treated differently? Conversely, would treating it differently itself be harmful?

[2.2] Artificial insemination

Artificial insemination is the procedure of transferring sperm, without also transferring ovum into the reproductive system of a woman. It can be carried out for a couple using the male partner's sperm. This is usually known as Artificial Insemination using a Husband's or partner's sperm or AIH. It can also be carried out using a donor's sperm. This is known as DI, or Donor Insemination.

Artificial insemination can be a relatively simple exercise, and some general practitioners will carry it out in their surgery. In other cases, the administration of fertility drugs is necessary and the woman may need to be treated in a specialised clinic.

The NSW Law Reform Commission (LRC) produced a Report on artificial insemination (AI Report) in which it treated that procedure as being different to other kinds of ART. The Australian states which have passed legislation in the area have also treated AI differently to other kinds of ART. In its AI report, the LRC stated

> "neither the law nor the parliament should presume to regulate the private sexual behaviour of mature competent persons, that the principles of personal freedom and autonomy should apply so far as possible and that if a woman chooses or a man and woman choose, to achieve pregnancy by AI that is no concern of the State".[1]

Consequently, it was of the view that AI, when carried out privately or gratuitously, was not a matter in which the State should intervene. However, it recommended that the law should restrict the practice of AI to registered medical practitioners and institutions where carried out publicly or for reward or by persons who hold themselves out as prepared to practice AI.

There is no evidence before the Department that, in NSW, anyone other than the medical profession has been publicly holding themselves out to perform AI, or has been performing AI for fee or reward.

Victoria, South Australia and Western Australia have each treated AI differently in their respective ART legislation. The Victorian Act deals only with AI when donor sperm is being used. It prohibits the carrying out of DI unless by a doctor approved to carry out DI under the Act, or under the supervision of such a doctor. In South Australia, a licence is required to carry out AI (as is required in relation to other kinds of ART) except where:

- it is carried out by a medical practitioner who has submitted his or her name for registration to the Health Commission and has made an undertaking to the Health Commission to observe the Code of Ethical Practice under the Act; or
- it is carried out gratuitously.

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1 AI Report p26

In Western Australia, a licence to carry out AI is not required (as it is for other kinds of ART) if the procedure is carried out by a medical practitioner who has applied for exemption from the licensing requirement. The practitioner must notify the Commissioner of Health of the procedures to be carried out and lodge an undertaking to observe and comply with the Code of Practice and any directions made under the Act. The Commission may impose conditions upon the practitioner's practice of AI.

In NSW, the supply of semen, rather than the carrying out of AI, is regulated by the Human Tissue Act. This is done from the point of view of minimising infection through contaminated donor semen. It is an offence under the Human Tissue Act for a person to carry on a business of supplying semen unless they are an exempt supplier or are authorised by the Director-General of the Department of Health. Authorisation conditions include requirements as to obtaining information regarding the medical suitability of the donor of semen, and the testing of donors for the presence of prescribed contaminants, being HIV, Hepatitis B and C, syphilis and HTLV I (Human T-lymphotropic Virus Type-I). The legislation does not apply to persons who carry out artificial insemination otherwise than as a business.

Several issues for discussion arise in relation to DI, which will be dealt with later in this paper. They stem from the fact that in DI, a person other than the parents who will be raising the child is brought into the conception equation. Accordingly, both the parents and the child have to deal with the question of whether information regarding this third person (ie, the donor) is made available and if so, in what form. There is also the question of the risks of infection to the mother and child which may arise from the utilisation of a third person's genetic material. Some argue that the State, having an interest in the welfare of persons who undergo medical treatments and in the welfare of children born as a result of medical interventions, has an interest in determining the conditions under which DI is provided.

It is more difficult, however, to determine what interests of a child and society are served by regulating AIH. There would appear to be no issues which arise as to infection control, consent between spouses, or questions as to the genetic heritage of the child, which are not similarly apposite to a child conceived as a result of sexual intercourse.

[2.3] Other Assisted Reproductive Technologies

Assisted Reproductive Technologies other than AI are often generically referred to as In Vitro Fertilisation or IVF. Strictly speaking, this covers technologies where fertilisation takes place outside the body of a woman (ie, in the laboratory). Colloquially, it covers other kinds of technologies such as Gamete Intra-Fallopian Transfer (GIFT) where fertilisation does take place inside a woman's body. GIFT involves the placement of ova and sperm in the fallopian tubes, where fertilisation takes place. The different kinds of ART treatment include many variations of IVF and GIFT including Zygote Intra Fallopian Transfer (ZIFT),Tubal Embryo Stage Transfer (TEST), Pro-Nuclear Stage Ovum Transfer (PROST) and Fallopian Embryo Transfer (FET). It also includes Intracytoplasmic Sperm Injection (ICSI). This is a procedure in which the ovum is injected with a single sperm in the laboratory to effect fertilisation before the fertilised ovum is transferred to the body of a woman.

In its Report on In Vitro Fertilisation, (IVF Report) the LRC was of the view that regulatory measures should be applied to the practice and procedures of IVF and GIFT. The States of Victoria, South Australia and Western Australia have also taken the view that these kinds of treatments should be regulated by legislation. In all three states, some kind of licence or approval is required to carry out any of these types of procedures.

The Victorian Act provides both for the licensing of centres and the approval of doctors who carry out ART procedures. The responsibility for licensing rests with the Infertility Treatment Authority, which is a body set up by the Act. A public or private hospital may apply to the Authority for a licence for all or any of the following activities: the carrying out of treatment procedures or treatment procedures of a particular kind; the forming of an embryo outside the body of a woman; the storage of gametes, zygotes or embryos and the undertaking of approved research. Doctors may apply to the Authority for approval: to carry out treatment procedures of a particular kind; to form an embryo outside the body of a woman; to carry out and be responsible for the carrying out of approved research. A doctor may only carry out a fertilisation procedure (that is, any ART not including donor insemination) if they are approved to carry out that kind of procedure. The place where the procedure is to be carried out must be licensed.

The South Australian Act prohibits the carrying out of an artificial fertilisation procedure except in pursuance of a licence granted by the Health Commission. The Act sets up a Council on Reproductive Technology which provides advice on the conditions of licences. Licences are not issued unless the Commission is satisfied that the

applicant has adequate staff and facilities. A licence will only be granted where it is necessary to fulfil a genuine and substantial social need.

In Western Australia, a licence is required from the Commissioner of Health to:

- carry out any procedure related to the storage of an egg intended for IVF, an egg in the process of fertilisation or an embryo;
- keep sperm, having been obtained from different men;
- carry out an artificial insemination procedure (other than artificial insemination for which an exemption can be obtained).

The licence is issued on the advice of a body set up under the Act called the Reproductive Technology Council . Before issuing a licence, the Commissioner must be satisfied as to the qualifications of the "person responsible" for the licence. Licences only allow practices to be carried out under the supervision of the person responsible and in relation to premises specified in the licence. A licence will only be granted where it is necessary to fulfil a genuine social need.

In NSW, there are no requirements for a registered medical practitioner or a clinic to hold a licence to perform any ART. Medical practitioners who do practice ART have certain guidelines which they should follow, although there is no legal sanction involved in the event of a breach of these Guidelines. In 1996, the National Health and Medical Research Council issued "Ethical Guidelines on Assisted Reproductive Technologies". In the event that the medical practitioner or clinic is accredited with the Fertility Society of Australia's Reproductive Technology Accreditation Committee, the practitioner must follow that body's Code of Practice in order to retain accreditation.

The question arises as to whether ART is so qualitatively different from any other kind of medical practice that medical practitioners require a licence from the State merely to carry out these treatments. The benefits of licensing could be said to be as follows:

- it ensures that only persons who hold appropriate qualifications are able to gain a licence and hence practice ART;
- it allows for the imposition of sanctions, such as the cancellation or suspension of a licence, in cases of misconduct;
- it allows for the imposition of conditions upon the practice of ART (such as the keeping of records, the approval of research);

- it allows the Government to raise revenue for the purposes of regulating ART through the imposition of licence fees.

However, there is no doubt that licensing represents a significant cost to both the State (in establishing a licensing authority and administering a licencing system) and to the medical practitioner (in terms of licence fees and expenditure to meet licencing requirements). Ultimately, some of these costs may be passed onto the consumer. The cost to the consumer of those ART services which are not publicly funded is already significant.

In order to justify licensing, it must be shown that there is some harm which may be caused to society by the practice of ART by medical practitioners, which does not exist in relation to those kinds of medical practice for which a licence is not required. If there is some harm identified, the question then arises as to the most appropriate and cost effective way of reducing or eliminating that harm or the risk of that harm. If some intervention is warranted, all the alternative methods of regulation must be examined.

For example, the above mentioned benefits of licensing may be able to be achieved in a variety of alternative, less intrusive and more cost effective ways. The provisions of the Medical Practice Act, for example, could be widened so as to prescribe standards in the form of regulations under that Act, which apply to medical practitioners in the carrying out of ART. This has already been done in relation to one other aspect of medical practice which involves a high risk of harm to the community: infection control. In the same way that doctors must observe the prescribed infection control procedures under the Medial Practice Act when carrying out any invasive medical procedure, they could be required to observe certain conditions or a code of practice when carrying out ART procedures. Failure to observe those conditions could be sanctioned in various ways, including a finding of unsatisfactory professional conduct, or professional misconduct.

Another alternative means of regulation, if any is necessary, would be to mandate accreditation with an already existing peer group accreditation body, such as the Fertility Society of Australia. In this way, the expense of establishing and maintaining a new regulatory system could be largely avoided.

Readers of this paper are invited to make submissions as to whether there is considered to be any harm in the current practice of ART by the medical profession such that State intervention is warranted in the form of licensing or some other regulatory intervention. Later sections of this paper discuss whether laws should be enacted to prevent certain practices and to mandate certain other practices. The creation of such laws does not depend

on the licensing or authorising of practitioners or ART clinics. The question to be answered here relates to whether ART is so qualitatively different to other kinds of medical practice, that conditions over and above those imposed by the State on the practice of medicine generally, should be imposed on the practice of ART.

Options for discussion

Is there any harm to the community, or the potential of harm to the community, in the current practice of ART (including Artificial Insemination) such that intervention from the State is necessary:

- in limiting the persons who are allowed to practice ART in NSW;
- to prohibit certain practices, mandate certain practices and/or require the observance of certain codes of practice.

Submissions may wish to address these issues separately in relation to Artificial Insemination and other types of ART.

[2.4] Codes of practice

Codes of practice regulating ART already exist. These are issued by the NHMRC and the Fertility Society of Australia and are discussed above. Codes of practice and guidelines, with or without statutory sanction, are a familiar means of regulation in medical practice.

The LRC in its IVF Report was of the view that a Code of Ethical Practice should be formulated by a statutory body set up specifically for that purpose. The statutory body was to be known as the “Biomedical Council” and its recommended membership included representation from the major universities, the medical profession, the law, consumers of ART services, religious bodies, an ethicist and a community representative.

The South Australian and Western Australian Acts make provision for a Code of Practice which must be complied with by persons licenced to practice ART. Similar bodies to the proposed Biomedical Council exist in those States. Victoria sets out relevant requirements for the practice of ART in its legislation.

If there is any role for the State to play in prescribing standards for the practice of ART, a code of practice may be one way of doing so. Such a code could be formulated by Government on the advice of a body such as that described by the LRC or by some other appropriate entity.

Options for discussion

If any State intervention in the practice of ART is identified as necessary, should a Code of Practice be considered as an appropriate means of regulation?

Should compliance with any such “State” Code of Practice be mandated by legislation?

Who should be responsible for formulating any such “State” Code of Practice?

PART III: ELIGIBILITY FOR ASSISTED REPRODUCTIVE TECHNOLOGIES

[3.1] Introduction

The question of whether ART should be treated merely as a medical treatment for infertility raises issues regarding access to that treatment. Should infertility be the only criteria to which a medical practitioner has regard when determining whether a person should be provided with ART treatment, or is it incumbent upon the medical practitioner (or the State) to have some regard to other factors which may be of importance to the child born as a result of the treatment? Is ART to be available to persons who are not infertile but cannot, or do not wish to, for a variety of reasons, engage in coitus?

The LRC recommended that before commencing a procedure of IVF, a medical practitioner should give due consideration to the following matters:

(i) whether the woman is a member of a couple who are infertile, or whose children are likely to be affected by a genetic abnormality or disease;

(ii) the welfare and interest of any child born as a result of the IVF procedure;

(iii) the home environment and stability of the household in which the child would live;

(iv) whether or not counselling is desirable;

(v) the prospective parents' physical and mental health, age and emotional reaction to IVF.

Failure to consider these issues should, in the LRC's view, be a basis for a possible finding of professional misconduct on the part of the practitioner.

The adoption of this recommendation would put a significant onus on medical practitioners to be the arbiters of all decisions regarding access to ART. Some medical practitioners and members of the community may be of the view that if the State considers these factors of importance, it should be enacting legislation which provides the terms of access to ART. Others may be of the view that the issue of whether to treat or not to treat a woman with ART is a matter for the practitioner and the patient, as it is with other kinds of medical treatment.

It may be helpful if the various issues raised over recent years with the Department and by other States in relation to access were discussed separately. In making submissions on each of these issues, readers are asked to identify what interest the State has in making decisions regarding the class of persons who should be given the opportunity to conceive through ART. For example, is any given eligibility criterion supported for the purpose of preventing harm to the child to be born (eg because of unsuitable parents), or harm to society generally (eg, through erosion of the family), or some other kind of harm. Conversely, eligibility criteria may themselves be thought to cause harm to society, eg through discrimination and intolerance to individuals or through the mandating by the State of private matters in which it has no interest. Specification of the reasons for supporting or not supporting eligibility criteria would be useful in determining the most appropriate way of addressing these complex issues.

[3.2] Relationship factors

The question is often raised in the community as to whether only couples should be allowed to have access to ART. Other States have attempted to legislate such a criterion in relation to ART, but have had to make compromises following recent court decisions.

Until recently, the Victorian Act required that a woman who undergoes a treatment procedure must be married. Marriage was not defined to include a de facto relationship, and therefore only legally married couples could have access to ART. Subsequent to the decision of MW v Royal Womens Hospital (see below) the Act was amended to extend access to de facto couples. Until recently, the South Australian Act provided that licences to practice ART were subject to a condition preventing the application of procedures except for the benefit of married couples, defined to include two people living together as husband and wife who are not married and who have cohabited for five years (either continuously or over a six year period). It is understood that subsequent to the decision in Pearce (discussed below) an amendment to that legislation will be made. A similar criterion applies in Western Australia.

The South Australian Supreme Court's decision in Pearce v South Australian Health Commission, (SA Supreme Court SCGRG 1114 of 1996; S5801, 10 September 1996) dealt with a plaintiff, a woman separated from her husband, who was denied IVF treatment because she did not meet the marriage criteria described above. The Court held that the provisions in the South Australian Act which prevented the application of procedures except for the benefit of married women were in direct conflict with the Sex Discrimination Act (Cth) 1984 which prohibits discrimination in the provision of

goods and services on the grounds of marital status. Hence, the provisions of the South Australian Act were held to be invalid insofar as they conflicted with the Sex Discrimination Act, because of the operation of section 109 of the Commonwealth Constitution. That section provides that, when a law of a state is inconsistent with a law of the Commonwealth, the latter shall prevail and the former shall, to the extent of the inconsistency, be invalid. In MW & Ors v Royal Womens Hospital & Ors (H96/26, 96,33 and 96/48, A Kohl, 12 March 1997), the Human Rights and Equal Opportunity Commission similarly held that denial of ART services to three women in heterosexual de facto relationships was contrary to the Sex Discrimination Act, notwithstanding the fact that the Victorian legislation (at the time) allowed only married women to have access to ART.

As a result of these two decisions, it appears that provisions which seek to legislate against access to ART on the basis of marital status are likely to be vulnerable to a challenge to their validity, pending any amendment of the Commonwealth Sex Discrimination Act, or any granting of an exception under that Act in relation to ART. It is likely that this would apply to other relationship criteria apart from marriage, that is, any requirement that the woman be in a relationship of any sort (be it a heterosexual or homosexual de facto relationship).

The Anti-Discrimination Act (NSW) 1977 also renders it unlawful to discriminate against a person on the basis of marital status or homosexuality in the provision of goods or services. There is a general exception where the discriminatory act is done in order to comply with any other legislation. Therefore, it would not be unlawful under the Anti-Discrimination Act 1977 for a practitioner to apply eligibility criteria based on marriage or de facto relationship status, provided the application of that criteria was mandated under NSW legislation. However, the issue regarding the Sex Discrimination Act (Cth) discussed above would remain.

The question of whether the State should prescribe eligibility factors based on relationship status therefore requires close examination.

Options for discussion

Is there a need for legislation or a State Code of Practice to prescribe any eligibility criteria for ART based on relationship factors?

[3.3] Infertility, genetic abnormality and disease

Infertility is, of course, one of the primary reasons couples seek access to ART. The risk of conceiving a child who suffers from a genetic disease or abnormality is also an accepted reason for a fertile couple to seek treatment with ART.

The Victorian Act provides that, before a woman undergoes a treatment procedure, a doctor must be satisfied on reasonable grounds, that the woman is unlikely to become pregnant from an ovum produced by her and sperm produced by her husband or de facto partner other than by a treatment procedure; or a doctor who has specialist qualifications in human genetics must be satisfied that, if the woman became pregnant from an ovum produced by her and sperm produced by her husband or partner, a genetic abnormality or a disease may be transmitted to a person born as a result of the pregnancy.

The inclusion of the transmission of “a disease” as a reason for treatment procedures would appear to encompass the situation where a fertile couple may seek treatment using a donor procedure because the husband has an infectious disease, such as Hepatitis C or HIV which may be passed onto the mother and/or the foetus if it were conceived utilising his sperm.

In South Australia and Western Australia, licence conditions prevent the application of ART to a couple unless they are, or appear to be, infertile or there is a risk that a genetic defect would be transmitted to the child if conceived naturally.

Prescription of a criteria of infertility may have an effect on access to the program by women who are not in a heterosexual relationship. If a definition of fertility relates to an inability to conceive as a result of intercourse, this would prevent women who are not engaging in intercourse from being considered infertile.

Options for discussion

Is there a need for legislation or a State Code of Practice which provides that access to ART be available only where:

- a medical practitioner is of the view that a woman is unlikely to become pregnant as a result of coitus with her husband/partner; or
- if the woman were to become pregnant from such coitus, a genetic abnormality or genetic disease may be transmitted to a child born as a result of the pregnancy; or
- if a woman was to become pregnant as a result of coitus with her husband/partner, a disease (other than a genetic disease) may be transmitted to the woman and/or to a child born as a result of the pregnancy?

[3.4] Home environment, stability of the household, economic factors, age and health of the parents: the doctor's discretion

The recommendations of the LRC concerning home environment and stability would appear to draw on the adoption experience. Adoption involves the State making decisions as to the welfare of a child already born. In the case of ART, the relevant decisions are as to the welfare of future children when they are born.

Couples intending to have children naturally are not required to submit to any assessment procedure. If the aim of ART is simply to allow infertile or subfertile couples to conceive as a fertile couple can, then one may question the justification for such an assessment. Medical practitioners may not wish to be put in the position of making decisions of this nature. In adoption, the assessment process is undertaken by the State which has the necessary resources and expertise at its disposal and which is responsible for the care of the child should they not be adopted. The same cannot be said for a medical practitioner giving treatment to an infertile couple.

This area encompasses many vexed questions. Some such questions which may arise for practitioners in NSW are whether ART should be available to couples:

- where the couple already have children (either from existing or prior relationships), but have subsequently become infertile (eg through age or illness);

- where one member of the couple has a terminal illness;
- where the woman has an infectious disease and there is the possibility of its transmission to the foetus conceived through ART;
- where one or both members of the couple suffer a debilitating mental or physical illness or disability which the practitioner feels will affect their ability to parent.

Victoria, South Australia and Western Australia do not specifically deal with these issues in their legislation, although their inclusion in a code of practice is not precluded. The Western Australian Act does state that the cause of a couple's infertility (a necessary requirement to access ART) cannot be age or a prescribed cause. Directions under the Western Australian Act provide that the medical practitioner treating the patient makes the final decision as to the eligibility of any participant on both legal and medical grounds, although the role of ART counsellors in assisting in this decision is highlighted.

The South Australian Code of Practice requires that treatment cannot be provided except where there is a referral by a medical practitioner stating that neither spouse is suffering from any illness, disease or disability that would interfere with their ability to care for a child. Both spouses must also sign a statutory declaration that neither is subject to a term of imprisonment, or has been found guilty of an offence involving violence, or a sexual offence involving a child or has had a child permanently removed from his or her custody (other than by adoption). A licensee may also refuse to give treatment if he or she is of the opinion, after assessment by a Child Protection Services Unit, that there is a reasonable likelihood of the couple not properly caring for, or nurturing, a child throughout childhood.

The Victorian Act includes the following provision:

It is Parliament's intention that the following principles be given effect in administering this Act, carrying out functions under this Act, and in the carrying out of activities regulated by this Act:

(a) the welfare and interests of any person born or to be born as a result of a treatment procedure are paramount;

(b) human life should be preserved and protected;

(c) the interests of the family should be considered;

(d) infertile couples should be assisted in fulfilling their desire to have children.

These principles are listed in descending order of importance and must be applied in that order.[2]

The South Australian Code of Practice states that a licensee must, in deciding whether or not to give infertility treatment, or to accept the donation of reproductive material from any person for use in infertility treatment, treat the welfare of any child that may be born in consequence of the treatment as the paramount consideration.

The question arises as to whether it is necessary to legislate in relation to any of these particular issues of eligibility, either in specific or general terms, to protect medical practitioners who exercise a discretion not to provide ART treatment on the basis that to do so may be contrary to the best interests of any child born as a result of that treatment.

Options for discussion

Is there a need for legislation or a State Code of Practice which prescribes eligibility criteria for persons wishing to access ART in respect of:

- age;
- economic status;
- home environment;
- mental or physical health of parents;
- criminal history of parents;
- parents who have had children removed from their custody?

Is there a need to include a guiding principle in legislation or a State Code of Practice which makes the welfare of the child to be born as a result of ART of paramount importance in the provision of ART?

2 Victorian Act, s 5.

[3.5] Consent to undergo an ART procedure

There is no legislated procedure in relation to consent to other kinds of medical treatment. The LRC was of the view that no legislation imposing compulsory requirements for consent in relation to ART procedures should be enacted. Rather, this matter should be left to the general common law principles that govern consent to medical treatment.

The Victorian legislation requires the written consent of the woman and her husband or de facto spouse to the carrying out of a treatment procedure as does the proposed South Australian Code of Practice. There is also a requirement under the Victorian Act that the couple be given sufficient information to enable them to make an informed decision about whether or not to undergo the procedure. The South Australian Act provides for consents to be in a prescribed form. The Western Australian Act provides that an in vitro fertilisation procedure must not be carried out unless an effective consent has been obtained. Directions under the Act require the consent of the woman and her husband or partner. They also require the provision of certain information to participants prior to consent being obtained, including information as to success rates, data to be kept in central registers and access to that data, legal status of the offspring, medical, social and secrecy implications in relation to the rearing of donor children.

The Fertility Society of Australia already gives guidance on the use of consent forms and recommends specific and separate consents for different types of ART including IVF, GIFT, PROST, donor ova, donor sperm and donor embryos. NHMRC Guidelines require that, prior to any ART procedure, a participant must be given all information which may be of significance to the participant in a way that is appropriate to, and sufficient for, informed decision making. Consent should be given in writing, following the provision of this information.

Under the Status of Children Act 1996 (NSW),[3] a husband must consent to his wife's treatment with ART with donor sperm for him to be presumed the father of the child, and therefore, obtaining the consent of the husband is good practice and should be documented. However, it is questionable whether there is a need for legislation to go further and prescribe the form in which consent should be obtained.

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3 Yet to be commenced at the time of writing

Options for discussion

Is there any need for legislation or a State Code of Practice dealing with the consent of the participants of ART or are the requirements of the general law sufficient?

[3.6] Counselling

The Fertility Society of Australia recommends that ART clinics provide counselling services with counsellors meeting the membership requirements of the Australian and New Zealand Infertility Counsellors Association. NHMRC Guidelines state that counselling should be available as an integral part of any ART program. Counselling may be provided within, or independently of, the clinic.

The LRC recommended that counselling should not be made compulsory for every IVF patient. However, it should be a compulsory condition of practice licences that adequate counselling facilities be available and be formally offered to all IVF clients.

In Victoria, a woman and her husband or de facto partner must have received counselling from an approved counsellor prior to undergoing a treatment procedure, as must donors of gametes and embryos. The South Australian Act does not make counselling mandatory. However, the Code of Practice requires adequate counselling to be given to the couple as to matters set out in the Code. In Western Australia, it is a condition of all licences that each participant must be given a suitable opportunity to receive proper counselling about the implications of the proposed procedures and other relevant and suitable information as is proper or as may be specifically required by the code or directions.

There are many types of medical treatment where the provision of counselling of patients is of great importance, and yet such counselling is not mandated by law. This would include the fields of genetic testing, organ and tissue donation and HIV services. The circumstances in which counselling is necessary and the way in which it should be provided are, in those areas, a matter of good medical practice. Some may argue that the same applies in relation to ART. Mandatory counselling may also be said to be an unnecessary infringement on the liberties of a person participating in an ART program. It may even be counter-productive where the couple does not wish to undergo counselling.

Options for discussion

Is there a need for any legislation or a State Code of Practice in relation to the counselling of participants and donors in ART procedures?

PART IV: RESEARCH ON EMBRYOS

[4.1] Definition of "embryo"

Before usefully discussing requirements as to research on embryos it is important to note the different definitions of this term which have been used in various contexts when discussing embryo experimentation.

In its IVF Report, the LRC stated:

> "Strictly, the term embryo refers to that period of development between the first and eighth weeks after fertilization has occurred. However, in the debate surrounding IVF it has been used to describe the fertilised ovum".[4]

The Victorian Act defines embryo as "any stage of embryonic development at and from syngamy". "Syngamy" is defined as "that stage of development of a fertilised oocyte [ovum] where the chromosomes derived from the male and female pronuclei align on the mitotic spindle". A zygote is defined as "the stages of human development from the commencement of penetration of an oocyte by a sperm up to but not including syngamy". These differing definitions of "embryo" and "zygote" are utilised to facilitate different requirements and prohibitions upon research on zygotes and embryos.

In Western Australia, "embryo" is defined as "a live human embryo, in the stage of development which occurs from the completion of the fertilisation of the egg or the initiation of parthenogenesis to the time when, excluding any period of storage, 7 completed weeks of the development have occurred". Prior to that stage, the egg is referred to as an "egg in the process of fertilisation".

In South Australia the term embryo is not defined.

For the sake of simplicity, this discussion paper will only use the term "embryo" which is defined as meaning the stages of human development from the commencement of penetration of an ovum by a sperm up to and including the ensuing stages of embryonic development. This usage of the term is consistent with that of the LRC.

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4 IVF Report, p xx.

[4.2] Research on embryos

There is no jurisdiction in Australia which prohibits research on embryos. The recommendation of the LRC was that no general prohibition of research on the human embryo should be enacted, although this was a majority (rather than a unanimous) recommendation. Most discussion on embryo research in the other States centres on the question of whether destructive research on embryos should be permitted. Destructive research upon an embryo may be defined as that which harms an embryo, renders it unfit for implantation into the body of a woman or renders it less likely that a pregnancy will result from the transfer of the embryo. It is noted that non-destructive research does not necessarily equate with therapeutic research. Research upon an embryo may be harmless to it, without being of any therapeutic benefit to the particular embryo.

The Victorian legislation provides that a person must not carry out any research, outside the body of a woman, involving the use of an embryo (ie a post syngamy embryo) if the embryo is unfit for transfer to a woman, or in the case of an embryo which is fit for transfer to a woman, if the research would harm the embryo, or make the embryo unfit for transfer to a woman, or reduce the likelihood of pregnancy resulting from the transfer of the embryo. These prohibitions do not apply to zygotes (the pre-syngamy embryo), although approval for research on zygotes is required under the Act. Therefore, destructive research on the embryo is only prohibited after syngamy.

In South Australia, standard conditions of research licences prevent research that may be detrimental to an embryo. In Western Australia, it is an offence to carry out research upon a fertilising egg, or an embryo without obtaining approval from the Council. Research which is not therapeutic to the embryo may not be approved.

If there is a view that destructive research on an embryo should not take place, the question arises as to whether there is any need for action by the State to ban such a practice. NHMRC Guidelines already state that embryo experimentation should normally be limited to therapeutic procedures which leave the embryo with an expectation of implantation or development. The Guidelines allow non-therapeutic research which does not harm an embryo to be approved by an Institutional Ethics Committee. They also allow destructive research to be approved by an Institutional Ethics Committee in “exceptional circumstances”. The question arises as to whether it is necessary to enact legislation which may merely repeat these Guidelines. It may be argued that the breach of NHMRC

Guidelines carries no legal sanction and therefore is not a sufficient incentive for compliance. However, embryo experimentation is a complex practice and requires extensive technological resources. It is unlikely to be carried out by other than hospitals and well funded institutions. The breach of NHMRC Guidelines can have dramatic effects for these institutions in terms of loss of funding and resources.

There is also the question of whether any prohibition on certain types of research could be policed by the State. The detection of such breaches by relevant authorities would be difficult.

[4.3] Creation of embryos for research

The LRC was of the view (by majority) that there should be no legislative prohibition upon the creation of embryos solely for the purpose of research. The NHMRC does not prevent the creation of embryos for research, nor does Victoria or South Australia. Victoria does however, prevent the development of a zygote past syngamy (which renders it an embryo under the legislation) for the purposes of research. The creation of embryos for research is prohibited in Western Australia.

The dissenting members of the LRC recommended that the creation of an embryo for the purpose of research or experimentation on it should be prohibited. The rationale for this view was that the fertilised ovum is morally entitled to a degree of respect and protection which would be violated by its creation solely for the purposes of research.

A prohibition upon the creation of embryos for research would confine research to so-called “spare embryos”. These are embryos which may be created in the course of treating a woman, but are not implanted into her body or donated to another couple. The LRC was of the view that arguments limiting research to spare embryos were “unconvincing” and the majority of the LRC were not persuaded that the intention with which a normal embryo is created should be a crucial factor in whether it can be used as a subject for research.

[4.4] Prohibition on development of embryos

Fourteen days is the time at which implantation of an embryo would normally take place in the uterus. It also represents the latest stage at which identical twins can occur and is the stage at which it is possible to tell whether the collection of cells will continue to develop as a normal embryo or whether it will take a different course. It is generally the time of the formation of the primitive streak.

Keeping or using an embryo after the appearance of the primitive streak or after 14 days, whichever is the earlier, is not approved by the Fertility Society Code of Practice. NHMRC Guidelines state that culturing of an embryo in vitro for more than 14 days is a prohibited/unacceptable practice. The LRC recommended that, accepting the principle that an embryo should not be allowed to develop beyond the time at which implantation would normally take place, no embryo should be kept alive longer than 14 days (excluding any time kept in storage).

South Australia appears to be the only State which specifically prohibits the culture of an embryo outside the human body after a developmental age of 14 days

If a ban on the development of embryos after 14 days is supported, the question arises as to whether there is a need for legislation to enact such a ban, given that it is already prohibited by NHMRC Guidelines. There is no evidence before the Department that institutions which carry out embryo research have, or are likely to, breach NHMRC Guidelines in this respect.

[4.5] Transfer of embryos which have been the subject of research

The LRC was of the view that no legislative prohibition should be enacted on the transfer to a woman of an embryo that has been the subject of research (by majority). Conversely, such transfer should not be compulsory.

The Victorian Act prohibits the transfer of a gamete used in research, an embryo formed from gametes used in research or an embryo used in research unless the transfer has been approved by the Infertility Treatment Authority. The South Australian Code of Practice prohibits the use of embryos which have been the subject of research unless a licensee, after consultation with an embryologist, is of the opinion that there is a reasonable expectation of that embryo implanting and developing normally. The couple must also consent to the transfer.

The Fertility Society of Australia Code of Practice does not approve of the use of embryos which have been appropriated for research for any other purpose. The NHMRC Guidelines are silent on the issue.

The question of whether an embryo which has been the subject of experimentation is fit for transfer into the body of a woman is essentially one which requires the exercise of clinical judgement.

The question will depend on the state of the embryo and whether there is an expectation that it will implant and develop normally. This may be an area in which it is inappropriate for the law to interfere.

Options for discussion

Is there a need for legislation or a State Code of Practice to be enacted which prohibits:

- destructive research on embryos;
- the creation of embryos for research;
- the keeping alive of embryos outside the body of a woman for longer than fourteen days (excluding any time in storage) or beyond the formation of the primitive streak, whichever is the earlier;
- the transfer of embryos or gametes to the body of woman that have been the subject of research?

[4.6] Regulation of Research

NHMRC Guidelines currently require that research involving the human embryo be approved by an Institutional Ethics Committee (IEC). There are some limits upon what an IEC can and cannot approve, as outlined in paragraph [4.2] above. As indicated by their name, IECs will usually be attached to a particular institution and will approve research by that institution, or institutions, with which it has some affiliation. There is no guarantee of consisitency in the decisions of IECs throughout the State. One IEC may allow a certain research project which another would reject. Some may argue that this is appropriate and reflects the fact that differing communities have differing views. Others may argue that it is not in the interests of ART research to have different standards across the State and that the situation creates, in theory at least, the potential for IEC “shopping”.

The States that have legislated in the area of ART have regulated ART research. The Victorian Act provides that any research outside the body of a woman involving an embryo or the formation of an embryo may only take place at premises licensed under the Act. In addition, the research must be approved under the Act. The South Australian Act provides that a person must not carry out research involving experimentation with human reproductive material except in pursuance of a licence granted by the Council. In Western Australia, separate research licences are not issued. However, approval is required from the Council to carry out research upon a fertilising egg or an embryo. The Council may specify circumstances where an application is not needed and the Code can grant a

general approval for certain types of research.
Thus, these States have attempted to standardise ART research across the State by requiring licences for research and/or requiring individual research projects to obtain ethical approval by a central body exercising the role of an IEC.

NSW already has one ethics committe which operates on a statewide basis. This is the Statewide Health Confidentiality and Ethics Committee which is organised and chaired by the Department of Health. It is constituted as an ethics committee under NHMRC Guidelines. It considers research proposals which have statewide implications. Projects approved by this ethics committee do not also need IEC approval.

It may be considered desirable to have some “central” ethics committee along the lines of the Statewide Health Confidentiality and Ethics Committee to consider ART research proposals. This would ensure a standardised approach to ART research. Submissions are invited as to whether this would be a useful mechanism in the approval of ART research in NSW.

The question of whether the State should be requiring institutions to hold a licence or authority to carry out ART research raises similar issues to licensing of practitioners. It must be remembered that licensing requirements do not presently exist for other forms of human research under NSW legislation. Therefore, in order to justify licensing of ART research, it must be shown that the present restrictions which apply in relation to other types of human research (the general law and NHMRC guidelines) are insufficient to protect the public interest in relation to ART.

Options for discussion

Would the establishment of a statewide ethics committee for approving ART research be of benefit to the community in developing a consistent approach to ART research in NSW?

Is there any harm to the community in the current level of regulation of ART research by the common law and NHMRC Guidelines such that further intervention is necessary by the State to:

- require persons who carry out ART research to hold a licence;
- mandate in legislation for the approval of ART research by an ethics committee?

PART V: PROHIBITION OF CERTAIN PRACTICES

[5.1] Cloning and trans-species fertilisation

The Government has announced its intention to prohibit the practices of trans-species fertilisation and cloning. This is consistent with the recommendation of the LRC in its IVF Report.

Victoria has banned both these practices. The legislation provides that a person must not carry out a procedure involving the mixing of sperm or ova produced by an animal with a gamete produced by a man or woman or with a zygote or an embryo formed from the gametes of a man and woman, unless the procedure is that of mixing animal ova with human sperm, is prescribed by the regulations and is carried out for diagnostic purposes. The exception is likely to be for the purposes of allowing certain tests for male subfertility which involve attempted penetration of a hamster ovum with human sperm (the “hamster test”). It is also stated that a person must not carry out or attempt to carry out cloning. “Clone” is defined as forming “outside the human body, a human embryo that is genetically identical to another human embryo or person”.

Both practices are prohibited in Western Australia and South Australia.

The LRC considered the practices of cloning and trans-species fertilisation as abhorrent and was of the view that they should be strictly prohibited by legislation. NHMRC Guidelines prohibit “experimentation with the intent to produce two or more genetically identical individuals, including development of human embryonal stem cell lines with the aim of producing a clone of individuals”. The mixing of human and animal gametes to produce hybrid embryos is also prohibited.

While this would appear to be generally agreed, it is noted that the definition of these two practices will require careful consideration. In relation to trans-species fertilisation, consideration should be given to an exception to allow for diagnostic testing as provided for in the Victorian Act. In relation to cloning, it is noted that certain research into DNA cloning holds potential to play a diagnostic role in the early detection of genetic defects. However, the definitions of cloning as given in the Victorian and Western Australian legislation should not prevent this research occurring.

Option for discussion

Should the proposed legislation prohibiting procedures involving the mixing of a gamete produced by an animal with a gamete produced by a man or woman create an exception where the procedure involves mixing animal ova and human sperm and is carried out for diagnostic purposes only?

[5.2] Other prohibited procedures: embryo flushing, alteration of genetic structure of gametes and embryos, other matters

The States which have legislated in the area of ART have variously banned or limited the following practices.

Embryo flushing

Embryo flushing involves the obtaining of an embryo from the body of a woman after fertilisation has taken place in vivo. During the time the pre-implantational embryo is floating free in the uterus it is flushed out and transferred to a recipient's uterus where implantation takes place. It therefore involves the displacement of a healthy embryo which is about to implant in the woman's uterus. The practice is prohibited in all three States which have legislated in the area, and is also prohibited by NHMRC Guidelines.

Alteration of the genetic constitution of a gamete, zygote or embryo

The Victorian Act prohibits the alteration of the genetic constitution of a gamete which is intended to be used in a treatment procedure or to form a zygote or embryo. The alteration of the genetic, pro-nuclear or nuclear constitution of a zygote or an embryo is prohibited except to alter the somatic cells for therapeutic purposes. The exception is to allow for somatic cell gene therapy which involves the introduction of pieces of DNA into human somatic (non-reproductive) cells. The aim is to improve the health of people with certain inherited diseases. A similar prohibition exists in the South Australian Code of Practice.

Gametes produced by children

The Victorian Act also prevents the use of gametes produced by a person under the age of 18 except in accordance with the regulations. Directions under the Western Australian Act prevent the acceptance of gametes or an embryo for donation from a person

aged under 18. There are some circumstances where use of gametes obtained from a child may be acceptable. For example, minors about to undergo certain treatments such as radiotherapy or chemotherapy may store some of their semen for future use should the therapy render them infertile. Generally, the prohibition would act to prevent minors from being gamete donors.

Ova derived from a foetus

The Victorian Act bans the use of ova derived from a foetus in an ART treatment procedure or in research. The use of ova from a foetus in ART procedures requires ethical consideration, due to the possibility of children being born never having had a living genetic parent. NHMRC Guidelines prohibit the use of fetal gametes for fertilisation.

Mixing gametes or embryos from more than one person

The Victorian and Western Australian Acts prohibit the carrying out of a treatment procedure using gametes produced by more than one person or embryos created using mixed gametes. This is to prevent an embryo being formed whose genetic heritage is uncertain. For example, fertilising an ovum using a mixture of semen produced from two or more donors will make it difficult to determine which donor is the genetic father of the child. The South Australian Code of Practice contains a similar provision. In its AI Report, the LRC stated that legislative regulation was not called for in relation to the use of mixed semen from two or more semen donors. However, it stated that the use of mixed semen and any other action aimed at causing confusion about a child's parentage should be regarded as falling outside the bounds of good medical practice. NHMRC Guidelines prohibit mixing of gametes or embryos of different parental origin so as to confuse the biological parentage of the conceptus.

Transfer of an embryo into a man or an animal

Transfer of an embryo into an animal is prohibited in Western Australia, Victoria and South Australia. Transfer of an embryo into the body of a man is prohibited in Victoria. Also prohibited in Victoria is the transfer of a parthenogenetic oocyte or parthenogene to the body of a person or animal. NHMRC Guidelines prohibit the placing of an embryo into a body cavity other than the human female reproductive tract.

Sex selection

The Victorian Act prohibits the performing of a treatment procedure or the use of a gamete or embryo with the purposes of producing, or attempting to produce, a child of a particular sex. There is an exception if it is necessary for the child to be of a particular sex so as to avoid the risk of transmission of a genetic abnormality or disease to the child.

Use of gametes of relatives

The South Australian Code of Practice prevents the use of reproductive material:

(a) where the wife's ova is used, of the wife's father, son, brother or half-brother.

(b) where the husband's sperm is used, of the husband's mother, daughter, sister or half-sister.

This would appear to address issues related to incest and the production of offspring of two people in a close genetic relationship.

Placing part of an embryo in a human body

The South Australian Code of Practice prohibits the placing of any cells extracted from an embryo into the body of any person.

Collection of gametes from a dead person

Various provisions of the other States' legislation prevent the use of gametes of a deceased person in ART procedures. Paragraph [6.5] discusses the use of gametes taken from a living person who dies before the gametes (or embryos formed from those gametes) are utilised. This is a separate issue to the collection of gametes from already deceased persons, which is under discussion here. NHMRC Guidelines prohibit the use in ART treatment of gametes or embryos harvested from cadavers.

As noted in the above discussion, many of the above practices are already prohibiited by the NHMRC. As discussed in several contexts above, if any of the above practices are considered unacceptable by society, it may not necessarily follow that legislation needs to be enacted to prohibit them. Current regulation by the NHMRC may be sufficient.

Options for discussion

Is there a need for legislation or a State Code of Practice to prohibit any of the following procedures:

- embryo flushing;
- the alteration of the genetic constitution of a gamete which is intended to be used in an ART procedure;
- the alteration of the genetic, pro-nuclear or nuclear constitution of an embryo except to alter the somatic cells for therapeutic purposes;
- the use of gametes produced by a person under the age of 18 except in certain prescribed circumstances;
- the use of ova derived from a foetus in an ART procedure;
- the carrying out of an ART procedure using gametes produced by more than one person or embryos created using mixed gametes;
- transfer of an embryo into an animal;
- transfer of an embryo into a body cavity other than the human female reproductive tract;
- treatment of a woman using ART with the purpose of producing a child of a particular sex except where necessary to avoid the risk of transmission of a genetic abnormality or disease;
- use of donor reproductive material from an immediate relative of the genetic parent of the potential offspring;
- the placing of any cells extracted from an embryo into the body of a person;
- collection of gametes from a dead person for use in an ART procedure?

[5.3] Payment for gamete and embryo donors

The question of payment of donors applies to other human tissue as well as reproductive material. Section 32 of the Human Tissue Act currently prohibits trade in human tissue but allows payment of the expenses of donors in certain circumstances. This provision of the Human Tissue Act will be dealt with in a later paper.

[5.4] Transfer of gametes and embryos between States and overseas

Requirements for the collection and donation of gametes and embryos differ from State to State and country to country. The question arises as to whether clinics should be able to utilise gametes or embryos brought to NSW from interstate or overseas, especially where the donors of the gametes or embryos have not been subject to the same screening procedures which may apply in NSW, or the same information has not been collected in relation to those gametes or embryos.

The Victorian Act prevents the import or export of gametes and embryos except with the approval of the Infertility Treatment Authority. Directions under the Western Australian Act also prevent importation of gametes and embryos from outside the State unless all the information as required by the legislation for the Donor Register is available. Exemptions may be granted on compassionate or other grounds.

Some countries allow the payment of donors for genetic material. An Australian couple may travel overseas and pay large sums of money for the right to use donor semen, ova or embryos. That couple could then make arrangements for that donor material to be transferred to NSW for treatment and implantation. This is not currently illegal in NSW. The question may be asked as to whether this is something that the law of NSW should address.

There is a shortage of donor semen for use in ART in NSW. Some NSW clinics have had to resort to obtaining semen from interstate. Imposing restrictions upon the use of gametes collected interstate or overseas may only exacerbate this shortage.

Options for discussion

Is there any need for legislation or a State Code of Practice to address the issue of the importation of gametes and embryos from outside NSW?

[5.5] Limitation on the number of offspring of donors

Directions issued under the Western Australian Act state that, for each donor of gametes, a licensee must limit to a maximum of five the number of known donor families, including families that may be interstate or overseas. The South Australian Code of Practice also sets a limit on the number of children born alive utilising the material of any one donor. The purpose of this is to lessen the chances of children born as a result of donor technology unknowingly entering into consanguineous relationships.

Options for discussion

Is there any need for legislation or a State Code of Practice to limit the number of offspring to be produced utilising the genetic material of any one donor?

PART VI: STORAGE, USE AND DISPOSAL OF EMBRYOS AND GAMETES

[6.1] Introduction

It is the advent of cryopreservation which has allowed the development of ART to today's highly sophisticated standards. Semen and ova which is donated can be frozen until it is used in treatment. A couple who has embryos formed for them which are not implanted may freeze those embryos for later implantation or for donation to another couple.

The law has not always kept up with these developments in technology. For example, it is not clear at law who, if anyone, "owns" stored genetic material. And yet, ownership is one of the fundamental bases upon which rights to possess and use "goods" is determined. There is no doubt that this uncertainty in the law has caused some difficulties for ART clinics, especially where persons who may be thought to have "rights" in relation to stored genetic material (donors, couples for whom embryos were formed) cannot, or will not, express views as to what should be done with such material.

[6.2] Time limit on storage of embryos and gametes

The Victorian Act provides that gametes must not remain in storage for more than 10 years or such longer period approved by the Infertility Treatment Authority. An embryo must not be stored for more than 5 years or any longer period approved by the Authority. Directions under the Western Australian Act provide that consents to store gametes must be renewed every 5 years up to a maximum of 15 years, although an extension may be granted by the Council. The South Australian Code of Practice sets a time limit for storage of embryos of 10 years.

NHMRC Guidelines state that embryos may be kept for a period not exceeding 10 years following which, if not used by the couple, they may be donated or allowed to succumb. At present, most fertility clinics require participants in ART programs to sign consent forms regarding their rights in relation to determining the storage of genetic material. The question arises as to whether there is any need for legislation which re-states the NHMRC Guideline, or prescribes a requirement different to the "10 year rule".

Options for discussion

Is there any need for legislation or a State Code of Practice to set an overall time limit on the storage of embryos and gametes? If so, for what period?

[6.3] Use and disposal of gametes

In Victoria, donors of gametes must consent to the kind of procedure in which their gametes are to be used. Where any embryo has been formed and the embryo is to be used for implantation into the body of a woman other than the woman for whom it was originally created, the consent of the donors of the gametes is required. Where a donor is married or living in a de facto relationship, the consent of the donor's spouse is also required. Divorce or separation after the consent negatives the requirement that the spouse's consent be obtained to a further use of the donor's gametes or an embryo or zygote created using the donor's gametes. If a donor marries or enters into a de facto relationship after he or she has given a consent, and the spouse of the donor objects to the use of the gametes or embryo formed using the gametes, the spouse may lodge an objection which prevents the use of the gametes, embryo or zygote. Where a known or identified donor is to be used, the parties must specifically consent to the use of material donated by a known donor.

In Western Australia, gamete donors have rights of control over their own gametes and must consent to any storage or use of the gametes they have provided. Gametes may be donated, in which case these rights are passed on to the licensee or other recipient, who may only use those gametes as the Act allows. The South Australian Code of Practice provides that a licensee must not use reproductive material for any purposes unless the person who produced the material has consented to the use of the material for that purpose.

The LRC recommended that the power to deal with and dispose of sperm and ova produced for IVF should vest in the respective gamete providers. In the case of an unconditional donation of gametes, the power to determine the use, storage and disposal of gametes should vest in the clinic.

NHMRC Guidelines state that the gamete provider and any spouse or partner of that person must give consent to the keeping or use of gametes and, if the intention is to create an embryo outside the body, the consent must specify the purpose for which the embryo may be used, namely:

- to provide treatment for the provider or the provider and a named partner;
- to provide treatment for others; or
- for specified research.

The Fertility Society's Code of Practice states that anyone consenting to the storage of their gametes must specify the maximum period of storage and state what is to be done with the gametes if he or she dies or becomes incapable of varying or revoking his or her consent. If the donated gametes are to be used for treatment and the donor is married or has a long term partner, the partner's written consent should be obtained.

It may be argued that gamete donation should be seen as an unconditional gift and that once a person has donated their gametes, they forfeit any rights to attach conditions to their use. This is the current situation as regards organ and tissue donation under the Human Tissue Act.

In any event, there is a question as to whether the law should intervene in determining these matters or whether it should be left to the participants to make their own arrangements in relation to these matters, bearing in mind the guidance which is already given to clinics in these matters by the NHMRC and Fertility Society of Australia.

[6.4] Use and disposal of embryos

In its IVF Report, the LRC recommended that, within the proposed storage limit of ten years, the stored embryo should not be used, dealt with or disposed of unless the couple for whom the ovum was fertilised agree. Where one member of the couple for whom the ovum was fertilised dies, the power to make decisions as to use or disposal should vest in the survivor. Where the couple are dead, the power to make decisions as to the use or disposal of the stored embryo vests in the clinic or storage facility.

The Victorian Act provides that the persons who have produced the gametes from which the embryo was formed must consent to its storage and that the embryo must not be removed from storage unless it is to be used for treatment or research (in which case the consent provisions in relation to each of those procedures apply) or the persons who produced the gametes from which the embryo is formed consent in writing and if either of those persons is married or in a de facto relationship, the consent of their spouse is also required.

The South Australian Code of Practice provides that a licensee must not keep an embryo in storage for the future use of a couple unless the couple have consented to that storage. Such a consent may be given subject to conditions as to how the embryo is to be dealt with or disposed of. Consents may be reviewed annually. Directions under the Western Australian Act state that consent is required to be given in relation to any use or keeping of any gametes or embryo.

There are many different scenarios which may arise in respect of the use of stored embryos. Stored embryos may be:

- formed for a couple using their own genetic material;
- formed for a couple using the wife's ovum and donor sperm;
- formed for a couple using a donated ovum and the husband's sperm;
- formed for a couple using both donated sperm and a donated ovum; or
- formed for a couple in any the above scenarios and donated to another couple (spare embryos).

Thus, in some cases there will be more than two persons who may potentially wish to give directions regarding the embryo.

Difficulties may be overcome if persons who donate embryos or genetic material for a specified purpose then relinquish their rights of direction and control over the donated material in favour of the person to whom the donation is made or, in the absence of such a person, the clinic.

Other dilemmas arise where both members of the couple who have powers of direction over the storage of an embryo disagree. It is suggested by the LRC that in such cases, the status quo be maintained. That is, the embryo would remain in storage until the statutory limit of storage or any longer period recommended by the Council has expired.

Some may argue that many of these dilemmas may be avoided by obtaining, prior to the formation of the embryo, the express consent to all contemplated procedures of all persons who may have an interest in its use. This is a matter for good clinical practice and legislative intervention may not be seen as necessary. Alternatively, some may argue that the issue of ownership and control of embryos is so uncertain that the law should take some role in preventing disputes over the use of embryos by mandating that certain consents be obtained prior to the formation of the embryo.

There is also the question as to whether the law should take any action in relation to those embryos currently in storage where the persons who gave consent to the storage of those embryos cannot be contacted, or will not give directions in relation to the storage or use of those embryos.

Options for discussion

Is there any need for legislation or a State Code of Practice to require the written consent and/or direction of a gamete donor (and his or her spouse) in relation to:

- the use of their gametes:
- the disposal of their gametes?

If so, precisely what consents and/or directions should gamete donors be required or permitted to give?

Is there any need for legislation or a State Code of Practice to require the written consent and/or direction of the couple/person for whom an embryo was formed in relation to:

- the use of that embryo
- the disposal of that embryo

If so, precisely what consent and/or directions should such a couple/person be required or permitted to give?

Is there any need for legislation to allow for the disposal of embryos and gametes currently in storage where persons who gave consent to the storage of those embryos and gametes cannot be contacted or will not give directions in relation to those embryos or gametes?

[6.5] Posthumous conception

The LRC was of the view that no legal regulation or prohibition of IVF was called for in relation to the use of IVF procedures to achieve pregnancy with the stored gametes of a deceased person.

The Victorian Act prohibits the use of gametes from a dead person or the transfer of embryos formed from the gametes of a dead person. This would prevent a woman being inseminated with her dead husband/partner's stored sperm or having an embryo formed using her dead husband/partner's stored sperm or having a stored embryo which was formed with her husband/partner's sperm when he was alive transferred to her body after his death. Directions

under the Western Australian Act state that no consent given by a gamete provider may include a consent for the posthumous use of the gametes. A person must not knowingly use gametes in an artificial fertilisation procedure after the death of the gamete provider. The South Australian Code of Practice states that a licensee must dispose of an embryo that is kept in storage for future use of a couple if either member of the couple dies, unless the storage consent specifies how an embryo is to be dealt with or disposed of in the event of death, in which case the licensee must deal with the embryo or dispose of it in accordance with those conditions.

It is noted that this discussion deals with gametes taken from a live donor who subsequently dies. The issue of removing gametes from an already deceased person is separately dealt with at paragraph [5.2]. Allowing ART to be utilised in circumstances where one partner has died may be contrary to the concept of ART being a medical procedure for the treatment of infertility. It is one thing, it may be argued, to assist an infertile couple to have a child. It is another matter to assist a woman to have a child in circumstances where a fertile couple could not. If eligibility criteria as to a woman being a member of an infertile couple are enacted, this alone may act to prevent the posthumous use of gametes or embryos.

However, some may argue that a woman should not be denied the chance to achieve pregnancy using her deceased husband's sperm or an embryo created using his sperm. The consequent problems that would inevitably arise as to succession and paternity should be resolved by amendments to the necessary legislation.[5] It may be argued that the law has no role to play in interefering with the choice of individuals in this regard.

A general prohibition on posthumous use of gametes would have application in relation to third party donors as well. Where a person who has made an unconditional donation of gametes dies, the clinic may be prevented from subsequently using any of those gametes for another couple. If a prohibition on the posthumous use of gametes is supported, consideration should be given to whether the death of a third party donor is to be included in that prohibition.

5 In the Tasmanian case of Estate of K: ex parte The Public Trustee (A 16/1996, Supreme Court of Tasmania, Slicer J, 22 April 1996) it was held that a child, being the product of his father's semen and mother's ovum, implanted i the mother's womb subsequent to the death of his father is, upon birth, entitled to a right of inheritance afforded by law.

Options for discussion

Is there a need for legislation or a State Code of Practice prohibitiing the use of :

- the gametes of a deceased person; and/or
- an embryo formed from the gametes of a deceased person,

in any ART procedure?

If so, should the death of third party donors be covered by such a prohibition, or only the death of a parent donor?

PART VII: RECORD KEEPING AND ACCESS TO INFORMATION

[7.1] Records to be kept

The LRC recommended that all clinical reports relating to IVF procedures and to the parties involved in that procedure should be retained. The extent of the records, their content, and the methods used to preserve anonymity are matters for good medical practice. No time limit should be fixed on the retention of the records of IVF clinics.

Licences in South Australia are issued subject to a condition that specified records be kept in relation to the artificial fertilisation procedures conducted and the source of the human reproductive material used. In Western Australia, licensees are required to keep certain information including:

- the identity of donors of gametes and their consents;
- biological parentage of embryos;
- place, period and method of collection and storage of gametes and embryos;
- the identity of persons to whom gametes or embryos are supplied;
- the identity of participants, the relevant procedure, and any known particulars of a child born as a result of a procedure.

The Victorian Act makes similar requirements of licensees.

The Fertility Society of Australia Code of Practice states that a permanent record must be kept of all procedures, identifying: the patients, donors and recipients of all gametes involved in fertilisation and embryo formation; the final outcome of any attempted fertilisation; and the final locations of any conceptions formed by IVF pregnancies.

NSW Department of Health policy (Circular 96/88) requires public hospitals to retain all records relating to ART for 35 years where a child is born, or if it is not known whether a child is born, if a pregnancy is achieved.

As participants in ART programs and children born as a result of ART procedures may seek access to this information at later stages in their lives, many would argue that legislation should mandate that ART records be retained permanently. It may also be argued that legislation should mandate the minimum content of such records.

Options for discussion

Is there a need for legislation or a State Code of Practice which requires ART providers to permanently keep records as to all ART procedures they carry out?

Is there a need for legislation to mandate the minimum content of such records? If so, what should that minimum content be?

[7.2] Access to information

The LRC made recommendations as to access of non-identifying information without consent but considered that access to identifying information should only be possible with the consent of the person whose identity was to be revealed.

The Victorian Act establishes a central register of information to be kept in relation to procedures involving donor gametes and embryos. Donors and parents of offspring born as a result of donor procedures can access non-identifying information as to recipients/donors as of right from the central register. Identifying information can be accessed with the consent of the person to whom the information relates. Children born as a result of donor procedures and their offspring can access both identifying and non-identifying information as of right. No identifying information may be accessed from the registers kept under the Western Australian Act. A donor may consent to the disclosure of identifying information regarding themselves under the South Australian Act. A licensee may give non-identifying information regarding a donor to a person conceived from that donor's genetic material over the age of 16, but must not disclose identifying information without the consent of the donor.

Non-identifying information

There would appear to be little contention as to the provision of non-identifying information to persons who have a legitimate interest in that information. The LRC was of the view that this legitimate interest must be proved. However, it may be argued that this information should be provided as of right to all participants in the program (donors, parents and children upon reaching adulthood) or at least to parents and children.

Some may argue that donors of genetic material should be encouraged to view their donation as an unconditional gift with no consequent entitlements to know the outcome of any procedures in which their donation was utilised. However, others may argue that there is no reason why non-identifying information regarding offspring should not be provided to donors.

Identifying information

The provision of identifying information will fall into two categories: where consent has been given by the person to whom the information relates, and where such consent has not been given.

In general, access to information is of most relevance in relation to donor procedures. Concerns have been raised by parents of children born as a result of donor procedures that they or their children have difficulty in obtaining information as to the child's genetic heritage. The amount of information provided tends to vary greatly from clinic to clinic. It is argued that it is in the best interests of a child to be able to access information as to their genetic heritage and the circumstances of their conception. Parallels are drawn between donor procedures and adoption, in that both involve the separation, to differing extents, of biological and social parenting. It is argued that it is a child's right to know the details as to both their biological and social parentage. Preventing a child from accessing such information may be detrimental to the child and may also constitute a denial of the child's rights.

Many have argued in support of the principle of openness and honesty within families, including openness about the circumstances of conception. Nevertheless, it remains a decision for each individual couple to determine whether or not to inform a child born as a result of a donor procedure of their genetic heritage. It is difficult to know how many parents of donor children inform their child of the facts surrounding their conception. However, where a child is so informed, they may have serious and genuine needs to access information as to their biological parentage. These needs may relate to the desire to have knowledge of their origins, and medical and genetic history. They may also wish to allay their concerns as to issues such as whether they bear a genetic link to a person with whom they are entering into a relationship. Some children may also feel a need to establish contact with the donor.

There would appear to be fewer concerns regarding the provision of identifying information where the person to whom the information relates consents. To deny the provision of information where consent has been given could be seen as unnecessarily paternalistic and would be contrary to the practice in relation to other medical records held by public health facilities.

Difficulties may arise in relation to accessing information where there is no consent. In Victoria, only children born as a result of donor procedures and their offspring may access identifying information as to the donor in the absence of the donor's consent. It is recognised that in some circumstances this may compromise the privacy of the donor. However, provided that the donor is told at the time of donation that certain information is to be recorded about them and may be accessed by offspring born as a result of the use of their donated gametes, concerns as to privacy may be allayed. It is also argued that what is in the best interests of the child is paramount over the interests of the donor.

Arguments against access to identifying information as of right by a child include the view that such a system will result in less people being willing to become donors. There is also the concern that women may be more reluctant to utilise donor procedures due to concerns that their offspring will be able to establish links with their biological parents.

It is also argued that the ability to ascertain one's genetic heritage is uncertain in relation to natural conception and there should be no reason to provide greater certainty in the realm of ART. This is based on the argument that, in a significant number of births, the registered or putative father is not the biological father of the child. Thus, uncertainty in genetic heritage also applies to children conceived naturally.

There is no doubt that persons other than offspring, parents and donors should not have access as of right to information held by clinics, except in exceptional circumstances. A statutory duty of confidentiality may be necessary to prevent the unauthorised disclosure of confidential information.

Options for discussion

Is there a need for legislation or a State Code of Practice which allows:

- children born as a result of donor procedures; and/or
- parents of such children, and/or
- offspring of such children,

to have access to either identifying or non-identifying information regarding relevant donors?

If so, is the consent of the donor necessary?

Is there a need for legislation or a State Code of Practice which allows donors to have a right to access either identifying or non-identifying information regarding children born using their donated genetic material?

If so, is the consent of the child, or the parent of the child, or both, necessary?

If any such legislation is enacted or Code of Practice made, should it provide that donors and participants of ART programs must be informed at the time of donation/consent to a procedure, of information that is required to be kept and of the persons who have a right of access to that information and the circumstances under which such access may be given?

If any such legislation is enacted or Code of Practice made, should it mandate the provision of counselling prior to the release of the information?

Is there a need for legislation or a State Code of Practice which imposes a statutory duty of confidentiality upon:

- persons providing ART services; and/or
- donors of gametes,

preventing the disclosure of any information except with consent or where permitted by law as discussed above?

[7.3] Responsibility for retaining information: a central register

The Victorian Act establishes a central register of information, which relates to treatments involving donor gametes and embryos. Clinics are required to forward information of the kind noted in paragraph [7.1] to a central register. Certain persons are given access to

information held by the register as described in paragraph [7.2]. The Western Australian Act also requires the Commissioner of Health to keep registers containing current information concerning the identity of participants, the outcome of procedures (showing the genetic origin of the gametes or embryos), the identity of children born as a result of the artificial fertilisation procedure, including the identity of each biological parent and relevant demographic and clinical information. A Public Health IVF Register and a Donor Register are maintained. The IVF Register will allow the Council to monitor the procedures of IVF for their long term outcomes and safety. The Donor Register records information about donors of reproductive material and children born from donor procedures. The Act provides for access to non-identifying information from the Register. No such registers are established under the South Australian Act.

Many have argued for the establishment of a central register in relation to donor procedures. A central register would allow participants in ART treatments involving donor material (donors, parents and children) to access information as to the use of their gametes or embryos (in the case of donors) or their genetic heritage or that of their offspring (in the case of parents and children). Without a central register, these persons would have to rely upon the clinics in which they or their parents were treated to have retained and stored the information in an accessible manner. In some cases, children born as a result of donor procedures or their offspring may not know which clinic or medical practitioner to approach to obtain this information. The storage of this information in a central register would ensure that access to such information was permanently available.

However, the compulsory central storing of any information concerning an individual raises serious issues of privacy for those persons. While it is recognised that many participants in ART procedures would welcome the retention of their personal information in a central register because of the advantages that flow from access to the information, it must also be recognised that the storage of this information may be against the wishes of some people. While it may be argued that parents and donors who do not wish to have information stored on a central register may choose not to participate in donor programs, the same cannot be said of offspring who will not have the opportunity to make such a decision. Their concerns may be the general concerns of any person who has information about them held centrally without their consent, including possible misuse of information and access to information by other persons. Although statutory safeguards to prevent misuse

and unauthorised access to information may be enacted, the mere fact of centralisation is a cause of concern to many people.

The arguments in favour of a central register rely on the view that proper access by persons with a relevant interest can only be facilitated where the information is centrally held. Thus, access can be centrally administered and regulated and relevant services can be offered to persons seeking to access information, such as counselling. It may be argued that the significance of the information to the person seeking access necessitates that it be administered by an appropriate authority and not by individual clinics.

The contrary view is that medical records generally are not held centrally. Furthermore if ART providers are required to keep proper records and maintain their records indefinitely, this may overcome concerns regarding destruction of records and access.

Options for discussion

Should ART providers be required by legislation or a State Code of Practice to forward all information that must be kept by them in relation to donor procedures to a central register?

Who should have responsibility for maintaining this central register and for administering access to it?

PART VIII: SCREENING OF DONORS AND INFECTION CONTROL

[8.1] Selection and screening of donors

Under the Human Tissue Act 1983, donors of semen must sign a certificate as to their medical suitability. The certificate is prescribed in the Human Tissue Regulation 1995 and requires information as to the medical history of the donor which is designed to elicit risk factors for the presence of HIV and other contaminants. There are penalties for knowingly providing false or misleading information.

Also under the Human Tissue Act, persons are prohibited from carrying on a business of supplying semen unless they are authorised by the Director-General of the Department of Health. Authorisations are subject to conditions, including that all third party donors of semen and husbands/partners whose semen is to be utilised in ART are tested for certain prescribed contaminants being HIV, Hepatitis B and C, HTLV I (Human T-lymphotropic virus Type-I), and syphilis. Where the semen is obtained from a third party donor, it must be quarantined for such a period of time as is recommended by the Fertility Society of Australia (currently six months) at the end of which the donor must be retested for the presence of the prescribed contaminants. This is to eliminate the possibility that the donor may have been in a "window period" of infection for one of the prescribed contaminants at the time of the initial testing. Other authorisation conditions require semen to be stored and labelled in an appropriate way and certain records to be kept. The premises of the authorised supplier must be accredited by the Fertility Society of Australia. There are no requirements regarding the supply of ova. Public and private hospitals are not required to be authorised under the Act and therefore ART clinics run by hospitals are not subject to these requirements.

The Fertility Society of Australia sets out screening procedures for donors which include: obtaining a family history as to inherited disorders; personal history of physical, mental or psychological disabilities; medical history of any children born to the donor; a physical examination; a semen and ova analysis and serology including blood group, syphilis, Hepatitis B and C and HIV. The screening process also involves other testing and the collection of physical and social history.

The Western Australian Act allows the Code to make provision for the method by which, and the extent to which, donors or prospective donors of gametes and embryos are to be assessed or selected. The South Australian Code of Practice requires prospective donors

to be screened in accordance with Fertility Society Guidelines. The Victorian Act is silent on the question of screening donors.

The LRC was of the view that legislation is not justified to prescribe qualifications for semen donors or procedures for the recruitment of donors or for the screening or testing of donors. It was of the view that it should be left to the medical profession to prescribe standard guidelines or rules for the selection and screening of donors. This, in effect, is what the Fertility Society of Australia has done.

Should NSW repeal its requirements that persons who engage in the business of supplying semen be authorised by the Department of Health? Is it sufficient that standards have already been prescribed by the Fertility Society?

Alternatively, should the law apply standards for screening of donors of ova and semen equally to all persons who may utilise such material, not just persons who carry on a business of supplying semen? Is there a danger that persons who carry out ART will not correctly screen prospective donors, such that legislation should be enacted requiring them to do so?

Options for discussion

Is there a need for legislation or a State Code of Practice which mandates certain minimum screening requirements to be applied to donors of ova and semen?

If so, what should these minimum requirements be?

[8.2] Statutory defence for infection through donor gametes and embryos

The Human Tissue Act provides a defence for authorised and exempt suppliers of blood and semen from actions taken by a person who has been infected with a prescribed contaminant by receiving infected blood or semen. The prescribed contaminants are HIV, Hepatitis B and C, HTLV I and syphilis. Exempt suppliers of semen are all public and private hospitals. Authorised suppliers of semen are those persons who have been authorised by the Director-General of the Department of Health as described at paragraph [8.1] above.

Where a woman has undergone ART with donor semen and the woman is infected by one of the prescribed contaminants as noted above, the supplier of the semen will have a statutory defence to any action in tort or contract as a result of the infection provided that:

- the donor of the semen had signed a certificate of medical suitability required by the Act;
- the blood of the donor had been tested for the prescribed contaminants using tests of a kind approved by the Minister; and
- the supplier was an authorised or exempt supplier.

The donor of the semen is protected from any action by the person infected with the contaminant provided he did not knowingly provide false or misleading information on the medical certificate.

At present, the defence does not extend to donor ova or embryos.

Donors of semen and ova may wish to be assured that they cannot be sued in relation to the transmission of a disease through their donated gametes. Protection for donors is dealt with in paragraph [8.3] below. However, in another discussion paper, the question of whether the statutory defence should exist only in respect of blood and then, only in respect of the Red Cross Blood Transfusion Service is discussed. The purpose of the statutory defence was to ensure the continued availability of blood for transfusion in the wake of the many cases of medically acquired HIV/AIDS which arose prior to the introduction of a test which safely detected HIV antibodies. The defence was extended to semen to cover artificial insemination. However, it may be questioned whether persons treated in ART programs who acquire an infection through donor gametes should have their common law rights to sue for damages limited by statute. It may be argued that such a limitation should only be imposed where the public health requirement is overwhelming.

The defence is available in Victoria in respect of semen, and also in respect of organ donation. In the remaining states, it is limited to blood only.

If the defence is to remain, the question arises as to whether it should be extended to donor ova and embryos as well.

Options for discussion

Should the statutory defence available to suppliers of semen in respect of the transmission of prescribed contaminants through semen under the Human Tissue Act 1983 be removed or should it be retained and extended to cover donor ova and embryos?

[8.3] Supply of false information by donors

The Human Tissue Act makes it an offence for donors of semen to knowingly provide false or misleading information on a medical certificate which is required by the Act prior to donation. As discussed above, this applies only to semen donation and does not extend to ova or embryo donation.

Should such a sanction be imposed by law upon donors, or are the provisions of the common law, in leaving a donor open to a legal action by a person who has suffered damage as a result of his or her provision of false information, sufficient in this regard? Conversely, should a donor be protected against an action by a recipient who has been infected through the use of the donor's genetic material, provided the donor did not provide false or misleading information when donating?

Options for discussion

Should the current offence in the Human Tissue Act regarding the supply of false information by a semen donor on a prescribed medical certificate be widened to a general offence of knowingly concealing or misrepresenting information, or providing false or misleading information about a person's health, when offering or agreeing to donate gametes or embryos for an ART procedure?

Is there a need for legislation to provide protection to donors against actions taken by recipients of donor gametes and embryos or children born as a result of donor gametes or embryos, for the transmission of an infectious disease or the inheritance of a genetic disease or disorder, provided that the donor did not breach the prohibition upon providing false or misleading information?

[8.4] Release of health information

The Code of Practice under the South Australian Act states that, where it comes to the knowledge of a licensee that a donor or a child born from donor gametes is suffering from a hereditary illness or disease, the licensee must obtain the advice of a medical practitioner with expertise in the field of genetics and disclose to other children born utilising that donor material (if over the age of 16) or their parents the occurrence of the illness or disease. Similar provisions apply to informing a donor where it comes to the licensee's attention that a child born from the donor's genetic material has developed such a disease or illness.

The LRC was of the view that the supply of information suggesting that a person's health is at risk involves an ethical duty of medical practitioners which operates in all areas of medical practice. The LRC therefore recommended that no statutory obligation should be created to require the supply of such information, rather the matter should be left to the courts for judicial determination.

Is it necessary for the State to intervene in this matter of good medical practice and mandate the disclosure of such material? The LRC's recommendation takes account of the fact that it would be difficult to draft a statutory provision which could cover all possible scenarios in which such questions may arise. Ultimately, a practitioner must have regard to his or her ethical duties.

However, it may be desirable to impose a specific duty upon practitioners to disclose information relating to genetic illnesses or diseases to participants in ART procedures.

Options for discussion

Is there a need for legislation or a State Code of Practice to impose a duty on medical practitioners who practice ART, where it comes to their knowledge that a donor child born as a result of donor material is suffering from a hereditary disease or illness, to disclose that information (without also disclosing the identity of the person suffering the disease or illness) to:

- any child (where over 18) or the parents of any child born as a result of the utilisation of the same donor material;
- the donor (if the donor is not the person whose illness or disease has come to the licensee's attention)?

PART IX: SURROGACY

[9.1] Introduction

The LRC defined surrogacy as an arrangement whereby a woman agrees to become pregnant and to bear a child for another person or persons, to whom she will transfer custody after birth. The definition excludes the situation in which the woman is already pregnant at the time the arrangement to hand over the child is made. The LRC was of the view that this latter situation was already dealt with adequately by the existing law. The definition of surrogacy utilised by the LRC is adopted for the purposes of this discussion paper.

The LRC was of the view that the practice of surrogacy was undesirable because:

- it involves the deliberate creation of new life for the purpose of alleviating infertility;
- the body of a woman is put to the service of the commissioning parties;
- the practice entails the planned separation of child and birth mother, at a very early age and permanently;
- it tends to ignore the interest of other members of the families of the participants;
- both the woman who is to act as the surrogate and the woman who commissions the child are placed at significant risk by the process because of the possibility of moral pressure being exerted on them to comply. Even in altruistic surrogacy arrangements there can be no guarantee that both women have exercised true freedom of choice;
- the legal recognition and enforcement of a surrogacy agreement is inconsistent with the philosophy that in all cases concerning guardianship or custody, the welfare of the child should be the paramount consideration.

Various approaches to surrogacy have been taken in subsequent publications examining the issue. These include the National Bioethics Consultative Committee reports on surrogacy (April 1990 and October 1990) and the Discussion Paper of the NSW LRC on “Review of the Adoption of Children Act 1965 (NSW)” (DP 34, 1994). It is not the intention of this discussion paper to reiterate in detail the moral, ethical, legal and social arguments for and against surrogacy. Readers are referred to the preceding publications for this purpose.

In summary, however, it can be said that the following additional reasons have been identified for supporting a prohibition on, or at least discouragement of, surrogacy:

- it involves treating children as a commodity to be ordered and sold or traded for payment (there is anecdotal evidence in the United States of commissioning parents refusing to take custody of the child when it is born);
- it involves the use of women as a means to an end;
- it challenges the basic concept of marriage and the family accepted by society by introducing a third party into the process of procreation which should be confined to the partnership between two people;
- it distorts the relationship/bond between mother and child;
- it devalues the bodies of women, relegating them to the role of incubator;
- there is a significant risk of harm to the surrogate mother because of potential psychological trauma associated with the breaking of the mother/child bond developed in utero and other trauma associated with the deliberate relinquishment of a child after birth;
- there is a risk of harm to the child due to confusing family relationships and due to the fact that a child may be unable to obtain information about his or her biological origin; and
- the surrogate mother may be exploited by commercial agents and suffer oppressive restrictions regarding life-style, diet, sexual relations, medical supervision etc.

The arguments in support of surrogacy are also well documented and include:

- surrogacy offers some couples the only chance of having a child genetically related to one or both and for this reason should not be ruled out;
- people have the right to make whatever arrangements they see fit to have children to form a family without intrusion from the State (principle of personal autonomy);
- there is nothing intrinsically immoral or anti-social in surrogate motherhood;
- it is impossible to prevent people from making private surrogacy arrangements, and therefore they should be allowed by the law; and
- prohibition of surrogacy will merely drive the practice underground thereby increasing the likelihood of exploitation of the parties involved and the creation of a “black market”.

The purpose of this discussion paper is to assess the current state of the law in NSW and other States, re-examine the recommendations of the LRC and to suggest legislative options for discussion by the community.

[9.2] The current law in NSW

There is no legislation in NSW which regulates surrogacy. Surrogacy is not specifically prohibited in NSW. However, a woman wishing to obtain a child through a surrogacy arrangement would be faced with significant difficulties. Firstly, there are the legal presumptions of parenthood which apply in this State. The birth mother of a child is presumed to be the mother of the child at law. If the birth mother is married, the child is presumed to be the child of the birth mother and her husband (Status of Children Act 1996 s 9)[6]. Similar presumptions apply if the woman is in a de facto relationship. A commissioning mother would have difficulty in becoming registered as the mother of the child in light of these presumptions and without committing an offence under the Births Deaths and Marriages Registration Act 1995. Where the child has been conceived through ART utilising the commissioning parents gametes, the law sets out an irrebuttable presumption that the donor of the gametes is not the parent of the child (Status of Children Act s 14). This section facilitates parenthood for persons involved in non-surrogate ART.

One way to overcome these difficulties is for the commissioning parents to adopt the child. However, the Adoption of Children Act 1965 (NSW) does not allow for the making of private adoption arrangements and adoptions can only be facilitated through the Department of Community Services. That Department has been approached to facilitate adoption arrangements in private surrogacy situations and, where it is clear that a surrogacy arrangement has taken place, has refused to assist with an adoption, referring the parties to the range of orders available under the Family Law Act 1975 in relation to custody and guardianship.[7]

Should a contract for surrogacy have been entered into and the birth mother subsequently refuse to relinquish the child, it is likely that the commissioning couple would have difficulties in enforcing the contract in a court of law. Although no cases of this kind appear to have come before a court in NSW, it is a generally held view that a court would refuse to enforce such a contract on the grounds that it is contrary to public policy.

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6 Status of Children Act 1996 had not commenced at the time of writing

7 NSW LRC "Review of the Adoption of Children Act 1965 (NSW)", DP 34, 1994, p 229. However, the NSW LRC has made recommendations that this approach to adoption and surrogacy should change. See "Review of the Adoption of Children Act 1965" Report 81, 1997, Ch 11.

Despite these difficulties it would appear that private surrogacy arrangements do occur in NSW and it is certainly the case that ART clinics have been approached to facilitate surrogacy arrangements. There is anecdotal evidence of couples travelling overseas to enter into surrogacy arrangements.

[9.3] The law in other States

A resolution of the Joint Meeting of Australian Health Ministers' Conference and the Council of Social Welfare Ministers in 1991 resolved that the States and Territories should legislate to:

- make any surrogacy arrangements void and unenforceable;
- make it an offence to arrange or agree to arrange surrogacy services or contract to provide technical or professional services to facilitate the creation of the pregnancy;
- make it an offence to arrange or agree to arrange surrogacy services or contract to provide technical or professional services to facilitate the creation of the pregnancy;
- make it an offence to induce a person to become pregnant for the purposes of surrendering custody and guardianship of, or rights in relation to, a child born as a result of the pregnancy;
- make it an offence to publish, or cause to be published, a statement, advertisement, notice or other document to the effect:
    - that a person is or may be willing to enter into a surrogacy contract;
    - that a person is seeking a person willing to enter into a surrogacy contract; or
    - that a person is willing to negotiate, arrange or obtain the benefit or a surrogacy contract on behalf of another.
- that where, despite the provisions of the legislation prohibiting surrogate motherhood, it comes to the attention of authorities that a child has been born as a result of a surrogate motherhood arrangement, full records of the child's social and biological parents should be obtained and lodged with the relevant registrar of births, deaths and marriages.

As a consequence of the above recommendations, the Ministers noted that there was no need for further work on the feasibility of regulating the practice of surrogacy.

The Ministers agreed that penalties and sanctions against third parties be applied through:

- the classification of any form of assistance in the arrangement of surrogacy as instances of professional misconduct subject to penalty by the appropriate professional bodies, boards or tribunals; and
- the withdrawal of licences or approval to practice reproductive medicine from medical organisations which participate in facilitating surrogacy arrangements.

Most states have now legislated to give effect to this Agreement.

The Victorian Infertility Treatment Act 1995 prohibits any commercial surrogacy arrangement, making it an offence to give or receive any payment or reward under a surrogacy agreement or for arranging a surrogacy agreement or for acting as a surrogate mother. The Act also prohibits advertising surrogacy services (either to act as a surrogate, or to seek a surrogate or facilitate a surrogacy agreement). All surrogacy agreements (both altruistic and commercial) are void. Similar provisions exist in Queensland under the Surrogate Parenthood Act 1988 which also prohibits altruistic surrogacy. The South Australian Family Relationships Act 1975 provides that a surrogacy contract is illegal and void. However, penalties are attached only in relation to receiving commercial surrogacy contracts and advertising for surrogacy contracts.

Surrogacy contracts are void and unenforceable in Tasmania under the Surrogacy Contracts Act 1993. Arrangement of a surrogacy contract (either commercial or altruistic) on behalf of others is an offence, as is the provision of technical or professional services aimed at achieving a pregnancy in a surrogate. Advertising that a person is willing to enter a surrogacy agreement, that the services of a surrogate are sought, or that a person is willing to arrange a surrogacy contract is also prohibited.

Under the Substitute Parent Agreement Act 1994 of the ACT, only commercial surrogacy arrangements are prohibited. The provision of professional or technical services to facilitate a commercial surrogacy arrangement is also prohibited. Non-commercial surrogacy agreements are void. There are offences for advertising to induce a person to enter a surrogacy agreement or purporting to seek a person who is willing to enter into a surrogacy agreement. It is an offence for a person other than a party to a surrogacy agreement to procure another person to enter into such an agreement.

[9.4] Welfare of the child principle

The LRC recommended that the welfare of the child should be the paramount consideration and should prevail over the interest of adults involved in surrogate motherhood. This recommendation is in contrast to other possible guiding principles such as those which rely on the principle of personal autonomy of the commissioning couple and the surrogate mother. The LRC stated that it felt justified in curtailing the freedom of adults in this situation in order to constrain the practice of surrogacy, as this was in the best interests of the child. It stated that the application of the welfare principle does not mean that the interests of others are always ignored or overridden. Rather, it means that their interests can be recognised only when they coincide with the interests of the child.

The Department agrees that the principle of the welfare of the child shall be paramount in its consideration of the regulation of surrogacy in NSW.

[9.5] Prohibition of commercial surrogacy

The LRC recommended that all forms of commercial surrogacy should be prohibited. It should be an offence to pay, receive, offer or solicit any reward for participation in, or facilitation of, a surrogacy arrangement or any part of a surrogacy arrangement.

This recommendation of the LRC was intended to prevent the rise of surrogacy brokering as occurs in some parts of the United States. It was intended that the prohibition on payment in relation to surrogacy extend to brokers, commissioning parents, women acting as surrogates as well as members of the medical or legal professions, psychologists, counsellors and those involved in family planning who accept payment for assisting in a surrogacy arrangement. The prohibition was intended to cover indirect payments, such as payments of the surrogate mother's expenses or the conferring of other benefits, such as accommodation, travel etc.

The LRC identified five aspects of the practice of commercial surrogacy which make it unacceptable.

- It permits profit to be made from the creation and transfer of custody of a child.
- It entails the use of a woman's body, and of human gametes, for commercial purposes.
- It creates a "profit motive" that encourages persons, mainly potential surrogates, to enter into surrogacy arrangements.

- The receipt of money may inhibit those immediately involved in the arrangement in reconsidering their decisions. Whether or not it is well-founded, a payment of money to the surrogate mother may lead her to believe that she cannot withdraw from the arrangement.
- It is tantamount to a trade in women and children which has never been countenanced in Australian society. The traditions reflected in our adoption and child welfare laws have always been opposed to the commercial exploitation of child rearing and we have always been careful to repose responsibility for the care of children in public or charitable institutions and not in private, commercial organisations.

A prohibition on commercial surrogacy is consistent with the legislation in other States and the resolution of the Health and Social Welfare Ministers in 1991.

Options for discussion

Is legislation necessary to prohibit all forms of commercial surrogacy such that it is an offence to pay, receive, offer or solicit any reward for participation in, or facilitation of, a surrogacy arrangement or any part of a surrogacy arrangement?

[9.6] Advertising

The LRC recommended that anyone who publishes or causes to be published a statement or advertisement offering or soliciting participation in a surrogacy arrangement should be guilty of a criminal offence. It should also be an offence to publish, advertise or cause to be advertised a statement that a person is willing to negotiate, arrange or obtain the benefit of a surrogacy arrangement on behalf of another.

The LRC intended these prohibitions to have a wide operation, attaching to paid promoters of surrogacy arrangements, surrogate mothers who advertise their services and to the commissioning couple. It would also extend to ART clinics which offer their services to assist in surrogacy arrangements.

Options for discussion

Is there a need for legislation providing that anyone who publishes or causes to be published a statement or advertisement offering or soliciting participation in a surrogacy arrangement be guilty of an offence? Should it also be an offence to publish, advertise or cause to be advertised a statement that a person is willing to negotiate, arrange or obtain the benefit of a surrogacy arrangement on behalf of another?

[9.7] Assisting in commercial and altruistic surrogacy

The LRC recommended that the following practices associated with surrogate motherhood should be prohibited, and criminal penalties should be imposed on anyone convicted of engaging in them except the immediate parties to the arrangement:

- any person, except one of the immediate parties to the arrangement, who knowingly arranges or undertakes to arrange an introduction between those who may be interested in participating in a surrogacy arrangement, or who in any other way knowingly assists in such an arrangement, or any part of such an arrangement would be guilty of an offence
- any person who drafts or assists in the drafting of a surrogacy agreement should be guilty of an offence.

It is noted that the LRC did not recommend the prohibition of altruistic surrogacy or the imposition of penalties upon commissioning parents or surrogate mothers in altruistic surrogacy. This is discussed further at paragraph [9.8] below.

Paid assistance in arranging surrogacy agreements is already covered by the option discussed at paragraph [9.5]. The above recommendation would only apply where persons offered assistance altruistically. Anyone acting as an intermediary or an assistant, including professionals, members of the immediate parties' families and their friends would be guilty of an offence. The recommendation arises as a result of the LRC becoming aware, during the process of drafting its report, of many individuals and organisations prepared to assist in surrogacy without receiving payment, including doctors, psychologists and those staffing family planning clinics, relatives and friends. The LRC was of the view that these persons should be subject to criminal penalties, although the actual participants in the arrangement should not.

This recommendation of the LRC was not unanimous. In relation to professional advice, the minority view of the LRC was that medical practitioners and other professionals should act according to ethical standards and what they perceive to be in the best interests of the child. The facilitating of an agreement which is void at law may be sufficient to prevent doctors and other professionals from engaging in the practice of assisting in surrogacy arrangements. However, some professionals may wish to have their position in relation to altruistic surrogacy clearly spelt out by the law, to assist them in difficult situations where they felt a conflict of interest may arise. However, it must be noted that the minority of the LRC was of the view that this was not a sufficient reason for extending criminal sanctions in this area.

In relation to non-professional persons such as friends and relatives, it may be difficult to justify the imposition of penalties upon these persons for assisting in altruistic surrogacy if the law imposed no such penalty upon the participants in the arrangement.

Options for discussion

Should the following practices associated with surrogate motherhood be prohibited by legislation, and penalties be imposed on anyone convicted of engaging in them:

- knowingly arranging or undertaking to arrange an introduction between those who may be interested in participating in a surrogacy arrangement, or in any other way knowingly assisting in such an arrangement, or any part of such an arrangement;
- drafting or assisting in the drafting of a surrogacy agreement?

Should such offences extend to the participants in the surrogacy arrangement itself?

[9.8] Altruistic surrogacy

Although the LRC was of the view that surrogacy should be discouraged by all practicable, legal and social means, it was not of the view that penalties should be imposed upon those who participate in private altruistic surrogacy arrangements. It was thought that the uncertainty of the law which would result from the other recommendations would be sufficient to discourage the practice. However, some may argue that such measures are not sufficient and that altruistic surrogacy arrangements should also be prohibited.

Options for discussion

Is there a need for legislation prohibiting altruistic surrogacy arrangements? Should it be an offence to act as a surrogate or enter into any arrangement (whether or not any payment is made) with another person to act as a surrogate?

[9.9] Status of surrogacy arrangements at law

The LRC recommended that surrogacy agreements should be void and unenforceable at law. It was of the view that the model of deliberate non-recognition of surrogacy at law (rather than the prohibition of altruistic surrogacy) is

> "consistent with our desire to discourage but not penalise the immediate parties to the agreement unless they advertise or pay or receive money for their involvement. We believe they should be counselled against entering into a surrogacy agreement and denied any assistance from the law in making or enforcing their arrangements. Legislation declaring these agreements void and unenforceable should achieve these purposes. If made void and unenforceable no action could be taken on the surrogacy agreement by either party and any money paid under its terms would not be recoverable."[8]

If altruistic surrogacy arrangements are made void, parents who seek to enter into altruistic surrogacy arrangements will be faced with the difficulties described at paragraph [9.2] above. The commissioning parents would have no remedies available should the birth mother not wish to part with the child.

Options for discussion

Is there a need for legislation which renders all surrogacy agreements void and unenforceable at law?

SUMMARY OF OPTIONS FOR DISCUSSION

ASSISTED REPRODUCTIVE TECHNOLOGIES AND THE LAW

Is there harm to the community, or the potential of harm to community, in the current practice of ART (including Artificial Insemination) such that intervention from the State is necessary:

- in limiting the persons who are allowed to practice ART in NSW;
- to prohibit certain practices, mandate certain practices and/or require the observance of certain codes of practice.

Submissions may wish to address these issues separately in relation to Artificial Insemination and other types of ART.

If any State intervention in the practice of ART is identified as necessary, should a Code of Practice be considered as an appropriate means of regulation?

Should compliance with any such “State” Code of Practice be mandated by legislation?

Who should be responsible for formulating any such “State” Code of Practice?

ELIGIBILITY FOR ASSISTED REPRODUCTIVE TECHNOLOGIES

Is there a need for legislation or a State Code of Practice to prescribe any eligibility criteria for ART based on relationship factors?

Is there a need for legislation or a State Code of Practice which provides that access to ART be available only where:

- a medical practitioner is of the view that a woman is unlikely to become pregnant as a result of coitus with her husband/partner; or
- if the woman were to become pregnant from such coitus, a genetic abnormality or genetic disease may be transmitted to a child born as a result of the pregnancy; or
- if a woman was to become pregnant as a result of coitus with her husband/partner, a disease (other than a genetic disease) may be transmitted to a child born as a result of the pregnancy; or
- a woman is unable to have unprotected coitus with her partner because of the risk of transmission of an infectious disease from one partner to the other?

Is there a need for legislation or a State Code of Practice which prescribes eligibility criteria for persons wishing to access ART in respect of:

- age;
- economic status;
- home environment;
- mental or physical health of parents;
- criminal history of parents;
- parents who have had children removed from their custody?

Is there a need to include a guiding principle in legislation or a State Code of Practice which makes the welfare of the child to be born as a result of ART of paramount importance in the provision of ART?

Is there any need for legislation or a State Code of Practice dealing with the consent of the participants of ART or are the requirements of the general law sufficient?

Is there a need for any legislation or a State Code of Practice in relation to the counselling of participants and donors in ART procedures?

RESEARCH ON EMBRYOS

Is there a need for legislation or a State Code of Practice to be enacted which prohibits:

- destructive research on embryos;
- the creation of embryos for research;
- the keeping alive of embryos outside the body of a woman for longer than fourteen days (excluding any time in storage) or beyond the formation of the primitive streak, whichever is the earlier;
- the transfer of embryos or gametes to the body of woman that have been the subject of research?

Would the establishment of a statewide ethics committee for approving ART research be of benefit to the community in developing a consistent approach to ART research in NSW?

Is there any harm to the community in the current level of regulation of ART research by the common law and NHMRC Guidelines such that further intervention is necessary by the State to:

- require persons who carry out ART research to hold a licence;
- mandate in legislation the approval of ART research by an ethics committee?

PROHIBITION ON CERTAIN PRACTICES

Should the proposed legislation prohibiting procedures involving the mixing of a gamete produced by an animal with a gamete produced by a man or woman create an exception where the procedure involves mixing animal ova and human sperm and is carried out for diagnostic purposes only?

Is there a need for legislation or a State Code of Practice to prohibit any of the following procedures:

- embryo flushing;
- the alteration of the genetic constitution of a gamete which is intended to be used in an ART procedure;
- the alteration of the genetic, pro-nuclear or nuclear constitution of an embryo except to alter the somatic cells for therapeutic purposes;
- the use of gametes produced by a person under the age of 18 except in certain prescribed circumstances;
- the use of ova derived from a foetus in an ART procedure;
- the carrying out of an ART procedure using gametes produced by more than one person or embryos created using mixed gametes;
- transfer of an embryo into an animal;
- transfer of an embryo into a body cavity other than the human female reproductive tract;
- treatment of a woman using ART with the purpose of producing a child of a particular sex except where necessary to avoid the risk of transmission of a genetic abnormality or disease;
- use of donor reproductive material from an immediate relative of the genetic parent of the potential offspring;
- the placing of any cells extracted from an embryo into the body of a person;
- collection of gametes from a dead person for use in an ART procedure?

Is there any need for legislation or a State Code of Practice to address the issue of the importation of gametes and embryos from outside NSW?

Is there any need for legislation or a State Code of Practice to limit the number of offspring to be produced utilising the genetic material of any one donor?

STORAGE USE AND DISPOSAL OF EMBRYOS AND GAMETES

Is there any need for legislation or a State Code of Practice to set an overall time limit on the storage of embryos and gametes? If so, for what period?

Is there any need for legislation or a State Code of Practice to require the written consent and/or direction of a gamete donor (and his or her spouse) in relation to:

- the use of their gametes;
- the disposal of their gametes?

If so, precisely what consents and/or directions should gamete donors be required or permitted to give?

Is there any need for legislation or a State Code of Practice to require the written consent and/or direction of the couple/person for whom an embryo was formed in relation to:

- the use of that embryo;
- the disposal of that embryo?

If so, precisely what consent and/or directions should such a couple/person be required or permitted to give?

Is there any need for legislation to allow for the disposal of embryos and gametes currently in storage where persons who gave consent to the storage of those embryos and gametes cannot be contacted or will not give directions in relation to those embryos or gametes?

Is there a need for legislation or a State Code of Practice prohibiting the use of:

- the gametes of a deceased person; and/or
- an embryo formed from the gametes of a deceased person,

in any ART procedure?

If so, should the death of third party donors be covered by such a prohibition, or only the death of a parent donor?

RECORD KEEPING AND ACCESS TO INFORMATION

Is there a need for legislation or a State Code of Practice which requires ART providers to permanently keep records as to all ART procedures they carry out?

Is there a need for legislation to mandate the minimum content of such records? If so, what should that minimum content be?

Is there a need for legislation or a State Code of Practice which allows:

- children born as a result of donor procedures; and/or
- parents of such children, and/or
- offspring of such children,

to have access to either identifying or non-identifying information regarding relevant donors?

If so, is the consent of the donor necessary?

Is there a need for legislation or a State Code of Practice which allows donors to have a right to access either identifying or non-identifying information regarding children born using their donated genetic material?

If so, is the consent of the child, or the parent of the child, or both, necessary?

If any such legislation is enacted or Code of Practice made, should it provide that donors and participants of ART programs must be informed at the time of donation/consent to a procedure, of information that is required to be kept and of the persons who have a right of access to that information and the circumstances under which such access may be given?

If any such legislation is enacted or Code of Practice made, should it mandate the provision of counselling prior to the release of the information?

Is there a need for legislation or a State Code of Practice which imposes a statutory duty of confidentiality upon:

- persons providing ART services; and/or
- donors of gametes,

preventing the disclosure of any information except with consent or where permitted by law as discussed above?

Should ART providers be required by legislation or a State Code of Practice to forward all information that must be kept by them in relation to donor procedures to a central register?

Who should have responsibility for maintaining this central register and for administering access to it?

SCREENING OF DONORS AND INFECTION CONTROL

Is there a need for legislation or a State Code of Practice which mandates certain minimum screening requirements to be applied to donors of ova and semen?

If so, what should these minimum requirements be?

Should the statutory defence available to suppliers of semen in respect of the transmission of prescribed contaminants through semen under the Human Tissue Act 1983 be removed or should it be retained and extended to cover donor ova and embryos?

Should the current offence in the Human Tissue Act regarding the supply of false information by a semen donor on a prescribed medical certificate be widened to a general offence of knowingly concealing or misrepresenting information, or providing false or misleading information about a person's health, when offering or agreeing to donate gametes or embryos for an ART procedure?

Is there a need for legislation to provide protection to donors against actions taken by recipients of donor gametes and embryos or children born as a result of donor gametes or embryos, for the transmission of an infectious disease or the inheritance of a genetic disease or disorder, provided that the donor did not breach the prohibition upon providing false or misleading information?

Is there a need for legislation or a State Code of Practice to impose a duty on medical practitioners who practice ART, where it comes to their knowledge that a donor child born as a result of donor material is suffering from a hereditary disease or illness, to disclose that information (without also disclosing the identity of the person suffering the disease or illness) to:

- any child (where over 18) or the parents of any child born as a result of the utilisation of the same donor material;
- the donor (if the donor is not the person whose illness or disease has come to the licensee's attention)?

SURROGACY

Is legislation necessary to prohibit all forms of commercial surrogacy such that it is an offence to pay, receive, offer or solicit any reward for participation in, or facilitation of, a surrogacy arrangement or any part of a surrogacy arrangement?

Is there a need for legislation providing that anyone who publishes or causes to be published a statement or advertisement offering or soliciting participation in a surrogacy arrangement be guilty of an offence? Should it also be an offence to publish, advertise or cause to be advertised a statement that a person is willing to negotiate, arrange or obtain the benefit of a surrogacy arrangement on behalf of another?

Should the following practices associated with surrogate motherhood be prohibited by legislation, and penalties be imposed on anyone convicted of engaging in them:

- knowingly arranging or undertaking to arrange an introduction between those who may be interested in participating in a surrogacy arrangement, or in any other way knowingly assisting in such an arrangement, or any part of such an arrangement;
- drafting or assisting in the drafting of a surrogacy agreement?

Should such offences extend to the participants in the surrogacy arrangement itself?

Is there a need for legislation prohibiting altruistic surrogacy arrangements? Should it be an offence to act as a surrogate or enter into any arrangement (whether or not any payment is made) with another person to act as a surrogate?

Is there a need for legislation which renders all surrogacy agreements void and unenforceable at law?

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