WESTERN AUSTRALIAN REPRODUCTIVE TECHNOLOGY COUNCIL

ANNUAL REPORT

1 JULY 2002- 30 JUNE 2003

Mr Mike Daube
Director General
Department of Health
189 Royal Street
EAST PERTH WA 6004

Dear Mr Daube

It is with pleasure that I submit to you this Annual Report of the Reproductive Technology Council (Council). This Report is for the financial year 2002-2003. It sets out details of reproductive technology practices in this State and activities of the Council during the year, as required by the *Human Reproductive Technology Act 1991* (HRT Act). It is in a form suitable for submission by you to the Minister for Health by 30 September 2003 and also, as is required, to be laid by the Minister before each House of Parliament.

The area of assisted reproductive technology (ART) has once again this year been significantly impacted by politics at both the state and national levels. Consequently this has influenced the work of the Council.

The *Acts Amendment (Lesbian and Gay Law Reform) Act 20*02 came into effect on 21 September 2002. This amended a number of pieces of legislation, including the HRT Act and the *Artificial Conception Act 1985*. This brought with it considerable ramifications for the work of the Council, particularly in providing updated general guidance in relation to eligibility for IVF procedures and on the legal status of children born in differing circumstances involving donation of human reproductive material.

On 19 December 2002 the *Prohibition of Human Cloning Act 2002* and *Research Involving Human Embryos Act 2002* were passed. These two Acts were the Commonwealth Parliament's response to a decision of the Council of Australian Governments (COAG) of 5 April 2002. COAG agreed that there should be consistent national legislation to ban human cloning and other unacceptable practices and to regulate certain activities involving the use of human embryos. Furthermore, COAG agreed that there should be a consistent approach to ART clinical practice, based on the standards set by the Reproductive Technology Accreditation Committee. To comply with the COAG agreement legislation has now also been passed in New South Wales, Queensland, Victoria, South Australia and Tasmania. The *Human Reproductive Technology Amendment Bill 2003* was introduced into the Western Australian Parliament on 26 June 2003. The Council has noted that the proposed changes are all consistent with relevant recommendations of the Select Committee that reviewed the HRT Act and reported in 1999 and therefore consistent with recommendations made by the

Council to the Select Committee. Passage of these amendments will bring further challenges to the Council, in guiding their implementation.

Implementation of another significant recommendation of the Select Committee was finalised during the year. On 18 November 2002, the Minister for Health officially launched the Voluntary Register of Information about Donation in Assisted Reproduction. The establishment of the Voluntary Register was publicised widely and the response from the community has been very positive.

The past year has seen changes to the Council membership after several years of a constant membership, as well as changes to the staff of the Reproductive Technology Unit.

I would like to commend current, past and new Council members for their contributions to the challenging matters that confront us. On behalf of all members of the Council, I want to thank Dr Sandy Webb for her guidance and support as Executive Officer to the Council from its inception in 1992, thank Ms Patrice Wringe for her invaluable support to the Council for the last few years and welcome Ms Antonia Clissa as the new Executive Officer. I would also like to acknowledge the ongoing legal, financial and administrative support by the Department of Health, which are vital to enable the Council to carry out its statutory duties.

Yours sincerely

Professor Con Michael AO
CHAIR
Reproductive Technology Council
26 September 2003

CONTENTS

EXECUTIVE SUMMARY

This Annual Report has been prepared by the Reproductive Technology Council (Council) for the Commissioner of Health, to comply fully with all the requirements of the WA *Human Reproductive Technology Act 1991* (HRT Act). The information in the Report enables the Commissioner to submit his own report to the Minister for Health, on the activities of the Council and the use of reproductive technology in the State during the financial year 2002- 2003, and is in a form suitable for the Minister to lay before both Houses of Parliament as required by the HRT Act.

The Report details the activities of the Council in the financial year 2002 - 2003. Information reported by clinics licensed under the HRT Act, gives summary information about their activities during the financial year 2002 – 2003. There is also detailed, collated information from the Reproductive Technology Register, which was established under the HRT Act when it came into operation on 8 April 1993. This information relates to treatments carried out in the calendar year 2001. In addition the report includes information from a variety of sources about various matters of significance to the public interest in reproductive technology.

There were significant changes made to Council membership this year. After a substantial delay owing to a government review of Statutory Bodies, several long-term vacancies following resignations of members have now been filled. Changes also took place between some existing members and deputy members. In February 2003 there were some significant staff changes to the Reproductive Technology Unit. Dr Sandy Webb was appointed to a new contract position in the Department of Health with responsibility to oversee the development implementation of amendments to the HRT Act. Dr Webb will continue to serve on the Council's Scientific Advisory and Licensing Committees. Ms Patrice Wringe has moved to another position in the Department of Health. However, she will continue to administer the Voluntary Register as well as serving on the Counselling Committee. Ms Antonia Clissa was appointed as the new Executive Officer in May 2003. She has served on Council as women's interest representative since 1997 and on the Counselling Committee since 1995.

Applications were made by four clinics for renewal of their practice and storage licences, which expired on 31 January 2003. Hollywood Fertility Centre Pty Ltd, In Vitro Laboratory (trading as Concept Fertility Centre), the Keogh Institute of Medical Research Inc. and Pivet Australia Pty Ltd were all re-issued with Practice and Storage Licences, by the Commissioner of Health on the advice of the Council, for terms expiring on 1 March 2006. The Practice and Storage Licences of Joondalup IVF expired on 31 January 2003. The premises and practice were taken over by a new Licensee, Fertility North Pty Ltd. The Commissioner of Health, on the advice of the Council, issued Fertility North with Practice and Storage Licences for terms expiring on 1 March 2004

At the national level the most significant development during the year was the passing of the *Prohibition of Human Cloning Act 2002* and *Research Involving Human Embryos Act 2002* on 19 December 2002. These two Acts were the Commonwealth

Parliament's response to a decision of the Coalition of Australian Governments (COAG) of 5 April 2002. COAG agreed that there should be consistent national legislation to ban human cloning and other unacceptable practices and to regulate certain activities involving the use of human embryos. Relevant legislation has now also been passed in New South Wales, Queensland, Victoria, South Australia and Tasmania. The *Human Reproductive Technology Amendment Bill 2003* was introduced into the Western Australian Parliament on 26 June 2003 and is expected to be debated in Parliament in September 2003.

Significant changes were introduced in state legislation when the *Acts Amendment (Lesbian and Gay Law Reform) Act 20*02 (the Act) came into effect on 21 September 2002. This Act amended a number of pieces of legislation, including the HRT Act and the *Artificial Conception Act 1985*. These amendments allow single women or women in a lesbian relationship, where they are infertile or whose children risk being affected by a genetic abnormality or disease, to access in vitro fertilisation procedures. Treatment will no longer be limited to married couples or de facto couples who have co-habited for an aggregate of five years in the previous six years.

In 2002 a Select Committee recommendation was implemented when the Minister for Health launched *the Voluntary Register of information about Donation in Assisted Reproduction* (Voluntary Register) in November. The Voluntary Register is the second such Register to be established in Australia and has been positively received by the community.

During the year Council recommended that work be undertaken to research the interpretation of Section 23 of the HRT Act as a response to the difficulties faced by clinics in assessing eligibility for IVF treatment. Council formed a Working Group which will develop clinical parameters to assist clinics in making decisions on whether participants meet the eligibility requirements of HRT Act in order to access IVF treatment. The Working Group will consider section 23 (e) of the HRT Act, which concerns the welfare of participants, and any child likely to be born from an IVF procedure. It is intended that the working group will consider the application of the *Equal Opportunity Act* 1984 (WA) and other legislation concerning discrimination so far as it relates to the provision of IVF services. Stakeholders will be invited to participate in the development process.

The Council provided a response to National Health and Medical Research Council's review of the *Ethical guidelines on the use of reproductive technology in clinical practice and research.* When these Guidelines are revised they will contribute to future policies and practices in Western Australia.

The budget allocation for the Reproductive Technology Unit, which includes funding for all operations of the Council, was $38,000. The Annual Report includes the financial statement for the year. The major expense for the year is payment of sitting fees for members of the Council and its committees.

This year is the first time that clinics will be required to report 2003 data electronically as part of their conditions of licence. The first lot of electronic data is expected at the end of June 2003. All clinics have been provided with the updated data structure for the Reproductive Technology Register.

MEMBERSHIP OF THE COUNCIL

30 June 2003

Professor Con Michael, Chair (Nominee of the Royal Australian and New Zealand College of Obstetrics and Gynaecology);
Ms Antonia Clissa, (Nominee of the Women's Policy Development Branch until May 2003);
A/Professor Jim Cummins, (Nominee of the Minister for Health;
A/Professor Jeanette Hacket, (Nominee of the WA Law Society);
Dr Roger Hart, (Nominee of the Department of Obstetrics and Gynaecology, University of WA);
Ms Stephanie Knox, (Nominee of the Health Consumers' Council);
Dr Mark McKenna, Deputy Chair (Nominee of the Australian Medical Association);
Ms Sue Hudd, (Nominee of the Minister for Community Development);
Dr Kaye Miller, (Nominee of the Health Consumers' Council);
Fr Joe Parkinson, (Nominee of the Minister for Health);
Dr Beverly Petterson, (Nominee of the Minister for Health);
Dr Sandra Webb, (Executive Officer, Senior Policy Officer Reproductive Technology, Department of Health, *ex officio* until May 2003) and
Ms Antonia Clissa, (Executive Officer, Senior Policy Officer Reproductive Technology, Department of Health, *ex officio* appointed May 2003).

Resignations:

Dr Kaye Miller, (Nominee of the Health Consumers' Council resigned in May 2003);
Ms Antonia Clissa, (Nominee of the Women's Policy Development Branch resigned in May 2003).

DEPUTY MEMBERS

Ms Linda Savage Davis, (Nominee of the WA Law Society);
Professor Alan Harvey, (Nominee of the Minister for Health);
Dr Martha Hickey, (Nominee of the Department of Obstetrics and Gynaecology, University of WA);
Mr Philip Matthews, (Nominee of the Minister for Health);
Ms Sue Midford, (Nominee of the Women's Policy Development Branch); and
Mr Peter Grey Searle, (Nominee of the Minister for Community Development);
Ms Amalia Burmas, (Research Officer, Reproductive Technology, Department of Health, *ex officio*);

COMMITTEES OF THE COUNCIL
TERMS OF REFERENCE AND MEMBERSHIP
30 June 2003

COUNSELLING COMMITTEE

Terms of Reference:
In relation to counselling-

1a) establishing standards for approval of counsellors as "approved counsellors", as required by the Code of Practice or directions of *Human Reproductive Technology Act 1991* for counselling within licensed clinics, and for counselling services available in the community;

b) recommending to the Reproductive Technology Council (Council) those counsellors deemed suitable for Council approval or interim approval, and reconsidering those referred back to the Committee by the Council for further information;

c) monitoring and reviewing of the work of any approved counsellor;

d) convening training programs for counsellors if required;

e) establishing a process whereby counsellors may have approval withdrawn or may appeal a Council decision;

f) reporting annually as required by Council for its annual report to the Commissioner of Health, including information on its own activities and information reported to it by Approved Counsellors;

2. Advising and assisting the Council on matters relating to consultation with relevant bodies in the community and the promotion of informed public debate in the community on issues relating to reproductive technology;

3. Advising the Council on matters relating to access to information held on the IVF and Donor Registers; and

4. Advising the Council on psychosocial matters relating to reproductive technology as the Council may request.

Membership:
Ms Sue Midford (Chair); Ms Antonia Clissa (appointed Acting Executive Officer February 2003 and Executive Officer, May 2003); Ms Stephanie Knox (consumer representative); Mr Peter Fox (consumer representative); Ms Colleen Brown (consumer representative); Mr Robert Sterry (consumer representative); Mr Peter Grey Searle; Ms Iolanda Rodino; Ms Patrice Wringe, Acting Executive Officer (until February 2003) (SPO, Department of Health).

SCIENTIFIC ADVISORY COMMITTEE

Terms of Reference:
With the agreement of the Minister for Health as required under s(10)(4) of the *Human Reproductive Technology Act 1991* (HRT Act) this Committee may-

Provide the Reproductive Technology Council (Council) with scientific advice in relation to:

any project of research;
embryo diagnostic procedure; or
innovative practice, for which the specific approval of the Council is (or may be)
sought;
the review of the Act which is to be carried out as soon as practicable after the expiry of 5 years from its commencement; and
any other matter as instructed by the Council.

Membership:
Professor Alan Harvey (Chair); A/Professor Jim Cummins; A/Professor Jeanette Hacket; Dr Mark McKenna; Mr Philip Matthews; Dr Beverly Petterson; and Dr Sandra Webb (*ex officio*); Ms Amalia Burmas *(ex officio)*.

EMBRYO STORAGE COMMITTEE

Terms of Reference:
With the agreement of the Minister for Health as required under s(10)(4) of the *Human Reproductive Technology Act 1991* (HRT Act), the Reproductive Technology Council (Council), by resolution under s11(1) of the HRT Act, may delegate this Committee to-

make decisions on applications for extension of the periods of storage of embryos on a case by case basis, based on the criteria agreed to by the Council, and to provide to the next meeting of Council details of all decisions made since the previous meeting; and

provide other advice or carry out other functions relating to the storage of embryos, as instructed by the Council.

Membership:
Mr Philip Matthews (Chair); Ms Sue Midford; Professor Con Michael; Ms Sue Hudd; Ms Antonia Clissa (*ex officio*) and Ms Amalia Burmas (*ex officio)*.

LICENSING AND ADMINISTRATION ADVISORY COMMITTEE

Terms of Reference:

1. Advise the Reproductive Technology Council (Council) on matters relating to licensing under the *Human Reproductive Technology Act 1991* (HRT Act), including the suitability of any applicant and the conditions that should be imposed on any licence.

2. Advise the Council generally as to the administration and enforcement of the HRT Act, particularly disciplinary matters.

3. Advise the Council as to suitable standards to be set under the HRT Act, including clinical standards.

4. Advise the Council on any other matters relating to licensing, administration and enforcement of the HRT Act.

Membership:

Dr Mark McKenna (Chair); Professor Con Michael; Dr Roger Hart; Ms Linda Savage Davis; Dr Sandra Webb; Ms Antonia Clissa; (*ex officio*) and Ms Amalia Burmas, *(ex officio)*

STAFF OF THE REPRODUCTIVE TECHNOLOGY UNIT

Dr Sandra Webb; Senior Policy Officer (Reproductive Technology)

Dr Sandra Webb; Executive Officer of the Council until May 2003

Ms Antonia R Clissa; Senior Policy Officer (Reproductive Technology) appointed February 2003

Ms Antonia R Clissa; Executive Officer of the Council appointed May 2003

Ms Patrice Wringe; Senior Policy Officer (Surrogacy) until February 2003

Ms Amalia Burmas; Research Officer (Reproductive Technology) and Deputy Executive Officer of the Council; and

Ms Joy Foyle; Administrative Officer (0.25FTE) appointed May 2003.

REPRODUCTIVE TECHNOLOGY COUNCIL 2002/2003: FINANCIAL STATEMENT

The Department of Health funds the administration of the HRT Act, including the operations of Council, which incorporates Infrastructure and Workforce Development funding of $38,000 per annum.

Income generated through the payment of application fees for licences or activities of Council does not directly generate income for the Council, as fee are payable to the Commissioner for Health.

	Expenditure ($)	**Income ($)**
Staff or Council:		
Training/Registration/Course Fees	122.73	
Travel/Accommodation intrastate		
Travel interstate Airfares Accommodation	 1,511.38 1,686.64	
Motor vehicle/Taxis	299.86	
TOTAL	**3,620.61**	
Food supplies/catering	**8.27** **1,370.96**	
Administration and clerical	**1,472.65**	
TOTAL	**2,851.88**	
Purchase of external services:		
Sessional fees: (External Consulting Fees) Reproductive Technology Council Council Committees: Counselling Scientific Advisory Embryo Storage Licensing and Administration Approved counsellors	14,690.09 4,828.00	
External consulting fees and advertising	5,000.00	
TOTAL	**19,690.09**	
Other expenses:		
RTC Sponsorship for FSA Conference	2,727.27	
RTC Sponsorship ANZICA workshop	500.00	
Books/magazines/subscriptions	551.20	
Freight and cartage/ postal	44.54	
Printing and stationery incl. Annual Report Telecommunication expenses	2,265.64	
Entertainment expenses		
TOTAL	**6,088.65**	
TOTAL	**32,340.46**	
Budget Allocation	**38,000.00**	

OPERATIONS OF THE COUNCIL

1 JULY 2002 TO 30 JUNE 2003

MEETINGS, MEMBERSHIP AND STAFFING

Meetings

The Reproductive Technology Council (Council) met on nine occasions during the year, with an average attendance of 71 per cent. The Counselling Committee met on eight occasions; the Scientific Advisory Committee on two occasions; the Licensing and Administration Advisory Committee (Licensing Committee) on two occasions; and the Embryo Storage Committee on five occasions. In addition various members of the Licensing Committee participated in site visits to each of the licensed clinics with members of the Reproductive Technology Accreditation Committee (RTAC), at the time of re-accreditation and re-licensing of all clinics.

Membership

In May 2003 there were changes to Council membership with the appointment of new members and deputy members and also some changes between existing members and deputy members. The new members were Dr Roger Hart and Ms Stephanie Knox. The new deputy members were Dr Martha Hickey and Ms Linda Savage Davis. Full details of membership of the Council and its Committees may be found elsewhere in this Report.

Dr Kaye Miller, who had served on the Council since 1997 as its consumer representative, resigned from Council and was replaced by Ms Knox. Dr Miller was also a very active member of the Licensing Committee. Ms Clissa was overseas for six months from July 2002 undertaking a Fellowship, which involved visiting fertility treatment, centres in the UK and USA. During her absence, deputy member Ms Midford, served as member representing the interests of women.

In February 2003 Dr Sandy Webb was appointed to a new contract position in the Department of Health with responsibility to oversee the development and implementation of amendments to the *Human Reproductive Technology Act 1991*. Ms Antonia Clissa was employed as Senior Policy Officer and Acting Executive Officer at that time and, when her appointment was finalised in May 2003, she was appointed by the Minister for Health to replace Dr Webb as Executive Officer (ex officio).

Staff assisting the work of the Council

Amalia Burmas, as Research Officer, continued to oversee the Reproductive Technology (RT) Register and liaise with the clinics. As Deputy Executive Officer she provided a very important supportive role to the Council and the RT Unit.

Ms Patrice Wringe continued in the RT Unit, performing executive functions for Council until she moved to another position in the Department of Health in February 2003. In November 2002, when the Minister for Health launched the Voluntary Register of Information about Donation in Assisted Reproduction (Voluntary Register) for the Department of Health, Ms Wringe undertook administrative responsibility. Ms Wringe also conducted a seminar "Counselling in Donation in

Assisted Reproduction" in November 2002. She continues to hold a part time position with responsibility to oversee the operations of the VR.

Ms Joy Foyle, Project Officer, began providing the Council with administrative support for one day a week from the beginning of May 2003.

Dr Webb will continue to work with the Council to provide advice in particular on scientific matters, and will serve on the Council's Scientific Advisory and Licensing Committees.

The Council gratefully acknowledges-
Secretarial support from Ms Phil Valladares;
Accounting and administrative support from Mr Lex Cassidy and Ms Pam Addison;
Data linkage by Ms Di Rosman and her staff in the Data Linkage Group;
The provision of data about birth outcomes by Ms Vivien Gee and her staff who manage the Midwives' Notification System; and
the continuing legal support of Ms Deborah Andrews of Legal and Legislative Services.

LICENSING MATTERS

- Renewal of licences for four clinics

Applications were made by four clinics for renewal of their practice and storage licences, which expired on 31 January 2003. Members of the Council's Licensing Committee reviewed the applications and participated in site visits to each clinic carried out by the RTAC as part of the RTAC process of re-accreditation of the clinics. Hollywood Fertility Centre Pty Ltd, In Vitro Laboratory (trading as Concept Fertility Centre), the Keogh Institute of Medical Research Inc. and Pivet Australia Pty Ltd were all re-issued by the Commissioner of Health, on the advice of the Council, with Practice and Storage Licences for terms expiring on 1 March 2006.

- Issuing of new licences for Fertility North

The Practice and Storage Licences of Joondalup IVF expired on 31 January 2003. The former Licensee made no application for renewal of its licence as the premises and practice were taken over by a new Licensee, Fertility North Pty Ltd. New licences were applied for by that Licensee prior to expiry of the Joondalup IVF licenses. Following review of the application and a site visit by members of the Council's Licensing Committee the Commissioner of Health, on the advice of the Council, issued Fertility North with Practice and Storage Licences for terms expiring on 1 March 2004. The clinic and facilities are well established, but the clinic's short initial term for the licences indicates the interest of Council in ensuring that progress in the clinic and arrangements for supervision by an experienced clinical mentor and scientific director are satisfactory.

- During the year the Commissioner of Health was notified of a change of licensee from the Pivet Medical Centre Pty Ltd to Pivet Australia Pty Ltd and also of a change of person responsible for the licences at that clinic.

- Nine medical practitioners requested revocation of their Exemptions from the requirement to be licensed to carry out artificial insemination (Dr A Basell, Dr JL Chaney, Dr RJ Cooper, Dr P Hugo, Dr JT Jeffery, Dr RD Mason, Dr AK Shannon, Dr JS Singh, Dr ME Ure). During the year there were no new applications for Exemptions.

Information circulated to Licensees

Licensees received information during the year about a number of important matters. Copies are included in Appendix 5.

- The Acts Amendment (Lesbian and Gay Law Reform) Act 2002 – Amendment of the Human Reproductive Technology Act 1991 and the Artificial Conception Act 1985 (September 2002)
- Clinic Protocol Manuals: essential elements (October 2002)
- Multiple Pregnancies (January 2003)

Matters of Public Interest

During 2002 authorised officers investigated whether there had been any contravention of the statutory requirements relating to eligibility for in vitro fertilisation (IVF) treatments, in two matters arising at a clinic
The first matter was initially referred by the Medical Board of Western Australia and arose following IVF treatment of a 49-year old post-menopausal woman who developed serious complications during the resultant multiple pregnancy. Section 23 (d) of the *Human Reproductive Technology Act 1991* (Act) provides that an IVF procedure is not to be carried out where the reason for infertility is age. Following investigation, the clinic changed its protocol in relation to treatment of women of advanced reproductive age to provide that women in established menopause will not be eligible for fertility treatment. In the circumstances disciplinary action was not taken against the clinic. The clinic was advised the situation would be monitored. The Reproductive Technology Council (Council) provided guidance to the clinic to the effect that section 23(d) of the Act appears to be directed at menopause, provided that it occurs within the normal age range. Each set of facts is to be assessed by clinics on a case-by-case basis.

The second matter arose following IVF procedures carried out on a woman with a history of serious medical conditions. The woman developed severe complications in pregnancy. Section 23(e) provides that a licensee must consider the welfare and interests of participants and any child likely to be born from an IVF procedure. Such a procedure must not be carried out if, in the opinion of the licensee, there is any cause in that consideration why it should not be carried out. Authorised officers under the Act investigated the matter. Subsequently new protocols were introduced by the clinic in an attempt to set some parameters in relation to eligibility under section 23(e) of the Act. Consideration of any disciplinary action was not finalised as at 30 June 2003.

The Council has established a working group which aims to develop clinical parameters to assist clinics in making decisions on whether participants meet the eligibility requirements of the Act in order to access IVF treatment.

Complaints

The Council received no formal complaints from participants during the year.

EMBRYO STORAGE APPLICATIONS

During the year the Council granted extensions in response to 404 applications, 64 more than last year. Of these applications 148 were made by couples for whom the embryos were stored and 256 were made by clinics on behalf of couples with whom they could not make contact. Of all applications received, 204 extensions (50.5%) were repeat extensions for a set of embryos that had previously been granted an extension.

The reasons that were provided by couples seeking extensions to the permitted storage period have been classified into a number of categories. The majority of couples applying were considering using the embryos in the future for their own treatment (89.9%). In 4.7 percent of cases the couples were planning to or in the process of donating embryos to another eligible couple. In the remaining 5.4 percent of cases the couple were undecided and applied for an extension to allow them more time to consider available options.

Extension applications made by clinics, rather than the people for whom the embryos are being extended, are usually made in cases where the clinic has lost contact with the patients (73.4%). In 6.3 percent of cases clinics applied for extensions on behalf of patients who had consented to the donation of their embryos, but for whom a suitable recipient couple had yet to be found.

In 20.3 percent of applications the clinic had been able to contact the patients but the patients had not sent in their application forms and the clinic applied on their behalf. In the majority of these cases (59.6%) the couple was seeking an extension of the storage period of their embryos to use them in their own treatment. In the remaining case the couple informed the clinic they either wanted to donate the embryos (19.2%), discard them (5.8%) or were undecided (15.3%)

Of the 256 embryo sets extended by Form 9, in 10 of these cases the Council later received the Form 8 application from the patient. In 6 of these cases the clinic had indicated they had been unable to contact the patients.

It was necessary to convene five meetings of the Embryo Storage Committee during the year. Of these, only one was necessitated by changes to the Council's meeting schedule, which could not have been anticipated by the clinics. The other four were all urgent meetings for embryo sets whose storage was due to expire prior to the next Council meeting.

RESEARCH AND INNOVATION

During the year the Council considered and approved two applications for specific approval for research.

R020 ASSET multi-centre trial on single embryo transfer.
Pivet Medical Centre;
Approved 10/09/02.

R021 Ovarian hyper-stimulation: a patho-physiological study.
Fertility North;
Approved 28/04/2003.

No applications for specific approval of innovative practices were made to the Council during the year.

Summary information on all currently approved research and innovative practices submitted by licensees with their annual reports may be found in Appendix 3.

The Council advised one clinician to seek HREC approval for a proposed study, although additional ethics or Council approvals were not required in relation to the obtaining of the data for the study. The study was considered to be a quality assurance study, and the recommendation to seek HREC approval was made in accordance with recent advice provided by the National Health and Medical Research Council: *When does quality assurance in health care required independent ethical review?* The study will compare the number of birth defects following IVF that were reported by the clinic, at birth, to the National Perinatal Statistics Unit (NPSU) with the number of birth defects reported by the Birth Defects Register from all the IVF treatments carried out in the particular clinic during the same years.

COUNCIL'S ROLE IN THE PROMOTION OF PUBLIC DEBATE ON REPRODUCTIVE TECHNOLOGY ISSUES

Seminars, workshops and other Council initiatives

Seminars

Psychosocial Issues

The Council considered various psychosocial issues during the year. This included establishing the Voluntary Register; continuing work on the manual for approved counsellors and reviewing information collected for donors. In maintaining its public education role there were 2 seminars conducted during the year. The first seminar was in November 2002 following the launch of the Voluntary Register and addressed donor issues; counselling during infertility treatment and counselling preceding the use of spare embryos for embryonic stem cell research. The second seminar was conducted in May 2003 and focused on the Donor Offspring perspective.

Establishment of the Voluntary Register

The Minister for Health, Mr Bob Kucera, launched the establishment of the *Voluntary Register of Information about Donation in Assisted Reproduction* (Voluntary Register) on 18 November 2002. This culminated three years of preparatory work.

The Voluntary Register is the second such Register to be established in Australia. Victoria established its Voluntary Register in March 2001.

The aim of the Voluntary Register is to assist parties to donation obtaining information about each other, in particular it is a service for donor offspring who wish to find out about their genetic origins. Donors who are willing to provide information to any donor offspring, or perhaps have contact with them, may also join the Voluntary Register.

The establishment of the Voluntary Register was publicised widely in the community to inform and encourage 'would be' applicants to join. The response from the community was very positive. The work of the Voluntary Register is limited by the lack of information about donations and treatments before 1980; and the limited information available before the RT Register was established in April 1993.

At the end of the financial year 2002 – 2003, 11 parents of donor offspring and nine donors had joined the Voluntary Register. A further 12 parents; two mature donor offspring; and nine donors had requested registration forms but had not returned the completed forms as at 30 June 2003.

Donor Offspring Perspective

The Counselling Committee conducted this seminar on 13 May 2003 as part of its ongoing commitment to community education with the focus on the Donor Offspring's journeys. The format included video screenings followed by small group discussion. The videos followed the life stories of two adult donor offspring from Canada and England and how they dealt with the lack of information about their genetic heritage. Approved Infertility Counsellors, Consumers and staff from fertility clinics were invited to attend. In total, 50% of those who attended were consumers including one adult offspring and the remainder were approved counsellors and representatives of the clinics. The feedback was extremely positive and the videos generated some very stimulating and interesting discussion.

Information Provided By Donors At Time Of Donation

This matter has been under discussion by the Counselling Committee during the past two years. Patients, clinic staff and interested members from the public outlined the significant issues some of which are included in Appendix 9. The Counselling Committee is still considering how best to collect comprehensive information from donors at the time of donation and is currently examining information on practices from other countries obtained during a Fellowship in 2002.

Counselling Services During Infertility Treatment

For some time there has been concern about the level of counselling services received by people in treatment. For example, the Parliamentary Select Committee that reviewed the legislation in the late 1990s recommended that an audit of counselling services be conducted, because counselling was not seen as an integral part of treatment.

The audit was conducted in 2001 - 2002. Patients, clinic staff and counsellors were surveyed. It was found that the majority of patients tend to have one session of

counselling at the beginning of treatment and very small numbers have any further counselling through the fertility clinic.

Writers who discuss the psychosocial aspects of infertility have found that most people experience some level of stress during ART assisted reproductive technology treatment, while others may suffer anxiety and depression. More information was therefore sought to understand the reasons for the poor uptake of counselling services.

Seminar participants were asked to comment on the timing of counselling for patients, for example at the beginning and/or further into the treatment process. They are also asked to identify what supports and assistance patients would like. See Appendix 9 for the significant points raised by participants. Ongoing discussion between the Council and the fertility clinics continue to highlight the importance of counselling as an integral part of treatment.

Regulating Embryonic Stem Cell Research And Counselling Preceding Embryo Donation.

The *Research Involving Embryos Act 2002* (Clth) establishes a framework for the regulation of research on *excess* ART embryos. Where those people for whom the embryos were created do not wish to use them, or donate them to others for treatment, or simply allow them to die they may donate them for research or some other use, such as development of embryonic stem cells.

People undergoing ART treatment have embryos created for future use in treatment. It is now unlikely for more than two embryos to be implanted at one time. Embryos to be used in later treatments are frozen. In the financial year 2001 – 2002, 3476 *frozen* embryos were used in treatments and 515 were allowed to succumb at the request of the couples. The primary purpose for the storage of embryos must relate to the future implantation of that embryo. Most embryos currently in storage will be implanted.

Any decision about 'spare' embryos can be difficult for people. Donating to research is another option for people to consider before, during and after treatment. See Appendix 9 for the significant issues raised by participants at the November 2002 seminar.

Relevant presentations and publications by Council members and staff

Council members

Associate Professor Jim Cummins

"Fertilization Failure: The Female Factor" Serono workshop ESHRE, Madrid, 29 June 2003

Genesis and Fate of the Preimplantation Embryo, Serono Symposium, Sorrento, Italy, 2002

Ageing, Reproduction and Infertility Serono Symposium, Gold Coast, Australia 2002

9th International Symposium on Spermatology, (Convenor, International Steering Committee) Cape Town, S. Africa 2002

Associate Editor, Human Reproduction

Associate Editor, Reproductive Biomedicine Online

Associate Editor, Biology of Reproduction

Consulting Editor, Biogerontology 2000

Professor Alan Harvey

Cell Replacement in Central Nervous System – *Why do we need it can we do it?* Stem Cell Research Forum – Embryonic and Adult Stem Cell Research as well as Legal and Ethical issues, Genetics Support Council, Perth 21 May 2003

"Stem Cells" – Catholic Doctors' Association, St John of God Hospital, 11 Sept 2002

"Stem Cells. Hope or Hype? Miracle or Moral Minefield?" X club, University House, Perth, 1 April 2003

"Stem Cells" Centre for Ethics, Christ Church Grammar School Perth, 12 June 2003

Fr Joseph Parkinson

"Ethics of Embryonic Stem Cell Research" Riverton, 23 July 2002

"Ethics of Embryonic Stem Cell Research" Floreat, 30 July 2002

"Ethics of Embryonic Stem Cell Research" Woodvale, 31 July 2003,

"Ethics of Embryonic Stem Cell Research" Applecross, 7 August 2002

"Ethics of Embryonic Stem Cell Research" Bunbury, 27 August 2002

"Ethics of Embryonic Stem Cell Research" Leederville, 28 August 2002

"Ethics of Embryonic Stem Cell Research" Subiaco, 11 September 2002

"Ethical Aspects of IVF and Alternative Fertility Treatments", Geraldton 2 May 2003

Ms Sue Midford

Donor issues in Counselling - RTC seminar 18 November 2002

Interview with "The West Australian" 11 December 2002 – article entitled "Donor Origins Available."

Interview with "The Sunday Times" 2 February 2003 - article entitled "IVF Dads Ask About Offspring."

Staff

Dr Sandra Webb

UWA Symposium on Law, Ethics and Genetics in an Age of Biotechnology, 2 August 2002 "The national regulation of human cloning and embryo research: is this an attainable goal?"

Genesis, Monthly meeting 19 May 2003: Embryo Storage Issues and the HRT Act.

WA Stem Cell Forum, 21 May 2003. The regulation of research involving human embryos in Australia: a time of transition.
Murdoch University V101, 23 May 2003. The regulation of research involving human embryos in Australia: a time of transition.

Ms Patrice Wringe
"Counselling in Assisted Reproduction." RTC Seminar - 18 November 2002.

Ms Antonia Clissa
Interview with "The Australian" 26 April 2003 - article entitled "Secret gift of life."
Genesis, Monthly meeting Monday 19 May 2003: Embryo Storage Issues and the HRT Act – attended with Dr Sandy Webb.

Attendance at relevant meetings by Council members with Council support
The Council sponsored the attendance of the Executive Officer, the Deputy Executive Officer and Acting Executive Officer to attend the 18th World Congress of Fertility and Sterility in November 2002 in Queensland.

OPERATIONS OF THE COUNSELLING COMMITTEE
1 JULY 2002 – 30 JUNE 2003

Meetings and membership

The Counselling Committee met on 8 occasions during the year. There were membership changes, which included three new consumer representatives. Due to a gender imbalance there was a decision to recruit at least one male member preferably with the experience of donation. Consequently there is one male member and a male deputy member. Therefore membership this year included four consumer representatives (Ms Knox, Mr Fox, Mr Sterry – Genesis & Ms Brown); two clinic counsellors, one of whom is a member of the Council (Ms Antonia Clissa and Ms Iolanda Rodino) Ms Clissa was overseas for 6 months from July 2003; and the Deputy Council member for the Department for Community Development (Mr Searle). Ms Suzanne Midford was again a very committed chair for the Committee. She attended most Council meetings (on which she is Deputy to Ms Clissa) to report on matters from the Counselling Committee. Ms Patrice Wringe continued as Executive Officer of the Committee until February. Ms Wringe has continued to attend the meetings in her role as registrar for the Voluntary Register. Ms Clissa was appointed Acting Executive Officer in February 2003 and Executive Officer in May 2003. Amalia Burmas attended all meetings, especially providing information on the scientific aspects of ART. The new members attended their first meeting on 24 July 2002.

The *Acts Amendment Lesbian and Gay Reform Bill 2001* became operational law, in September 2002 permitting single and lesbian women, who are infertile, to access IVF treatment. The Committee has recruited a member to represent the interests of single and lesbian women lesbian to ensure that their viewpoint is considered.

Key Focus Areas

The Committee was involved in establishing the Voluntary Register. The Committee has also continued to:

- work on a procedure manual for approved counsellors.
- reviewed data collected for donors by comparing systems used by various centres nationally and internationally.
- review training requirements for approved counsellors.
- prepare and conduct a seminar for consumers, approved counsellors and clinic staff focusing the donor offspring perspective
- plan for a workshop to be conducted on Known and Anonymous Donation for same sex couples later in 2003.

NH &MRC Ethical Guidelines on the Use of Reproductive Technology in clinical practice and research

The Committee provided input for these guidelines, which were incorporated in the Council's response.

Establishment of a Voluntary Register

The Select Committee recommended the establishment of a voluntary register for persons involved in past donation. The Voluntary Register was launched in November 2002 by the Minister for Health and provides a service for donor offspring who wish to find out about their genetic origins. Donors who want to know if a child has been

born as a result of their donations(s) and/or are willing to provide information to any donor offspring may also join the Register.

Procedure Manual for Approved Counsellors

Following an interactive seminar for approved counsellors in May 2001, it was agreed that a procedure manual would be prepared to guide the work of approved counsellors. The manual includes:

- the components of different types of counselling;
- specific issues pertinent to infertility counselling;
- promoting the best interests of children;
- the role of assessment, seeking a second opinion and conducting psychological tests in infertility counselling;
- the employment of approved counsellors in clinics; and
- the annual reporting of infertility counselling services.

A draft manual was completed in January 2003. The Counselling Committee has continued to steadily progress work on the manual during the year, which has included consultations with other infertility counsellors in Western Australia. Due to the constant developments in this area there will need to be regular amendments. The manual is undergoing the final stages of editing and will be distributed to Approved Counsellors before the end of 2003.

Training for Counsellors

Due to the need from increasing numbers of counsellors who are seeking recognition as approved counsellors to access training in ART and with fewer opportunities for gaining this experience it was agreed by the Committee and endorsed by Council that prospective applicants need to attend at least 3 Counselling Committee endorsed events before their application will be considered. It was also agreed that once counsellors have been granted Approved Counsellor status that they will be required to attend at least 3 Council endorsed events each year. This underpins the Counselling Committee's existing commitment to provide at least 3 training events in each calendar year, which would meet the requirements for training counsellors.

New 'approved counsellor' applications

The Committee received applications from six new applicants who sought to be recognised as approved counsellors. On recommendations from the Committee, the Council granted approval to the six applicants as 'approved counsellors' under the HRT Act. All applicants' approvals were subject to them undertaking quarterly supervision from an experienced counsellor and providing a brief report to the Executive Officer on a quarterly basis. These were Ms Jeanie Barnett, Ms Michelle Collins, Dr Marjorie Collins, Ms Marion Connelly, Ms Elizabeth Webb and Mr Tony White.

REPRODUCTIVE TECHNOLOGY REGISTER

Research involving Register data

A follow up study, being conducted by Ms Michele Hansen and Prof Carol Bower, on outcomes of Western Australian children born following ART commenced in 2002. The initial study involved data linkage from the Reproductive Technology (RT) Register of all treatments from 1993 to 1997 to the Midwives' Notification of Birth System and the Western Australian Birth Defects Registry, to identify infants conceived through ART who had birth defects diagnosed up to one year of age.

As part of the follow up study the RT Register was involved in the linkage of all IVF and GIFT treatments occurring in 1998 and 1999 to the Midwives' Notification of Birth System to identify any births. This information has been provided to the researchers for linkage to the Birth Defects Registry, the Hospital Morbidity Data System, the Cerebral Palsy Register and the Intellectual Handicap Register.

The report of the 2001 data from the RT Register may be found in Appendix 4.

Updates to the RT Register

In late 2001 the Australia and New Zealand Assisted Reproduction Database (ANZARD) was established, with the intention that all ART clinics in Australia and New Zealand provide treatment information electronically to this data collection. Clinics were required to start reporting to this database from all treatments commencing from 1st January 2002. The aim of the RT Register was to streamline data collection for clinics so that a single database in each clinic could be used to collect the data for all required reporting by clinics.

During 2002, work commenced on developing a new data structure for the RT Register. Where appropriate, RT Register fields were matched to those in the ANZARD data structure for consistency in reporting. Western Australian licensees were provided with the new data structure in November 2002, with the intent of incorporating additional fields into the database they were using for data collection for ANZARD.

Requests for information from the Register

With the introduction of national legislation into use of excess IVF embryos for research a number of requests were received regarding the number of embryos in storage in Western Australia. Information was also extracted on the number of embryos that may be affected by proposed legislative amendments to the *Human Reproductive Technology Act (1991)*, where the storage period of embryos would increase from three to ten years with the possibility of an extension.

Several requests for information were received from the Voluntary Register. These were from recipients requesting non-identifying information on the donor and donors requesting information on the outcomes of their donations.

Further requests for information included information about the age of women undergoing ART treatment and the number of embryos being stored from each fertilisation attempt.

SIGNIFICANT DEVELOPMENTS IN REPRODUCTIVE TECHNOLOGY DURING THE YEAR

Progress towards nationally consistent legislation relating to cloning, human embryo research and ART

The *Human Reproductive Technology Amendment Bill 2003* was tabled in the WA Parliament on 26 June 2003. These amendments arose out of a decision made on 5 April 2002 by the Council of Australian Governments (COAG).

As party to this agreement the WA Government committed-

- to introduce nationally consistent legislation to ban cloning of whole humans and other unacceptable practices in reproductive technology
- to legislate to regulate human embryo research through a licensing scheme administered by the National Health and Medical Research Council (NHMRC)
- to a nationally consistent approach to the regulation of ART clinical practice, based on providers of ART services being accredited by the Reproductive Technology Accreditation Committee (RTAC) of the Fertility Society of Australia (FSA).

The Bill seeks to amend the *Human Reproductive Technology Act 1991* (HRT Act) as follows:

- Insert a new Part 4A that mirrors offence provisions contained in the Commonwealth *Prohibition of Human Cloning Act 2002*.
- Insert a new Part 4B that mirrors provisions relating to the licensing of embryo research contained in the Commonwealth *Research Involving Human Embryos Act 2002*. Persons in WA who wish to use excess ART embryos will require a licence from the NHMRC Licensing Committee, which is established under the Commonwealth legislation, whether or not they come within the Commonwealth's Constitutional power. There are some consequential amendments to the HRT Act to remove the sections that effectively prohibit embryo research in WA and to ensure that certain uses of excess ART embryos that are exempt from the Commonwealth provisions are subject to the requirements of the HRT Act.
- Accreditation by RTAC is made a condition of an ART practice or storage licence for practitioners in WA. There are also amendments to remove major areas of inconsistency in clinical practice between the HRT Act and the national standards that apply through the RTAC Code of Practice and ethical guidelines associated with RTAC accreditation (NHMRC *Ethical Guidelines on Assisted Reproductive Technology*). These amendments principally relate to storage and diagnostic testing of embryos, extend the permitted period of storage to 10 years and allow the pre-implantation genetic diagnosis of embryos subject to approval by the Council.
- Amendment is also made that would allow access to in-vitro fertilisation (IVF) treatment to avoid transmission of a non-genetic disease such HIV or hepatitis.

All amendments are consistent with recommendations made in 1999 by the Select Committee that reviewed the *Human Reproductive Technology Act 1991,* apart from the amendment relating to access to IVF to avoid transmission of a non-genetic disease, which dealt with a new development not considered by the Select Committee.

Commonwealth legislation giving effect to the COAG agreement (the *Prohibition of Human Cloning Act 2002* and the *Research Involving Human Embryos Act 2002*) has been fully in force from 19 June 2003. Amendments to the HRT Act are required to avoid any inconsistency with Commonwealth legislation. By September 2003 legislation giving effect to the COAG decision had been passed in New South Wales, Victoria, Queensland, South Australia and Tasmania.

Recent changes to Section 23 as a result of the Gay and Lesbian Law Reform

The *Acts Amendment (Lesbian and Gay Law Reform) Act 2002* came into effect on 21 September 2002. This Act amended a number of pieces of legislation, including section 23 of the HRT Act.

The effects of these changes are summarised below:

- A woman who is unable to conceive a child for medical reasons, or whose child is likely to be affected by a genetic abnormality or disease, is allowed access to *in vitro* fertilisation. There is no restriction of whether the woman is married, single or in a de facto relationship with a person of the same or opposite sex.
- Heterosexual couples where the woman is not infertile but there is a medical reason preventing the couple conceiving a child (eg male is infertile) or their child is likely to be affected by a genetic abnormality or disease are allowed access to *in vitro* fertilisation.
- Removes the requirement that a heterosexual de facto couple wishing to access *in vitro* fertilisation procedures must have been in a relationship for 5 out of the last 6 years.
- A "donor" of gametes or embryos used in an artificial fertilisation procedure is not a parent of a resulting child. This means that a sperm or ova donor, or embryo donors, including a known donor, has/have no parental rights or responsibilities in respect of a resulting child. This does not apply in circumstances where a sperm provider is married to, or in a de facto relationship with, the mother. In that case section 6 provisions apply and the sperm provider will be the father of the child if he consented to the procedure.

These changes do not impact sections 23(d) or 23(e) and these remain requirements.

NH&MRC Ethical Guidelines on the Use of Reproductive Technology in Clinical Practice and Research

The WA Reproductive Technology Council prepared a response, in consultation with the Scientific Advisory Committee and the Counselling Committee.

Members endorsed the NH&MRC guiding principles especially "a commitment to the long term welfare of people who are born as a result of the use of reproductive technology" and " a commitment to the long-term welfare of the individuals both women and men who use reproductive technology". A number of suggestions were made as to how this may better be achieved than in the current draft.

RTC Website

The Council website was established several years ago and maintained by Murdoch university faculty member and Council member A/Professor Jim Cummins. This year the Department of Health has agreed to maintain and update the website. It recently went live with a new more easily accessible web address. www.rtc.org.au. There are plans to create a logo and modernise the site.

The Establishment of a Voluntary Register of Information about Donation in Assisted Reproduction.

As stated in the Operations of the Counselling Committee the Voluntary Register was launched by the Minister for Health in November 2002 and is now fully operational.

Working Group to Clarify Section 23 of the *Human Reproductive Technology Act (1991)*

Following two Department of Health investigations during the year relating to complaints about possible contraventions of section 23 the HRT Act 1991 the Council decided at its January and March 2003 meetings, to set up a working group to give detailed consideration of these provisions of the HRT Act. The aim is to develop clinical parameters to guide clinics in selecting only eligible participants under the HRT Act to undergo IVF procedures. It is intended that specialist IVF service providers be invited to participate in the development process.

APPENDIX 1

LICENCES AND EXEMPTIONS

LICENCES CURRENT UNDER THE HUMAN REPRODUCTIVE TECHNOLOGY ACT AT 30 JUNE 2003

In Vitro Laboratory Pty Ltd trading as Concept Fertility Centre, SUBIACO
Practice and Storage Licences.

Keogh Institute for Medical Research (Inc), NEDLANDS
Practice (AI only) and Storage Licences.

Hollywood Fertility Centre Pty Ltd, NEDLANDS
Practice and Storage Licences.

Pivet Australia Pty Ltd, LEEDERVILLE
Practice and Storage Licences.

Fertility North Pty Ltd, JOONDALUP
Practice and Storage Licences.

MEDICAL PRACTITIONERS WITH AN EXEMPTION FROM THE REQUIREMENT TO BE LICENSED TO CARRY OUT ARTIFICIAL INSEMINATION: JULY 31 2003

Exemptee No	Name	Suburb	Post Code
E023	Dr PK Bairstow	Bunbury	WA 6230
E034	Dr RT Chapman	Katanning	WA 6317
E011	Dr M J Cohen	Cottesloe	WA 6011
E027	Dr DP Day	Kelmscott	WA 6111
E001	Dr ZN Dorkhom	Bunbury	WA 6230
E057	Dr LG Green	Newman	WA 6753
E031	Dr PD Green	Australind	WA 6233
E040	Dr MC Hamdorf	Dunsborough	WA 6281
E050	Dr R Kirk	Carnarvon	WA 6701
E046	Dr TP Knight	Mandurah	WA 6210
E024	Dr DN Lawrance	Kelmscott	WA 6111
E025	Dr HH Leslie	Exmouth	WA 6707
E016	Dr KA McCallum	Kalgoorlie	WA 6430
E003	Dr KT Meadows	Collie	WA 6225
E032	Dr D Mildenhall	Albany	WA 6330
E051	Dr WD Patton	Rockingham	WA 6168
E015	Dr BD Roberman	Subiaco	WA 6008
E017	Dr C Russell-Smith	Kwinana	WA 6167
E039	Dr T Silbert	Morley	WA 6062
E022	Dr BGA Stuckey	Nedlands	WA 6009
E029	Dr JM Vujcich	West Perth	WA 6050
E028	Dr RJ Watt	Mandurah	WA 6012
E049	Dr M Zafir	Albany	WA 6330

APPENDIX 2

APPROVED COUNSELLORS

WESTERN AUSTRALIAN
R*eproductive* T*echnology* C*ouncil*
Approved Counsellors
August 2003

Name	Professional Address	Telephone Number
Ms Jill Bain*	Concept Fertility Centre, c/- KEMH Bagot Road, Subiaco WA 6008	(08) 9382 2388 Fax (08) 9381 3603
	57 Canning Beach Road, Applecross WA 6153	Tel / Fax (08) 9364 3665.
Mr John Bluntschli	Roe Street Centre for Human Relationships-FPWA, 70 Roe St, Northbridge WA 6003	(08) 9228 3693 Fax (08) 9227 6871
Ms Maxine Chapman*	Suite G10, Chelsea Village, 145 Stirling Hwy, Nedlands WA 6009	Tel / Fax (08) 9386 2088
Ms Deborah Foster-Gaitskell*	62 Churchill Avenue, Subiaco WA 6008	(08) 9271 3582 Fax (08) 9388 3740
	Hollywood Fertility Centre, Hollywood Private Hospital Monash Avenue, Nedlands, WA 6009	(08) 9346 7100 Fax (08) 9386 1463
Ms Elyse Frankel	Perth and Hills Division of General Practice, 48A James Street GUILDFORD PO Box 354 GUILDFORD WA 6935	0414 764 663
	27 Alvan Street, Mount Lawley WA 6050	0414 764 663 Fax (08) 9473 1754
Ms Lisa Hamilton	Pivet Medical Centre, 166-168 Cambridge St, Leederville WA 6007	(08) 9382 1677 Fax (08) 9382 4576
Ms Celine Harrison	KEMH Social Work Dept, Centre for Women's Health Bagot Road, Subiaco WA. 6008	(08) 9340 2777 Fax (08) 9340 2775
Ms Jane Irvine	Roe Street Centre for Human Relationships-FPWA, 70 Roe St, Northbridge WA 6003	(08) 9228 3693 Fax (08) 9227 6871
	Keogh Institute for Medical Research A Block, 3rd Floor QE Medical Centre Nedlands. WA 6009	(08) 9346 2008 Fax (08) 9380 6387
Mr Jeff Irwin	C/ PO Box 234, Capel WA. 6271,	Tel / Fax (08) 9727 1197
	South West Mental Health Services 18 West St Busselton WA. 6280,	(08) 9754 4744 Fax (08) 9754 4747
Ms Rosemary Keenan*	Suite 7 - 126 Grand Boulevard, Joondalup WA 6027	(08) 9300 0460 Fax (08) 9300 0459
Ms Lisa McCombe	C/- Advanced Personnel Management 58 Ord Street, WEST PERTH WA 6005	(08) 9486 1244 Fax (08) 9486 1344
Ms Sue Midford*	2/36 Ormsby Tce, Mandurah WA 6210	(08) 9446 9860 (Appointments) Mobile 0411 590 566
Dr Kaye Miller	Palm Springs Medical Centre, 3 Halliburton Drive, Warnbro WA 6169	(08) 9593 2033 Fax (08) 9593 1913
Ms Helen Mountain	C/ Genetic Services of WA King Edward Memorial Hospital Centre for Women's Health Bagot Road, Subiaco 6008	(08) 9340 1525 Fax (08) 9340 1678
Ms Kate Orr	1974 Wanneroo Road, NEERABUP WA 6031	(08) 9407 4545 Fax (08) 9407 4500 Mobile 0417 905 395
Ms Iolanda Rodino*	64 Farrington Road, Leeming WA 6149	(08) 9389 7212
Ms Kay Rosen	Private Practice, 36 Carnarvon Crescent, Mt Lawley WA 6050	(08) 9444 1617
Ms Kate Tudor Owen	Roe Street Centre for Human Relationships-FPWA, 70 Roe St, Northbridge WA 6003	(08) 9228 3693 Fax (08) 9227 6871
Ms Margaret van Keppel*	267 Walcott Street North Perth WA 6006	(08) 9443 3655 Fax (08) 9443 8665
	Pivet Medical Centre, 166-168 Cambridge St, Leederville WA 6007	(08) 9382 1677 Fax (08) 9382 4576
Ms Elizabeth Webb	Fertility North, Suite 213, Specialist Medical Centre, Joondalup Health Campus, Shenton Ave Joondalup WA 6027	(08) 9400 9965
	Mental Health Unit, Joondalup Health Campus Shenton Ave, Joondalup WA 6027	(08) 9400 9788 Fax (08) 9400 9069

*** Qualified to assist with child-related 'Telling Issues' associated with donor conception.**
The professional address is provided first followed by an alternate address if applicable.

INFERTILITY COUNSELLING
'APPROVED COUNSELLORS'

The role of 'approved counsellors' under the Human Reproductive Technology Act 1991 (WA)

When experiencing infertility or involved in its treatment through assisted reproduction (such as IVF and donor insemination), individuals and couples can, at various times, need or want to see a counsellor. This may be to discuss personal issues, seek assistance in decision making, or to seek support. For example those dealing with the psycho–social issues of infertility, or those considering the donation or use of donated human reproductive material (eg sperm donors) may wish to seek this support. Counselling is an accepted and useful resource for those experiencing the difficult emotional and psycho–social processes that most people experience in these situations.

Counselling is to distinguished from

- the information which is given to everyone seeking treatment;
- the normal relationship between the clinician and the person seeking treatment; and
- the process of assessing people for treatment.

The aims of counselling are to provide people with the opportunity

- to explore personal and family issues related to infertility;
- to understand the personal implications of the available treatment options;
- to seek help in making decisions about treatment that is acceptable to them; and
- to seek support before, during and after treatment.

Whilst the benefits of counselling are generally recognised, consumers are not obliged to accept counselling. The exception to this is when individuals and couples are considering treatment using gametes or embryos from donors who are ***known*** to them. In this case, the donors and recipients, and any spouse or partner, **must** attend counselling. In addition, fertility clinics are encouraged, but not obligated, to make counselling available for *all* donors of human reproductive material (such as sperm donors) or donor insemination patients. The list of 'Approved Counsellors' must be made available to them. Counselling assists with the better understanding of the complex issues involved in donation, for both the potential donors and recipients.

Counsellors who assist people seeking infertility treatment need to have a knowledge and understanding of the complex issues involved. For this reason the Western Australian Reproductive Technology Council recognises some counsellors as 'Approved Counsellors' under the *Human Reproductive Technology Act 1991* (Act).

'Approved counsellors' must be qualified and experienced counsellors, who also possess a significant knowledge of the issues associated with fertility and infertility. They must also demonstrate evidence of keeping up to date with technological developments. A list of 'approved counsellors' is provided overleaf. Counsellors on this list include those working in fertility clinics licensed under the Act as well as those working in the general community.

In Western Australia all fertility clinics are licensed under the Act, and must provide access to counselling to all people undergoing IVF treatment, with some counselling being provided at no extra cost in the overall treatment fee. There is currently an entitlement to counselling at the rate of one hour per IVF treatment cycle, plus one additional hour when the decision is made to withdraw from further IVF treatment.

For Further information please contact your Doctor or

The Executive Officer
R*eproductive* T*echnology* C*ouncil*
189 Royal Street
East Perth WA 6004
Phone (08) 9222 4260 Fax (08) 9222 4236
Email Antonia.Clissa@health.wa.gov.au

APPENDIX 3

OPERATIONS OF LICENSEES FOR THE FINANCIAL YEAR 2002/2003

OPERATIONS OF LICENSEES FOR THE FINANCIAL YEAR 2002/2003

BACKGROUND

This summary was put together from information submitted, as required by the *Human Reproductive Technology Act 1991* (Act), about six Storage Licences and five Practice Licences authorising artificial fertilisation procedures including in vitro fertilisation (IVF) under the Act. In addition, one other Practice licensee, and medical practitioners who are Exempt from the requirement to be licensed to carry out artificial inseminations reported (as required), on their provision of intra-uterine insemination. Information about patients referred from the public fertility clinic at King Edward Memorial Hospital to the Concept Fertility Centre, has been provided by Concept.

All information was submitted in a collated form and referred to the financial year which ended at 30 June 2003. While it is not possible to provide any data on outcomes of treatments undertaken during the financial year just ended because of the necessary lag time required for reporting, this summary shows the scale and type of activities carried out under the licences.

The Practice and Storage licences held by Joondalup IVF terminated on 31 January 2003. Fertility North took over the clinic at Joondalup and Practice and Storage licences issued to Fertility North commenced on 1 February 2003.

In Appendix 4 of this Report there is additional detailed information from the Reproductive Technology Register, including short-term outcomes of all treatments, for the calendar year 2001.

SUMMARY

Semen storage and donation

From Table 1 it can be seen that semen was donated to WA Storage Licensees by 35 men during 2002/2003. Of these 25 were new donors. This is a substantial increase in both the total number of donors and the number of new donors when compared to the previous year (21 and 10 respectively). The age distribution of donors (Table 2), indicates that the majority (67.6%) were 30 years of age or older. This continues the general trend seen over the last ten years, towards a greater number of older donors. Table 3 indicates there were substantially more single donors (74.3%) than donors in a married/de facto relationship (25.7%).

Reporting by Exempt practitioners and the Sperm Banks indicated that during the year only one Exempt practitioner had been supplied with donor sperm. Additionally, one interstate medical practitioner was supplied with donor semen during the year, with the approval of the Council under Direction 6.2. This approval was based on an undertaking by that practitioner to ensure that all recipients were fully informed about requirements of the Act, and knew in particular that information about outcomes of treatments would be provided to the WA Reproductive Technology Register. Four

Exempt practitioners who failed to submit an Annual Report (including any 'zero return') will be followed up, however no storage licensee indicated sperm was supplied to these practitioners. In the course of submitting their Annual Reports four other Exempt practitioners requested revocation of their Exemptions.

Embryo storage

Table 4 shows that the total number of embryos in storage at the end of the year was 12,097. This was 1288 more than at the same time last year. The total number of embryos in storage has continued to increase since 1993, in recent years by just over 1000 per year. A total of 5195 embryos were stored following treatment and 3523 stored embryos were used in treatments during the year. In all 328 embryos were allowed to succumb at the request of the participants. A paper audit of the numbers of embryo in storage in one clinic resulted in a revision of the total number in storage at that clinic at 30 June 2002. It is timely for record keeping about embryo storage in all clinics to be reviewed again, to ensure that the transition to electronic storage of this information is now effective.

In many jurisdictions public concern is being expressed as similar increases in the numbers of embryos in storage are being widely experienced. There is particular concern among some members of the public that, following implementation of legislation around the country that will now permit the approval of some destructive embryo research in all jurisdictions, there may be a tendency for the systematic creation of embryos in excess of clinical needs, so that more embryos become available for research. However, it should be noted that to date the increases in WA have been occurring in spite of the fact that in WA there has been a prohibition on all embryo research and a requirement under the HRT Act (Direction 8.4) that where a couple have more than two embryos in storage, the licensee must not allow the creation of any more embryos. This Direction is being complied with and is routinely monitored. The steady increase in the numbers of embryos in storage is a reflection of the clinical uncertainty that inevitably accompanies each cycle of stimulation, fertilisation and subsequent implantations. This clinical uncertainty makes any decision to restrict the number of embryos created in a particular cycle extremely unlikely when the focus of the participants and the clinician is on a potential child.

WA is unique in having a decade of information on the creation and use of all embryos since 1993, as reported in summary form in Appendix 4. To address concerns about indirect creation of embryos for research, this type of information will form an important baseline for comparison, when the HRT Act is amended to permit embryo research to be approved here.

In Vitro Fertilisation (IVF), Frozen Embryo Transfer (FET) and Gamete Intra Fallopian Transfer (GIFT) treatments

Table 6 shows that during the last financial year 981 women began oocyte retrieval cycles for IVF, 598 began FETs and 4 began GIFT procedures.

A total of 3020 cycles were begun for IVF, frozen embryo transfer or GIFT, again slightly more than in the previous year. Most of this increase could be attributed to the increase in the number of FET cycles. It can be seen that of all cycles begun, 1606 (53.2%) were for IVF and 1408 were for frozen embryo transfer. Overall frozen

embryo transfer cycles made up 46.6% of all cycles begun, compared to 42.5% last financial year. GIFT cycles (6) made up only 0.2% of all cycles begun.

Of the 1612 cycles begun for fresh IVF or GIFT with ovarian stimulation, 88.7% proceeded to oocyte retrieval and 81.9% proceeded to transfer fresh embryos or gametes. Of the 1408 frozen embryo transfer cycles begun, 1207 (85.7%) proceeded to transfer.

Overall, donated human reproductive material was involved in 4.3% of all IVF or GIFT oocyte retrieval cycles begun during the year, and 10.5% of all frozen embryo transfer cycles. In 3.8% of all oocyte retrieval cycles begun donor semen was used (62 cycles); donor eggs were used in 0.5% of all IVF cycles begun (8 cycles). There were no IVF cycles which involved the use of fresh donor embryos, however donor embryos were used in 2.1% of all FET cycles begun (30 cycles).

Of all 1425 IVF treatment cycles with successful oocyte retrieval, 669 (46.9 %) used intra-cytoplasmic sperm injection (ICSI). Fresh or frozen sperm retrieved from the epididymis or testis was reported to have been used in 101 of the ICSI treatment cycles.

Summary reports on Council approved research and innovative practices

Although data collected through the RT Register continues to allow follow-up of outcomes after ICSI, clinics performing ICSI are no longer required to report on its use with their Annual Reports as in 2002 the Council agreed that ICSI should no longer be considered an innovative practice. ICSI is now an accepted part of routine IVF around the world.

- Current approved research and innovative practices.

Research

R007 The impact of Tobacco and Caffeine consumption on the outcomes of in Vitro Fertilisation-embryo transfer.
Pivet Medical Centre
Approved 28/2/95; PhD thesis submitted July 2003

R016 Does ICSI increase the risk of major birth defects?
TVW Telethon Institute for CHR
Approved 24/11/98; publication in the New England Journal of Medicine 2002;
Ongoing.

R019 Phase III, Multicentre open label randomised trial to assess the efficacy and convenience of orgalutron.
Pivet Medical Centre
Approved 8/8/00;
Closure set for May 2003 with initial data analysis being coordinated by Organon. Data from frozen embryos still being collected.

R020 ASSET multicentre trial on single embryo transfer

Pivet Medical Centre
Approved 10/09/02.
No particpants recruited during this financial year.

Innovative clinical/laboratory practices

I 002 Use of SAIZAN (Growth Hormone) in ovulation induction
Pivet Medical centre
Approved 23/11/93
Report 2003 indicated use in 18 cycles for 17 women, with 3 ongoing pregnancies, 1 ectopic pregnancy and 1 spontaneous abortion.

I 008 Assisted hatching
Pivet Medical Centre
Approved 13/11/00
Report 2003 indicated use in 114 fresh embryo treatment cycles and 113 frozen embryo cycles.

I009 Assisted hatching
Concept Fertility Centre
Approved 6/2/01.
Report 2003 indicated use in 220 cycles: 75 IVF, 55 ICSI and 90 FET.

I010 Blastocyst transfer
Concept Fertility Centre
Approved 20/3/01
Report 2003 indicated use in 3 cycles using fresh and 8 cycles using frozen embryos.

I011 In vitro culture of human embryos to Blastocyst stage
Pivet Medical Centre
Approved 19 /06/011
Report 2003 indicated use in 40 cycles using fresh embryos and 17 cycles using frozen embryos.

I012 Assisted Hatching
Hollywood Fertility Centre
Approved 20/3/01
Report 2003 indicated use in133 fresh and 106 frozen cycles.

The two clinics with approval to carry out blastocyst culture provided data from a total of 43 fresh and 25 frozen embryo cycles where this was carried out, resulting in a total of 22 clinical pregnancies (32% per cycle begun.) Most of the cycles (83%) were carried out in one clinic, which had a substantially higher clinical pregnancy rate than the other clinic.

Three clinics with approval to carry out assisted hatching provided data that showed this procedure had been used in a total of 377 fresh and 309 frozen embryo cycles, with a total of 115 clinical pregnancies (17% per cycle begun). All three clinics performed similar numbers of procedures, but the outcomes varied substantially between clinics,

from 9-24% clinical pregnancies per cycle begun. Two of the clinics submitted the data in a form which allowed comparison of the clinical pregnancy rates between fresh and frozen cycles in the clinic and in each case the outcomes within the clinic were very similar.

At this stage data reported for both assisted hatching and blastocyst culture did not provide information on the numbers of embryos transferred but this will be available at a later date from the RT Register. A variety of factors, including patient selection, may explain this considerable range in success rates for assisted hatching and it is of interest to explore this further.

- *Serious morbidity and mortality in women undergoing treatment*

Overall the four clinics reported a total of 25 cases of severe ovarian hyper-stimulation relating to 1612 IVF and GIFT stimulation cycles (1.6% stimulation cycles, with a clinic range of 0 –2.4%). The average number of follicles above 12cm for women who were affected by severe ovarian hyperstimulation was 18.8.

There were no reports of severe pelvic infection, and no reported cases of mortality in association with fertility treatment during the year. There were two cases of other serious morbidity reported at two separate clinics. Both were related to bowel complications.

- *Intra-uterine insemination (IUI)*

The Council is continuing to monitor IUI carried out by licensees and Exempt practitioners. A total of 1174 IUI cycles were reported by five Practice licensees and two Exempt practitioners. The overall ongoing clinical pregnancy rate per treatment cycle carried out was 7.2% (84 ongoing pregnancies), and of the pregnancies, 70 were singleton (83.3%), 12 were twin (14.3%), one was triplet (1.2%) and one was unknown (1.2%).

The information provided showed that 73.2% of the IUIs used the partner's sperm and 26.8% used donor sperm. Of all cycles carried out, the majority (55.6%) did not involve the use of ovulation induction. Clomid was used in only 9.8% of the cycles, and gonadotrophins were used in 34.6% of the cycles.

The one set of triplets reported followed gonadotrophin stimulation using the partner's sperm (AIH). Of the twelve sets of twins reported, all followed ovulation induction by gonadotrophins, one set was after donor insemination and the remaining 11 after AIH.

- *Counselling*

Based on the reporting forms it was found that 820 sessions of counselling were conducted during the year, that is 14 per cent down on last year. Just over ninety-two per cent (92.6 %) of patients who had counselling had one session of counselling compared to 83.5% last year. The majority of patients (80.4%) had counselling for clarifying information and this was consistent across all clinics. Almost twenty per cent (19.5%) of patients had support/therapeutic/decision making counselling compared to

12 per cent last year.

There was a small increase this year in the number of patients that had more than one session of counselling in the clinics that provide IVF services. There were 85 patients across all clinics compared to 77 last year. On average these patients had two to three sessions of counselling compared to two or less last year. The most frequently stated reason for having more than one session was for a 'matter related to infertility', followed by 'seeking support' and 'seeking information'.

The clinics that provided information on 'method of payment' (sixty per cent) indicated that generally there was no separate fee charged for counselling.

Counselling for people affected by donation – either as donors or recipients - made up 38.4 per cent (39% in 2001/02) of all counselling. Across clinics performing IVF the range was 28.8 per cent to 56.9 per cent of all counselling conducted.

- *Significant changes to routine practice reported by licensees during the year.*

No new changes to routine practice of licensees were reported at the time of annual report submission by licensees. However, a number of routine changes were received through the year.

- *Treatment of patients referred from the Public Fertility Clinic*

During the year a number of patients from the King Edward Memorial Hospital (KEMH) Infertility Clinic were referred for treatment at the Concept Fertility Centre, which reported on the treatments and their outcomes. As can be seen from Table 7, the results for this year indicate a decline in the number of public patients treated compared to previous two years. During the year 71 fresh IVF and 127 FET treatment cycles were conducted. This year 20 of the IVF cycles involved micro-manipulation (ICSI). Two fresh IVF cycles used donated reproductive material, one sperm and the other oocytes.

In addition, Concept reported 141 artificial inseminations (33 DI, 108 AIH) patients between 1 July 2002 and 30 June 2003. None of these resulted in ongoing pregnancies.

Complaints

A total of 18 formal complaints were reported by clinics for issues including accounting, clinical treatment and general practice organisation.

TABLE 1: NUMBER OF SEMEN DONORS

	1995/96	1996/97	1997/98	1998/99	1999/00	2000/01	2001/02	2002/03
No. current Donors	49	32	28	22	45	43	21	35
No. new donors in last year	30	20	11	15	30	24	10	25

TABLE 2: SEMEN DONOR AGES

Age of Donor (years)	Frequency (%)							
	1995/96	1996/97	1997/98	1998/99	1999/00	2000/01	2001/02	2002/03
18-25	19 (38.8)	11 (34.3)	6 (21.4)	8 (36.4)	7 (16.3)	8 (18.6)	6 (30.0)	7 (20.6)
26-30	8 (16.3)	8 (25.0)	8 (28.6)	0 (0)	5 (11.6)	2 (4.7)	3 (15.0)	4 (11.8)
31-35	13 (26.5)	7 (21.9)	4 (14.3)	6 (27.3)	4 (9.3)	7 (16.3)	3 (15.0)	5 (14.7)
36-40	3 (6.1)	4 (12.5)	6 (21.4)	1 (4.5)	12 (27.9)	13 (30.2)	6 (30.0)	11 (32.4)
41-50	6 (12.2)	2 (6.3)	3 (10.7)	7 (31.3)	12 (27.9)	11 (25.6)	0 (0)	6 (17.6)
>50	0 (0)	0 (0)	1 (3.6)	0 (0)	3 (7.0)	2 (4.7)	2 (10.0)	1 (2.9)
Total	49 (100)	32 (100)	28 (100)	22 (100)	43[2] (100)	43 (100)	20[1] (100)	34[1] (100)

[1] age missing for one donor
[2] age missing for two donors

TABLE 3: MARITAL STATUS OF SEMEN DONORS

	Frequency (%)							
Status	1995/96	1996/97	1997/98	1998/99	1999/00	2000/01	2001/02	2003
Single	34 (69.4)	25 (78.1)	20 (71.4)	14 (63.6)	28 (62.2)	23 (53.5)	10 (47.6)	26 (74.3)
Married/de facto	13 (26.5)	6 (18.8)	6 (21.4)	5 (22.7)	12 (26.7)	14 (32.6)	9 (42.9)	9 (25.7)
Divorced/sep.	2 (4.1)	1 (3.1)	2 (7.1)	3 (13.6)	5 (11.1)	6 (14.0)	2 (9.5)	0
Total	49 (100)	32 (100)	28 (100)	22 (100)	45 (100)	43 (100)	21 (100)	35 (100)

TABLE 4: TOTAL NUMBER OF EMBRYOS IN STORAGE JUNE 30

YEAR	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003
No Embryos	1870	2821	3456	4697	6108	7317	8692	9665*	10809	12097

TABLE 5: DISPERSAL OF STORED EMBRYOS 2001/2002

	No of embryos
Transferred between clinics in WA	1079
Transferred to clinics outside WA (Patients moving interstate/overseas)	68
Transferred into WA clinics from interstate or overseas	12
Used in frozen embryo transfer treatments	3523
Allowed to succumb with consent of couples	328

TABLE 6: IVF/GIFT TREATMENTS: Four year data

	IVF Fresh embryo transfer				IVF Frozen embryo transfer				GIFT				Total			
	1999/2000	**2000/01**	**2001/02**	**2002/03**	**1999/2000**	**2000/01**	**2001/02**	**2002/03**	**1999/2000**	**2000/01**	**2001/02**	**2002/03**	**1999/2000**	**2000/01**	**2001/02**	**2002/03**
No of women treated	977	1047	961	981	510	667	561	598	12	5	3	4	n/a	n/a	n/a	n/a
No of cycles begun	1529	1543	1603	1606	988	1196	1187	1408	16	6	4	6	2533	2745	2794	3020
No of cycles with oocyte retrieval	1114	1357	1341	1425	-	-	-	-	14	6	1	5	1128	1363	1342	1430
No of cycles with gamete or embryo transfer	1003	1209	1206	1316	832	980	1016	1207	14	6	1	5	1849	2195	2223	2528
No of cycles using donor:																
Semen	37	25	19	62	19	25	14	43	0	1	0	0	56	51	33	105
Ova	10	11	10	8	22	60	74	75	0	0	0	0	32	71	84	83
Embryo	1	0	3	0	36	20	31	30	-	0	0	0	37	20	34	30
Total	48	36	32	70	77	105	119	148	0	1	0	0	125	142	151	218
No of cycles where embryos stored	670	763	841	890	-	-	-	-	9	4	0	0	679	767	841	890
No of cycles from which human reproductive material was donated:																
Ova donated	21	33	30	32	-	-	-	-	0	0	0	0	21	33	30	32
Embryos donated	0	0	6	0	-	-	-	-	0	0	0	0	1	0	6	0
Breakdown of treatment cycle details																
No of cycles with IVF/GIFT same cycle	0	0	1	0	-		-	-	-	-	-	-	0	0	1	0
No of cycles with sperm retrieval	102	90	53[+]	101	-		-	-	-	0	0	-	102	90	53[+]	101
No of cycles with ICSI*	463	556	656	669	-		-	-	-	-	-	-	466	556	656	669
No of cycles with Fallopian embryo transfer	6	2	1	2	3	2	1	0	-	-	-	-	9	4	2	2

*ICSI is Intra Cytoplasmic Sperm Injection, a form of microinjection. [+] Data from one clinic not available.

TABLE 7: IVF AND RELATED TREATMENT OF PUBLIC PATIENTS

	No. of Patients				No. of Treatment Cycles			
	1999/2000	**2000/2001**	**2001/2002**	**2002/2003**	**1999/2000**	**2000/2001**	**2001/2002**	**2002/2003**
IVF	46	87	77	50	62	126	114	71
GIFT	0	0	0	0	0	0	0	0
FET	20	19	64	39	42	101	142	127
TOTAL	**66**	**106**	**141**	**89**	**104**	**227**	**256**	**198**

APPENDIX 4

REPORT FROM THE REPRODUCTIVE TECHNOLOGY REGISTER: JANUARY 1 TO DECEMBER 31 2001

REPORT FROM THE REPRODUCTIVE TECHNOLOGY REGISTER: 1 JANUARY TO 31 DECEMBER 2001

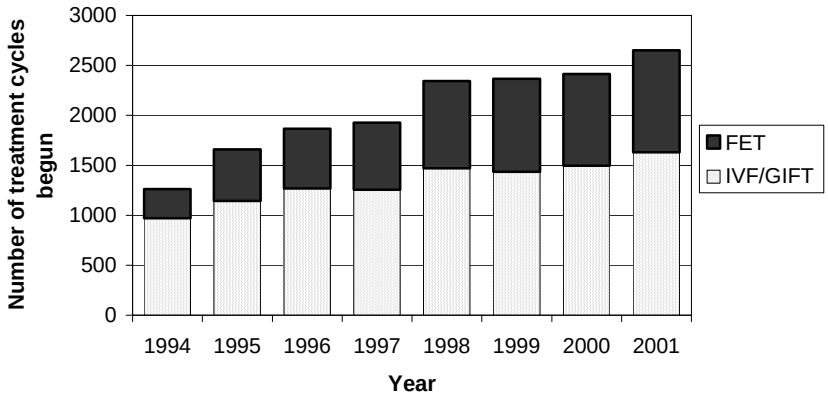
This is the ninth report from the Reproductive Technology Register established from 8 April 1993 under the WA *Human Reproductive Technology Act 1991*. This report summarises information about artificial fertilisation procedures undertaken in Western Australia between 1 January and 31 December 2001. The information for in vitro fertilisation (IVF)/Gamete Intra-fallopian transfer (GIFT) procedures was reported to the register by 4 licensees, and Donor Insemination (DI) treatments were reported by 5 licensees and 2 exempt practitioners.

Comparisons are made throughout the summary to data reported in previous years[1-7] and to National data published in the latest assisted conception report by the Australian Institute of Health and Welfare's National Perinatal Statistics Unit (NPSU)[8]. Clinical pregnancies and those pregnancies resulting in one or more live births are expressed as rates per 100 treatment cycles that reach the stage of oocyte retrieval or, in the case of frozen embryo transfers, per 100 embryo transfer cycles, to allow comparisons to national data reported by the NPSU.

Summary of the 2001 data on the Reproductive Technology Register.

There was a total of 2651 treatment cycles begun for IVF and related procedures (GIFT and frozen embryo transfer (FET)) in 2001, an increase of 9.90% compared to the previous year (2412). The majority of these (1632) were stimulation cycles for IVF or GIFT (see Table 2), and 1019 were for FET (see Table 8). Figure 1 (below) shows the increase in number of treatment cycles begun each year since 1994 for IVF/GIFT and FET procedures. In 2001 there was a marked increase in the number of procedures commenced compared to the previous three years (1998-2000) where there appeared to be a stabilisation. The number of FET procedures in 2001 (1019) represented the largest number of FET cycles commenced since the procedure was established and 103 more cycles than last year. In 2001 treatment cycles begun for frozen embryo transfer represented 38.4% of all treatment cycles begun.

Figure 1: Number of treatment cycles begun for IVF/GIFT and FET, 1994-2001



During 2001, 1175 women (60 more than the previous year) underwent stimulation cycles for egg retrieval (Table 2). The average number of IVF/GIFT stimulation cycles commenced per woman was 1.4, with a median of 1.

Cancellation of stimulation cycles for IVF or GIFT occurred in 15.7% of cases, which is similar to last year (2000: 15.6%). A wide clinic range was also evident (3.1%-21.5%), which may in part reflect the different ovulation induction regimes used by the clinics. Of those egg retrievals attempted, only 0.7% were performed by laparoscopy while 99.3% were by trans-vaginal ultrasound. This represents a further decline in the use of laparoscopy which in 1994 was used in 31% of egg retrievals. There were more eggs retrieved on average by trans-vaginal ultrasound (10.5, median = 9) than by laparoscopy (8.4, median = 7). The overall mean and median for both techniques combined were 10.5 and 9 respectively. This is a slight decrease in the mean number of eggs retrieved compared to last year (10.8). Attempted egg retrievals were almost all successful (98.4%) with a narrow clinic range (96.1%-99.3%).

Eggs were donated in 3.2% of successful egg retrievals, and 33.5% of retrievals resulted in one or more eggs being discarded. There were no eggs used for experimentation.

During the reporting period, the most frequently used ovulation induction drugs were: Gonal F, Pregnyl, Profasi and Puregon. The drugs Clomid, Cetrotide, Humegon, Metrodin, Progynova and Saizen were also used in ovulation induction but in a smaller proportion of cycles. As part of Down Regulation prior to ovulation induction the two drugs Lucrin and Synarel were commonly used. Orgalutram and Cetrotide were used in a limited number of cases.

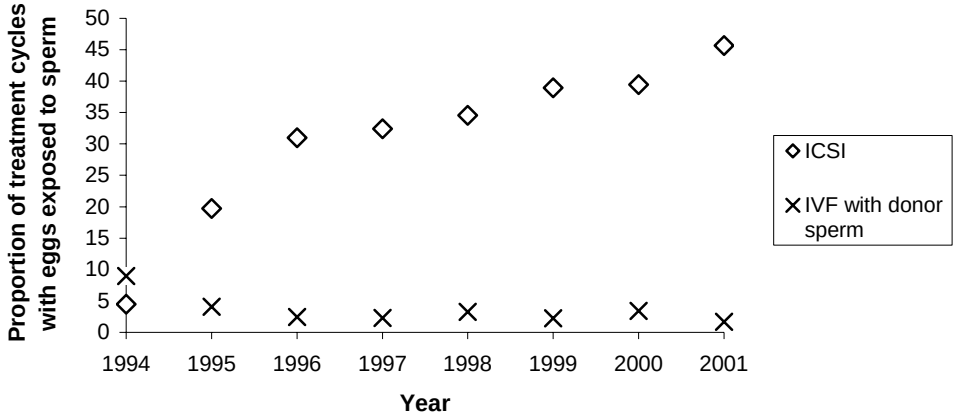
Between 1 January and 31 December 2001, 1335 women had embryo transfers (fresh or frozen) or egg transfers (GIFT) (see Table 3). This represents a 6.5% increase compared to the 1253 women having embryo transfers in 2000, and a 94.3% increase compared to 1994. The majority of these women (46.8%) had only fresh embryo transfers, although 29.4% had only frozen embryo transfers, and 23.4% had both IVF and FET transfers. Of the 1335 women treated in 2001, table 4 shows most had only one transfer during the year (58.1%), although 27.2% had two transfers and 10.0% had three. Sixty-two women had more than three transfers, the highest being 1 woman who had 6 transfers during the reporting period. The mean number of transfers per woman in this period was 1.6 and the median 1.

Table 5 summarises the fertilisation and embryo dispersal data for treatment cycles commenced between 1 January and 31 December 2001. There were 1360 cycles with eggs exposed to sperm, a further increase on 2000 where there were 1265 cycles. Since the commencement of the Register the number of cycles with eggs exposed to sperm has increased each year. The average number of eggs exposed to sperm per treatment cycle was 9.6 (median 8) with a clinic range from 9.1 to 10.2 (and the median varied between the clinics from 8 to 9.5).

Use of Intra-cytoplasmic sperm injection (ICSI) to achieve fertilisation was used in 45.7% of treatment cycles with eggs exposed to sperm, with a wide clinic range (38.3%-51.1%). This is quite a significant increase from last year where ICSI was used in 39.4% of attempted fertilisations. During 2001, there was another increase in the

proportion of ICSI treatment cycles, accounting for of 6.3% more cycles in 2001, than in 2000. Figure 2 (below) depicts this trend and the corresponding drop in the use of donor sperm in IVF treatment cycles.

Figure 2: Proportion of treatment cycles with eggs exposed to sperm using ICSI or donor sperm, 1994-2001



Fertilisation of one or more eggs occurred in 97.4% of treatment cycles with eggs exposed to sperm (Table 5). The range between clinics for successful fertilisation per egg exposed to sperm was narrow (70.0%-74.1%), and for all clinics combined was 71.9%. Donor sperm was only used in 1.7% of treatment cycles, a decrease from 2000 when it was used in 3.4% and the lowest use of donor sperm since 1994 when data was first collected (see Figure 2 above). The fertilisation rate using husbands' sperm was slightly lower than that using donor sperm (71.9% vs 72.1%). There appears to be no consistent pattern over the years regarding fertilisation rates for donor compared to husbands' sperm, as in 2000, 1998 and 1997 husbands sperm had higher fertilisation rates then donor sperm (2000: 74.1 vs 73.8, 1998: 74.2% vs 70.0% and 1997: 73.0% vs 67.6%), but the opposite was true in 1999 and 1996 (1999: 73.6% vs 75.2% and 1996: 71.3% vs 80.7%).

Fresh embryo transfer (IVF-ET) occurred in 88.1% of treatment cycles with successful fertilisation, with a wide clinic range from 80.4% to 94.0% (see Table 5). These proportions do not just reflect the effectiveness of fertilisation and embryonic development. They will also be affected by the proportion of GIFT cycles in which eggs were also exposed to sperm for embryo storage rather than being used in the GIFT procedure. However, in 2001 there was only one case of GIFT in which eggs were also exposed to sperm for embryo cryopreservation. Other factors that influence whether embryos will be fresh transferred include clinic preference in fresh transfer vs. freezing of higher quality embryos, differences in medication regimes between clinics, patient factors and/or deferring transfer of embryos when ovarian hyper-stimulation syndrome may develop.

Embryos were frozen in 64.2% of treatment cycles with successful fertilisation (see Table 5), and some embryos were allowed to succumb in 58.0% of treatment cycles. The majority of embryos that were allowed to succumb were reported by clinics to have been abnormal or to be degenerating (92.2%).

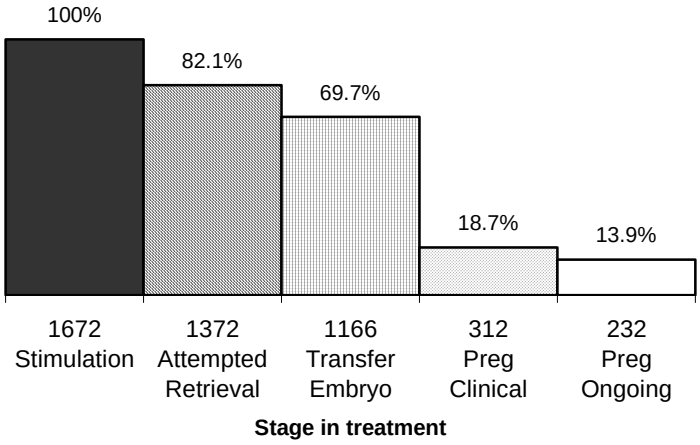
Fresh Embryo Transfer (IVF-ET):

There were 1166 fresh embryo transfers in 2001, only 63 more than the previous year (see Table 6). Donor egg embryos and donor sperm embryos were used in 1.1% and 1.5% of fresh embryo transfers respectively. In one case (0.1%) both donor eggs and donor sperm were used in the embryos. There were 311 clinical pregnancies resulting from IVF embryo transfer (22.7 per 100 egg retrieval cycles) and 230 ongoing (16.8 per 100 egg retrieval cycles, with a clinic range of 12.7-21.5). These pregnancy rates were slightly higher than in 2000 when there were 21.9 clinical pregnancies per 100 egg retrieval cycles and 15.3 ongoing pregnancies per 100 egg retrieval cycles.

The 2001 fresh embryo transfer (including ICSI) pregnancy rates reported for all Australian and New Zealand clinics combined were slightly higher than those observed for the WA clinics (25.9 clinical pregnancies per 100 oocyte retrieval cycles, and 21.1 ongoing pregnancies at 20 weeks per 100 oocyte retrieval cycles).[8]

The clinical pregnancy rate based on all treatment cycles with stimulation begun for IVF-ET was lower than the rate per egg retrieval attempted. These lower rates can be attributed to the relatively high number of cycles which were cancelled prior to retrieval. Figure 3 illustrates that there were 18.7 clinical pregnancies per 100 stimulation cycles begun, and 13.9 ongoing pregnancies per 100 stimulation cycles.

Figure 3: Results in subsequent phases of IVF-ET treatment, in 2001



Of the confirmed 226 pregnancies with live births, 93.2% were singleton, 16.8% were twin and there were no triplets. The proportion of multiple births is markedly lower that that observed in 2000 when they represented 21.8% of live births. National data for 2000[#] indicated that 22.1% of 'IVF pregnancies' following fresh *or* frozen embryo transfer resulted in multiple births (the data does not distinguish between fresh and frozen transfers).

There were 264 live births in 2001, 3 stillbirths and 3 neonatal death. This represents a perinatal mortality rate of 22.6 per 1000 total births. There was one triplet pregnancy where all three babies were still births. There were three neonatal deaths, one a

singleton and two twins from the same pregnancy. The 2000 perinatal mortality rate for *all* babies born in Western Australia was 9.6 per 1000 total births.[9]

As the proportion of multiple births is influenced by the numbers of embryos transferred, the Reproductive Technology Accreditation Committee (RTAC) encourages the transfer of no more than 2 oocytes or embryos in most circumstances. The mean number of embryos replaced per fresh embryo transfer in WA was 1.9, and the median 2 (clinic range 1.7-2.1 with a median of 2 for all clinics). In WA the percentage of cycles where more than two oocytes or embryos were transferred was 12.0%. This is slightly lower than that observed for all Australian and New Zealand IVF clinics combined (15.4%).[8] There appears to be variability in the number of embryos replaced at fresh transfer between the three Western Australian clinics. The number of times more than two embryos were replaced ranged between clinics from 0.9% to 23.2% of fresh embryo transfer cycles. This difference may influence the overall proportion of multiple births in each clinic (range 6.3%-21.5% of pregnancies with live births).

Table 1 (below) compares the live birth pregnancy rate and the proportion of multiple births where one, two, three, and four fresh embryos were transferred in WA in 2001. Multiple births only occurred in treatments where either two or three embryos were transferred. The overall proportion of multiple births was higher for 3 embryo transfer than 2 embryo transfers (23.1% vs. 18.7%). There were no cases of live born triplets in IVF fresh embryos transfers in 2001, however there was one triplet pregnancy where all three babies were stillborn. There were only 7 transfers where 4 embryos were replaced.

An analysis of the implantation rate (the proportion of embryos replaced at fresh transfer which resulted in a live birth) varied between the clinics from 8.0% to 14.6%. The implantation rate for all clinics was 11.6%. Implantations rates were highest for single embryo transferred (1 embryo: 13.2%; 2 embryos: 12.8%). The implantation rate for cycles where three embryos were transferred were significantly lower than when one or two embryo are transferred (3 embryos: 7.3%).

Table 1: Live birth pregnancy and multiple birth rates by the number of fresh embryos transferred at IVF-ET between January 1 and December 31 2001.

Number of embryos transferred	*Number of fresh embryo transfers*	*Number of pregnancies with live births*	*Number of live births*	*Live birth rate (% of treatment cycles with embryos transferred)*	*Multiple birth rate (% of pregnancies with live births)*	*% higher order multiples (% of pregnancies with live births)*	*Number of stillbirths and neonatal deaths*	*Stillbirths and neonatal deaths (per 1000 total births)*
One	220	29	29	13.2	0	0	0	0
Two	793	171	203	21.6	18.7	0	6	29.1
Three	146	26	32	17.8	23.1	0	0	0
Four	7	0	0	0	0	0	0	0
Total	1166	226	264	19.4	16.8	0	6	22.5

Gamete Intra Fallopian Transfer (GIFT):

GIFT transfers accounted for only 0.2% of all assisted conception transfer procedures performed in 2001. Only three clinics carried out GIFT treatments with half the treatments carried out by one clinic. There were an estimated* 4 treatment cycles begun for GIFT which represented 0.3% of egg retrieval cycles attempted (Table 7). The number of GIFT treatments in 2001 (4) was three less than the number in 2000 (7). GIFT has been in decline since 1994 (1999: 25, 1998: 26, 1997: 74, 1996: 90, 1995: 140, 1994: 286), currently being used only in special circumstances such as where a couple has ideological reasons not to participate in IVF. Donor material was not used in any of the GIFT procedures, and the mean number of eggs replaced at transfer was 2.0 (median 2).

There were no clinical pregnancies resulting from GIFT treatment in 2001. These rates are not compared to national data due to the small number of GIFT transfers carried out in Western Australia in 2001.

Frozen Embryo Transfer (FET):

Table 8 summarises treatment cycle information for the 708 women who undertook frozen embryo transfer procedures in the reporting period. This represents a further increase in the number of women undergoing FET (2000: 654, 1999: 636, 1998: 590, 1997: 476, 1996: 419, 1995: 372, 1994: 232). There was also a substantial increase in the number of FET cycles during 2001 (1019), from that of 2000 (916). The 1019 treatment cycles begun for FET accounted for 33.3% to 51.3% of all transfer procedures (for IVF, GIFT and FET) in the different IVF clinics. Embryo transfer occurred in 96.2% of treatment cycles begun for FET, and 10.5% of these involved donated material. Donor eggs were used in 7.1% of transfers, donor sperm in 1.5%, both sperm and donor egg in 0.4% and donor embryos were used in 1.5%.

The mean number of embryos transferred at FET was 1.9 (and the median 2). There were 222 clinical pregnancies (22.7 per 100 embryo transfer cycles) and 185 ongoing pregnancies (18.9 per 100 embryo transfer cycles with a clinic range of 12.6-24.0). The ongoing pregnancy rate in 2000 was slightly lower (15.0 per 100 embryo transfer cycles). There were 175 pregnancies with confirmed live births, 86.3% were singleton, 13.7% twins and 0.6 were triplets. There were 3 still births and 0 neonatal deaths following FET treatment in 2001.

National data on pregnancy rates following frozen embryo transfer for all Australian and New Zealand clinics are reported separately for transfers of frozen/thawed embryos created by ICSI and those created by standard IVF. It is possible to combine the data to allow comparison to Western Australian figures. The overall clinical pregnancy rate for Australia and New Zealand following FET in 2001 was 18.8 per 100 embryo transfers with an ongoing pregnancy rate at 20 weeks of 15.0 per 100 embryo transfers.[8]

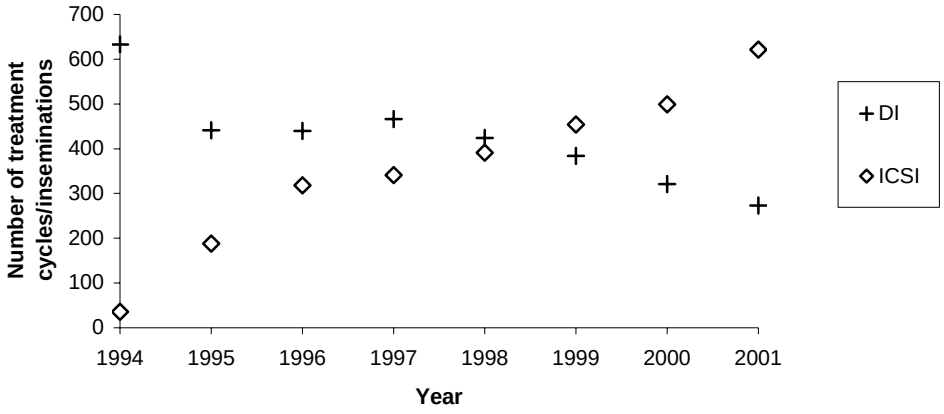
A large number of factors may be important in determining the wide clinic range in live birth pregnancy rates seen for FET (10.9-22.8 per 100 embryo transfer cycles). The average number of eggs collected per retrieval in each clinic will influence the number of embryos developed, in turn influencing the number available for freezing. In addition, clinic preference in fresh transfer vs. freezing of higher quality embryos will affect the quality of frozen embryos replaced and therefore the pregnancy rate in each clinic.

Drugs used in preparation for FET included: Gonal F, Primogyn, Puregon, Profasi, Progesterone Pessaries, Pregnyl, Progynova, and Proluton. There were also a number of natural cycles where drugs were not used.

Donor Insemination (DI):

Donor insemination (DI) treatments and outcomes carried out in the reporting period are summarised in Table 9. There were 273 DI treatments undertaken by 114 women in 2001, slightly less than the 321 DI treatments undertaken in 2000. Figure 4 below shows the decline and subsequent stabilisation in the use of Donor Insemination with the introduction of ICSI to Western Australian fertility clinics in 1994 and 1995. As is illustrated, in the last three years, the number of donor insemination treatments was less than the number of ICSI treatments.

Figure 4: Number of treatment cycles using ICSI and number of donor inseminations, 1994-2001



The mean number of inseminations per woman treated in 2000 was 2.4 (median 2), with a clinic range of 1.0 to 3.0 (and a median range of 1-2). There were 37 clinical pregnancies as a result of DI treatment (13.6 per 100 insemination treatments) and 32 ongoing pregnancies (11.7 per 100 insemination treatments). The proportion of pregnancies with live births varied between the clinics, from 0 to 50.0 per 100 insemination treatments. This difference may be influenced by the differing patterns in the use of ovulation induction between clinics. Of 30 pregnancies with confirmed live births, 90.0% were singleton and 10.0% were twin. These resulted in 26 live births, with no still births or neonatal deaths. More up to date information on the use of intra-uterine insemination (IUI) by licensees and exemptees may be found in the summary report of clinic data for 2000/01 earlier in this report and these data. In addition to IUI using sperm from donors, includes information about IUI using sperm from the husbands/partners.

Table 10 summarises the use of donated human reproductive material in 2001. Fifty-two egg donors, 101 sperm donors and 13 embryo donor couples all donated material used in this period. There were 19 babies born of treatment cycles involving donor eggs, 42 babies through treatment involving donor sperm, 3 babies were born from donated embryos and a set of twins born from combined donor egg and donor sperm embryos.

Notes:

Multiple birth comparisons are made to national data for the 1999 calendar year as 2000 results had not yet been published at the time of printing.

* As information reported to the register does not differentiate between egg retrievals attempted for fresh IVF or GIFT, the number for each has been estimated in Tables 6 and 7. This estimation assumes that failed collections for IVF and GIFT would be equivalent and reflects the ratio of IVF:GIFT transfers actually carried out.

Acknowledgments:

We would like to thank Ms Vivien Gee, Coordinator of the WA Midwives' Notification System; Dr Tim Green, Research Officer for the WA Midwives' Notification System; Ms Carol Garfield, Database Administrator for the LinkData Project and Ms Lexie Stoney, Research Officer for the LinkData Project; for their assistance in providing information on confinements and neonatal deaths and implementation of an internal linkage of the Reproductive Technology Register.

References:

1. The Western Australian Reproductive Technology Council, 2002 Annual Report: July 1 2000 – June 30 2001.
2. The Western Australian Reproductive Technology Council, 2001 Annual Report: July 1 2000 – June 30 2001.
3. The Western Australian Reproductive Technology Council, 2000 Annual Report: July 1 1999 – June 30 2000.
4. The Western Australian Reproductive Technology Council, 1999 Annual Report: July 1 1998 – June 30 1999.
5. The Western Australian Reproductive Technology Council, 1998 Annual Report: July 1 1997 – June 30 1998.
6. The Western Australian Reproductive Technology Council, 1997 Annual Report: July 1 1996 – June 30 1997.
7. The Western Australian Reproductive Technology Council, 1996 Annual Report: July 1 1995 – June 30 1996.
8. Dean J and Sullivan E. 2003 Assisted conception Australia and New Zealand 2000 and 2001. AIHW cat. No. PER 22. Sydney: Australian Institute of Health and Welfare National Perinatal Statistics Unit (Assisted Conception Series no.7).
9. Gee V. and O'Neill M.T. (2003) Perinatal Statistics in Western Australia, 2001. Nineteenth Annual Report of the Western Australian Midwives' Notification System. Health Information Centre, Health Department of Western Australia. Perth, Western Australia.

TABLE 2: IVF/GIFT egg retrievals and dispersals between 1 January and 31 December 2001

	Treatment Cycles				Women
	N	%	%	%	N
IVF/GIFT treatment begun:	1632 (131-562)	100.0			1175
No. cycles begun per woman -					
Mean:					1.4
(range[1])					(1.1-1.4)
Median:					1
(range[1])					(1-1)
Cancelled:	256	15.7			
(range[1])	(4-121)	(3.1-21.5)			
Total egg retrievals attempted[2] -	1376	84.3	100.0		
(range[1])	(127-505)				
Laparoscopy:	9[3]		0.7		
Trans Vaginal Ultrasound:	1367		99.3		
Failed retrievals:	22		1.6		
(range[1])	(3-8)		(0.7-3.9)		
Successful egg retrievals:	1354		98.4	100.0	
(range[1])			(96.1-99.3)		
Mean number of eggs per successful retrieval -					
All:	10.5				
(median)	9				
Laparoscopy:	8.4				
(median)	7				
Trans Vaginal Ultrasound:	10.5				
(median)	9				
With eggs exposed to sperm:	1345[4]			99.3[2]	
With eggs transferred at GIFT:	4			0.3[2]	
With eggs donated:	43			3.2[2]	
With eggs used for experimentation:	0			0.0[2]	
With eggs discarded:	454			33.5[2]	

Footnotes:

1) (range[1]) gives the range of results from the four IVF clinics.

2) These categories are not exclusive.

3) One cycle which was a combined laparascopy and t/v ultrasound is included

4) Ten of these retrieval lead to two separate fertilisations and two lead to three separate fertilisations, therefore there were 1265 fertilisations.

TABLE 3: Number of women having different combinations of transfers[1]: IVF-ET, GIFT or Frozen Embryo Transfers (FET) between 1 January and 31 December 2001

Transfer Type	N	%
IVF-ET only	625	46.9
FET only	391	29.3
GIFT only	3	0.2
IVF-ET & FET	313	23.5
GIFT & FET	0	0.0
IVF-ET & GIFT	0	0.0
IVF-ET, GIFT & FET	1	0.1
TOTAL	**1333**	**100.0**

Footnotes:
1) Where "transfers" include GIFT and frozen embryo transfers as well as all fresh embryo transfers.

Note: IVF-ET is used here to denote all fresh embryo transfers, and FET to denote all frozen embryo transfers.

TABLE 4: Number of women having different numbers of IVF-ET, GIFT, or FET transfers[1] between 1 January and 31 December 2001

No. of Transfers[1]	N	%
1	773	58.0
2	363	27.2
3	135	10.1
4	42	3.2
5	19	1.4
6	1	0.1
TOTAL	**1333**	**100.0**

Footnotes:
1) Where "transfers" include GIFT and frozen embryo transfers as well as all fresh embryo transfers.

Note: IVF-ET is used here to denote all fresh embryo transfers, and FET to denote all frozen embryo transfers.

TABLE 5: IVF Laboratory data (fertilisation and embryo dispersal) for treatment cycles commenced between 1 January and 31 December 2001

	Treatment Cycles			Eggs/Embryos			Women
	N	%	%	N	%	%	N
Eggs exposed to sperm: (range[1])	1360 (122-507)	100.0		13103	100.0		1100
Mean number of eggs exposed to sperm per treatment cycle: (range[1])				9.6 (9.1-10.2)			
Median: (range[1])				8 (8-9.5)			
Using husband sperm: (range[1])	1337	98.3 (96.7-98.6)					
Using donor sperm: (range[1])	23	1.7 (1.4-3.3)					
Using micro-manipulation - (range[1])	621	45.7 (38.3-51.1)					
ICSI:	621	45.7					
SUZI:	0	0.0					
PZD:	0	0.0					
PZD/SUZI:	0	0.0					
Failed fertilisation: (range[1])	36	2.6 (1.1-3.7)					
Fertilisation occurred: (range[1])	1324 (119-490)	97.4	100.0	9418	71.9	100.0	
Using husband sperm: (range[1])				9245	71.9[2] (70.0-73.5)		
Using donor sperm: (range[1])				173	72.1[2] (50.8-87.7)		
Fresh embryo transfer (range[1])	1166		88.1 (80.4-95.0)	2269	17.3	24.1	
Embryo freezing (range[1])	850		64.2 (47.1-75.9)	5191	39.6	55.1	
Embryo donation	0		0.0	0	0.0	0.0	
Embryos discarded	768		58.0	1958	14.9	20.8	

Footnotes:

1) (range[1]) gives the range of results from the four IVF clinics.

2) The denominators for these calculations are not shown in this table.

3) The majority of embryos were discarded due to abnormal fertilisation or abnormal development (1806) and 152 surplus embryos were discarded.

TABLE 6: IVF-ET (fresh IVF embryo transfer) transfers and outcomes between 1 January and 31 December 2001

	Treatment Cycles				Women	
	N	%	%	%	N	%
Egg retrievals attempted for IVF-ET:	1372[2]	100.0				
(range[1])	(126-504)					
With embryos transferred -	1166[3]	85.0	100.0		939	100.0
(range[1])	(113-405)					
Donor -						
Egg:	13		1.1			
Sperm:	17		1.5			
Egg+Sperm:	1		0.1			
Embryo:	0		0.0			
Number embryos per transfer -						
Mean:	1.9					
(range[1])	(1.7-2.1)					
Median:	2					
(range[1])	(2-2)					
Clinical pregnancy -						
Yes:	311	22.7	26.8		309	32.8
(range[1])		(17.5-26.4)	(19.5-31.5)			
No:	855	62.3	73.3		631	67.2
Blighted ovum:	26	1.9	2.2			
Missed abortion:	36	2.6	3.1			
Spontaneous abortion:	4	0.3	0.3			
Ectopic:	12	0.9	1.0			
Therapeutic abortion:	3	0.2	0.3			
Ongoing clinical pregnancy at 20 weeks:	230	16.8	19.7		230	24.5
(range[1])		(12.7-21.5)	(14.2-25.6)			
Late pregnancy loss:	0	0.0	0.0		0	0.0
Pregnancies with live births:	226[4]	16.5	19.4	100.0	226	24.1
(range[1])		(12.7-21.5)	(14.2-25.6)			
Plurality:						
1	188	13.7	16.1	93.2		
(range[1])		(11.9-16.8)	(13.3-20.1)	(78.5-93.8)		
2	38	2.8	3.3	16.8		
(range[1])		(0.8-4.6)	(0.9-5.5)	(6.3-21.5)		
3	0	0.0	0.0	0.0		
(range[1])						
Live Births:	264	19.2	22.6			
Still Births:	3[5]	0.2	0.3		1	0.1
Neonatal deaths (within 28 days of birth):	3[6]	0.2	0.3			

Footnotes:

1) (range[1]) gives the range of results from the four IVF clinics.

2) As the data do not distinguish between IVF and GIFT stimulations, this number is an estimate. It assumes that failed collections for IVF and GIFT would be equivalent and reflects the ratio of IVF:GIFT transfers actually carried out.

3) One treatment where both fresh and frozen embryos were transferred together in the same procedure are included in this table.

4) Three women were lost to follow up and their birth details were unavailable therefore they are excluded from confinement data.

5) All three babies from a triplet pregnancy

6) One singleton and both of the babies from two twin pregnancies

TABLE 7: GIFT transfers and outcomes between 1 January and 31 December 2001

	Treatment Cycles			Women	
	N	%	%	N	%
Egg retrievals attempted for GIFT*:	4	100.0			
(range[1])	(0-2)				
With eggs transferred -	4	100.0	100.0	4	100.0
(range[1])	(0-2)				
Donor -					
Egg:	0		0.0		
Sperm:	0		0.0		
Egg+Sperm:	0		0.0		
Number eggs per transfer -					
Mean:	2				
(range[1])	(0-3.0)				
Median:	2				
(range[1])	(0-3)				
Clinical pregnancy -					
Yes:	0	0.0	0.0	0	0.0
(range[1])					
No:	1	100.0	100.0	4	100.0
Blighted ovum:	0	0.0	0.0		
Missed abortion:	0	0.0	0.0		
Spontaneous abortion:	0	0.0	0.0		
Ectopic:	0	0.0	0.0		
Therapeutic abortion:	0	0.0	0.0		
Ongoing clinical pregnancy at 20 weeks:	0	0.0	0.0	0	0.0
(range[1])					
Late pregnancy loss:	0	0.0	0.0	0	0.0

Footnotes:
1) (range[1]) gives the range of results from the four IVF clinics.

TABLE 8: Frozen Embryo Transfers between 1 January and 31 December 2001

	Treatment Cycles				No. of Embryos		Women	
	N	%	%	%	N	%	N	%
Treatment cycles begun for FET:	1019	100.0					708	100.0
(range[1])	(57-429)							
Cancelled:	16	1.6					13	1.8
Number embryos thawed:					3350	100.0		
Number embryos flawed:					1450	43.3		
Totally failed thaw:	23	2.3					23	3.2
Embryos transferred -	980	96.2	100.0		1900	56.7	687	97.0
Own:	875		89.3		1696			
Donor -								
Egg:	71		7.2		134			
Sperm:	15		1.5		34			
Egg + Sperm:	4		0.4		8			
Embryo:	15		1.5		28			
Number embryos per transfer -								
Mean:					1.9			
(range[1])					(1.7-2.2)			
Median:					2			
(range[1])					(2-2)			
Clinical pregnancy -								
Yes:	222	21.8	22.7				218	30.8
(range[1])		(12.3-29.3)	(14.3-30.1)					
No:	758	74.4	77.3				469	66.2
Blighted ovum:	14	1.4	1.4					
Missed abortion:	18	1.8	1.8					
Spontaneous abortion:	2	0.2	0.2					
Ectopic:	1	0.1	0.1					
Therapeutic abortion:	2	0.2	0.2					
Ongoing clinical pregnancy at 20 weeks:	185	18.2	18.9				185	26.1
(range[1])		(10.9-23.4)	(12.6-24.0)					
Late pregnancy loss:	0	0.0	0.0				0	0.0
Pregnancies with live births:	175[2]	17.2	17.9	100.0			175	24.7
(range[1])		(10.9-22.8)	(12.6-23.4)					
Plurality:								
1	151	14.8	15.4	86.3				
(range[1])		(10.3-18.8)	(11.9-19.2)	(82.1-100)				
2	24	2.4	2.4	13.7				
(range[1])		(0-3.8)	(0-3.9)	(0-16.7)				
3	1	0.1	0.1	0.6				
(range[1])		(0-0.3)	(0-0.3)	(0-1.2)				
Live Births:	202	19.8	20.6					
Still Births:	3[3]	0.3	0.3				2	0.3
Neonatal deaths (within 28 days of birth):	0	0.0	0.0					

Footnotes:

1) (range[1]) gives the range of results from the four IVF clinics.

2) Eight women were lost to follow up and their birth details were unavailable therefore they are excluded from confinement data.

3) Both babies from a twin pregnancy and one singleton

TABLE 9: Donor Insemination treatments and outcomes carried out between 1 January and 31 December 2001

	Treatment Cycles			Women	
	N	**%**	**%**	**N**	**%**
DI carried out:	273	100.0		114	100.0
(range[1])	(2-132)				
No. DIs per woman treated -					
Mean:				2.4	
(range[1])				(1.0-3.0)	
Median:				2	
(range[1])				(1-2)	
Clinical pregnancy -					
Yes:	37	13.6		36	31.6
(range[1])	(1-14)	(10.6-100)			
No:	236	86.4		78	68.4
Blighted ovum:	0	0.0			
Missed abortion:	5	1.8			
Spontaneous abortion:	0	0.0			
Ectopic:	0	0.0			
Therapeutic abortion:	0	0.0			
Ongoing clinical pregnancy at 8 weeks:	32	11.7		32	28.1
(range[1])		(9.4-100)			
Late abortion (post 8 weeks):	0	0.0		0	0.0
Pregnancies with live births:	30[2]	11.0	100.0	30	26.3
(range[1])		(0.0-50.0)			
Plurality:					
1	27	9.9	90.0		
(range[1])		(0.0-50.0)	(66.7-100)		
2	3	1.1	10.0		
(range[1])		(0.0-3.1)	(0.0-33.3)		
3	0	0.0	0.0		
(range[1])					
Live Births:	33	12.1			
Still Births:	0	0.0		0	0.0
Neonatal deaths (within 28 days of birth):	0	0.0			

Footnotes:

1) (range[1]) gives the range of results from 5 holders of Practice Licenses and pooled results from 6 Exemptees who performed 1 or more DI's during the period.

2) Two women were lost to follow up and there birth details were unavailable therefore they are excluded from confinement

TABLE 10: Donation of Human Reproductive Material between 1 January and 31 December 2001

	IVF-ET	GIFT	FET	DI	TOTAL
Number of Treatment Cycles -					
Donor Egg:	13	0	71	-	84
Donor Sperm:	17	0	15	273	305
Donor Egg+Sperm:	1	0	4	-	5
Donor Embryo:	0	-	15	-	15
Number of Babies Born -					
Donor Egg:	6	0	13	-	19
Donor Sperm:	5	0	4	33	42
Donor Egg+Sperm:	2	0	0	-	2
Donor Embryo:	0	-	3	-	3
Number of Donors Used -					
Donor Egg:	14	0	43	-	52[1]
Donor Sperm:	16	0	11	74	101[1]
Donor Embryo[2]:	0	-	13	-	13

Footnotes:

1) There were 101 individual sperm donors and 52 individual egg donors whose sperm and eggs were used in 2000. These total donor numbers are not equivalent to the sum of donors in the IVF-ET, GIFT, FET and DI categories for these fields as the same donor may be used in more than one type of transfer eg for DI inseminations as well as in an IVF treatment cycle.

2) Embryo donors are considered as a couple

APPENDIX 5

INFORMATION CIRCULATED TO LICENSEES

NOTICES

Notice: *Acts Amendment (Lesbian and Gay Law Reform) Act 2002*

Acts Amendment (Lesbian and Gay Law Reform) Act 2002 – Amendment of the *Human Reproductive Technology Act 1991* and the *Artificial Conception Act 1985*

The *Acts Amendment (Lesbian and Gay Law Reform) Act 20*02 (the Act) comes into effect on 21 September 2002. The Act amends a number of pieces of legislation, including the *Human Reproductive Technology Act 1991* (the HRT Act) and the *Artificial Conception Act 1985* (the AC Act). For your information, attachment A provides a copy of the relevant sections of the HRT Act and the AC Act showing the changes that are made by the Act.

The terminology of "de facto partner" and "de facto relationship" are used throughout the Act. In relation to the HRT Act and the AC Act these terms are interpreted in accordance with provisions that have been inserted in the *Interpretation Act 1984*. The definitions of de facto relationship and de facto partner include same sex relationships as well as heterosexual relationships. The definition of de facto relationship does not rely on a specified duration of the relationship, but provides a range of matters that should be considered in relation to a decision about whether a person is in a de facto relationship. The relevant section, section 13A of the *Interpretation Act 1984* is also included at attachment A.

The effect of the changes to the HRT Act and the AC Act are summarised below.

HUMAN REPRODUCTIVE TECHNOLOGY ACT 1991

- The amendments makes provisions that allow a woman who is unable to conceive a child for medical reasons, or whose child is likely to be affected by a genetic abnormality or disease, to have access to *in vitro* fertilisation procedures. There is no restriction on whether the woman is married, single or in a de facto relationship with a person of the same or opposite sex. The provision that the reason for the infertility must not be age remains a requirement.

- Provision is also made for heterosexual couples to access *in vitro* fertilisation procedures where the woman is not infertile, but there are medical reasons preventing them conceiving a child, (for example the man is infertile) or their child is likely to be affected by a genetic abnormality or disease. A fertile single woman, or a fertile woman in a same sex relationship, is not able to access *in vitro* fertilisation procedures, but is able to access artificial insemination, under the direction of a licensee, to attempt to achieve a pregnancy.

- The amendments remove the requirement that a heterosexual de facto couple wishing to access *in vitro* fertilisation procedures must have been in a relationship for five out of the last six years. Although this requirement has been removed it is noted that the stability of the relationship is still a relevant consideration in section 23(e). Section 23(e) requires that an *in vitro* fertilisation procedure can not be

provided without consideration of the welfare and interests of any child who may be born as a result of the procedure.

- There are also some consequential amendments to:

  - allow the Code of Practice or directions issued under the HRT Act to make provision for identifying the persons on whose behalf gametes, eggs in the process of fertilisation or embryos are developed or stored, and clarify that the development or storage may be on behalf of a single woman or lesbian couple

  - reflect the position that gametes or embryos may be stored on behalf of either a couple or a single person

  - provide that rights to control, or power to deal with or dispose of an egg in the process of fertilisation or an embryo that is outside of the body of a woman, may vest in a single woman or in a couple.

ARTIFICIAL CONCEPTION ACT 1985

The amendments make provision for legal status of a child born to a woman in a same sex relationship. The amendments also clarify some uncertainty that previously existed about the legal status of the donors of gametes or embryos where the husband or de facto partner of a woman undergoing an artificial fertilisation procedure had not given consent to the procedure.

- The definition of "fertilization procedure" is replaced with a definition of "artificial fertilisation procedure" that refers to the definition in the HRT Act. This clarifies that all fertility treatments covered under the HRT Act (including GIFT procedures) are covered by the AC Act.

- Where a woman undergoes an artificial fertilisation procedure and gives birth to a child as a result, she is the mother of the child, whether she provided the ovum or not.

- Where a woman undergoes an artificial fertilisation procedure with the consent of her same sex de facto partner, the partner will be legally recognised as a parent of any child born as a result. The consent of the partner is presumed, but the presumption is rebuttable. The new section is consistent with the provisions in section 6 relating to a man who consents to his wife or de facto partner undergoing an artificial fertilisation procedure.

- A "donor" of gametes or embryos used in an artificial fertilisation procedure is not a parent of a resulting child. This means that a sperm or ova donor, or embryo donors, including a known donor, has/have no parental rights or responsibilities in respect of a resulting child. This does not apply in circumstances where a sperm provider is married to, or in a de facto relationship with, the mother. In that case section 6 provisions apply and the sperm provider will be the father of the child if he consented to the procedure.

Directions and Guidelines

As a result of the changes to the eligibility requirements and the changes to the AC Act the Directions under the HRT Act published in the Western Australian Government Gazette on 3 October 1997 (the Directions) and the Draft Guidelines (the Guidelines) published in the Western Australian Gazette on 22 March 1993 require amendment.

In the interim, where the term "de facto partner" appears in the Directions it should be interpreted in accordance with the Interpretation Act and which includes a reference to the same sex de facto partner.

Where the word "couple" appears in the Directions it should be interpreted as including a reference to a single woman who is undergoing treatment not as a member of a couple.

In particular:

- Where a woman seeking IVF treatment has a spouse, or de facto partner (including a same sex partner) any person to whom the licence applies must ensure that that spouse or de facto partner has given effective consent to the procedure.

- A person to whom a licence applies or an Exempt practitioner should ensure that information provided to a donor or donors of gametes or embryos about the effect of the *Artificial Conception Act 1985* reflects the amendments set out above.

- Where a woman is seeking to use sperm from a known donor the person to whom a licence applies or an Exempt practitioner should clarify and document the nature of the relationship between the woman and the donor. If the relationship is a de facto relationship consent procedures for de facto partners must be complied with.

- In relation to decisions about storage of an embryo created or donated for for the purposes of providing IVF treatment to a single woman, the woman has right to make such decision in her own right.

- Consideration of the eligibility for IVF should continue to be fully documented, including the assessment of the welfare of the participants and any resulting child, which is still required under section 23 of the HRT Act.

Clinics should consider whether their current procedures and consent forms require amendment to give effect to the changes introduced by the *Acts Amendment (Lesbian and Gay Law Reform) Act 2002*. If amendments are made the revised forms and procedures should be forwarded to the Reproductive Technology Council for approval.

Marked up version of legislation as amended by the *Acts Amendment (Lesbian and Gay Law Reform) Bill 2001*

ARTIFICIAL CONCEPTION ACT 1985

AN ACT relating to the status of persons conceived by artificial means and for related purposes.

Commencement

2.This Act shall come into operation on a day to be fixed by proclamation.

Interpretation

3.(1)A reference in this Act to a married woman includes a reference to a woman who is living with a man as his de facto partner.

(2)A reference (however expressed) in this Act to the husband or wife of a person —

(a)

(a) is, in a case where the person is in a de facto relationship with a person of the opposite sex, a reference to the person's de facto partner; and

(b) does not, in that case, include a reference to the spouse (if any) to whom the person is actually married.

(3) In this Act –

"artificial fertilisation procedure" has the meaning given by the *Human Reproductive Technology Act 1991.*

Application

4.(1)The provisions of this Act apply —

(a) in respect of an artificial fertilisation procedure carried out before or after the commencement of this Act either within or outside Western Australia; and

(b) in respect of a child born before or after the commencement of this Act either within or outside Western Australia.

(2)Nothing in this Act affects the vesting of property in possession or in interest before the commencement of this Act.

Rule relating to maternity

5.(1)Where a woman undergoes an artificial fertilisation procedure in consequence of which she becomes pregnant and the ovum used for the purposes of the procedure was taken from some other woman, then for the purposes of the law of the State, the pregnant woman is the mother of any child born as a result of the pregnancy.

Rule relating to paternity

6.(1)Where a married woman undergoes, with the consent of her husband, an artificial fertilisation procedure in consequence of which she becomes pregnant, then for the purposes of the law of the State, the husband —

(a) shall be conclusively presumed to have caused the pregnancy; and

(b) is the father of any child born as a result of the pregnancy.

(2)In every case in which it is necessary to determine for the purposes of this section whether a husband consented to his wife undergoing an artificial fertilisation procedure, that consent shall be presumed, but the presumption is rebuttable.

6A. Rule relating to parentage – same sex de facto relationships

(1) Where a woman who is in a de facto relationship with another woman undergoes, with the consent of her de facto partner, an artificial fertilisation procedure in consequence of which she becomes pregnant, then for the purposes of the law of the State, the de facto partner of the pregnant woman –
(a) shall be conclusively presumed to be a parent of the unborn child; and
(b) is a parent of any child born as a result of the pregnancy.

(2) In every case in which it is necessary to determine for the purposes of this section whether a de facto partner consented to her de facto partner undergoing an artificial fertilisation procedure, that consent shall be presumed, but the presumption is rebuttable.

Donor of genetic material

7.(1)Where —

(a) a woman becomes pregnant in consequence of an artificial fertilisation procedure; and

(b) the ovum used for the purposes of the procedure was taken from some other woman,

then for the purposes of the law of the State, the woman from whom the ovum was taken is not the mother of any child born as a result of the pregnancy.

(2)Where —

(a) a woman becomes pregnant in consequence of an artificial fertilisation procedure; and

(b) a man (not being the woman's husband) produced sperm used for the purposes of the procedure,

then for the purposes of the law of the State, the man referred to in paragraph (b) —

(c) shall be conclusively presumed not to have caused the pregnancy; and

(d) is not the father of any child born as a result of the pregnancy.

HUMAN REPRODUCTIVE TECHNOLOGY ACT 1991

AN ACT to establish the Western Australian Reproductive Technology Council; to require the compilation of a Code relating to the practice of, the procedures used in, and the ethics governing, human reproductive technology; to make provision with respect to the use of that technology in relation to artificially assisted human conception and for the regulation of certain research; and for related purposes.

WHEREAS:

A. In enacting this legislation Parliament is seeking to give help and encouragement to those eligible persons who wish to be parents.

B. Parliament considers that the primary purpose and only justification for the creation of a human egg in the process of fertilisation or embryo *in vitro* is to assist persons who are unable to conceive children naturally due to medical reasons or whose children may be affected by a genetic abnormality or disease, to have children, and this legislation should respect the life created by this process by giving an egg in the process of fertilisation or an embryo all reasonable opportunities for implanting.

C. Although Parliament recognises that research has enabled the development of current procedures and that certain non harmful research and diagnostic procedures upon an egg in the process of fertilisation or an embryo may be licit, it does not approve the creation of a human egg in the process of fertilisation or an embryo for a purpose other than the implantation in the body of a woman.

D. Parliament considers the freezing and storage of a human egg in the process of fertilisation or an embryo to be acceptable only: —

(i) as a step in the process of implanting; and

(ii) only in extraordinary circumstances once the freezing and storage of eggs can be carried out successfully.

The Parliament of Western Australia enacts as follows:

…

The Code and directions, generally

21. Without limiting the generality of section 14 (1) (c), the Code, or directions, may make provision as to —

(a) the criteria by which the appropriateness of a proposed artificial fertilisation procedure is to be assessed;

(b) the means of determining and evaluating the considerations which should or may be taken into account before an artificial fertilisation procedure is commenced, including the diagnostic procedures involved;

(c) the method by which, and the extent to which, donors or prospective donors of gametes, eggs in the process of fertilisation or embryos are to be assessed or selected;

(d) the practice and procedures to be carried out in relation to the collection, keeping, use and disposal of gametes, eggs in the process of fertilisation or embryos, or for securing that such eggs or embryos are in a suitable condition for implantation;

(e) the responsibilities of persons carrying out any procedures to which this Act applies;

(f) the establishment of a basis for determining questions as to the control of, and the power to deal with or dispose of, gametes, eggs in the process of fertilisation or embryos;

(g) the means of disposal, or prohibitions or restrictions in respect of the disposal, of gametes, eggs in the process of fertilisation or embryos;

(h) limitations to be placed on the use of gametes, eggs in the process of fertilisation or embryos which may be donated by any one individual donor;

(i) the means of identifying, for the purposes of sections 24 and 26, the person or persons on behalf of whom any gametes, egg in the process of fertilisation or embryo are stored, kept for implantation or developed which, in accordance with consents given, may be –

(i) a woman or man; or

(ii) a couple who are married, or in a defacto relationship with each other whether they are different sexes or both female;

(j) the circumstances in which any egg in the process of fertilisation or embryo derived from the use of reproductive technology shall be allowed to succumb;

(k) what, for the purposes of this Act, may constitute an authorized diagnostic procedure in relation to any egg in the process of fertilisation or an embryo or an approved project of research, or may be carried out or performed in any particular kind of research, and what shall not;

(m) the assessment of applications seeking approval to carry out any project of research;

(n) the requirement that prior approval of an Institutional Ethics Committee specified in, or ascertainable by reference to, those

Rules, be a condition applicable to any particular practice, kind of practice or procedure or kind of procedure;

(o) the making, retention and confidentiality of records; and

(p) such other matters relating to the practice of reproductive technology as may be specified in, or are required by or to be carried out or determined in accordance with, the regulations.

When procedures may be carried out

23. An *in vitro* fertilisation procedure may be carried out where —

(a) it would be likely to benefit —

(i) persons who, as a couple, are unable to conceive a child due to medical reasons;

(ia) a woman who is unable to conceive a child due to medical reasons; or

(ii) a couple or a woman whose child would otherwise be likely to be affected by a genetic abnormality or disease;

(b) each of the participants required to do so has given an effective consent;

(c) the persons seeking to be treated as members of a couple are —

(i) married to each other; or

(ii) in a de facto relationship with each other and are of the opposite sex to each other;

(d) the reason for infertility is not age or some other cause prescribed for the purpose of this paragraph; and

(e) consideration has been given to the welfare and interests of —

(i) the participants; and

(ii) any child likely to be born as a result of the procedure,

and in the opinion of the licensee that consideration does not show any cause why the procedure should not be carried out,

but not otherwise.

Storage

24.(1)In relation to the storage of any eggs, sperm, egg in the process of fertilisation or embryo —

(a) the primary purpose stated in any consent to the storage of an egg in the process of fertilisation or any embryo must relate to the probable future implantation of that egg or embryo; and

(b) the Code may make provision as to what, in particular circumstances, constitutes an excessive time for the storage of —
(i) eggs or sperm;

(ii) an egg in the process of fertilisation; or

(iii) an embryo,

but no egg in the process of fertilisation or embryo shall be stored for a period in excess of the permitted storage period except with the approval of the Council under subsection (1a).

(1a)The Council may approve in writing a longer storage period for an egg in the process of fertilisation or an embryo if it considers that there are special reasons for doing so in a particular case.

(1b)An approval under subsection (1a) may be subject to conditions and is to specify the date on which the longer storage period ends.

(1c)An approval under subsection (1a) can only be given before the end of the permitted storage period, or if a longer storage period has previously been approved under subsection (1a), before the end of that period.

(1d)The Council is to inform the Minister of each approval given under subsection (1a), but in such a manner that the identity of the biological parents cannot be ascertained from the approval.

(2)Where the person or persons on behalf of whom the storage of any gametes, egg in the process of fertilisation or embryo was undertaken have died, or the licensee otherwise does not have and can not obtain any instructions or consent required for the purposes of this Act in relation to the storage the control and the power of disposal are deemed to vest in the Commissioner of Health who shall, subject to section 22 (6) and any instructions or conditions to which effect may then be given, direct that any such egg or embryo be made available for the purpose of providing treatment for a specific recipient, unless a court of competent jurisdiction otherwise requires.

(3)Where a licensee is directed by the Commissioner to allow any gametes, egg in the process of fertilisation or embryo to succumb the licensee shall be required thereupon to comply and shall not be liable to any person for so doing.

(4)In this section —

``**permitted storage period''** means —

(a) in the case of the storage of an egg in the process of fertilisation or embryo starting before 8 October 1993, the period ending 7 October 1996; and

(b) in any other case, 3 years.

…

Control, dealing and disposal in relation to an egg in the process of fertilisation or an embryo

26.(1)In relation to rights to the control of, or power to deal with or dispose of, any egg in the process of fertilisation or embryo that is outside the body of a woman —

(a) each person on whose behalf it is developed or is being, or is to be, kept for implantation has, subject to section 7 (1) (j), the right to decide how an egg in the process of fertilisation or embryo is to be dealt with or disposed of, so that —

(i) such a person shall have, while storage continues, the right to review the decision to store from time to time and may withdraw consent or vary the terms of any consent; and

(ii) any question as to the nature or extent of the respective rights or powers may, subject to subsection (2), be referred to a court of competent jurisdiction;

(b) in the event of the death of one member of a couple in whom the rights are vested, those rights vest solely in the survivor;

(c) where from any gametes an egg in the process of fertilisation or embryo is developed, whether or not with effective consent, the individual rights of a gamete provider or person to whom the gametes were provided and of a licensee cease at the moment fertilisation begins and the rights thereafter vest jointly in the couple on whose behalf that egg or embryo was ~~developed;~~ developed, or vest in the woman on whose behalf that egg or embryo was developed;

(d) where an egg in the process of fertilisation or an embryo has been developed on behalf of a couple or a woman and is no longer required for that purpose, if all the participants in a proposed procedure give an effective consent it may be donated for the purpose of providing treatment for a specific recipient; and

(e) on the commencement of an implantation procedure the rights in an egg in the process of fertilisation or in an embryo vest in the woman receiving it, whether or not —

(i) that recipient was eligible to undergo the procedure;

or

(ii) any consent required was given or, if given, was effective.

(2)Where rights in relation to an egg in the process of fertilisation or an embryo are vested in a couple and the couple disagree about its use or continued storage, the Commissioner of Health shall, on application by a member of that couple, direct the licensee storing the egg or embryo to ensure that the storage is maintained subject to —

(a) payment of the proper charges of the licensee for the storage;

(b) any limitation as to the time of storage prescribed or determined in accordance with section 24 (1) (b); and

(c) any order made by a court of competent jurisdiction which otherwise requires.

Interpretation Act 1984

13A. References to de facto relationship and de facto partner

(1) A reference in a written law to a de facto relationship shall be construed as a reference to a relationship (other than a legal marriage) between 2 persons who live together in a marriage-like relationship.

(2) The following factors are indicators of whether or not a de facto relationship exists between 2 persons, but are not essential —

(a) the length of the relationship between them;

(b) whether the 2 persons have resided together;

(c) the nature and extent of common residence;

(d) whether there is, or has been, a sexual relationship between them;

(e) the degree of financial dependence or interdependence, and any arrangements for financial support, between them;

(f) the ownership, use and acquisition of their property (including property they own individually);

(g) the degree of mutual commitment by them to a shared life;

(h) whether they care for and support children;

(i) the reputation, and public aspects, of the relationship between them.

(3) It does not matter whether —

(a) the persons are different sexes or the same sex; or

(b) either of the persons is legally married to someone else or in another de facto relationship.

(4) A reference in a written law to a de facto partner shall be construed as a reference to a person who lives, or where the context requires, has lived, in a de facto relationship.

(5) The de facto partner of a person (the **"first person"**) is the person who lives, or lived, in the de facto relationship with the first person.

".

INFORMATION

Information: Clinic Protocol Manuals:

1. General Introduction

Many of the following details for inclusion in clinic protocol manuals will already be contained in your current clinic protocol manuals. However the details set out here are provided to clarify what particular details of your clinic's protocols the Reproductive Technology Council (Council) expects to find in each clinic's protocol manuals.

As these detailed requirements have not yet been formalised as requirements under the *Human Reproductive Technology Act 1991* (HRT Act), they will simply be reviewed and discussed with you when preparing recommendations for the impending re-licensing of each clinic with a view to formalising the requirements and formal approval of the relevant sections of your protocols in the future.

Clinic protocol manuals must comply with RTAC/NATA standards generally (Directions 1.1,1.3). However, the protocols for which approval of the Reproductive Technology Council (Council) is essential are limited to those to which the requirements of the *Human Reproductive Technology Act 1991*[1] (HRT Act) are relevant.

Details will be set out later in this document, but generally the requirements will be for all relevant *routine laboratory procedures* to be documented in a detailed manual for which the approval of Council is required (Direction 9.1). In addition the manuals should contain the details set out below relating to *management and staffing* of the clinic. The manual should also include details of any *innovative procedures* or *research* being carried out subject to the specific approval of the Council. This may require inclusion of some clinical details (such as clinical criteria relevant to patient selection for application of an approved innovative procedure). Details of other *clinical* protocols of interest are also set out below. Whether further clinical details should be documented and reviewed by the Council is a matter still under consideration by the Council.

Directions 9.2 and 9.3 set out the processes to be adopted by licensees when changes or additions to relevant procedures in the clinics are contemplated. Guideline 9.2 explains the difference between procedures suitable for General or Specific approval. These mechanisms leave potential for the licensee's judgement to be exercised as to which changes may be introduced without specific prior approval, but also ensure that all changes are ultimately approved by the Council (Directions 2.29(v), 2.35, 2.36).

All changes to relevant protocols, patient information and consent forms must be recorded in the clinic's protocol manual, permanently annotated with date and version. All significant changes to procedures are to be notified at least at the time of annual reporting (Direction 2.29(v)).

[1] Relevant sections of the *Human Reproductive Technology Act 1991* and Directions will be quoted

Where relevant the protocol manual should refer to appropriate sections of the HRT Act and directions and use cross-referencing to other sections of the manual.

2. Protocols relating to Management and Staffing

(Ss. 29(5)(b); 51(2)(a))
RTAC guidelines 1.1-1.8

2.1. Protocols setting out the requirements to **notify** Commissioner of Health of changes in circumstances or details of the licensee to operations at the clinic should be set out clearly and complied with (Directions 2.32-2.34, 2.36) (RTC[2]).

2.2. **Organisational charts** and **JDFs** should set out relationships and responsibilities for all staff. (RTC)

JDFs should be included for the person responsible (S.51); the medical director; other medical staff; nursing staff; laboratory manager; embryologists; clinic counsellor; etc as required by RTAC. (RTC)

2.3. Protocol establishing a program for regular **staff meetings** and the keeping of records from those meetings showing dates; attendance; matters discussed. (RTC)

2.4. A program for **staff training** and keeping of records from these training programs showing dates; attendance; matters covered. (RTC)

2.5 Protocols for regular **QA** of laboratory procedures and record keeping from these. (RTC)

3. Details of Processes for Ensuring Informed Consent of all Participants

3.1. **Information sheets for patients** that provide information about all treatments and procedures that are subject to the HRT Act (all artificial fertilisation procedures, storage of gametes and embryos and all other uses of gametes and embryos), with appropriate date, version and authorisation. Where relevant these should be written in accordance with and refer to the Directions (Directions 4.1-4.2) (RTC);

3.2. **Consent forms** relevant to treatments and procedures as above, with appropriate date, version and authorisation (RTC); and

3.3. Details of the manner in which directions with regard to **counselling** are to be complied with (Directions 5.1-5.8) (RTC).

4. Details of Clinical Protocols

In relation to **clinical** matters and the **responsibilities of medical practitioners** under the Act, there should be-

4.1. A JDF for the Medical Director, providing evidence that they meet RTAC standards (RTC);

[2] RTC indicates that this section of the Protocol Manual must be reviewed and approved by the Council. Other sections detailed here are also of interest to the Council.

4.2. A protocol for **training** and **oversight** of other clinicians by the Medical Director (RTC);

4.3. Protocols for **medical practitioners**, referring them to matters elsewhere in the Protocol Manual that they are **explicitly responsible for under the Act**, for example relating to -

Consents, information giving and counselling generally (Directions s.3,4,5)

The responsibility of medical practitioner for assessment of eligibility and keeping of records about this; treatment details and outcomes (S.23, 44(1)(b); direction 7.2)

The requirement for a six month cooling off for known donor, fresh oocytes (direction 5.8)

The minimum age for donation (7.1)

The limit to repeated ovarian stimulation (Direction 8.4)

The prohibition on posthumous use of gametes (Direction 8.5)

The prohibition on development of embryos other than with a view to future implantation (8.6)

Protocols and limitations on import and export of donated material (directions 6.1-6.4)

The limitation on export of embryos for purposes that would be against the law in WA (eg surrogacy; embryo research and PGD).

4.4. Other **clinical** protocols of interest-

What medication protocols are used for Flare Up, Down Regulation etc.

What criteria are used to determine when cycles are to be cancelled prior to OPU to prevent OHSS development.

What criteria are used to determine when all embryos will be frozen to prevent OHSS.

What criteria are used to determine when cycles are to be cancelled as not enough follicles are developing.

Information: Multiple Pregnancies

Multiple pregnancies

How do multiple births occur?

There are two processes which can result in a multiple pregnancy

- One fertilised egg splits very early in development to form two or more identical (monozygotic) multiples. These children have the same genetic make up.
- A menstrual cycle produces two or more eggs which are fertilised, implant and develop in the uterus at the same time. Like all siblings, these children have, on average, half their genes in common and are known as fraternal or di/tri/etc - zygotic twins, triplets or higher multiples.

How frequent are multiple births?

In the general population the multiple birth rate varies depending on ethnic background and increases with maternal age. In Western Australia the proportion of infants from multiple pregnancies has risen from 2% to almost 3% over the past two decades. The increase has been due to an increase in maternal age and the impact of infertility treatments.

The use of drugs to stimulate the ovary usually results in the production of a number of eggs in one cycle which increases the chance of a multiple conception.

The multiple birth rate following IVF and ICSI is determined by the number of embryos that are implanted. In Western Australia approximately 22 per cent of babies born following these procedures were from multiple pregnancies (RTC Annual Reports). Most multiple births resulting from infertility treatments are fraternal, although there is a small increase in the rate of identical twinning.

What are the risks associated with a multiple pregnancy?

Risks for the baby include:

- **Preterm birth**

  Approximately 7% of singletons, 50% of twins and virtually all triplets and higher multiples are delivered before 37 weeks of gestation. The rate of delivery before 33 weeks gestation is 1.3% in singletons and 15% in multiples.

- **Low birthweight**

  Weight at birth depends on gestational age at delivery and growth rate. Multiples tend have a low birth weight primarily because they are often delivered preterm. However they also grow more slowly, especially in the latter part of pregnancy, due to limits on the maternal supply of nutrients and space within the uterus. Approximately 5% of singletons and 50% of multiples weigh less than 2500 grams at birth and approximately 1% of singletons and 14% of multiples have birth weights under 1500grams.

Preterm birth and low birthweight are associated with increased risks of death and neurological impairment. Hence these babies are more likely to be admitted to a to a high-risk nursery.

- **Perinatal death**

Perinatal mortality, which includes stillbirths and deaths before the twenty eighth day of life, is more frequent in infants from multiple births than in singletons. In WA from 1990-2000, 1.2% of singletons, 4.7% of twins, 11.6 % of triplets and 17.8% of higher multiples died in the perinatal period.

- **Cerebral Palsy**

Neurological impairment is also more common in children from multiple pregnancies. The rate of cerebral palsy is approximately 2 per 1000 in singleton children (range 1-3, WA 1.6). The risk increases 4-5 fold in twins and 17-20 fold in triplets.

Most of the increased risk of early death and cerebral palsy is explained by the higher rate of preterm birth in multiples, but there is also a small increase in risk, especially in monozygotic twins, for infants born at term.

- **Rates of perinatal death or cerebral palsy per pregnancy**

Since each twin or triplet in a multiple pregnancy carries a separate risk, the rates of adverse outcome per multiple pregnancy are considerably greater than the risks for each infant. The risk of at least one death or case of cerebral palsy per pregnancy is 1.7% for a singleton, 10% for a twin and 19% for a triplet pregnancy.

- There is also an increase in the risk of speech and reading problems in toddlers from multiple births.

Increased risks for the mother during multiple pregnancy include

- High blood pressure
- Severe bleeding after delivery
- Gestational diabetes
- Premature labour
- Higher caesarean section rates

Possible problems for the family after delivery

- Fatigue and sleep deprivation in the early stages after discharge from hospital
- The financial burden in providing for two or more children

These considerations are particularly important in triplet or higher order pregnancies.

APPENDIX 6

PUBLICATIONS: REPRODUCTIVE TECHNOLOGY COUNCIL

PUBLICATIONS:
REPRODUCTIVE TECHNOLOGY COUNCIL

1. A Summary of the Human Reproductive Technology Act (Booklet).
2. Cloning, Stem Cell Research and Transgenics: Proceedings from the seminar convened by the Reproductive Technology Council in 2002. Reproductive Technology Council, Perth. ISBN 0 7307 0099 2.

3. Questions and Answers on the Donation of Human Reproductive Material: (Booklet) revised 2002.

4. Donor Insemination: The facts (leaflet).

5. Semen Donation: The facts (leaflet).

6. What the Human Reproductive Technology Act Means for You (leaflet).

7. Talking to Children about Donor Conception Western Australian Reproductive Technology 2002 (leaflet).

8. Infertility Counselling and the list of Approved Counsellors: (Flier) revised July 2002.

9. Infertility Information: General information and support for infertility, and patient rights and dealing with concerns about services you have received. (Leaflet): revised 2002.

10. Life after ART Developing Families (2002). Proceedings from a seminar convened by the Reproductive Technology Council in 2001. Reproductive Technology Council, Perth. ISBN 0 7307 0095 X.

11. Assisted Reproduction: Considering the interests of the child (2000). Proceedings of a seminar convened by the Reproductive Technology Council in 1999. Reproductive Technology Council, Perth. ISBN 0 7307 0095 X.
12. Surrogacy: from different perspectives (1998). Proceedings of a seminar convened by the Reproductive Technology Council in 1997. Reproductive Technology Council, Perth. ISBN 0 7307 0090 9.

13. ICSI (Intra-cytoplasmic sperm injection): Weighing up the benefits and risks of this innovative treatment for male infertility (1997). Proceedings of a seminar convened by the Reproductive Technology Council in 1996. Reproductive Technology Council, Perth. ISBN 0 646 32138 2.

14. Genetic Selection through Reproductive Technology: State of the art and implications (1996). Proceedings of a seminar convened by the Reproductive Technology Council and the Hereditary Disease Unit in 1994. Health Department of WA, Perth. ISBN 0 7309 8379 X.

15. Age and Assisted Reproduction: Contributions to the ethical debate (1994). Invited papers from a workshop convened by the Council in April 1994. Reproductive Technology Council, Perth. ISBN 0 646 23185 5.

16. Discussion paper on Human Embryo Experimentation (Booklet) (1991). Interim Reproductive Technology Council, Perth.

17. A Summary of the Human Reproductive Technology Act (Booklet).

18. Cloning, Stem Cell Research and Transgenics: Proceedings from the seminar convened by the Reproductive Technology Council in 2002. Reproductive Technology Council, Perth. ISBN 0 7307 0099 2.

19. Questions and Answers on the Donation of Human Reproductive Material: (Booklet) revised 2002.

20. Donor Insemination: The facts (leaflet).

21. Semen Donation: The facts (leaflet).

22. What the Human Reproductive Technology Act Means for You (leaflet).

23. Talking to Children about Donor Conception Western Australian Reproductive Technology 2002 (leaflet).

24. Infertility Counselling and the list of Approved Counsellors: (Flier) revised July 2002.

25. Infertility Information: General information and support for infertility, and patient rights and dealing with concerns about services you have received. (Leaflet): revised 2002.

26. Life after ART Developing Families (2002). Proceedings from a seminar convened by the Reproductive Technology Council in 2001. Reproductive Technology Council, Perth. ISBN 0 7307 0095 X.

27. Assisted Reproduction: Considering the interests of the child (2000). Proceedings of a seminar convened by the Reproductive Technology Council in 1999. Reproductive Technology Council, Perth. ISBN 0 7307 0095 X.

28. Surrogacy: from different perspectives (1998). Proceedings of a seminar convened by the Reproductive Technology Council in 1997. Reproductive Technology Council, Perth. ISBN 0 7307 0090 9.

29. ICSI (Intra-cytoplasmic sperm injection): Weighing up the benefits and risks of this innovative treatment for male infertility (1997). Proceedings of a seminar convened by the Reproductive Technology Council in 1996. Reproductive Technology Council, Perth. ISBN 0 646 32138 2.

30. Genetic Selection through Reproductive Technology: State of the art and implications (1996). Proceedings of a seminar convened by the Reproductive

Technology Council and the Hereditary Disease Unit in 1994. Health Department of WA, Perth. ISBN 0 7309 8379 X.

31. Age and Assisted Reproduction: Contributions to the ethical debate (1994). Invited papers from a workshop convened by the Council in April 1994. Reproductive Technology Council, Perth. ISBN 0 646 23185 5.

32. Discussion paper on Human Embryo Experimentation (Booklet) (1991). Interim Reproductive Technology Council, Perth.

APPENDIX 7

FUNCTIONS OF THE COUNCIL AND ANNUAL REPORTING REQUIREMENTS UNDER THE *HUMAN REPRODUCTIVE TECHNOLOGY ACT 1991*

FUNCTIONS OF THE COUNCIL

The general functions of the Reproductive Technology Council are covered in section 14 of the Human Reproductive Technology Act 1991, and in effect set its Terms of Reference. Amendment of the Act in 1996 allowed the Council to grant extensions to permitted storage of embryos to the Council.

Functions of the Council (generally)

"14. (1) Subject to section 13(2), the functions of the Council are-

(a) to advise the Minister-

(i) on reproductive technology and any matter that is connected with, or incidental to, reproductive technology; and

(ii) generally, as to the administration and enforcement of this Act;

(b) to advise the Commissioner of Health-

(i) on matters relating to licensing under this Act, including but not limited to the suitability of any applicant for a licence or of any licensee to carry out particular procedures or approved research and as to the conditions that should be imposed on any licence; and

(ii) generally as to the administration and enforcement of this Act and particularly on disciplinary matters, having regard to any findings made by, or report received from, a committee of inquiry appointed under section 38;

(c) after consultation with bodies representing persons having relevant expertise or sections of the public having appropriate interests, to compile and to cause to be published, to review, and to amend, a Code of Practice which-

(i) sets out Rules, guidelines and relevant information;

(ii) establishes the ethical standards required of licensees, and gives effect to the principles specified in, and the requirements of, this Act; and

(iii) provides for such other matters as may be instructed by the Minister, or as the Council may determine,

regulating the proper conduct of any reproductive technology practice, and of any procedure, required to be licensed and the proper discharge of the functions of the person responsible and other persons to whom a licence applies, having due regard to this Act;

(d) subject to paragraph (e), to encourage and facilitate, research-

(i) into the cause, prevention and treatment of all types of human infertility, adequate attention being given both to female and to male infertility; and

(ii) as to the social and public health implications of reproductive technology;

(e) to ensure that no project of research is carried out by or on behalf of a licensee upon or with-

(i) any egg collected in the course of an *in vitro* fertilisation procedure;

(ii) gametes intended for subsequent use in an artificial fertilisation procedure;

(iii) any egg in the process of fertilisation;

(iv) any embryo; or

(v) any participant,

otherwise than in accordance with this Act and pursuant to a general or specific prior approval given by the Council;

(f) to consider applications for, and where proper grant, approval to carry out research to which paragraph (e) applies;

(g) to promote informed public debate, and to consult with bodies representing the public or sections of the public, on the ethical, social, economic and public health issues that arise from reproductive technology;

(h) to communicate and collaborate with other bodies having similar functions, in Australia and elsewhere,

and, generally, to give effect or to cause effect to be given to the objects of this Act.

(2) The Council shall not grant approval to any research being conducted, or any diagnostic procedure to be carried out, upon or with an egg in the process of fertilisation, or any embryo, unless the Council is satisfied-

a) that the proposed research or procedure is intended to be therapeutic for that egg or embryo; and

b) that existing scientific and medical knowledge indicates that no detrimental effect on the well-being of any egg in the process of fertilisation or any embryo is likely thereby to occur.

(3) Where a person contravenes-

(a) any provision of, or requirement under, this Act, not being a direction; or

(b) any direction given by the Commissioner, being a direction which is consistent with the Code or is not inconsistent with-

(i) ethical guidelines laid down by the National Health and Medical Research Council, as for the time being prescribed;

(ii) criteria established by the Reproductive Technology Accreditation Committee for the Fertility Society of Australia, as for the time being prescribed; or

(iii) a provision of, or any principal set out in, or requirement under, this Act, as from time to time amended,

the Council shall endeavour to ensure, if necessary by disciplinary action under section 38, that effect is given to that provision, requirement or direction."

Functions of the Council in relation to permitted embryo storage

"24. (1) In relation to the storage of any eggs, sperm, egg in the process of fertilisation or embryo -

(a) the primary purpose stated in any consent to the storage of an egg in the process of fertilisation or any embryo must relate to the probable future implantation of that egg or embryo; and

(b) the Code may make provision as to what, in particular circumstances, constitutes an excessive time for the storage of -

(i) eggs or sperm;

(ii) an egg in the process of fertilisation; or

(iii) an embryo,

but no egg in the process of fertilisation or embryo shall be stored for a period in excess of the permitted storage period except with the approval of the Council under subsection (1a).

(1a) The Council may approve in writing a longer storage period for an egg in the process of fertilisation or an embryo if it considers that there are special reasons for doing so in a particular case.

(1b) An approval under subsection (1a) may be subject to conditions and is to specify the date on which the longer storage period ends.

(1c) An approval under subsection (1a) can only be given before the end of the permitted storage period, or if a longer storage period has previously been approved under subsection (1a), before the end of that period.

(1d) The Council is to inform the Minister of each approval given under subsection (1a), but in such a manner that the identity of the biological parents cannot be ascertained from the approval."

ANNUAL REPORTING REQUIREMENTS UNDER THE ACT

The requirements for reporting on the use of reproductive technology in the State are set out in section 5 (6) and clause 11 of the Schedule to the Human Reproductive Technology Act 1991, as follows:

"**5(6).** A report on the use of human reproductive technology in the State during the preceding financial year shall be furnished annually by the Council to the Commissioner who shall thereafter submit the annual report required by clause 11 of the Schedule to the Minister who shall, within 14 sitting days after submission of that report, cause copies of it to be laid before each House of Parliament";

and from the Schedule-

"**Annual Report on Reproductive Technology**

11. (1) The report to be furnished by the Council to the Commissioner of Health on the use of reproductive technology in the State and the operations of the Council in the preceding year ending 30 June shall be so furnished by such a date as, in the opinion of the Commissioner, will enable the Commissioner to submit an annual report to the Minister not later than 30 September in each year.

(2) The report to be furnished by the Council to the Commissioner, and the annual report to be submitted to the Minister, under subclause (1)-

(a) shall set out-

(i) any significant developments in the use of, or in the procedures or techniques used in, reproductive technology during the year, whether in the State or elsewhere;

(ii) details of research specifically approved by, or being conducted with the prior approval of, the Council during that year;

(iii) in statistical terms, the activities of persons licensed under this Act and carried on during that year; and

(iv) any discernible social trends that became apparent during that year and are, or may be, attributable to the use of reproductive technology;

(b) shall contain particulars of-

(i) any contravention of this Act, or of any terms, condition or direction relating to a licence or exemption; and

(ii) any other matter within the responsibilities of the Council or the Commissioner,

that is, in the opinion of the Council or of the Commissioner, of significance to the public interest;

and

c) shall, if that is practicable, be combined with any annual report that may be required to be submitted in relation to this Act under the *Financial Administration and Audit Act 1985."*

APPENDIX 8

VOLUNTARY REGISTER

APPENDIX 9

RTC Seminar Held in November 2002

Participants Responses

COUNSELLING SERVICES DURING INFERTILITY TREATMENT

PARTICIPANT RESPONSES

What do you see as the role of counselling in assisted reproductive technology?
Counselling has a definite place in ART.
Counsellor should be considered part of team
Information giving is sometimes perceived as assessment
Counsellor-patient relationship can be tenuous or absent
Role of counsellor as a bridge
Role is to support, educate and inform
The counsellor should be more available during treatment and pre-treatment
There should be more information in General Practitioners' waiting rooms, and more information provided to General Practitioners
Counsellors challenge the focus on the final outcome
Inadequacy of current system, counselling is imperative.

What do patients want from counselling?
Individuality
Ongoing support
Availability when required especially at a time of crisis, eg failed cycle
Continuity of counsellor
More counselling for male partner
List of approved counsellors available to patients
Counselling to be confidential
Patient must have the freedom to complain without fear of retribution
Flexibility
No extra expense
Informality
Not to sense that they are being tested for suitability for treatment
Patient support groups provide informal support

When do patients want counselling?
When they ask for it, including a 1800 number after hours
Nurses are fantastic but busy
Prior to treatment commencement
After pregnancy loss and failed treatment
Follow up after birth.

REGULATING EMBRYONIC STEM CELL RESEARCH

PARTICIPANT RESPONSES

What are your views about stem cell research?
Views of the group about the value placed on the embryos ranged from: human life; potential life; clump of cells; and not human but requiring respect
Allowing embryos to be used for research (not just stem cell research) wants something good to come from a sad situation (i.e. if it is going to die this gives a positive outcome). Language used is similar to discussion about donating organs - possibly similar issues of grief and hope involved
Note apparent preference of using the stem cells to produce knowledge that may help others in the community, rather than concentrating on the donation (eg helping siblings of existing children or helping others in the community) Some may wish to set conditions – i.e. only consent for particular research, eg infertility research.

What counselling/information/support would you consider would be helpful for people when considering donating 'spare' embryos for research?
Pain of relinquishment in adoption: issues may be similar
Issues regarding grief, relinquishment, leaving treatment, etc need to be dealt with; the grief of 'giving up' or moving on
What to tell the children – how to tell children that their sibling embryos were used for research and what that might mean for the children
Different people have different needs/views; there may be differences of opinion between the couple
Need to be clear in information/counselling that an early human life is involved
Counselling needs to challenge; not to simply make people comfortable about a decision they have already made
Scientific issues may need to be addressed, especially if there is a desire to donate embryos for a particular form of research
Considerable problems with embryos from donated gametes – potentially as many as four couples involved to counsel (In stem cell research, all **donors must** give consent prior to donation, so if a couple is donating embryos which were an earlier donation to them, the original donors must also consent to the use of the embryos for research).
Information about the possibility of donating 'spare' embryos for research should be given at the beginning of treatment, when first creating or storing embryos.

Major issues in counselling:

Is the embryo excess to desire to use for own pregnancy?
What are the options for use of the 'spare' embryos -allowed to die, -donated for pregnancy, -use of research (and if the latter, for any research or for a particular type of research).

Who could best provide this counselling?
Need people who understand - ART, relinquishment/grief/ exit counselling, research options It is not likely that all three will currently be found in one person (although some genetic counsellors come close)
Need to consider panels or teams of counselling expertise
Need to suggest that universities offering counselling courses include science issues as elective options in qualifications.
Counsellors should have formal qualifications (as indicated above) and experience

Should counselling be mandatory?
No, but its availability should be mandatory, and this needs to extend beyond one session. 'Mandatory' counselling is a misnomer.
Who pays: Options Medicare as the gift of embryos for research is valuable to the nation Compulsory cost – provision of counselling included in every research application

. INFORMATION PROVIDED BY DONORS AT TIME OF DONATION

PARTICIPANT RESPONSES

Significant issues highlighted included the following:
Updating medical information for past donors;
Donors may find it difficult to tell family members about the donation, particularly in situations where they were guaranteed anonymity at the time of donation;
Recipients are focused on having a child and once they achieve a pregnancy may not wish to discuss donor issues until after the child is born; or they wish to have more information but are reluctant to ask as it may jeopardise their chances in a small donor pool;
Time lag between donation and pregnancy can create a significant age difference between the donor and the offspring;
The information that participants believed would be requested by donor offspring includes: the number of children in donor's family of origin; the number of children born from all the donations; ancestry of donors parents and grand parents; and occupations of parents of donor.