NSW Law Reform Commission REPORT 58: OUTLINE (1988) - ARTIFICIAL CONCEPTION: IN VITRO FERTILIZATION

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Participants

New South Wales Law Reform Commission
The Law Reform Commission is constituted by the Law Reform Commission Act 1967. Pursuant to section 12A of the Act the Chairman has constituted a Division for the purposes of the In Vitro Fertilization reference. The members of the Division are:

Chairman

Ms Helen Gamble

Part-time Commissioners

Dr Susan Fleming

Ms Eva Learner

Mr Keith Mason QC

Mr Russell Scott, Deputy Chairman of the Commission was Commissioner in Charge of the reference from its inception in October 1983 until his resignation from the Commission on 17 June 1988.

Members of the Commission's staff who participated in the preparation of the Report are the Research Director, Mr William J Tearle, and Mr Ian Collie, Ms Fiona Curtis, Ms Gail Morgan, Ms Leanne O'Shannessy and Ms Juliet Potts.

Preface

As part of its general reference on Artificial Conception the Commission has a reference to inquire into and report on the need to make laws on in vitro fertilization of human ova with human sperm (IVF) and transfer of the resulting embryo to the human uterus (FT). Pursuant to this reference we have published a Report on In Vitro Fertilization which has been presented to the Attorney General, the Honourable JRA Dowd, LLB, MP. The terms of reference are set out in full in the Report.

This Outline provides a brief statement of the major features of the final Report. It also sets out the recommendations made by the Commission. However the Report is the authoritative statement of the Commission's views and the reasons for the Commission's recommendations are to be found in it. In the event of any inconsistency the Report prevails over the Outline.

Copies of the final Report are available from:

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Outline of the In Vitro Fertilization Report

The New South Wales Law Reform Commission's report on In Vitro Fertilization has been released by the Attorney General, the Honourable JRA Dowd, LLB, MP. It recommends that practice and research in IVF should continue. By a majority of three of its members to two, the Commission has recommended that all types of research be permitted on the human embryo. The minority recommends that research be restricted to research of a therapeutic non-destructive nature. The views of the minority are contained in an Appendix to the Report.

The principal recommendation made in the Report is for the establishment of a council to be called the New South Wales Biomedical Council. The Council will advise the Minister for Health and develop guidelines for the medical profession in the practice and research of IVF. The Commission recommends that the Council consist of 11 members appointed by the Governor to be drawn from a wide range of disciplines and fields of interest as well as the general community. There should be equal numbers of men and women on the Council. The functions of the Council fall into three areas:

> Policy Advice - the Commission recommends that the New South Wales Biomedical Council should be given responsibility to advise the Minister on all aspects of biomedicine, including the reproductive technologies. This advice should provide the guidance the Commission regards as necessary for future legislation in the area.
>
> Practice - the Council will provide advice on the practice of IVF and make recommendations to the Minister on conditions to be attached to IVF practice licences. It is recommended that these licences will be administered by the Department of Health which will issue and review compliance with the licences.
>
> Research - the Commission recommends that the New South Wales Biomedical Council should also be the Organisation which assesses and approves all research projects proposed in the future. Any individual or institution which intends to engage in IVF research would be required to obtain a licence. The Council will monitor each project closely and have power to revoke research licences.

There are some matters which the Commission recommends should not be left for decision by the NSW Biomedical Council. The Commission recommends that these matters should be embodied in legislation from the outset. They are:

> The process known as cloning and any research involving trans-species fertilization should be prohibited.
>
> The maximum period for which a human embryo can be stored should be 10 years.
>
> No human embryo should be permitted to develop in vitro beyond the time when implantation would normally occur (14 days).
>
> An embryo should not be used, dealt with or disposed of except with the consent of the couple for whom the ovum was fertilized.

The Commission’s Recommendations

The New South Wales Biomedical Council

Recommendation 1

Legislation should establish a Council to be called the New South Wales Biomedical Council, with membership and functions as follows:

Membership

(i) There shall be no more than 11 members of the Council.

(ii) Members shall be selected to represent one or more of the following disciplines or fields of interest:

The community

Infertility support groups

Health care planning

Medicine including reproductive medicine

Biomedical research including research related to human reproduction

Law

Representative of the Department of Health

Moral theology

Philosophy and ethics

Women's health

Social science

(iii) There should be as far as possible, an equal representation of men and women.

Functions

(i) To advise the Minister on any question or issue arising in relation to biomedicine.

(ii) To promote (by the dissemination of information and in other ways) informed public debate on ethical, social and scientific issues that arise from reproductive technology and biomedicine generally.

(iii)To formulate, and keep under review, a code of ethical practice to govern the use of artificial fertilization procedures and research on the human embryo.

(iv) To advise the Minister on the conditions to be included in practice and research licences.

(v) To promote research into the causes of human infertility.

(vi) To advise the Minister on questions arising out of or in relation to reproductive technology.

(vii) To collaborate with other bodies carrying out similar functions in Australia.

(viii) To provide for compulsory review of the storage of embryos by IVF clinics (Recommendation 22) and as part of this function, to make decisions as to the transfer or discontinuance of storage of records (Recommendation 29).

(ix) To review the 10 year limit on the storage of embryos (Recommendation 22).

(x) To set out in a code of ethical practice the nature of information required to be recorded by IVF clinics (Recommendation 28).

(xi) To make decisions as to access to non-identifying information when there is no agreement between the record-keeper and the person seeking access to that information (Recommendation 30).

(xii) To consider and approve or disapprove all research projects proposed by holders of research licences (Recommendation 19) and as part of this function, to consider and approve or disapprove any proposal in such a project to allow the transfer to a woman of an embryo that has been the subject of research (Recommendation 16).

(xiii) To monitor developments in relation to access to identifying information, with a view to making recommendations to the Minister if circumstances alter (Recommendation 32).

(xiv) Such other functions as the Minister may specify from time to time.

Code of Ethical Practice

Recommendation 2

A code of ethical practice should be formulated and kept under review by the Biomedical Council. The Code should be reviewed regularly by the Council but the following matters should be included in the Code by legislation at the outset:

(i) An embryo may only be stored for 10 years, after which it may not be kept alive. (Recommendation 22).

(ii) An embryo may not be used, dealt with or disposed of ' unless the couple for whom the ovum was fertilized agree. Where one of the couple dies, the survivor retains the power of use, dealing and disposition. Where both die, such power vests in the clinic or storage facility. (Recommendations 24, 25 and 26).

(iii) No embryo should be allowed to develop in vitro, beyond the point at which implantation would normally occur, and should therefore not be kept alive longer than 14 days (excluding any period in storage.) (Recommendation 15).

Practice of IVF

Regulation Not Prohibition

Recommendation 3

(i) There should be no prohibition of the practice of IVF or GIFT by legislation or other official action.

(ii) Regulatory measures should be applied to the practice and procedures of IVF and GIFT in accordance with the succeeding recommendations.

A Licensing System Controlled by the Department of Health

Recommendation 4

Legislation should be enacted to establish a licensing system whereby the practice and procedures of IVF may be both carried out and controlled under conditions consistent with the public interest. The conditions of the licences should be determined by the New South Wales Biomedical Council and the system should be administered by the Department of Health.

Medical Practitioners Only

Recommendation 5

IVF should only be practised or performed by, or under the direction of, a medical practitioner.

Clinics to be Licensed

Recommendation 6

Legislation should provide that all IVF clinics are required to obtain a practice licence which should include the following conditions:

(i) A condition defining the kinds of artificial fertilization procedures authorized by the licence.

(ii) A condition requiring the licensee to ensure that the Council's Code of Ethical Practice is observed.

(iii) A condition requiring that IVF will be practised only by or under the direction of a medical practitioner (Recommendation 5).

(iv) A condition requiring that adequate counselling facilities be available and be formally offered to prospective patients (Recommendation 10).

(v) Such other conditions as the Minister may determine.

Admission to IVF Program

Recommendation 7

Legislation should be enacted to provide that before commencing or authorizing the commencement of a procedure of IVF and ET in relation to a woman, 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 interests 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 parent's physical and mental health, age and emotional reaction to IVF and ET.

Consent to Treatment

Recommendation 8

No legislation imposing compulsory requirements for consent should be enacted. This matter should be left to the general common law principles that govern consent to medical treatment.

Medical Misconduct

Recommendation 9

Breach of the duty imposed by Recommendation 7 should be capable of being found to be "misconduct in a professional respect" either within section 27(2) of the Medical Practitioners Act 1938, or by a comparable provision.

Counselling of Patients

Recommendation 10

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 prospective IVF patients in every IVF clinic.

No Special Legal Liability

Recommendation 11

No legislation should be enacted to impose any specific legal liability upon medical practitioners or parents of IVF children to pay compensation for damage or injury resulting from IVF. This matter should be left to the courts for judicial determination.

Research on Human Embryo

Recommendation 12

No general prohibition of research on the human embryo should be enacted (by majority).

Recommendation 13

The Commission recommends the two procedures known as cloning and trans-species fertilization should be prohibited.

Recommendation 14

No general legislative prohibition should be enacted to prohibit the creation of embryos solely for the purpose of research (by majority).

Recommendation 15

Accepting the principle that an embryo should not be allowed to develop beyond the time at which implantation would normally take place, the Commission recommends that no embryo be kept alive longer than 14 days (excluding any time kept in storage).

Recommendation 16

No general 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 made compulsory. The New South Wales Biomedical Council should be given the duty and power of considering and permitting the transfer of such embryos as part of its function of considering each research protocol (see Recommendation 19).

Recommendation 17

Legislation should be enacted to establish a licensing system whereby research on the human embryo may be both carried out and controlled under conditions consistent with the public interest. This system should be administered by the New South Wales Biomedical Council.

Recommendation 18

Legislation should provide that any person or institution intending to carry out research on the IVF embryo, should be required to obtain a research licence, which should include the following conditions:

(i) Defining the kinds of research authorised by the licence.

(ii) Requiring the licensee to observe a code of ethical practice formulated by the Council in relation to such research.

(iii) Requiring the licensee to maintain adequate records.

(iv) Such other conditions as the Council may determine.

Recommendation 19

Every research project proposed by a licensee shall, in addition to the usual process of approval through institutional ethics committees, be submitted to the New South Wales Biomedical Council for consideration and approval.

Recommendation 20

The New South Wales Biomedical Council should supervise and review each institution's research records.

Storage and Disposal of Embryo

Ethical Code to Regulate

Recommendation 21

Subject to the other recommendations made in this report, legislation should be enacted to provide that the IVF embryo may not be stored or dealt with except in accordance with the Code of Ethical Practice. The Code should regulate all dealings with the IVF human embryo.

Ten Year Limit on Storage

Recommendation 22

There should be an overall time limit placed on the storage of embryos. The Commission recommends an initial limit of 10 years, after which the embryo may not be kept alive. Power should be vested in the New South Wales Biomedical Council to vary that limit and provide for compulsory review of storage by a clinic at prescribed intervals.

Consent to Use and Disposal of Gametes

Recommendation 23

(i) The power to deal with and dispose of sperm and ova produced for IVF should vest in the respective gamete providers.

(ii) In the case of the unconditional donation of gametes, the power to determine the use, storage and disposal of gametes should vest in the IVF clinic.

Consents to Use and Disposal of Embryos

Recommendation 24

Within the proposed time limit the stored embryo cannot be used dealt with or disposed of unless the couple for whom the ovum was fertilized agree.

Recommendation 25

Where one of the couple for whom the ovum was fertilized dies the power to make decisions as to use or disposal vests in the survivor.

Recommendation 26

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.

Record Keeping and Access to Information

Clinics to Keep Records

Recommendation 27

All IVF records should be created, kept and maintained by the IVF clinics themselves.

Code of Ethical Practice

Recommendation 28

All clinical reports relating to the IVF and ET procedure 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. in addition the New South Wales Biomedical Council should be empowered to set out facts which must be recorded in the Code of Ethical Practice.

Recommendation 29

No time limit should be fixed on the retention of the records of IVF clinics. Transfer or discontinuance of storage of records should only be allowed on permission of the Biomedical Council.

Access to Non-Identifying Information

Recommendation 30

A statutory entitlement should be created whereby IVF children, gamete donors and any other person, upon showing "good cause" may have access to recorded non-identifying information either by agreement with the record keeper or, failing agreement, upon the decision of the New South Wales Biomedical Council.

Access to Identifying Information

Recommendation 31

No person should have a legal right of access to information that may identify a party to IVF and no record keeper may divulge such information, unless:

(i) The person who is the subject of the information formally consents.

(ii) The disclosure of information is required for the administration or enforcement of provisions of the IVF legislation.

(iii) The disclosure of information is required in the course of the official duties of persons engaged in the administration of a hospital or other place where IVF procedures are carried out or records relating to IVF or the donation of gametes are kept.

(iv) The information is required for the purposes of medical research and its release has been approved by the Biomedical Council.

(v) A judge or magistrate orders disclosure in connection with any legal proceedings or report of those proceedings.

Biomedical Council to Review

Recommendation 32

The Commission acknowledges the concerns expressed in relation to access to identifying information therefore in recognition of the possible claims of IVF children the New South Wales Biomedical Council should be vested with the power to review legislation implementing Recommendation 30 with a view to recommending alterations as changing circumstances dictate.

Legislation to be Retrospective

Recommendation 33

Legislation creating access to non-identifying information should be retrospective in respect of records in existence at the time the legislation takes effect. In relation to identifying information, the Commission makes no recommendations as to retrospectivity.

Confidentiality and the Donor

Recommendation 34

Subject to the preceding recommendations in relation to access to identifying and non-identifying information, legislation should be enacted to give the gamete donor the same duties of confidentiality and anonymity as a patient, particularly for the purposes of record keeping.

Non-Disclosure by Donor

Recommendation 35

A criminal offence should be created in relation to a person who knowingly conceals or misrepresents information about his or her health when offering or agreeing to donate his or her gametes for the purposes of IVF.

Release of Health Information

Recommendation 36

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 Commission therefore recommends that no statutory obligation should be created to require the supply of such information. This matter should be left to the courts for judicial determination.

Parentage of IVF Child

Maternity

Recommendation 37

Where IVF involves the use of donated ova, legislation should be enacted to determine conclusively the issue of maternity by stating that the woman who gives birth to a child will be presumed at law to be its mother.

Posthumous Conception and Inheritance

Recommendation 38

Subject to Recommendation 39, no legal regulation or prohibition of IVF is called for in relation to the use of IVF procedures to achieve pregnancy with the stored gametes of a deceased person.

Recommendation 39

Where a child is conceived posthumously through the IVF process, that is, where a human ovum is fertilized in vitro af ter the death of one or both of the gamete providers, the Commission makes the following recommendations:

(i) The law should allow, or should not preclude a specific testamentary gift in favour of a posthumously conceived child or a child born from a stored embryo.

Recommendation 40

Where the ovum of a deceased woman is fertilized by IVF, the subsequent transfer of the embryo will necessarily involve another woman. The circumstances therefore cannot be equated with the circumstances referred to in Recommendation 39(ii), and the Commission makes no recommendations. This matter will be considered in our report on surrogate motherhood.

Registration of Birth

Recommendation 41

There should not be any alteration in the law relating to the registration of births of IVF children where donated reproductive tissues have been used.