REPORT OF THE COMMITTEE APPOINTED BY THE WESTERN AUSTRALIAN GOVERNMENT TO ENQUIRE INTO THE SOCIAL, LEGAL AND ETHICAL ISSUES RELATING TO IN VITRO FERTILIZATION AND ITS SUPERVISION.

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30th September, 1986.

The Hon. I.F. Taylor, MLA,
Minister for Health,
Health Department of Western Australia,
Curtin House,
60 Beaufort Street,
PERTH W.A. 6000.

Dear Mr. Taylor,

I am privileged to present to you the Report of the Committee established by the Western Australian Government to enquire into the social, legal and ethical issues relating to in vitro fertilization and its supervision.

The task has not been easy because of the moral, ethical and religious issues inevitably raised in a Committee of Inquiry such as this. Although the Committee worked well together it was not surprising that there were some differences of opinion on these sensitive issues. Despite these differences the recommendations made were, with a few exceptions, unanimous.

I would like to record my sincere gratitude to all the Committee members for their support following my appointment as Chairman. I am indebted to them for their industry and commitment so that the Report could be finalized. The Committee especially thanks Mrs. J.M. Anstead, Executive Secretary, for her diligence and for compiling the minutes of the many meetings and making them quickly available as a comprehensive report of our deliberations. The Committee could not have functioned without her enthusiasm and commitment.

On behalf of the Committee I respectfully present this report to you. It is their hope that the carefully considered recommendations will provide a basis for the establishment of ethical guidelines relating to the treatment of infertility and especially in vitro fertilization.

Yours sincerely,

C.A. Michael.

C.A. MICHAEL, MD, FRCOG, FRACOG
Chairman of Committee
Nominee of the Vice-Chancellor
(The University of Western Australia)
Associate Professor of Obstetrics and Gynaecology

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OCTOBER 1986

Letter to the Honourable Minister for Health, Ian F Taylor, M.L.A.

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INTRODUCTION

A Committee to enquire into the social, legal and ethical issues relating to In Vitro Fertilization, was established in June 1983 by the Honourable the Minister for Health, Mr Barry Hodge M.L.A. An Interim Report was prepared and submitted to the Minister for Health on 16 August 1984.

At the time of writing, similar Committees of Inquiry into artificial methods of conception have been established in all other Australian States. Most have since completed their final reports.

During its deliberations this Committee has been aware of the duplication of time and effort by the several State Committees. In most instances the general principles and issues surrounding artificial methods of conception are common to all States. Some issues, however, have required debate on a local basis.

The Committee has never regarded itself as having a mandate to impose moral standards upon the community at large. Rather, it has attempted to interpret and commend prevailing ethical standards and insights in the area of artificial methods of conception.

The Committee believes that there has been confusion within the community about infertility and its related treatment programmes including advanced reproductive technological procedures. In order to clarify what precisely these procedures involve the Committee believes that a programme of infertility education in the community would be of advantage. It is especially of the opinion that the preventive aspects of infertility should be emphasised in such a programme.

Given the rapid advances of reproductive research and the inability of the general public to keep abreast of all the issues raised, many questions remain unanswered. The Committee has attempted to define and debate the key issues, and this report makes recommendations concerning the regulation of bio-medical research.

Although the Committee acknowledges that it is difficult to establish ethical standards which are acceptable to all sections of the public and to the medical profession, it nonetheless recommends that guidelines be established at least at a State, and preferably at a National level. The Committee does not wish in any way to inhibit research relating to infertility or the establishment of infertility treatment programmes. It is, however, concerned to ensure that such activities are properly regulated and that practitioners involved are accountable to a review committee as the investigation and treatment continues to incorporate new ideas and methods.

During the time taken for the Committee to prepare the report, community attitudes on artificial conception appear, at least slightly, to be changing. It would be inappropriate to assume that the recommendations in this report will always be applicable to guide changing future practice. Thus, it may be necessary for many of the recommendations to remain under continual review and to be modified whenever the state of future research, knowledge and public opinion so demand.

GLOSSARY

A.I.	Artificial insemination.
A.I.D.	Artificial insemination using sperm from a donor.
A.I.H.	Artificial insemination using sperm from the husband.
AZOOSPERMIA	Absence of spermatozoa in the semen.
BLASTOCYST	The early stages of development of an embryo at about 8-10 days after conception.
CRYOPRESERVATION	Freezing of biological material for storage purposes.
DONATED EMBRYO	A fertilized ovum where neither partner has made a genetic contribution.
EMBRYO	The early stages of development up to 7 weeks of pregnancy. During this short period almost all of the major structures have formed.
EMBRYONIC DISC	The phase of early development occurring at the end of the second week of pregnancy in the human.
E.T.	Embryo transfer, i.e. transfer of the embryo into the uterus.
EXCESS EMBRYO	Where the number of fertilized ova exceeds the number of embryos returned to the uterus.
FALLOPIAN TUBES	Two small hollow tubes on each side of the uterus which lie in contact with the ovary on either side. Ova from the ovaries are transmitted into the tubes and fertilization takes place here.
FETUS	The developing embryo which has achieved recognizable human features - 8 weeks onwards.
FOLLICLE	A small sac within the ovarian cortex and containing the developing ovum.
GAMETE	An ovum or a spermatozoon.
G.I.F.T.	Gamete intra fallopian transfer - the gametes are placed in the outer ends of the fallopian tubes.
INFERTILITY	Describes a condition of a couple who in spite of repeated attempts at conception are unable to produce children.

I.V.F.	In vitro fertilization - fertilization outside the body.
LAPAROSCOPY	Visual examination of the female pelvic organs using a telescope inserted through a small incision in the abdominal wall.
N.H & M.R.C	National Health and Medical Research Council
OLIGOSPERMIA	Scarcity of spermatozoa in the semen.
OOCYTE	Egg cells produced in the ovaries.
OVARIES	Glandular organs giving rise to ova and female hormones.
OVULATION	The process by which an ovum is released from the ovary.
OVUM	A mature oocyte just prior to ovulation.
OVUM COLLECTION	Collection of ova from ovarian follicles often by laparoscopy.
PRIMITIVE STREAK	Early sign of organisation of what is to be the embryo out of unformed tissues. Its appearance is usually complete by the 14th day of development and it appears at the edge of the embryonic disc.
PROST	Pronuclear stage transfer. Transfer of a fertilized ovum in its early stage of development into the fallopian tube.
SEMEN	Fluid secretion containing sperms.
SPERMATOZOA	The male free swimming cells produced by the testes and which fertilize the ovum.

Chapter 1. The Committee And Its Operation

1. Appointment

The Committee to investigate In Vitro Fertilization and related matters in Western Australia was established in June 1983. The Minister for Health confirmed the appointment of the following members of the Committee:

Associate Professor R.A. Barter
Pathologist -
Nominated by the Board of Management, King Edward Memorial Hospital for Women.

Dr P. Brine
President of the Medical Board of Western Australia -
Nominated by the Australian Medical Association.

The Most Reverend Dr.P.F. Carnley
Anglican Archbishop of Perth -
Nominated by the Anglican Church.

Miss R.J. Denny
Director of Nursing, King Edward Memorial Hospital for Women -
Nominated by the Minister.

Dr K.A. Hockey
Medical Officer-in-Charge, Irrabeena, and Geneticist King Edward Memorial Hospital for Women and Princess Margaret Hospital for Children -
Nominated by the Minister.

The Reverend C.R. Honey
Master, Kingswood College, University of Western Australia -
Nominated by the Minister.

Dr G.D.R. Lilburne
Obstetrician and Gynaecologist -
Nominated by the Royal Australian College of Obstetricians and Gynaecologists.

Mr R.J. Meadows Chairman - Retired 29 May 1986
Barrister and Solicitor, Chairman of the Ethics Committee of the Law Society of Western Australia -
Nominated by the Law Society of Western Australia.

Associate Professor C.A. Michael, Chairman from 29 May 1986
Obstetrician and Gynaecologist, Department of Obstetrics and Gynaecology, University of Western Australia -
Nominated by the Vice-Chancellor, University of Western Australia.

Mrs M.A. Papaelias
President 1982 - 1985 - "Concern for the Infertile Couple"
Nominated by the Minister.

The Reverend Father W.J. Uren
Rector, St Thomas More College, University of Western Australia - Nominated by the Most Reverend Sir Launcelot Goody, Roman Catholic Archbishop of Perth.

The Executive Secretary of the Committee is Mrs J. M. Anstead, Co-ordinator Bioethics Epidemiology Branch within the Health Department of Western Australia. The Committee remains indebted for her invaluable assistance throughout the deliberations.

Dr P. Brine retired from the Committee on 28 June 1984, and his place was taken by Dr M.F. Quinlan, who was nominated by the Australian Medical Association.

On 28 June 1984 the Minister for Health agreed to the co-option of Dr A. F. Dickey of the Law School of the University of Western Australia. Dr Dickey's expertise was sought in order to offer opinion on the legal issues.

On Thursday 29 May 1986, Mr R.J. Meadows retired from the Committee, and Associate Professor C.A. Michael was appointed to the Chairmanship of the Committee by the Honourable the Minister for Health, Mr Ian Taylor, M.L.A.

2. Terms of Reference

The terms of reference given to the Committee by the Minister for Health are as follows:

> To consider the social, ethical and legal issues arising from In Vitro Fertilization. To advise on the relevance of any recommendations from similar committees both in Australia and overseas, and to supervise the practice of In Vitro Fertilization in Western Australia.

3. Operation of the Committee

The Committee met on ten occasions before the preparation of the Interim Report which was submitted to the Minister for Health on 16 August 1984. Since that time the Committee has met on a further fifteen occasions.

Submissions were called from the public by means of advertisements placed in the daily press. Fifty-eight submissions were received. A list of those members of the public making written submissions is included in Appendix II of this Report.

The Committee considered whether it should hold public hearings, but, having given this matter careful consideration, decided not to do so. The Committee interviewed Dr J.L. Yovich and Dr T.D. Thomas, the principal members of the two teams providing I.V.F. services in the State of Western Australia. In addition to the personal interviews, Dr Yovich and Dr Thomas were invited to make written submissions.

The Committee interviewed Dr. E. Keogh of the Institute of Reproductive Biology at the Queen Elizabeth II Medical Centre. Discussions related to the management of sperm donation, together with criteria, record-keeping and screening of donors.

During its deliberations the Committee was assisted and directed by the many reports and references in the literature relating to artificial conception. The reports included those of the Committees from other Australian States, the Warnock Report and the publication from the Royal College of Obstetricians and Gynaecologists (London).

The then Chairman, Mr R.J. Meadows, and the Executive Secretary, Mrs J. M. Anstead, visited the Queen Victoria Medical Centre in Melbourne in June 1985. The purpose of that visit was to obtain up-to-date and comparative information relevant to IVF issues.

A meeting was held with Professor W.A. Walters and Professor C. Wood from the Department of Obstetrics and Gynaecology, Queen Victoria Hospital. A meeting was also held with Professor Louis Waller, Sir Leo Cussen Professor of Law, Monash University, and Chairman of the Victorian Committee examining similar issues.

4. Scientific Sub-Committee and Research Officer

As a result of one of the recommendations made in the Interim Report, the Minister for Health agreed to appoint a Research Officer to evaluate the existing practice of IVF in Western Australia. This evaluation continues as a three year study in conjunction with Dr. C.D.J. Holman, Director of the Epidemiology Branch within the Health Department of Western Australia. On the 1st July 1985 Mrs S Webb was appointed as Research Officer. The Committee established a Scientific Sub-committee to oversee the work of the Research Officer and to report back to the full Committee from time to time. This Committee comprised :

Associate Professor C.A. Michael Chairman

Dr K.A. Hockey

The Reverend C.R. Honey - (The Reverend David Robinson represented Mr Honey on one occasion.)

Chapter 2. Organisation Of Infertility Services In Western Australia

1. Incidence of Infertility

The incidence of infertility in the community is estimated to be 10 per cent. No accurate data is available to support this. In approximately one third of infertile couples, the problem lies with the female partner, in another one third with the male partner, and in the remainder with a combination of factors in both partners.

As a result of the rapid expansion of reproductive technology over the last decade, an attempt has been made to accumulate accurate statistics concerning the incidence of infertility. This has aided further research into several aspects of infertility.

2. Types of Treatment

Treatment is directed at the cause of the infertility:

i) Artificial Insemination (AI)

Artificial insemination using the husband's (partner's) semen or donor semen has been practised for some decades. This technique is used where the male partner has oligo- or azoospermia.

ii) Donor Ova

In cases of female infertility treatment may include the donation of ova. However, the indications for such procedures in infertility management are few.

iii) Surgery

Surgery for infertility includes re-establishment of patency of the fallopian tube and removal of pelvic adhesions. Such surgery has become increasingly successful as a result of sophisticated techniques.

iv) Stimulation of Ovulation

This is undertaken in those patients whose infertility is the result of failure of ovulation.

v) In Vitro Fertilization

IVF and related procedures are in wide use, usually where there is disease or absence of the fallopian tubes. The use of IVF has been extended to treat other causes of infertility. In addition donor gametes have been used in IVF. The procedure is expensive and currently returns a low rate of success. The cost of such a modality of treatment inevitably places it within the reach of only a small percentage of the infertile community. Currently IVF in Western Australia is conducted only on a private basis.

Other techniques have been recently established. These include GIFT (Gamete Intrafallopian Transfer) and PROST (Pro-nuclear Stage Transfer). At this time it is too early to evaluate these techniques in terms of successful pregnancy.

3. Availability

In vitro fertilization (including GIFT and PROST) and ovum donation are available in the private sector, and are not available at this time in the public hospital system in Western Australia. A recommendation was made in the Interim Report of this Committee to the effect that IVF and related procedures should be introduced into the public hospital system.

All other infertility services are freely available both in the private and public sectors. Gynaecologists generally in Western Australia offer a basic infertility investigatory service. However, it is believed that a greater degree of specialization is necessary for more sophisticated procedures. The Royal Australian College of Obstetricians and Gynaecologists has accepted that reproductive medicine (including infertility) should be a sub-specialty of gynaecology, and that further training will be necessary to achieve the necessary expertise in this discipline.

A specialist infertility clinic has been established at King Edward Memorial Hospital in order to offer specific investigation and treatment to infertile couples. Infertile patients attending the hospital should be referred to this clinic.

Arrangement of outpatient services may be necessary to ensure that more effective services are provided. This will reduce the tendency for infertility patients to be given low priority on waiting lists.

4. Eligibility for Treatment

The Committee recommends that programmes for the treatment of infertility should in principle be available only to married couples and couples in a stable de facto relationship.

There are no strict criteria for selection and entry of a couple into an IVF programme. When IVF is established in the public hospital system then such selection criteria will have to be formulated by the hospital concerned and be under the direction of a suitably constituted institutional ethics committee. The criteria should be stated publicly and be applicable.

IVF in Western Australia is currently conducted in two units in private practice. These units have their own selection criteria. Ideally selection guidelines should be established by those working in the field of IVF together with an Ethics Committee and the criteria should be reviewed periodically. There may be a place for a National regulatory body to undertake this review for all States.

The Committee is concerned that IVF services at present are only available to those patients in Western Australia covered by private medical insurance and recommends that such service also be made available in the public hospital system. The Committee is mindful of the economic and budgetary implications involved.

5. Counselling

Education and counselling of the infertile couple entering an IVF programme is essential. This is even more important when donor gametes are used in the treatment cycle. Currently most of this counselling is undertaken by the medical attendants and is often inadequate. Ideally, specially trained counsellors should be available, and counselling should take place before, during and after the treatment cycle. Support must be available following a failed treatment cycle when disappointment is an inevitable consequence.

Prior to entry into a further cycle, counselling, with regard to the timing of treatment, and the attendant social and psychological issues must again occur, so that the couple do not find themselves in another emotionally disturbing situation, and without support.

Chapter 3. Artificial Insemination

1. Introduction

The Committee has not been specifically requested to consider AID. It has nonetheless felt itself obliged to do so because donor semen is often used in the process of in vitro fertilization. There are at present no established guidelines in Western Australia governing either AID or IVF.

Approximately 30% of infertile marriages are caused by problems involving the male partner. AID is frequently used in such cases. It is also used where blood group incompatibility exists between the partners and when it is necessary to avoid the transmission of certain genetic disorders. It may also be used occasionally where the husband has a physical disability.

2. Current Procedure

The procedure involved in AID is as follows. Donor semen is placed in the proximity of the cervix at ovulation. The time when the cervix is ready to receive the semen is determined by a number of clinical, endocrinological and ultrasonographic tests. The donor semen is usually obtained frozen from a semen bank. Donors are screened according to criteria set by each bank and the anonymity of each donor is guaranteed. The practice of mixing semen, even with that of a woman's partner, does not usually occur.

The majority of the Committee believes that the anonymity of the donor needs to be preserved in the practice of AID. Nevertheless, a mechanism should exist to make it possible to trace a donor of semen in the event of congenital abnormalities occurring in pregnancies

resulting from AID. In this way information relevant to the condition of the offspring can be gained concerning the donor. If necessary, further donations can be discontinued.

Because there are added risks for inherited disorders caused by dominant new mutations in males, no donation should be permitted from a man who has attained the age of 40 years. There should be a limit on the number of donations that a man may make in his lifetime in order to limit the possibility of consanguineous relationships accidentally occurring. The limit should be set by the proposed Licensing and Supervisory Authority and Bioethics Committee (see Chapter 9).

A donor should have the right to require that his stored frozen semen be discarded at any time. Stored semen should be routinely discarded after it has been frozen for four years in accordance with the procedure currently being followed by the Reproductive Biology Unit at the Queen Elizabeth II Medical Centre. The Committee is of the opinion that this time limit is arbitrary, but believes that there should be such a limit and that the current limit poses no medical risks to either the woman so inseminated or the prospective child. The Committee recommends that this time limit should be reviewed at an early date by the proposed Licensing and Supervisory Authority and Bioethics Committee.

3. Ethical Issues

Community attitudes to AID vary considerably. These range from objection to the method of collection of the donor semen to the intrusion of a third party into the procreative dimensions of the marital relationship. It has even been interpreted by some as adultery and thus as

a threat to the integrity of marriage. However, it may be argued that the category of adultery is inappropriate on the grounds that no act of sexual union is involved, nor is there any element of duplicity or unfaithfulness. Instead, it may seem more appropriate to think of AID as an extension of the long accepted practice of adoption whereby the infertile couple agree to "adopt" a gamete. From this point of view AID is ethically acceptable.

The Committee recommends that AID should not be made available to single women or to women living in homosexual relationships. The Committee understands the problem of infertility as a condition of married heterosexual couples. It believes that the community at large will regard AID as acceptable only to promote families among married couples and couples living in a stable de facto relationship.

Some doubts about the wisdom of AID have also been expressed in the light of the possible psychological and emotional effects that may result when a child discovers that he or she has been conceived by such a procedure. The Committee has no positive information concerning these possible effects. It notes that there is today a strong body of opinion concerning the importance of children being able to discover such details of their background. However, in the case of AID the majority of the Committee believes it important that strict anonymity of donors be preserved. On the basis of an authoritative submission to the Committee, it came to the view that a lack of anonymity may result in difficulty in obtaining donors.

The majority of the Committee believes that the established practice of AID is ethically acceptable and that it may properly be extended to IVF.

Chapter 4. In Vitro Fertilization And Embryo Transfer - General Principles

1. Introduction

Fertilization of the ovum normally occurs in the fallopian tube. The blastocyst resulting, moves downward to implant in the uterus. Following this the fertilized ovum passes down the fallopian tube and implants in the uterus. If the fallopian tubes are absent, blocked, diseased, or damaged the process of upward migration of the sperm to fertilize the ovum and downward movement of resulting fertilized ovum cannot occur.

Such causes of female infertility are common, and before IVF the possibility of a pregnancy was remote. If impregnation and implantation take place in these circumstances of tubal disease there is a high risk of an ectopic pregnancy resulting. IVF has been designed especially to overcome these problems and has been extended to include patients with other unexplainable causes of infertility.

IVF first resulted in achieving a live-born child in England in July 1978 (Edwards and Steptoe). Since this time ten IVF units have developed throughout Australia, the first successful live-birth occurring in Melbourne in June 1980 (Wood and Johnston). In Western Australia the first recorded live-birth was in July 1982 (Pivet).

Two units are now established in Western Australia with a success rate of 15% to 20% of embryo transfers as quoted in the Interim Report to the Minister in 1984.

The normal rate in naturally achieved conception of failure to proceed beyond early embryonic development is around 70%, under which circumstances subjects might

often not be aware of being pregnant. Examination by clinical means would be negative and the pregnancy being diagnosable only by laboratory tests. Generally speaking even informed members of society are not aware of these figures either for embryonic wastage following natural conception or IVF.

2. Technique and Procedure

A mature ovum is collected at laparoscopy from a follicle on the surface of the ovary just before ovulation. The ovum is then mixed with the semen and fertilization occurs in a glass vial. When the fertilized ovum begins to divide, it is current practice to transfer it to the uterus at the 4 - 8 cell stage.

The chances of a successful pregnancy are improved if more than one embryo is fertilized and implanted in each treatment cycle. In order to collect multiple ova, the ovaries are artificially stimulated by drugs. This process is known as superovulation, and sometimes results in the possibility for insertion of up to four fertilized ova into the uterus.

The success rate of fertilization is of the order of 75%. Not all fertilized ova (embryos) develop satisfactorily and only recognizably normally developed embryos are inserted into the uterus. The optimum number of embryo transfers for a successful pregnancy is considered to be two or three.

This leads to a high risk of multiple pregnancy with its attendant complications of both miscarriage and premature delivery. Additional problems follow from premature births with its possibilities for perinatal morbidity and subsequent neurological handicaps. Parental stress in such cases is usually significant.

Patients entering the scheme should therefore be as fully aware as possible of the reasons for and against inserting one or more fertilized ova into the uterus. This is especially important in an ethical sense as multiple insertions are performed both to spare the mother repeated laparoscopies and to utilize the operator's time effectively. Such efforts towards economy is the reason for the higher rate of occurrence of multiple births in IVF programmes, with the well known adverse consequences for some of the offspring.

There are also the additional moral and ethical problems associated with the care or disposal of excess fertilized ova after, for example, three are chosen for insertion from a vial containing five.

Patients must have explained to them such consequences of multiple embryo transfer and should be accorded full opportunity of taking part in the decision-making process.

3. Eligibility for Treatment

i) Married Couples

The Committee in the Interim Report considered married couples to be eligible for treatment using IVF where other efforts have failed to achieve a pregnancy and where the embryos are transferred into the wife's uterus. There appears to be significant community support for this view.

ii) De facto Relationship

A principal concern of the Committee regarding de facto relationships related to lack of real information at the present time regarding the home environment in which the prospective child is to be reared.

The Artificial Conception Act 1985 includes within the scope of the term, "married couple", a woman living with a man as his wife on a genuine domestic basis although not married to him. The Act is specifically directed at establishing the parentage of children born as a result of AI and IVF.

iii) Age

The Committee recommends that the age for consent and entry into an IVF programme should be 18 years. While little discussion took place on the maximum age of the woman for entry into such a programme, it would seem appropriate to limit the age to 38 years.

This is consistent with other published ethical guidelines and takes into account the medical and genetic considerations regarding pregnancy occurring in women who are older than 38 years.

4. Counselling

Counselling is presently undertaken by the medical practitioners involved with IVF treatment, but limitations of time lessen the opportunity that the couple should have to think and to talk their problems through with a person experienced in the many issues. The multi-disciplinary approach to counselling (involving nurses, social workers, psychologists and geneticists) which is available in the teaching hospitals is considered to be appropriate to the particular needs of the couples undergoing IVF treatment.

The Committee recommends that each couple seeking admission to an IVF programme should be provided with clear and comprehensive information about the procedure.

The couple must be advised of any risks involved in the programme, its likely duration, and should be given accurate information about the prospects of success. The risks of failure and its emotional consequences should also be discussed as should the interests of the prospective child. This will then permit each couple to express in writing its free and informed consent to participate in such a programme.

5. Consent

Written consent in the prescribed form by both partners before starting an IVF programme is essential. The couple involved should be given all the available information and counselled about the possibility of multiple pregnancy and the problems relating to any remaining excess embryos.

The Committee recommends that a written consent form be available to and signed by the couple only after thorough consideration following adequate counselling.

The Committee also recommends that consent is essential for the method of use, or disposal of excess embryos obtained through I.V.F.

6. Location of the Practice of IVF.

Currently IVF is only available to couples in Western Australia in private medical practices. There is no public facility for IVF. The Committee views the ability to afford such treatment as an unacceptable basis for selection into an IVF programme. On the other hand, the wishes of taxpayers who would not support IVF may have to be taken into account.

The Committee is also of the view that IVF should be undertaken only in association with a major teaching hospital. The present private institutions could then be included under the control of a nominated teaching hospital with all of its appropriate supervisory committees.

Such a practice would be desirable for the following reasons:

i) IVF would be available to a wider section of the community and not just to those with the financial resources.

ii) The practitioners associated with IVF would be subject to peer review.

iii) The practice of IVF would be governed by existing ethics committees within the teaching hospital.

iv) There would be greater availability of trained counsellors.

Such supervision of IVF could be undertaken by the Authority recommended in Chapter 9 of this report. This should later be extended to the National level, and that Authority could regulate those infertility services involving the manipulation and exchange of gametes. Its main function would be supervisory.

7. Status of the Embryo

The Committee recognises that there is no uniform opinion concerning the status of the embryo. Some arguments which were expressed in the Committee favour the view that any embryo should be recognised as having the status

of a human person with rights of care and protection from the moment of fertilization. Others claim that such status should be accorded only when the process of conception is complete and individuation (the formation of a distinct and separate individual human embryo) has been fixed.

Many consider that, although genetic identity is fixed at fertilization, human individuation, cannot be said to have been established until after the development of the "primitive streak", the resultant elimination of the possibility of twinning, and implantation in the uterus, up to fourteen days later.

The Committee considers that the developing status of the embryo must therefore be considered as this is relevant to the practice of freezing and to the possibility of experimentation.

Matters regarding the status of the early embryo require further discussion and clarification. If this does not occur then the normal interests and rights of the child to care and protection will be prejudiced. A review of current legislation may also be necessary.

Chapter 5. In Vitro Fertilization And Embryo Transfer Donor Procedures And Experimentation

1. Sperm Donation

The use of donor sperm in the practice of IVF can be seen to be an extension of the existing practice of AID.

Opposition has been expressed to AID (see Chapter 3) and to the use of donor sperm in IVF on moral and social grounds. The Committee is aware of these objections but the majority of its members do not consider the practice to be ethically unacceptable (see above). The majority of the Committee therefore recommends that the use of donor sperm be allowed in IVF where the husband is azoospermic, or severely oligospermic, providing that the following conditions are satisfied:

i) The donor remain anonymous;

ii) Following appropriate screening as to donor suitability, and guarantees of anonymity having been given, the donor be counselled, and his informed consent in writing be obtained;

iii) There be a confidential register of donors, recording medical and genetic background and personal characteristics. The genetic and medical information recorded in the register be made available in confidence, only to a medical practitioner through application to the proposed Licensing Authority. No information concerning the social, psychological and genetic background of the donor be made available to the couple or the resulting child;

iv) Counselling be given to the couple;

v) The informed consent in writing of the participating couple be obtained;

vi) Any child born as a result of IVF involving donor sperm be regarded in law as the child of the participating couple (this is presently the case under Western Australia's Artificial Conception Act 1985); *

vii) The donor have no parental right or duties in relation to the child, and in law shall not be regarded as the father of the child; *

viii) There be a rebuttable legal presumption that the husband has consented to the use of donor sperm; *

ix) The husband and wife be registered as the father and mother in the register of births. (This is presently the case in Western Australia).

The Committee recommends that sperm banks be the only source of the donor sperm, and operate under license from the Licensing and Supervisory Authority. This would ensure supervision of these banks, and would minimise any potential problems related to inherited disorders.

2. Ovum Donation

Unlike AID, ovum donation has not been widely endorsed or ethically approved. Counselling is therefore more important. A problem concerning ovum donation is the relative complexity of collection and donation procedures.

* ARTIFICIAL CONCEPTION ACT 1985.

Apart from one reported instance, cryopreservation of ova has been unsuccessful until recently. There is no long interval between collection and donation of the ovum and fertilization. This is unlike sperm donation where freezing is possible and use is successful.

As in the case of the sperm donation, ovum donation should not be made by a minor, nor should ova be donated by friends or relatives of the recipient. A majority decision of Committee was that anonymity would be mandatory.

The possible indications for ovum donation are fewer than for sperm donation. Such indications would include Turner's syndrome, or where the female is a carrier of hereditable disease. Also the processes involving the acquisition of an ovum are much more complex than for sperm, and the operator must be satisfied that acceptance for the donation will not be withdrawn after the ovum is obtained at much cost to the donor. The Committee emphasises the possible emotional consequences surrounding ovum donation where a medical and surgical procedure (ovarian hyperstimulation and laparoscopic collection) is undertaken to achieve a pregnancy in another woman.

The Committee recommends that in every case consent for ovum donation and ovum acceptance should each be the subject of a separate written agreement.

The majority of the Committee agrees in principle to the use of donor gametes in the practice of IVF, and considers that donor ova be permitted in IVF subject to the following conditions:

i) The donor remain anonymous;

ii) Following appropriate screening as to donor suitability, and guarantees of anonymity having been given, the donor be counselled, and her informed consent in writing be obtained.

iii) There be a confidential register of donors, recording medical and genetic background and personal characteristics. The genetic and medical information recorded in the register being made available in confidence, only to a medical practitioner through application to the proposed Licensing Authority. No information concerning the social, psychological and genetic background of the donor be made availabe to the couple or the resulting child;

iv) Counselling be given to the couple;

v) The informed consent in writing of the participating couple be obtained;

vi) Any child born as a result of IVF involving donor ova be regarded in law as the child of the participating couple. (This is presently the case under Western Australia's Artificial Conception Act 1985); *

vii) The donor have no parental rights or duties in relation to the child, and in law shall not be regarded as the mother of the child; *

viii) There be a rebuttable legal presumption that the husband and wife have consented to the use of donor ova; *

* ARTIFICIAL CONCEPTION ACT 1985.

ix) The husband and wife be registered as the father and mother in the register of births (This is presently the case in Western Australia).

3. Embryo Donation

This is a very complex issue and requires special consideration. Embryo transfer may involve three different situations:

i) An ovum obtained by ovum collection is fertilized outside the body by a donated sperm. The embryo is then transferred to a woman who is unable to produce an ovum and has an infertile husband.

ii) The ovum is released naturally at the normal time in the donor's cycle and is obtained by uterine flushing. Insemination is then performed with sperm from the husband of the infertile woman (or donor sperm if the husband is infertile). The embryo is then transferred to the uterus of the infertile woman.

iii) An excess embryo is obtained during the course of normal IVF procedures. These are then frozen and used by the parents at future IVF attempts; they are not available for donation to a third party.

The Committee agreed that embryo donation, frozen or otherwise, and to which there had been no genetic input from either parent, should not normally be permitted and should also be a matter of appeal to an Ethics Committee.

Further, embryo donation should only be considered in the case of those rare couples whose infertility cannot be resolved by other means or where an hereditary disorder may be

transmitted. The donor of both sperm and ova must give explicit consent in writing.

If embryo donation were to be permitted, then legislation similar to that recommended in ova and sperm donation would need to be instituted. The Committee notes that as Western Australian law stands at present, there is no certainty as to who are the parents of a child born as a result of embryo donation. The Committee accordingly recommends that legislation be enacted to make it clear that the mother who receives the donated embryo, and her husband or de facto husband, alone, are regarded as the parents of the resulting child, and that the donors of the ovum and the sperm not be regarded as the parents of the child.

4. Cryopreservation

Embryo freezing is practised to preserve excess embryos generated at the time of IVF hyperstimulation of the ovaries which results in multiple egg collection. The reason for cryopreservation of excess embryos is that the infertile female would then not have to undergo a further laparoscopy and egg collection in a subsequent cycle if the current IVF cycle was unsuccessful in achieving a pregnancy.

The ethical problems which arise include the right to ownership of the embryos, the length of time the embryo remains in storage and the subsequent disposal.

There is little convincing evidence that the practice of freezing, thawing and implanting embryos offers pregnancy rates comparable to those when transfer is undertaken immediately after fertilization.

It may be concluded that some form of damage may have occurred to the stored embryo during the freezing and thawing process. A successful pregnancy could not therefore be established. The data available at this time of publication seems insufficient to substantiate a definitive recommendation.

The Committee agreed that embryo donation, frozen or otherwise, and to which there had been no genetic input from either parent, should not normally be permitted and should also be a matter of appeal to an ethics committee. While freezing of sperm and its storage is acceptable, freezing of ova is still in the early stages with successful fertilization having been reported in one couple to date. (South Australia).

5. Experimentation

The Committee discussed this at length. It considered the freezing and thawing of embryos, with its poor outcome in relation to pregnancy, as experimental. Realistic benefits have not been forthcoming. Some members of the Committee were of the opinion that no experimentation should be permitted unless there was a reasonable presumption that the experiment would benefit the embryo undergoing the procedure, viz; ("therapeutic experimentation").

The Committee agreed that if "non-therapeutic" experimentation was accepted, for as yet to be defined reasons, the embryos should not be specifically generated for this purpose. Any experimentation on excess embryos must have the informed consent of the couple for whom the embryo was generated. This would also include consent for disposal of such embryos. The Committee concurred

with the Warnock Report that the embryo should not be used as a research subject beyond fourteen days after fertilization.

In addition, an embryo which has been used for research should not be transferred in any situation. Ethical regulation of such scientific research poses ongoing problems as events unfold.

Guidelines need to be established so that there is adequate regulation without the risk of impeding acceptable advances in the disciplines of developmental biology and management of infertility.

If ethical guidelines cannot be satisfactorily established it may be necessary to recommend legislation to provide that the limit of experimentation on embryos be up to the fourteenth day after fertilization. Such a Licensing Body or Bioethics committee may, and perhaps should, impose further restrictions on embryo research.

Chapter 6. SURROGATE MOTHERHOOD

1. Introduction

A surrogate mother is "a woman who acts for another woman by having a child for her".

Surrogate motherhood, is not an exclusively modern experience. The Bible, for instance, records occasions when surrogacy was employed to remedy childlessness.

In the biblical story slaves were involved in the surrogacy arrangements. In the 20th century, however, surrogacy is not imposed, but is entered into freely through a contractual agreement. The surrogate agrees to give up the baby at birth to the persons with whom the contract has been made.

The practice of surrogacy has significant implications for the community:

"Surrogate motherhood contracts raise important legal and social issues. If the law were to make them effective it would be necessary to assume direct control of personal behaviours and to assert dominion over the body of the surrogate. Such contracts prescribe conditions under which a child is to be conceived, born and handed over. Major questions of public policy are involved. Litigation has already taken place in England and in the United States following disputes between parties to such contracts."

In a number of situations, surrogacy includes some form of financial remuneration. These range from quite a sizeable amount of money to mere reimbursement of expenses. In cases of what might be described as altruistic surrogacy, (e.g. one sister carrying the pregnancy for her sister), there is no monetary exchange.

2. Forms Of Surrogacy

Surrogacy may take various forms :

i) Where the surrogate provides the egg. Thus, the surrogate is the genetic mother of the child, as well as the birth mother. However, the husband may or may not be the genetic father. Sometimes this form of surrogacy is referred to as surrogacy with artificial insemination.

ii) Where the embryo is implanted in the surrogate mother. The surrogate is the birth mother, though not the genetic mother of the child. The child may or may not be the child of one of, or both, the infertile couple. This form of surrogacy is sometimes referred to as surrogacy with IVF.

The Warnock Report notes that there are certain circumstances in which surrogacy would be an option for alleviating infertility. For example, there are women who have severe pelvic disease which is unable to be remedied by surgery, or women who have no uterus. It is further suggested that surrogacy may also help those who have undergone repeated miscarriages. Another example might be a case of a genetic mother who, though fit to care for a child once it is born, is deemed by medical opinion to be unsuitable to undergo a further pregnancy.

3. Opinion on Surrogacy

While the Committee considered many reasons for surrogacy, it was of the opinion that surrogacy should at this time not be permitted or recognized as an acceptable procedure for the alleviation of infertility. The Committee based its opinion on the reservations that had been expressed about this approach to parenthood in a wide cross-section of reports from professional and goverment bodies.

If surrogacy were ever to be permitted then the Committee believes that:

i) the interests of the unborn child should be of paramount importance;

ii) there be established a clear definition in law of who the mother is;

iii) there be no form of advertising or commercialism for any surrogacy arrangements.

Some of the many ethical concerns that need research and examination relate to some extent, to depersonalization of reproduction, changes in social attitudes to childbearing, problems relating to surrogate anonymity, concerns over the "buying and selling of infants", and having a baby without the inconvenience of pregnancy.

Chapter 7. Counselling Services

1. Introduction

Counselling and its companion services can be defined as:

> "A communication process that gives couples the opportunity to discover for themselves individual resolutions to many potential problems and uncertainties relating to infertility and the IVF programme"

This implies a non directive approach.

This definition covers the need for information, education, choice, (self) selection, communication and support throughout. All participants must be aware of the implications, their rights and their duties.

The introductory section of this report refers to general infertility counselling and AID practice. This section will now discuss counselling for IVF participants.

2. Reports

The IVF Ethics Committee reports in the U.K. - Warnock Queensland - Demack, Victoria - Waller, Tasmania and South Australia have all dealt extensively and in detail with the justification and requirements for counselling in the setting of IVF. The Asche Report has summarised most of the important points.

Submissions

The Infertility Support Group, "Concern For The Infertile Couple" noted problems in the variable acceptance of counselling by infertile couples and the variable

encouragement given to counsellors by the medical and scientific members of the team.

The Roman Catholic archdiocesan report drew attention to the arduous nature of the programme with the statistics testifying to its frequent failure in comparison to the normal failure rate.

There was complete agreement within the Committee that couples must receive counselling. The Committee further points out this should be offered in an appropriate manner. Attention is drawn to the likely difficulty and the cost of recruiting and training suitable counsellors.

It was felt that for adequate counselling to occur, the services should be conducted under the aegis of a major teaching hospital where there are registered nurses and social work staff who may be attached to the infertility clinics to ensure adequate and continuing counselling services. This would increase the need for nurses and social workers, and would have budgetary implications.

With regard to the qualification and training of counsellors, it would seem that health care professionals receive the most appropriate basic training. Physicians, psychologists, nurses, social and pastoral workers can provide this service if they have the appropriate qualifications and commitment. The Committee recommends that all such disciplines require a post basic training within the field of IVF if they are to acquire the necessary information, knowledge and skills in communication and supportive care.

3. Current Situation In Western Australia

Consent forms already referred to in the previous section are used by both clinics conducting IVF in this State. It is uncertain whether these are completed for every participant or whether they are appropriately witnessed by a third party.

Informal counselling has been provided on an ad hoc basis with the doctors doing their own counselling accessible by appointment and through laboratory staff. Certain members of staff are more readily available than others. Some may have fulfilled the counselling role adequately. No formal counselling is routinely given, though some counselling services are now being offered to those couples who fail to conceive.

For one year, March 1983 to March 1984, "Concern", the Group for the Infertile Couple, did have a trained counsellor available. However, funding for the Commonwealth Employment Project was subsequently not available. The professional counselling service had, therefore, to be withdrawn.

4. Future Counselling Requirements In Western Australia

1. In Principle

The following recommendations are derived from the Asche Report and summarise those of the other reports:

i) Counselling should be an important and integral part of all infertility and reproductive technology programmes.

ii) Recognition should be given to the nature and purpose of the different components of counselling: that is, the provision of information; confidentiality, support, selection and screening.

iii) Counselling should be provided by those professionals and agencies with relevant expertise and experience. There should be co-operation with the medical unit which performs the procedure. Some independence should be preserved.

iv) The current criteria governing selection to the reproductive technology programme need to be reviewed so that they take into account social and psychological factors along with medical considerations.

v) Appropriate procedures should be established for determining eligibility for admissions to such programmes.

vi) It is recommended that the proposed National Council on reproductive technology as a matter of priority give consideration to the most effective means of providing counselling services in reproductive technology programmes on a uniform basis throughout Australia.

2. In Practice

The IVF teams should be encouraged to adopt the following practices:

i) Counselling is undertaken prior to commencement, during and after participation in the programme. In the event of sudden changes of

procedure such as failure to achieve fertilization with husband's sperm and the necessity for use of donor sperm in such eventuality be included in the prior counselling to avoid hasty decision making. It should be provided by a suitably qualified counsellor who is acceptable to the couple and to the team.

ii) It forms an integral part of the team management with the counsellor introduced at the initial intake session so that the role is appreciated by the client and used appropriately.

iii) An opportunity should be offered for ongoing contact as required so that questions including medical ones, can be answered or referred to the appropriate team member. Regular communication with the team must be ensured.

iv) A supportive relationship must be developed to cover the possiblity of failure and to allow future resolution of the feelings of worthlessness that may ensue.

v) Consent should be written on designated forms and witnessed by a third person.

vi) As previously recommended in the introductory section, teams should operate within, or relative to a major teaching hospital to allow inclusion of a wider selection of the community regardless of their financial status and where the practice is subject to peer review. Most importantly suitable counselling services would become available in this situation.

7. Conclusions And Recommendations

There are undoubtedly certain important issues for Western Australia as follows:

The provision of counselling in general for infertility. This is a matter for wider consideration. We recommend in this regard that a suitable section of the Health Department in conjunction with the Western Australian State Committee of the Royal Australia College of Obstetrics and Gynaecology be asked to develop some suitable guidelines and to ensure their implementation.

The Committee considers, however, that IVF counselling must be made freely available in Western Australia to assist in the selection of couples; to guarantee full reliable information; to support decisions and to follow up outcome.

The Committee makes these recommendations well aware of the likely financial implications with regard to recruitment, selection, training and payment of suitably qualified personnel.

Chapter 8. Infertility Education Of The Community

The Committee believes there is a general lack of community knowledge relating to the cause and management of infertility. While in a proportion of couples there is no known avoidable cause of the infertility, community education is necessary if the avoidable causes of infertility are to be identified. A better understanding of the social, psychological, ethical and financial problems surrounding infertility may then be achieved.

1. Medical Profession

The causes of infertility should be considered and attention directed to the avoidable aspects. The medical profession need to be made aware of the techniques and procedures that are available for the treatment of infertility. This is a rapidly expanding field and the recent developments should be communicated to the profession. Any programme of continuing education for the medical profession should include such an update. In particular, attention should be directed to the prevention of pelvic inflammatory disease of which the major causes are sexually transmissible disease or post-abortal infection.

The Women's Health Committee of the NH & MRC is concerned about the increasing frequency of pelvic inflammatory disease and its often inadequate treatment. This may result in fallopian tube disease and pelvic scarring and subsequent infertility. It is noted that a major research project for the Women's Health Committee may help with the education process.

2. Community Education

The community should be made aware of the incidence and causes of infertility. Some of these causes are related to the gynaecological consequences of a multiplicity of sexual partners. The community should appreciate the high cost of reproductive technology and that prevention of a proportion of tubal infertility can result through a reduction in the incidence of pelvic inflammatory disease.

An effective education programme could be initiated in primary and secondary schools. In this way pelvic infection and its sequelae may be prevented. Such a programme in schools should include an examination of the emotional aspects of infertility and community expectations surrounding the creation of families.

The Committee believes the community should be informed of the availability of infertility services and of specific infertility treatment programmes. Information relating to the details of access to such services should be freely available through schools, surgeries, hospitals and the media. The Health Promotion Branch of the Health Department of Western Australia in conjunction with other appropriate government agencies should be involved in developing, promoting and implementing such appropriate programmes.

Chapter 9. Regulation Of Reproductive Technology And Research

1. Maintenance Of Records

The Committee understands that the two clinics which currently practise artificial conception procedures keep satisfactory records on matters concerning semen donation, artificial insemination and artificial conception. These records are, however, the private records of the clinics. The information that they contain is determined by the clinics themselves and only they have access to it.

The Committee believes that certain information concerning semen donation, artificial insemination and artificial conception should be kept in a central register under the auspices of the Health Department of Western Australia. This register would service a number of functions. It could be used to provide information for medical practitioners, both in Western Australia and elsewhere. It could also provide important statistical data. The information required to be contained in the register should include information concerning semen and ovum donors, recipients of artificial conception procedures, and statistical information concerning IVF and similar reproductive procedures, including the number of conceptions and live births that result from these procedures.

Individuals involved would require to be reassured as to the confidentiality of stored information. Such information would be basically non-identifiable in character. Appropriate guidelines for release of and/or access to health records should be considered by the Authority appointed to maintain the register.

The Committee accordingly recommends that:

(a) an official and centrally located register by established to contain information relating to both semen donation and artificial conception.

(b) the register be kept under the auspices of the Health Department of Western Australia.

(c) the information to be contained in the register be prescribed by, and access to this information be strictly controlled by, the Licensing and Supervisory Authority (see next section).

(d) regular notification of the required information be a condition of a grant of a practice licence (see the next section).

2. Licensing And Supervisory Authority And Bioethics Committee

In the Committee's Interim Report, it noted that two clinics currently practise artificial conception procedures. The Committee is impressed by the work conducted at these clinics and with the high medical standards under which they operate.

However, the fact remains that the work done at these clinics is uncontrolled other than by the ordinary legal and medico-ethical limitations that apply to doctors and clinics generally, and by the good sense and responsibility of those who practise in these establishments. Both of the existing clinics have established ad hoc ethics committees of their own about which the Committee has no detailed knowledge.

Future clinics may operate quite differently. The very fact that clinics which practise artificial conception procedures are, in a very real sense, engaged in the processes by which children are created, makes public supervision of these clinics essential.

In its Interim Report, the Committee recommended that the practice of IVF in Western Australia be conducted either at, or under the auspices of, the King Edward Memorial Hospital for Women. It reiterates this recommendation here in its final report and now extends this recommendation to the other artificial conception procedures of GIFT and PROST. In addition, the Committee recommends the establishment of a Licensing and Supervisory Authority and a Bioethics Committee.

3. Licensing And Supervisory Authority

The function of the Licensing and Supervisory Authority would be to control the practise of all procedures concerning artificial conception in Western Australia. It would have detailed information on the practices which engage in artificial conception procedures, including the collection and storage of semen. It should also control and oversee all human research on human gametes and embryos in Western Australia, including the research conducted at tertiary institutions.

The Authority itself should be a Statutory Authority, answerable to the Minister for Health. The Committee recommends that the Authority comprise principally, but not exclusively, medical practitioners and biological scientists who have a sound knowledge of artificial conception procedures. It should be an expert Authority which has the respect and confidence of the Western Australian Parliament, those specialists who practise in the field of artificial conception, and the community at

large. In order to be seen to be impartial, the Authority should not contain any person who is currently engaged in, or who has any close association with any person or body that is currently engaged in, the practice of artificial conception procedures or research. Those members other than medical practitioners and biological scientists should have a professional background and a special interest in the field. In the Committee's opinion, no one should be permitted to engage in any artificial conception procedure (including the collection or storage of gametes), or conduct research on human gametes or embryos, unless he or she is licensed to do so, or is acting under the supervision of a person licensed to do so, by the Licensing and Supervisory Authority.

Moreover, no artificial conception procedure or research on human gametes or embryos should take place in any premises unless the premises are licensed by this Authority. Both forms of licence should be valid for a limited period and be renewable. Licensed premises should be subject to inspection by representatives of the Authority at any time, and the licence should be terminable at any time for breach of any of the requirements laid down by the Authority.

Subject to any specific directions of the Minister for Health, the Licensing and Supervisory Authority should be responsible for prescribing the conditions for any person, whether a medical or para-medical practitioner or a scientist, to perform or assist at any particular artificial conception procedures, or to conduct research on human gametes and embryos. The Authority should also be responsible for prescribing the standards required for premises to be used for such procedures.

4. Bioethics Committee

The Bioethics Committee should be a broadly based committee which has the power to recommend those ethical standards to be followed by specialists engaged in artificial conception procedures or in research on human gametes and embryos. Its function would be to ensure that the practices adopted in such procedures and research do not contravene the broad limits tolerated by the Western Australian community as a whole. It should report to the Licensing and Supervisory Authority who would ensure that the standards specified by the Committee are adhered to. The Committee should, however, also have the right to report directly to the Minister for Health if it believes that this is called for in any particular circumstance.

The Bioethics Committee should have both prescriptive and advisory functions. In other words, it should have the power to set ethical standards and to advise and consult with enquirers in respect of such standards.

The Western Australian Government, medical practitioners, medical organisations, academic and research institutions, and all persons holding a licence from the Licensing and Supervisory Authority should, moreover, have the power to require licence holders to seek the Bioethics Committee's advice and consultation on prescribed matters. Unless the Minister for Health decides the contrary in respect of any particular decision, the decisions of the Committee on ethical standards should be binding, and should be enforceable by the Licensing and Supervisory Authority.

The Committee believes that the Bioethics Committee should also represent the wider community, and that it should have the full confidence both of the community in

general and of those who practice or do research in artificial conception procedures in particular. It accordingly recommends that the composition of this Bioethics Committee be as follows:

(i) at least one medical practitioner who is familiar with artificial conception procedures;

(ii) at least one medical graduate with research experience who has an interest in artificial conception;

(iii) at least one lawyer, one minister of religion, one registered nurse, one trained counsellor, and a lay man and a lay woman, each of whom has a special interest in artificial conception procedures.

The majority of the Bioethics Committee should fall within category (iii). The Minister for Health should attempt to ensure that, so far as is reasonably possible (but without placing any undue constraints upon the appointment of otherwise appropriate candidates), the membership of the Bioethics Committee consist of an equal number of men and women, and younger as well as older members of the community. Membership would be consistent with the recommendations of the NH & MRC as to composition and function of an Institutional Ethics Committee.

List Of Recommendations

The Committee recommends that:

1. Ethical guidelines for research into artificial conception be established on State and preferably National level.

2. Programmes for the treatment of infertility should in principle be available only to married couples and couples in a stable de facto relationship.

3. AID should not be made available to single women or women living in homosexual relationships.

4. IVF services be also available in the public hospital system and should not be dependent on patient's ability to afford the service.

5. The age for consent and entry into an IVF programme be 18 years.

6. Each couple seeking admission to an IVF programme be provided with clear and comprehensive information about the procedure.

7. A written consent form be available to and signed by the couple entering an IVF programme.

8. Consent be essential for the method of use, or disposal of excess embryos obtained through IVF.

9. The use of donor sperm be allowed in IVF where the husband is azoospermic or severely oligospermic.

10. Sperm banks be the only source of the donor sperm and operate under licence from a Licensing and Supervisory Authority.

11. In every case consent for ovum donation and ovum acceptance should be the subject of a separate written agreement.

12. Existing legislation be clarified so that the mother who receives the donated embryo and her husband are regarded as the parents of the resulting child, and that the donors of the ovum and the sperm not be regarded as the parents of the child.

13. Surrogacy should at this time not be permitted or recognised as an acceptable procedure for the alleviation of infertility.

14. All couples undergoing IVF receive counselling.

15. Health care professionals undertaking counselling require post-basic training within the field of IVF in order to acquire the necessary information, knowledge and skills in communication and supportive care.

16. Counselling be undertaken along the lines enunciated in the Asche Report.

17. Suitable guidelines for counselling of infertile couples be established by the Health Department of Western Australia in conjunction with the Western Australian State Committee of the Royal Australian College of Obstetricians and Gynnaecologists.

18. An official and centrally located register be established to contain information relating to both semen donation and artificial conception.

19. The register be kept under the auspices of the Health Department of Western Australia.

20. The information to be contained in the register be prescribed by, and access to this information be strictly controlled by, the Licensing and Supervisory Authority.

21. Regular notification of the required information be a condition of a grant of a practice licence.

22. The Licensing and Supervisory Authority comprise principally, but not exclusively, medical practitioners and biological scientists who have a sound knowledge of artificial conception procedures.

23. The Bioethics Committee comprise:

    (i) at least one medical practitioner who is familiar with artificial conception procedures;

    (ii) at least one medical graduate with research experience who has an interest in artificial conception;

    (iii) at least one lawyer, one minister of religion, one registered nurse, one trained counsellor, and a lay man and a lay woman, each of whom has a special interest in artificial conception procedures.

Expression of Dissent

As the nominee of the Roman Catholic Archbishop of Perth on the In Vitro Fertilization Ethics Committee of Western Australia, it is with considerable regret that I find I must express a dissentient opinion in respect of many of the recommendations submitted to the Minister for Health by the Chairman on behalf of the Committee.

The reasons for these expressions of dissent will be found in detail in the submission prepared by the Diocesan Bioethics Committee of the Roman Catholic Archdiocese of Perth in response to the Interim Report published by the In Vitro Fertilization Ethics Committee in August, 1984. This Response is available from the Secretary of the Diocesan Committee at St John of God Hospital, P.O. Box 14, Subiaco, 6008.

Two main concerns underlie my dissentient opinions:

Firstly, I do not believe sufficient account has been taken, from a moral point of view, in the present practice of in vitro fertilization and the procedures consequent upon it, of the hazards to which incipient and developing embryonic, fetal and infant human life is exposed by the procedure. This concern is relevant especially to the continuing high rate of embryo loss presently experienced in IVF. It relates also to the selecting

of embryos for transfer on criteria other than that of viability, and to selective fetal abortion where multiple pregnancy occurs. It bears, too, on the recommendations of the Committee approving the present practices of freezing embryos and of experimenting on "surplus" embryos, even though both these practices be limited and strictly monitored.

The Roman Catholic Church (in this respect, like the Warnock Committee) does not presume to pronounce definitively on the moment at which human personalization is effected. Nonetheless (and, in this respect, unlike the Warnock committee), it firmly maintains the inviolability of the human embryo from the moment of fertilization, and it rejects as morally unacceptable any procedures which, even for the benefit of future generations, intentionally destroy, discard, or irresponsibly jeopardize the developing life of a human embryo.

Secondly, I view with considerable concern a procedure a present consequence of which (and one which is sanctioned by the Committee) is that "surplus" embryos are frozen and stored for extended indefinite, or even definite, periods. This introduces a "brave new world" aspect into our community and civilisation. With it come all the attendant problems and temptations associated with embryo freezing and thawing, with embryo flushing, embryo experimentation, embryo donation, eugenic breeding, surrogacy, ectogenesis, cloning etc.

If IVF is to be permitted in our community (and I am not necessarily assuming it should be), there is, I believe, only one way to avoid these varieties of genetic manipulation of "surplus" embryos. Only a strictly limited number of ova should be fertilized with the husband's sperm in each IVF procedure, and all the viable embryos resulting from this procedure should be transferred immediately (or as soon as possible) to the wife's uterus (the "simple case" for the purposes of this "expression of dissent").

If multiple pregnancies are to be kept at a minimum, this will mean that only one, two, or at most three, ova should be fertilized in each procedure. From this limitation it will follow that, if the initial attempt is unsuccessful, subsequent attempts will require abstraction of further ova rather than recourse to "surplus" frozen embryos.

There are risks involved in this further surgical abstraction. I am informed, however, that they are comparatively minor, and that they will be further alleviated by the development of new methods of aspirating the follicles which will require only a local, as opposed to a general, anaesthetic. This alternative to the present practice of freezing "surplus" embryos not only is more likely, on present figures, to produce a pregnancy for the infertile, but also it is preferable to exposing the embryo

(and our community and civilisation) to the hazards associated with the varieties of embryo experimentation and manipulation to which I have alluded.

If IVF and ET, then, is to be sanctioned and approved by the government and community (and, once again, I am not assuming it should be), I believe it should be restricted to the so-called "simple case" between husband and wife which I have outlined in the preceding paragraphs. The practice will then remain a clinical procedure for the benefit of the infertile couple rather than a highly questionable exercise in scientific experimentation and manipulation. I therefore call upon those involved in the programmes and those in authority in our community to reinstate the practice as an exclusively clinical procedure in the foregoing terms, and to restrict the research and experimental aspects of the present programmes to those which have a direct bearing on the success of the clinical procedure, and which do not involve the destruction, discarding or jeopardizing through experiment, of the human embryo.

In line, therefore, with these two main concerns which I have proposed:

1. I reserve my opinion on the recommendation of the Committee that IVF between husband and wife be regarded as ethically acceptable. It is only if it were to be restricted to the "simple case" between husband and wife

as outlined above, that I would be prepared to consider the clinical aspects of the present procedure even as morally defensible.

2. I would strongly support a recommendation that IVF, if it is to be permitted, should not be extended to de facto couples. The N.S.W. Law Reform Commission in August, 1983, published a Report concerning de facto legislation in that State. While I firmly support the general thrust towards legislative reform of the Report, there are figures cited in the Report which make me doubt the wisdom of extending IVF even to stable de facto couples.

These figures relate that after two years 59% of these couples were still together, and that after five years about 20% of these relationships had persisted. But after ten years only 8% of the couples were still living together in a stable relationship. Even though the rate of dissolution of marriages has risen considerably in the community in recent years, an I.V.F. child born of a married couple still has a 6 - 8 times better chance at the age of ten of being supported in a family relationship by both parents than he/she would have if his/her parents were in a stable de facto relationship when the child were conceived.

Granted these statistics, I cannot believe it to be in the best interests of the prospective child that IVF should be extended even to stable de facto couples. I therefore dissent from the Committee's recommendation.

3. If IVF is to be permitted in the community, I am in general agreement with the recommendations of the Committee concerning the other criteria for eligibility of married couples for IVF, with those concerning the provision of counselling and information, and with those concerning the licensing and supervision of the practice of IVF in Western Australia. There should be, I believe, qualified community non-medico/scientific representation on both the Licensing and Supervisory Authority and the Bioethics Committee.

4. I am also in general agreement with the recommendations of the Committee concerning consent to treatment and acceptance of married couples within an IVF programme. I would add that, as far as possible, the programmes should be sufficiently flexible to accommodate the varying moral demands which, in respect of certain aspects and consequences of the programme, the participating married couples may wish to impose. In particular, the right of a married couple to ask that only the "simple case" procedure be performed should be respected, i.e., that no more embryos be generated than are intended to be transferred immediately to the wife's uterus,

5. However, I must dissent from the Committee's basic recommendations approving the use of donor gametes and donor embryos in IVF programmes. The use of donor gametes and donor embryos, whether in artificial insemination or in IVF programmes, radically compromises the exclusivity of the procreative dimension of the marriage relationship. It is therefore, I believe, not morally acceptable.

If, however, despite this objection to the procedure, the majority of the Committee do continue to approve the use of donor gametes and donor embryos, I am in general agreement with the further recommendations of the Committee concerning the regulation and reimbursement of donors, the legal dispositions affecting the ownership of embryos, and the legislative changes necessary to legitimate IVF children born of donor gametes or embryos. In line with the recent Victorian and Swedish adoption legislation, I would support the prima facia right of such a child, on attaining its majority and having received appropriate counselling, to know the identity of its genetic parents. In this aspect, I dissent from the majority opinion of the Committee, which maintains strict anonymity for donors.

6. While I believe that the freezing of embryos for a short period (1 - 2 months), to promote implantation in cases where immediate transfer becomes impossible, in principle adds no further significant moral dimension to that involved in the "simple case", in general the present routine practice of cryopreservation of embryos (and that more or less indefinitely), with its high rate of embryo loss in the thawing process, constitutes an unnecessary further jeopardizing of embryonic life, and is therefore morally unacceptable.

In addition, cryopreservation opens the way to all the further consequences of embryo experimentation and genetic manipulation, and the subsequent destruction and discarding of embryos under experiment, to which I have drawn attention. I therefore cannot support the recommendation that the present practice of cryopreservation of embryos be permitted, even under the closely monitored supervision the Committee recommends.

7. Nor can I support in any way the Committee's recommendation, however limited, that experimentation on "surplus" embryos be permitted. I do appreciate the value of the distinction drawn by the Committee between embryos that are generated specifically for experimentation and those that become "surplus" after a

pregnancy has had a successful outcome. However, once again in practice I believe the distinction will be blurred, and the demand for embryo experimentation will ensure that there will always be a ready supply of "surplus" embryos available for experimentation. In no circumstance, however, would I condone experimentation on embryos (whether "surplus" to a successful pregnancy or generated specifically for that purpose) that results ultimately in the destruction or discarding of embryos under experiment, or in any non-therapeutic jeopardizing of their viability.

9. I am in general agreement with the recommendations of the Committee concerning surrogacy. I would further submit that its possibility in the community should be limited through legislative intervention. I also fully support the general thrust of the Committee's recommendations on counselling, on the regulation of reproductive technology and research, and on the need for infertility education. Thus, if IVF is to be permitted in the community, there is a need for it to be subject to licence in the first instance, and then to be regulated and closely monitored by authorities who have a strong community representation.

In conclusion may I go on record in expressing my appreciation to other members of the Committee for the highly conscientious and professional manner in which the meetings of the Committee

were convened and conducted over a three year period. Although, as no doubt has become clear in the presentation of this statement of dissent, there are many points at which I disagree with the sentiments of the majority of members, I have always been accorded every opportunity to present my dissenting opinion, and the matters I have brought forward have been discussed in a spirit of understanding and courtesy. I trust that the recommendations of the Committee will be accepted in the same spirit by the Minister for Health and his colleagues in government.

Finally, may I express my thanks to the Executive Secretary of the Committee, Mrs Jacqueline Anstead, for the way in which she has facilitated the business of the Committee, and has been so prompt in supplying the relevant reports and documentation.

(Rev.) W J Uren, S.J.

24 September 1986

APPENDIX 1

INTERIM REPORT OF THE IN VITRO FERTILISATION ETHICS COMMITTEE OF WESTERN AUSTRALIA

4276c - 6 - 16.8.84

INTERIM REPORT OF THE IN VITRO FERTILISATION ETHICS COMMITTEE OF WESTERN AUSTRALIA

1. Formation of the Committee

The Committee was formed in June 1983. The Honourable the Minister for Health called for nominations for membership of the Committee from various bodies and in turn nominated four members himself.

The Committee is chaired by Mr Robert Meadows - barrister and solicitor - Chairman of the Ethics Committee of the Law Society of Western Australia - nominated by the Law Society of Western Australia.

The members of the Committee in alphabetical order are:

Associate Professor R.A. Barter - Director of Laboratory Services, King Edward Memorial Hospital for Women - nominated by The Board of Management, King Edward Memorial Hospital for Women.

Doctor Peter Brine - President of the Medical Board of Western Australia - nominated by the Australian Medical Association.

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The Most Reverend P.F. Carnley - Anglican Archbishop of Perth - nominated by the Anglican Church.

Miss Rosalind J. Denny - Director of Nursing, King Edward Memorial Hospital for Women - nominated by the Minister.

Doctor Athel Hockey - Senior Medical Officer Irrabeena and Geneticist, and King Edward Memorial Hospital for Women and Princess Margaret Hospital for Children - nominated by the Minister.

The Reverend Colin Honey - Master of Kingswood College at the University of Western Australia - nominated by the Minister.

Doctor Geoffrey Lilburne - Obstetrician and Gynaecologist - nominated by the Royal Australian College of Obstetricians and Gynaecologists.

Associate Professor C.A. Michael - Department of Obstetrics and Gynaecology at the University of Western Australia - nominated by the Vice Chancellor, University of Western Australia.

Mrs. Margaret Papaelias - President of "Concern for the Infertile" - nominated by the Minister.

The Reverend W. Uren - Rector of Saint Thomas More College, University of Western Australia - nominated by the Most Reverend Sir Launcelot Goody - Catholic Archbishop of Perth.

The Executive Secretary of the Committee is Mrs J.M. Anstead - Principal Staff Development Officer, Education Services Branch, Department of Public Health. The Committee is indebted to Mrs Anstead for her invaluable assistance in arranging meetings, keeping minutes and her efficiency in co-ordinating the affairs of the Committee.

2. The Committee's Terms of Reference

In appointing the Committee the Minister stated its terms of reference to be:

"To consider the social ethical and legal issues arising from in vitro fertilisation, to advise on the relevance of any recommendations from similar committees both in Australia and overseas and to supervise the practice of in vitro fertilisation in Western Australia."

The Committee was informed that its responsibilities were on-going and that it had a relatively free hand to determine its operating procedures and the extent to which it wished to involve itself in any aspect of the terms of the reference.

Although it was not asked to report to the Minister within any specified time the Committee took the view that it should prepare an interim report to appraise the Minister of the work it had been doing and of what recommendations it had to make at this stage. The Committee perceives that it will make reports to the Minister from time to time. It is envisaged by the Committee that the Minister would make its reports public.

3. Work of the Committee

The work of the Committee is still in its preliminary stages.

The Committee has met on ten occasions and in summary:-

(a) has discussed at length the broad issues relating to IVF;

(b) has interviewed Dr. J.L. Yovich and Dr. T. Thomas, two medical practitioners practising IVF;

(c) considered reports and other literature relating to IVF, in particular the reports of the Royal College of Obstetricians and Gynaecologists published in March 1983 and the reports published by its Victorian

counterpart which is generally known as the Waller Committee and more recently the report of the Demack Committee in Queensland;

(d) defined the questions which it considered required the attention of the Committee and established a priority list in relation to those questions;

(e) considered a number of those questions and formulated recommendations to the Minsiter;

(f) prepared this interim report.

4. <u>The Practice of In Vitro Fertilisation in Western Australia</u>

Before dealing with this question specifically it is necessary to describe what is meant by In Vitro Fertilisation. It is the process whereby an egg recovered from the ovary by laparoscopy is fertilised by sperm in the laboratory. The resultant embryo is then transferred to the uterus.

The collection of eggs normally takes place after a series of tests have been undergone by the woman and after the administration of drugs to stimulate the production of more than one egg in each cycle. The menstrual cycle is monitored to determine how the eggs

are ripening and this is followed by further tests. Collection is sometimes preceded by a hormone injection that triggers off ovulation a day and a half later. The woman is taken to the operating theatre and under general anaesthetic her peritoneal cavity is filled with carbon dioxide. A small hole is made in the umbilicus through which a viewing instrument is passed. Another small hole is made for the needle to pass into the cyst which forms on the ovary immediately prior to expelling a ripe egg. Through this needle the fluid from the ovary is aspirated into a glass tube. The fluid is taken into a laboratory for identification of eggs.

Sperm are then provided by the intending father. These are centrifuged and washed prior to being used for fertilisation.

Fertilisation is attempted after the egg has been held in an incubator for 5-6 hours. The egg and sperm are brought together in a culture medium. Once fertilisation has occurred this is confirmed microscopically by the presence of two nuclei in the embryo(s).

Depending upon the team performing the procedure one or more embryos is transferred to the mother usually at the 4 or 8 cell stage. The transfer is effected by a fine

bore tube which is passed into the uterus and the embryo is injected in a drop of fluid.

The mother remains in hospital for about 36 hours and then rests at home for several days. Weekly blood hormone tests are then conducted for the first 12 weeks for the purpose of diagnosing and monitoring pregnancy.

As indicated earlier in this report the Committee interviewed Dr. J.L. Yovich and he informed the Committee that initially he had commenced the practice of IVF in the Department of Obstetrics and Gynaecology of the University of Western Australia at the King Edward Memorial Hospital for Women, but this had discontinued in 1981 because financial and other support was not available at the hospital. Accordingly he and his team had gone out on their own and set up an IVF clinic at Avro Hospital. Subsequently the team had split up and he had gone his separate way and formed a new team.

Dr. Yovich was currently actively engaged in the practice of IVF.

As indicated the Committee also interviewed Dr. T. Thomas who informed the Committee that when Dr. Yovich left the team operating at the Avro Hospital he was asked to replace him. This was in mid-1982 although it was not

until November 1982 that the first patients under his team were admitted.

Reference will be made to various aspects of the information obtained from Doctors Yovich and Thomas in the course of considering the various questions relating to IVF which are considered in this report.

5. <u>The process of IVF in which the gametes are obtained from husband and wife and the embryos are transferred into the uterus of the wife.</u>

This was the first question considered by the Committee.

This is the normal situation. The Committee was informed that in the case of one team 90% of cases involved husband and wife. In the case of the other team the great majority of cases involved husband and wife.

Whilst some reservations were expressed by some members of the Committee regarding IVF in principle, the Committee came to the majority view that IVF in such circumstances was ethically acceptable and recommended that it be so recognised.

<u>Recommendation</u>. The process of IVF in which the gametes are obtained from husband and wife and the resulting

embryos are transferred into the uterus of the wife be regarded as ethically acceptable.

The Committee emphasises that this recommendation was subject to the adoption of the Committee's remaining recommendations outlined in this report.

6. De facto Relationships

As previously indicated, both of the teams engaged in the practice of IVF had treated couples who were not husband and wife. It is therefore necessary for the Committee to form a view as to whether this is ethically acceptable and if so under what conditions.

The Committee discussed at length the question of whether IVF should be made available to couples who were living in a de facto relationship. There were differing views amongst the Committee members.

The Committee regarded this as an area in which it should receive submissions from the community before taking a final position. The Committee also considered that it should take into account the public debate which is current on this issue and moves contemplated by the legislature regarding de facto relationships.

The Committee seeks the consent of the Minister to call for submissions on this and other issues referred to later in this report and, depending upon the response received, to hold public hearings.

Accordingly, at this stage the Committee is not prepared to make a recommendation to the Minister on this question.

7. <u>To what extent should couples who wish to participate in IVF have exhausted other medical procedures to overcome their infertility before being permitted to undertake IVF.</u>

The Committee noted the Waller Committee's recommendation:-

"When infertility has proven unresponsive to other means of treatment or the couple has sought alternative treatment for a period in excess of 12 months then such couple shall be entitled to be selected to join in the in vitro fertilisation programme if they are otherwise suitable candidates for treatment."

The Committee regarded the requirement for alternative treatment as arbitrary. It did not take account of the case where it was apparent from the outset that no alternative treatment was possible or was likely to be as successful as IVF. The Committee considered that if it be the case that IVF is to be regarded as ethically acceptable if it be the most efficacious treatment then it should be offered. In deciding whether IVF was appropriate, the high cost of that treatment was a factor to be considered.

Recommendation. The Committee recommends that a couple should be eligible for IVF if this is in all the circumstances the most appropriate means of treatment to overcome their infertility.

8. Counselling and Information

A number of things emerged from the Committee's inquiry.

(a) Participation in the IVF programme is particularly arduous for the woman.

(b) In spite of media publicity the full extent of the procedure is not widely understood.

(c) It is important for participants to be fully informed of the nature and implications of the procedure.

(d) Participants require counselling and support, both before, during and after the procedure.

(e) Counsel and support are particularly necessary where the procedure had been unsuccessful.

The Committee noted the recommendations of the Waller Committee regarding the dissemination of information which was in the following terms:-

> "The Committee believes that each couple seeking admission to an IVF programme must be provided with clear and comprehensive information about the programme. Each couple must be advised of any risks involved in the programme, and of its likely duration, and given the most accurate information about the prospects of success. This will then permit each couple to express in writing their free and informed consent to participate in the programme."

The Committee was concerned about the apparent lack of understanding in the community as to the relatively low success rate with IVF. The best reported results to the Committee were to the effect that in only 1 in 12 patients was a diagnosed pregnancy achieved and that live births occur in perhaps as few as 1 in 20 patients.

Appended to the report are details of the results of IVF treatment carried out by the two teams practising IVF in Western Australia - Appendix 1.

The results appear to be consistent with those achieved in other programmes and it is evident that the rate of success is increasing.

In order to monitor the IVF programme in Western Australia the Committee believes that a confidential register should be established in which a record of each IVF attempt is kept. The form of the register and how it is to be maintained should be the subject of further determination.

The Committee considers that potential participants in the programme should be given the fullest of information regarding all aspects of the programme and endorses the recommendation of the Waller Committee.

Furthermore, the Committee is of the view that the counselling of participants is of considerable importance.

Recommendation. The Committee recommends that all persons proposing to undertake IVF be provided with comprehensive information about all aspects of the programme and in particular about the prospects of success. This information should be provided in a written form to enable mature consideration of the information.

Counselling should be provided to participants in IVF both before, during and after participation. Such counselling should be provided by appropriately trained counsellors.

A register be established to record all IVF attempts.

9. Consent

It seems that doctors rely on both oral and written consent. The Committee considered that a written form of consent was essential.

This Committee has examined the form of consent used by Dr. Thomas and the Monash University team. The Committee considers that a written form of consent should be given by both intending participants substantially in the form used by the Monash University team. A copy of that form of consent is appended to this report - Appendix 2.

Recommendation. Both intending participants in IVF should sign a written form of consent substantially in the form appended to this report. Such consent form should only be signed after mature consideration of information regarding IVF and after counselling.

10. In What Hospitals Should IVF be Practised

It will have been noted that initially the practice of IVF was carried out at the King Edward Memorial Hospital for Women. For reasons which have been briefly indicated earlier in this report those who were involved in the practice of IVF were constrained to set up a clinic at a private hospital if they were to continue. It has now evolved that there are two clinics in Western Australia where IVF is practised and both these clinics are conducted at private hospitals.

It was considered by the Committee that it was not desirable that such an innovative procedure should at this stage be undertaken other than under the auspices of a major teaching hospital. This is not to say that the IVF clinic need be within the precincts of the teaching hopsital itself, although this would be more desirable. The Committee recognised that there were unusual problems in the practice of IVF, such as the availability of operating theatres and other facilities, which must necessarily be available on short notice, and these may not be available when required in the context of the administration of a teaching hospital. However if the practice of IVF was conducted at locations where it was possible to provide these facilities as and when required, but under the umbrella of a major teaching hospital, the most desirable situation could be achieved.

The Committee saw the association with a major teaching hospital as desirable for a number of reasons including:

(a) IVF would be accessible to a wider section of the community and not just those who could afford treatment at a private hospital.

(b) Those practising IVF would be subject to the overview of their peers.

(c) The practice of IVF would be governed by existing ethics committees within teaching hospitals.

(d) The availability of counselling by trained counsellors.

The Committee considered that the King Edward Memorial Hopsital for Women was the hospital under which auspices the practice of IVF should be conducted.

Recommendation. The Committee recommends that the practice of IVF in Western Australia be conducted either at or under the auspices of the King Edward Memorial Hospital for Women.

11. Under What Criteria should IVF be available to Intending Participants

This was another question in respect of which the Committee considered it would like to have the advantage of input from the community. It is a question which raises fundamental issues in circumstances where the number of patients to whom the treatment can be offered is limited. The Committee was firmly of the view that financial ability to pay for the cost of the treatment should not be regarded as an acceptable basis for selection. However as to the other issues raised by this question the Committee reserves its position until it has examined submissions received from the community and the other materials available to it.

Accordingly the Committee makes no recommendation on this issue at this stage.

As indicated earlier in this report there are a number of issues which the Committee has yet to address. Not necessarily in order of priority these issues are:-

(a) Should the use of donor sperm be permitted and if so in what circumstances and subject to what conditions?

(b) Should the use of donor ova be permitted and if so in what circumstances and subject to what conditions?

(c) Should donor embryo be permitted and if so in what circumstances and subject to what conditions?

(d) Should cryo preservation of sperm, ova and embryos be permitted and if so in what circumstances and subject to what conditions?

(e) Should all embryos be transferred and if not what should be done with excess embryos?

(f) Should experimentation on embryos be permitted and if so in what circumstances and subject to what conditions?

(g) What legislative changes (if any) are required in order to render lawful the practice and procedures of IVF?

(h) What legislative changes are required in order to protect the status of children born as a result of IVF?

In order to assist it in the consideration of the final two questions the Committee requested the Minister to appoint Dr Anthony Dickey of the Law School of Western Australia to the Committee because of his special knowledge and expertise in relation to these issues. The Committee is pleased to note that the Minister has acceded to its request.

In conclusion the Committee requests of the Minister that he appoint a research officer to devise and conduct an evaluation of IVF in Western Australia in co-operation with the medical practitioners who are working in this area and that this evaluation be proceeded with while this Committee continues its deliberations.

This request is made on the grounds that as is the case with all medico social procedures where the immediate and long term outcome is uncertain they require evaluation. The Committee lacks answers to many of the questions asked by its members and

the community with regard to IVF. An evaluation such as that proposed should be an integral part of the IVF procedure.

The design of the evaluation should be prepared under the direction of a member of the National Health and Medical Research Council Epidemiology Research Unit. It would be necessary for the unit to be reimbursed for these services and funding of the evaluation project generally will be required.

In the Committee's view the design of the evaluation should provide for immediate and long term follow up of:-

(a) children born as a result of IVF;

(b) the effect on the marriages and de facto relationships as the case may be of the parents;

(c) the costs associated with the procedure and any changes in costs;

(d) any differences observed between those in whom the procedure has been used as a treatment for infertililty and those for whom the procedure has been used because of risks of transmitting a serious genetic disorder;

(e) the outcome for those parents where IVF treatment has proved unsuccessful;

(f) in instances where disclosure of the mode of conception is made to the child or other family members the effect that this disclosure has.

The study should consist of a case control design with at least two control groups:-

(1) parents where conception occurs naturally;

(2) parents where conception is achieved by using other methods of treatment for infertility.

The Committee would see itself as receiving regular reports under these research arrangments and this will allow the Committee to continue to deliberate on the issues involved in the knowledge that some attempt is being made to measure the results and the effect of IVF from which the Committee can make a considered and informed judgment on these issues. It would also allow the Committee to follow through the recommendations already made in this report and to suggest modifications where necessary. In the absence of such research the Committee is concerned that it will become increasingly difficult to control the situation.

APPENDIX I

DR. JOHN YOVICH

RESULTS TO 30 JUNE 1984

Number of patients treated (i.e. have reached the stage of laparoscopy to collect oocytes)	330
Number of IVF attempts	465
Number of diagnosed pregnancies	46
Number of live births (including 1 set of non-identical twins, 1 set of identical twins and 1 set of non-identical triplets)	24

AVRO HOSPITAL

SUMMARY OF PATIENTS 1.1.84 - 30.6.84

Patients commenced treatment (c)		77	
(ET84/76 collected in July)			
" " cancelled		11	
" " underwent follicle aspiration		63	
Total follicles aspirated			
Large	2.0 cm	165	
Medium	1.5 - 2.0 cm	42	
Small	1.5cm	15	
		94	316 (4.8/asp)
Total oocytes collected			
Immature		39	
Slightly immature		117	
Mature		60	
Slightly atretic		30	
Atretic		11	
Damaged		2	
(including 3 collected from P.O.D.)			259 (3.9/asp)

Patients with oocytes fertilised	63	
Total oocytes fertilised		193
Patients re-implanted	62	
Total embryos re-implanted		161

(balance of fertilised oocytes either:

1: polyspermic

2: did not cleave

3: badly fragmented (non-viable)

No. Embryos transferred	1	2	3	4
No. Transfers	13	16	16	17
(a)				
No. of Pregnancies (Chemical)	2	2	5	12
(b)				
No. of Pregnancies (Clinical)	1		3	6

Patients showing chemical pregnancy	a)	21	(33.9%/transfer)
Patients showing clinical pregnancy	b)	10	(19.2%/transfer to 8/6/84)

(one patient has since delivered @ 21 weeks a male infant due to cervical incompetence)

Addendum:

(a) Chemical pregnancy evidenced by a significant rise in endogenous BHCG over 2 consecutive samples taken 2/3 days apart.

(b) Clinical pregnancy evidenced by presence of foetal heart on ultrasound.

(c) Number allocated at commencement of programme.

Births:

No. live births - 4 (2 male and 2 female)
(including 1 set of male infant twins)

APPENDIX 2

PATIENT CONSENT FORM FOR IN VITRO FERTILIZATION

We agree to the procedure of in vitro fertilization and embryo transfer and understand the following:-

(1) There is no guarantee of success.

(2) The risk of laparoscopy as done for oocyte pick-up.

(3) The possible risk of foetal malformation.

(4) The availability of tests to detect foetal malformation during pregnancy.

Witness: .....

Signed : Husband..... Wife.....

Date : .....

APPENDIX 2

LIST OF SUBMISSIONS

Abortion Law Repeal	W.A.
Adoption Jigsaw W.A. (Inc.)	W.A.
Avro Invitro Fertilization Unit	W.A.
Mr & Mrs R Aitkens	W.A.
Mrs R G Alman	W.A.
Baptist Churches of W.A.	W.A.
Mrs Helen Byrne	W.A.
Bunbury Senior High School	W.A.
Catholic Archdiocese of Perth	W.A.
Mrs M A Cole	W.A.
Committee of the Calvanistic Political and Social Association	W.A.
Concern for the Infertile Couple	W.A.
Country Women's Association	W.A.
Ms S Cox et al	W.A.
Dr P B Cullity	W.A.
Mrs E A De Leo	W.A.
Mrs Debbie Foster	W.A.
Mr & Mrs D J Franks	W.A.
Mr & Mrs R S Fraser	W.A.
Lillian Gonzalez	W.A.
M J Gonzalez	W.A.
Dr Patrick W Gill	W.A.
Mrs P Halligan	W.A.
Mr Louis M Hayter	W.A.
Mrs E Jendry	W.A.
Mrs Jean Jenkinson	W.A.
Mrs Ruth Jeffreys & Mrs Fay Ward	W.A.
Dr Duncan Jefferson	W.A.
Mrs E Kempton	W.A.

Michael J van Kampen	W.A.
King Edward Memorial Hospital for Women	W.A.
Cath & Rod Loller	W.A.
Mrs J Lyons	W.A.
Mrs Deborah MacDonald	W.A.
Mr Murray Masters	W.A.
Mrs M Morgan	W.A.
Mr Alan Mitter	W.A.
Mr & Mrs Richard O'Grady	W.A.
Mrs A P Oostryck	W.A.
Mr R G Paterson	W.A.
Perth Apostolic Church	W.A.
Right to Life Association	W.A.
The Very Reverend David Robarts, Dean of Perth	W.A.
Ms Megan Sassi	W.A.
P F & S M Smith	W.A.
Mrs Tamar Sofair	W.A.
Mr David Smith, Member for Mitchell	W.A.
St Vincent's Bioethics Centre	MELBOURNE, VIC.
Ms Bev Thiele et al	W.A.
The Family Planning Association of Western Australia (Inc.)	W.A.
Mrs P Thompson	W.A.
Mrs Yvonne C Vea	W.A.
Mrs Enid Vincent	W.A.
Associate Professor E D Watt	W.A.
Westminster Presbyterian Church	W.A.
Women's Electoral Lobby	W.A.
Women's Service Guild of Western Australia Inc.	W.A.
Dr John Yovich	W.A.

SIGNATORIES:

ASSOCIATE PROFESSOR C A MICHAEL (CHAIRMAN)

ASSOCIATE PROFESSOR R A BARTER

THE MOST REVEREND DR P F CARNLEY

MISS R J DENNY

DR A F DICKEY

DR K A HOCKEY *

THE REVEREND C R HONEY

DR G D R LILBURNE

MRS M A PAPAELIAS

DR M F QUINLAN *

FATHER W J UREN

J M ANSTEAD (EXECUTIVE SECRETARY)

* Unavailable at time of publication