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 2003-2004. 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 2004 and also, as is required, to be laid by the Minister before each House of Parliament.

The area of assisted reproductive technology (ART) this year has been dominated by state level debate on amendments to the HRT Act, which were introduced into the Western Australian Parliament on 26 June 2003. The *Human Reproductive Technology Amendment Act 2004* and the *Acts Amendment (Prohibition of Human Cloning and Other Practices) Act 2004* have now both passed through both Houses of Parliament.

Most significantly, when proclaimed, these amendments will bring the WA legislation into consistency with a nationally agreed legislative scheme that prohibits human cloning and regulation of the use of human embryos in research. The amendments also bring in some other important changes to the law relevant to many IVF participants, such as extending the time embryos may be stored from 3 to 10 years. Council will also be permitted to approve the pre-implantation genetic diagnosis of embryos (PGD), previously prohibited in WA.

A significant implication for licensed ART clinics is that accreditation by the Reproductive Technology Accreditation Committee (RTAC) will be a legal requirement as a condition of licence. The implementation of these amendments will bring new challenges and significantly impact on the work of Council over the coming year.

The work of the Council is not possible without the ongoing support of a significant number of people. Among these I would like to thank Dr Sandy Webb for continuing to provide the Council with expert guidance and for her work with the PGD (Implementation) Technical Advisory Committee. 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 2004

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 2003- 2004, 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 2003 - 2004. Information reported by clinics licensed under the HRT Act, gives summary information about their activities during the financial year 2003 – 2004. 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 2002. In addition the report includes information from a variety of sources about various matters of significance to the public interest in reproductive technology.

The area of assisted reproductive technology (ART) this year has been significantly impacted by the complexities of politics at the state level. Debate centred on amendments to the HRT Act, which were introduced into the Western Australian Parliament on 26 June 2003. The *Human Reproductive Technology Amendment Act 2004* and the *Acts Amendment (Prohibition of Human Cloning and Other Practices) Act 2004* have now both passed through both Houses of Parliament.

Most significantly, when proclaimed, these amendments will bring the WA legislation into consistency with a nationally agreed legislative scheme that prohibits human cloning and other unacceptable practices (such as creating an embryo simply for research) and regulation of the use of human embryos in research. A significant implication for licensed ART clinics of the amendments to the HRT Act is that accreditation by the Reproductive Technology Accreditation Committee (RTAC) will be a legal requirement as a condition of licence.

The amendments also bring in some other important changes to the law relevant to many IVF patients such as extending the time embryos may be stored from 3 to 10 years. As an application for extension cannot be considered after the expiry of the storage period and clinics are no longer able to apply for an extension, people with embryos in storage will need to take the responsibility to keep the clinic informed of any change of their contact details and keep track of the expiry date.

Council will also be permitted to approve the genetic testing of embryos, previously prohibited in WA. Where the embryo is to be implanted, Council approval is to be based on scientific and medical knowledge that indicates the procedure is 'unlikely to leave the embryo unfit for implantation' and there is 'a significant risk of a serious genetic abnormality or disease being present in the embryo'. Importantly these procedures may only be considered for people who are eligible for IVF under the HRT Act, that is they are unable to conceive a child for medical reasons (ie they are infertile), or their child is known to be likely to be affected by a genetic abnormality

or disease. The Council could not approve the use of PGD for sex selection unless it was in association with a serious sex-linked genetic disease. The HRT Act does now allow potential for the Council to approve PGD being carried out in WA, and it is likely that WA clinics will gain approval for some procedures to be carried out for WA patients. It is however likely that, at least initially, approval will be sought for genetic material to be exported for testing in genetics laboratories that are already operating effectively in other states.

There were two significant changes made to the law relating to disclosure of identifying information in cases of donation of human reproductive material. Donor offspring upon reaching the age of 16 may be given identifying information about the donor following approved counselling. A recommendation made by the Select Committee on the HRT Act in their report to the WA Parliament in 1999. Parents who have used donated human reproductive material to form their families may consent on behalf of their minor children for sharing of identifying information about the donor and recipients where both parties request this. This is to follow counselling to address, in particular, what may be in the best interests of the child.

Another change of great importance to some patients is that the amended Act may now allow approval for the use of IVF in the treatment of those whose offspring may be affected not just by a genetic disease, but an infectious disease (such as HIV).

The Commissioner of Health, on the advice of the Council, issued Fertility North Pty Ltd with Practice and Storage Licences for a two-year term expiring on 1 March 2006.

During the year Council continued the research work begun in 2002-2003 into the interpretation of Section 23 of the HRT Act as a response to the difficulties faced by clinics in assessing eligibility for IVF treatment. Stakeholders have been invited to participate in a seminar scheduled for November 2004. This will contribute to the process of informing the Council Working Group in the development of clinical parameters to assist clinics in making decisions on whether participants meet the eligibility requirements of HRT Act in order to access IVF treatment.

As part of the its role in public education the Council in collaboration with the Genomics Directorate of the Department of Health and Murdoch University held a seminar on PGD and changes to the WA legislation where over 300 people attended. Council also collaborated with the Equality Rules community legal education project in conducting a seminar for 50 same sex participants who have formed or intend to form their families using assisted reproductive technology

The Council provided a response to the NSW Department of Health's Consultation Draft Assisted Reproductive Technology Bill 2003. This consultation process will serve to inform the NSW Department of Health on a range of issues relating to the social and ethical aspects of ART, which were identified in a government review as needing to be addressed through specific legislation.

The budget allocation for the Reproductive Technology Unit, which includes funding for all operations of the Council, was $37,393. 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.

MEMBERSHIP OF THE COUNCIL
30 June 2004

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

DEPUTY MEMBERS

Dr Angela Cooney, (Nominee of the Australian Medical Association);
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);
Ms Sonja Lundie-Jenkins, (Nominee of the Health Consumers' Council);
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 2004

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 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; Ms Amalia Burmas (*ex officio) and* Ms Antonia Clissa (*ex officio)*.

SCIENTIFIC ADVISORY COUNCIL

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; 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)

Ms Antonia R Clissa; Senior Policy Officer (Reproductive Technology) and Executive Officer of the Council

Ms Patrice Wringe; Senior Policy Officer (Voluntary Register) until February 2004

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

Ms Joy Foyle; Administrative Officer (0.25FTE).

REPRODUCTIVE TECHNOLOGY COUNCIL 2003/2004
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 $37,393 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	220.00	
FSA Registrations	3590.92	
Travel/Accommodation intrastate		
Travel interstate Airfares Accommodation		
Motor vehicle/Taxis	38.96	
Food supplies/catering	1270.09 38.50 3.55	
Administration and clerical		
TOTAL	**5162.02**	
Purchase of external services:		
Sessional fees: (External Consulting Fees) Reproductive Technology Council Council Committees: Counselling Scientific Advisory Embryo Storage Licensing and Administration Approved counsellors	24,424.00	
External consulting fees and advertising	756.65 454.55	
TOTAL	**25,635.2**	
Other expenses:		
RTC Sponsorship PGD seminar	454.55	
Books/magazines/subscriptions	599.63	
Freight and cartage/ postal	4.55	
Printing and stationery incl. Annual Report Telecommunication expenses	1070.65	
Resource development eg - video	3,500.00	
Total	**5629.38**	
Less credits registrations	**61.82**	
TOTAL	**36,364.78**	
Budget Allocation	**37,393.00**	

OPERATIONS OF THE COUNCIL
1 JULY 2003 TO 30 JUNE 2004

MEETINGS, MEMBERSHIP AND STAFFING

Meetings

The Reproductive Technology Council met on ten occasions during the year, with an average attendance of 81 per cent. The Counselling Committee met on nine occasions; the Scientific Advisory Committee on two occasions; the Licensing and Administration Advisory Committee (Licensing Committee) on one occasion; and the Embryo Storage Committee on seven occasions.

Membership

In October 2003 Ms Patrice Wringe was appointed as the member representing the interests of women and Ms Sonja Lundie-Jenkins was appointed as deputy member representing participants in reproductive technology. Dr Angela Cooney was appointed as deputy member to Dr Mark McKenna representing the Australian Medical Association (AMA)

Staff assisting the work of the Council

There were no changes to the staff assisting the work of the Council. As Research Officer, Ms Amalia Burmas, continued to oversee the Reproductive Technology (RT) Register and liaise with the clinics. As the Deputy Executive Officer Ms Burmas continued to provide a pivotal role to the Council and the RT Unit. As Senior Policy Officer, Ms Antonia Clissa has been responsible for management of the RT Unit and continued to offer policy advice to the Commissioner of Health and Minister for Health. In February 2004 Ms Clissa took over the management of the Voluntary Register. As Executive Officer Ms Clissa has performed executive functions for Council and continued to liaise with licensed clinics, approved counsellors and the Department of Health's legal services.

Ms Patrice Wringe continued to hold a part time position with responsibility to oversee the operations of the Voluntary Register until February 2004.

Ms Joy Foyle, Project Officer, has continued to provide the Council with administrative support for one day a week.

Dr Sandra Webb has continued to work with the Council to provide expert scientific advice and serve on the Council's Scientific Advisory and Licensing Committees. She will also be executive officer for the PGD (Implementation) Technical Advisory Committee.

The Council gratefully acknowledges-

Management support from Ms Merran Smith and Mr Tony Satti, the secretarial support from Ms Denise Jesnoewski and 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 and Ms Daphne Andersen of Legal and Legislative Services.

LICENSING MATTERS

- Renewal of licences for Fertility North Pty Ltd.

The Practice and Storage Licences of Fertility North were due for renewal on 1 March 2004. . On recommendation from the Council the Commissioner of Health granted Fertility North licences for 2 years until the 1 March 2006, to bring them in line with the other WA clinics.

Four medical practitioners requested revocation of their Exemptions from the requirement to be licensed to carry out artificial insemination (Dr LD Brett, TW Cottee, D Mildenhall, T Silbert). During the year there were no new applications for Exemptions.

Information circulated to Licensees

Licensees received interim information concerning proposed changes to Section 49 of the *Human Reproductive Technology Act 1991* (HRT Act) relating to the release of identifying information about donation.

Matters of Public Interest

Possible contravention of statutory requirements relating to eligibility for *in vitro* fertilization (IVF) treatments in matters arising at a clinic was reported but not finalised in 2002-2003. Authorised officers investigated the facts concerning IVF procedures carried out at a clinic licensed under the HRT Act on a woman with a history of serious medical conditions. The woman developed severe complications in the resulting pregnancy. The Commissioner of Health did not give effect to a summary determination against the licensee and person responsible under the licence for contravention of section 23 of the HRT Act, as a result of an apparent inconsistency between the HRT Act and its subsidiary legislation. Following investigation, the clinic introduced new protocols in order to set some parameters for practice in relation to eligibility of participants for IVF.

As a consequence, in March 2004 Council provided advice to the Commissioner of Health anticipating the need for amendment to Direction 7.2. That Direction provides that the licensee must ensure that the medical practitioner treating the patient makes the final decision as to eligibility of any participant to an IVF procedure, on both legal and medical grounds. Effectively, this may limit disciplinary proceedings being successfully brought against any person except the treating medical practitioner, in respect of a contravention of the provisions concerning eligibility for IVF.

Direction 7.2, which is subsidiary legislation, could be seen as limiting the written law under which it is made. The HRT Act enables disciplinary proceedings to be brought against a licensee, person responsible and certain other persons authorised under the

licence (including the treating medical practitioner or Medical Director) for contravention of section 23 of the Act, which concerns eligibility of participants to undergo an IVF procedure.

It is anticipated that changes will be made to the relevant Direction along with amendments to the subsidiary legislation following passage of the *Human Reproductive Technology Amendment Bill 2003* through Parliament.

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 539 applications, 135 more than last year. Of these applications, 215 were made by the participants for whom the embryos were stored and 324 were made by clinics on behalf of participants with whom they could not make contact. Of all applications received, 279 extensions (51.8%) were repeat extensions for a set of embryos that had previously been granted an extension.

The reasons that were provided by participants seeking extensions to the permitted storage period of their embryos have been classified into a number of categories. The majority of participants were considering using the embryos in the future for their own treatment (91.9%). In 0.9 per cent of cases the applicant were planning to or in the process of donating embryos to another eligible couple. Additionally, there were 1.9% indicating they intended to donate their embryos for research should this option became available. In the remaining 5.3 per cent 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 on behalf of the people for whom the embryos are being extended, are usually made in cases where the clinic has lost contact with the participants (84%). In 3.7 per cent of cases clinics applied for extensions on behalf of participants who had consented to the donation of their embryos, but for whom a suitable recipient couple had yet to be found.

In 12.3 per cent 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 (70%) 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 to research (10%), discard them (2.5%) or were undecided (17.5%).

Of the 324 embryo sets extended by Form 9, in 5 of these cases the Council later received the Form 8 application from the patient. In all of these cases the clinic had indicated they had been unable to contact the patients.

It was necessary to convene seven meetings of the Embryo Storage Committee during the year. Of these, one was held during a holiday period where there was a 2 month break between Council meetings. The other six 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 of innovative procedures.

I013 Blastocyst Culture
Hollywood Fertility Centre;
Approved 23/09/2003

I014 ART treatment for couple where the male is HIV positive
Concept Medical Centre;
Approved 08/06/2004

There were no applications received for specific approval of research procedures by the Council during the year. Three approved research projects were completed or cancelled during the year. At the end of the financial year there were eight active approvals for innovative procedures and four active specific approvals for research projects.

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

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

Seminars

PGD (Preimplantation Genetic Diagnosis) and Changes To The Human Reproductive Technology Law In Western Australia.

This public seminar was conducted on 28 May 2004 at Murdoch University cosponsored by the Reproductive Technology Council, Genomics Directorate of the Department of Health and the Genetic Support Council of WA. The seminar focused on assisted reproductive technology and changes to the *Human Reproductive Technology Act (1991)*, which were being debated in Parliament at the time. The amendments once proclaimed will bring Western Australia into line with a nationally agreed legislative scheme that prohibits human cloning and regulation of the use of human embryos in research. The amendments will also make other changes to the law of significance to many IVF participants such as extending embryo storage from 3 to 10 years, allowing genetic testing of embryos previously prohibited in WA and approval for the use of IVF in the treatment of those whose offspring may be affected not just by a genetic disease but also an infectious disease (such as HIV).

Parenting, Reproductive Technology, Counselling and the Law

In October 2003, Council collaborated with the Equality Rules* community legal education project in conducting a seminar for 50 same sex participants who have formed or intend to form their families using assisted reproductive technology. The session outlined the psychosocial implications of family formation using anonymous and known donors, the developmental needs of the children and the legislative requirements for counselling in these circumstances. The feedback for this seminar was extremely positive. *(Equality Rules is joint project of Gay and Lesbian Equality (WA) Inc and supported by Legal Aid WA and Slater and Gordon Lawyers)

Posthumous Conception: Ethics and Practicalities" by Dr Gulam Bahadur (UK)
Council sponsored the plenary session by Dr Bahadur at the Fertility Society of Australia Conference held in Perth in November 2003. This session examined the complexities surround posthumous assisted reproduction and the moral, ethical and legal concerns. Issues of informed consent, legal definition of paternity for those born as a result of such circumstances as well the need to protect the welfare of future offspring. Dr Bahadur stressed the importance of accountability and transparency on the part of the ART clinics. The requirement of sufficient time and the role of counselling to assist the bereaved participants in the decision making process was also highlighted.

Council Initiatives
Dr Jacky Boivin – Visiting Associate Professor from School of Psychology, Cardiff University U.K.
Dr Boivin was invited to address the Council in February 2004 on her research findings concerning infertility patients' access to counselling. Dr Boivin has published numerous journal articles on psychosocial issues relating to infertility including counselling/intervention effectiveness, stress levels across stages of IVF.

New South Wales, Department of Health Consultation Draft Assisted Reproductive Technology Bill 2003
The WA Reproductive Technology Council prepared a response, in consultation with the Scientific Advisory Committee and Counselling Committee. The focus of the Consultation Draft Bill was on those aspects of ART services, which are currently unregulated. It does not propose a full licensing system for ART providers, as it is reliant on the fact that the clinical aspects of ART services are already sufficiently regulated. Council's response included comments on eligibility criteria, consent to the use of gametes and resulting embryos, preparation and decision making counselling in cases of known donation and establishment of a central voluntary register.

RTC Website and Logo
The Council website has been updated and expanded with the assistance of the Department of Health IT Branch. Several new sections have been added so that the website is an educational tool as well as for information dissemination. Council selected a logo developed by the Marketing and Communications Branch of the Department of Health. This has been used in the website design and Council stationery.

Working Group To Clarify Section 23 of the Human Reproductive Technology Act (1991)
During the year Council continued the research work begun in 2002-2003 into the interpretation of Section 23 of the HRT Act as a response to the difficulties faced by clinics in assessing eligibility for IVF treatment. Stakeholders have been invited to participate in a seminar scheduled for November 2004. This will contribute to the process of informing the Council Working Group in the development of clinical parameters to assist clinics in making decisions on whether participants meet the eligibility requirements of HRT Act in order to access IVF treatment.

RELEVANT PRESENTATIONS AND PUBLICATIONS BY COUNCIL MEMBERS AND STAFF

Council members

Associate Professor Jim Cummins

The role of mitochondria in the establishment of oocyte functional competence EUR J OBSTET GYN R B, 115: S23-S29 Suppl. 1 JUL 1 2004

"The Disappearing Male" Serono Symposia International, Esplanade Hotel, Fremantle, organized by Anne M. Jequier and Jim Cummins, 2 November 2003. Proceedings published in Reproduction, Fertility and Development 16 (5) 2004 (http://www.publish.csiro.au/nid/44.htm)

Member of local organizing committee, Fertility Society of Australia 22nd Annual Scientific Meeting, Perth November 2-5 2003.

"PGD (Pre implantation Genetic Diagnosis) And Changes To The Human Reproductive Technology Law In Western Australia" (Jim Cummins - convenor) Kim E. Beazley Lecture Theatre (public seminar as part of the undergraduate course BMS101 - Introduction to the Human Body), 28 May 2004.

Professor Alan Harvey

What's all the fuss about stem cells? *Young President's Organisation (YPO),* Perth, April 2004 (Invited Speaker and Panel Discussion).

Invited to chair symposium and public forum "Pre implantation Genetic Diagnosis and changes to the Human Reproductive Technology law in Western Australia." Murdoch University, 28 May 2004.

Dr Roger Hart

Publications

Hart R. - Unexplained infertility, endometriosis and fibroids. *British Medical Journal* 2003; 327:721-4

Hart R, Hickey M, Franks S. Definitions, Prevalence and Symptoms of Polycystic Ovaries and Polycystic Ovary Syndrome. *Best Practice & Research Clinical Obstetrics and Gynaecology* 2004 (In Press)

McGurgan, P., Maouris P., Hart R., Hammond I., Pavey T., Lowe B. Case Report: En caul delivery of the fetus to facilitate cell salvage. *Australian and New Zealand Journal of Obstetrics and Gynaecology.* 2004 (In Press)

Hart R, Hickey M, Maouris P, Buckett W, Garry R. Excisional surgery versus ablation surgery for the management of ovarian endometriomata. *Cochrane Database of Systematic Reviews (Protocol)* 2004.

Presentations

"Evidence Based Fertility Treatment" King Edward Hospital Grand Round, July 2003.

'Polycystic Ovarian Syndrome' Stars Symposium, Subiaco Theatre, Perth September 2003.

Management of the Endometrium", Australian Society of Ultrasound Medicine, Perth Sept 2003.

"Evidence-Based Medicine Forum - Luteal support". Fertility Society of Australia, Perth November 2003.

"Fertility Options for Women with a Cancer Diagnosis". Australian Oncology Society, Perth November 2003.

"Fertility Options for Women with a Cancer Diagnosis". Oncology Nurses and Pharmacists Society of Australia, Perth July 2004.
"Polycystic Ovarian Syndrome" General Practitioners Seminar Busselton May 2004.
"Fertility options for women undergoing cancer treatment", RL Hutchinson Lecture, Perth 2004.
George O'Neil, Roger Hart, Hulse G, Chiera V, Hanson R, Burton P. Naltrexone and the treatment of PCOS. Fertility Society of Australia, Perth 2003.

Ms Sue Midford
Preparation for Known and Anonymous Donation Seminar - psychosocial and counselling issues and legislative requirements in the use of assisted reproductive technology - 15 October 2003.
Fertility Society of Australia Conference, chaired plenary session "Posthumous Conception: Ethics and Practicalities" by Dr Gulam Bahadur (UK) - Perth, 5 November 2003.

Staff
Dr Sandra Webb
Dr Webb's term on the Australian Health Ethics Committee (AHEC) came to an end this year, but she continued to serve on AHEC's Committee to Review the Ethical Guidelines on Assisted Reproductive Technology (CREGART), reviewing the National Health and Medical Research Council's 1996 *Ethical Guidelines on Assisted Reproductive Technology.* She also continued to serve on the national Gene Technology Ethics Committee and the WA Gene Ethics Committee.

Presentations
'Is it business as usual in Australia's ART clinics?' Scientists in Reproductive Technology Annual Meeting, 1 November 2003.
'The new national legislative scheme banning human cloning and other unacceptable practices and regulating human embryo research'. Gene Technology Ethics Committee, 10 November 2003.
'Controversies surrounding the uses of human embryos: new national legislation'. Glyde In Community Centre, 27 November 2003.
'Stem Cell Legislation' - Young Executives, 29 April 2004.
'Human Assisted Reproductive Technology and the Law' BMS 101 – Murdoch University, 28 May 2004.
'The National Regulation of Human Assisted Reproductive Technology: Is this an attainable goal?' Murdoch University and RTC Seminar on PGD and Changes to the Law, 28 May 2004.

Ms Amalia Burmas
Fertility Society of Australia - Presentation – 'The Plight of Embryos in Storage in Western Australia' – 3 November 2004.
Genesis Newsletter – 'Embryos in Storage in WA' – Summer Edition 2003.

Attendance at relevant meetings by Council members with Council support
The Council sponsored the attendance of the Executive Officer, the Deputy Executive Officer and several Council members to attend the Fertility Society of Australia meeting held 2-5 November 2003 in Perth.

OPERATIONS OF THE COUNSELLING COMMITTEE
1 JULY 2003 – 30 JUNE 2004

Meetings and membership

The Counselling Committee met on 9 occasions during the year. Council extended Ms Colleen Brown's term on the Committee until 30 June 2004. Ms Suzanne Midford continued in her role as chair for the Committee. The rest of the membership remained constant except for Mr Peter Grey Searle (Nominee of the Minister for Community Development) has taken 12 months leave from December 2003. Mr Hans-willem van Hall is representing the Department for Community Development during Mr Searle's absence.

Key Focus Areas

The focus for the Committee has been on planning seminars and resource development for consumers.

The Committee has continued to:

- consider training of counsellors seeking recognition as 'approved counsellors'.
- work on manual for approved counsellors.
- work on upgrading the RTC website and RTC logo
- plan for resource development in the form of a video for same sex parents who have used assisted reproduction for family formation.
- develop information for participants concerning rights in accessing Assisted Reproductive Technology Services.
- plan for a workshop to be conducted on "IVF eligibility issues" later in 2004.

Seminars

Parenting, Reproductive Technology, Counselling and the Law

In October 2003, members of the Counselling Committee gave presentations on the psychosocial aspects of donation and the development needs of children as well as the legislative requirements for counselling for 50 participants. For further information see section on Operations of Council.

Approved Counsellors

Manual for Approved Counsellors

This was completed at the end of 2003 with changes pending due to various sections (such as embryo storage, PGD and access to identified donor information) being impacted by the amendments *to the Human Reproductive Technology Act 1991*, the subject of debate in the WA Parliament throughout the year.

Counselling Services During Infertility Treatment

The Counselling Committee has continued to consider the concern about the role of the counsellor and the level of counselling services received by people in treatment. In February 2004 the Council invited Dr Jacky Boivin, visiting clinical psychologist and Associate Professor at the School of Psychology, Cardiff University to address the Council on her research findings concerning infertility patients access to counselling. Dr Boivin's findings highlighted that there were many patients (~85%) for whom provision of appropriate information may provide enough support to help them through their treatment. However, she also highlighted that counselling was more likely to be accessed if it was being promoted to established patients who were

likely to benefit from counselling. From annual reporting provided by the clinics in this financial year there has been a 20% increase in counselling provided from the previous year. The majority of participants almost eighty eight per cent have had one session of counselling.

The Counsellor as an Integral Member of the Team

The Counselling Committee has been developing an issues paper following recommendations from the Council's audit of counselling, clinic counsellors, and Genesis consumer support group that consideration be given to infertility counsellors becoming an integral part of the clinic team.

Approved Counsellor Applications

The Committee did not receive any new applications for approved counsellors during the year. Council agreed to continue to recognise Ms Helen Mountain as an approved counsellor until 30 June 2005. Ms Elizabeth Webb was granted unconditional approved counsellor status until 30 June 2005 while Council granted Ms Marion Connelly a further 6 months conditional status until December 2004 to comply with quarterly supervision requirements. Ms Jeannie Barnett, Dr Marjorie Collins and Mr Tony White decided not to proceed with their approved counsellor recognition beyond the 12 months conditional period. Council agreed not to continue to recognise Ms Michelle Collins as an approved counsellor as she did not meet the eligibility requirements.

Other Counselling Committee Initiatives

Information Provided By Donors At Time Of Donation

The Counselling Committee has continued to consider how best to collect comprehensive information from donors at the time of donation and has examined information on practices from other countries. Due to the complexity of the task a subgroup is being formed to draw up recommendations for the larger Committee to consider.

Submission to the New South Wales, Department of Health Consultation Draft Assisted Reproductive Technology Bill 2003

The Counselling Committee provided advice on the New South Wales, Department of Health Consultation Draft Assisted Reproductive Technology Bill 2003. The response was incorporated into the Council's submission.

REPRODUCTIVE TECHNOLOGY REGISTERS

Requests for information from the RT Register

Data was provided to the Council during the year to assist in the examination of the use of intra-cytoplasmic sperm injection (ICSI) and trends in embryo storage. With the potential amendments to the HRT Act, allowing embryo research, Council was interested in examining the patterns in storage of embryos and use of stored embryos. Results of this study were presented at the 2003 Fertility Society of Australia Annual Scientific Meeting. Council agreed they would regularly monitor the number of embryos being created for treatment.

Council was concerned about the increasing use of ICSI since its introduction and whether the procedure was being used in circumstances where it had been proven to be effective. Information from the register indicated, that over the study period, ICSI was used in 30.8% of first cycles compared to 39.4% of all cycles. In first cycles where ICSI was used in 90.8% there was a male cause of infertility, which may have affected the ability of the sperm to fertilise the oocyte.

There were four requests from licensed clinics for data from the RT Register. The first request was for information on treatments where participants were seeking treatment as the male partner had had a vasectomy with unsuccessful reversal. The other requests were related to a quality assurance study being conducted collaboratively by three clinics. In these cases the RT Register assisted in confirming details of birth defects in offspring born after ART.

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 comparisons of fresh versus frozen transfer, information about the age of women undergoing ART treatment, the number of donor offspring born in WA and the number of babies born from different ART procedures.

The report of the 2002 data from the RT Register can be found in Appendix 4.

Research involving RT Register data

During the year there were two research projects commenced using data from the RT Register. Ms Amy Wiltshire, a PhD student in the School of Public Health at the University of Western Australia, was undertaking the first. This study would examine the impact of ART on the health of women participants. The RT Register data would be linked to morbidity data, the WA Cancer Registry and the Mental Health Information System to study health outcomes.

The second project involved data derived from a previous study using data from the RT Register. This previous study, conducted by Dr Carol Bower and Ms Michele Hansen, from the Institute of Child Health Research, examined outcomes of ART children born in WA. The researchers were seeking approval to provide non-identifying data on children identified to have Beckwith-Wiedemann syndrome, to a Victorian research team. This collaborative study would examine the prevalence of Beckwith-Wiedemann syndrome in ART children.

Voluntary Register of Information about Donation in Assisted Reproduction

From the launch of the Voluntary Register (VR) in November 2002 to the end of June 2004 there have been a total of 67 requests for applications to join the register. There have been 38 registrants and 29 applications not returned. The registrants have included 20 parents of donor-conceived offspring compared to 11 in the previous year, 15 donors compared to 9 in the previous year and 3 donor-conceived adults and none in the previous year. From the requests for applications to join the register but not returned there were 17 parents of donor-conceived offspring, 11 donors and 1 donor conceived adult.

SIGNIFICANT DEVELOPMENTS IN ASSISTED REPRODUCTIVE TECHNOLOGY DURING THE YEAR

AMENDMENTS TO WA'S HUMAN REPRODUCTIVE TECHNOLOGY ACT 1991

Amendments to WA's Human Reproductive Technology Act 1991 (HRT Act) were passed in State Parliament on 1 July 2004. Most significantly, when proclaimed, these amendments will bring the WA legislation into consistency with a nationally agreed legislative scheme that prohibits human cloning and other unacceptable practices (such as creating an embryo simply for research) and regulates the use of human embryos in research.

Donating Embryos For Research

Where embryos that have been created for use in fertility treatment are no longer required, the people who have responsibility to make decisions about the embryos (usually the couple for whom they were created) have several options. They may ask for the embryos to be removed from storage and allowed to die; they may donate them to another couple for treatment; or, as a consequence of the recent amendments, they may now donate them for use in research or in the training of clinic staff etc.

Any use of embryos in research is strictly regulated and requires a licence issued by the National Health and Medical Research Council's Embryo Research Licensing Committee. The consent to donate embryos for such a use is to be a two-step process. First the embryos must be declared to be 'excess ART embryos' and further consent to use the embryos must be quite separate and explicitly relate to a particular project. To be licensed, the research must use the minimum number of embryos required, have prior approval by a Human Research Ethics Committee, and be expected to contribute to a 'significant advance in knowledge or improvement in technologies for treatment'.

Changes Relating To Embryo Storage

The amendments also bring in some other important changes to the law relevant to many IVF patients, extending the time embryos may be stored from 3 to 10 years and clarifying who may apply to the Reproductive Technology Council (Council) for an extension to this. The Council may grant an extension on a case by case basis, but there must be 'special reasons' for them to do so.

As an application cannot be considered after the expiry of the storage period and clinics are no longer able to apply for an extension, people with embryos in storage need to take the responsibility to keep the clinic informed of any change of their contact details and keep track of the expiry date. Clinics will attempt to contact people with stored embryos at least three months prior to the expiry date, to remind them of their responsibility and the consequences if no extension is obtained (that is, the embryos must be removed from storage and allowed to die if no further instructions are obtained from the people responsible for the embryos).

Pre-Implantation Genetic Diagnosis (PGD)

The amendments will also permit the Council to approve the genetic testing of embryos, previously prohibited in WA. Where the embryo is to be implanted, Council approval is to be based on scientific and medical knowledge that indicates the procedure is 'unlikely to leave the embryo unfit for implantation' and there is 'a

significant risk of a serious genetic abnormality or disease being present in the embryo'.

Importantly these procedures may only be considered for people who are eligible for IVF under the HRT Act, that is they are unable to conceive a child for medical reasons (ie they are infertile), or their child is known to be likely to be affected by a genetic abnormality or disease. The Council could not approve the use of PGD for sex selection alone, that is unless it was in association with a serious sex-linked genetic disease.

The role of the clinical geneticist and specialised genetic counselling in referring participants for embryo diagnostic procedures and preparing them for decisions to be made, and their role in assessing the seriousness of a particular genetic abnormality for a particular participant is still to be considered by the Council. It is likely that requirements will vary, depending on the circumstances (eg whether the test is to be carried out to detect a serious genetic disorder known to occur within a family or to screen the embryos for an older woman already on the IVF program).

The HRT Act does now allow potential for the Council to approve PGD being carried out in WA, and it is likely that WA clinics will gain approval for some procedures to be carried out for WA patients. It is however likely that, at least initially, approval will be sought for genetic material to be exported for testing in genetics laboratories that are already operating effectively in other states.

Changes To The Criteria For Eligibility For IVF

Another change of great importance to some patients is that the amended Act may now allow approval for the use of IVF in the treatment of those whose offspring may be affected not just by a genetic disease, but an infectious disease (such as HIV).

RTAC Accreditation

A significant implication for licensed ART clinics of the amendments to the HRT Act is that accreditation by the Reproductive Technology Accreditation Committee (RTAC) will be a legal requirement as a condition of licence. For clinics that are RTAC accredited already this has no immediate practical ramifications.

Disclosure Of Identifying Information In Cases Of Donation Of Human Reproductive Material

There were two significant changes made to the law relating to disclosure of identifying information in cases of donation of human reproductive material. Donor offspring upon reaching the age of 16 may be given identifying information about the donor following approved counselling. This was a recommendation made by the Select Committee on the HRT Act in their report to the WA Parliament in 1999. Parents who have used donated human reproductive material to form their families may consent on behalf of their minor children for sharing of identifying information about the donor and recipients where both parties request this. This is to follow counselling to address, in particular, what may be in the best interests of the child.

SUMMARY REPORTS FROM RELEVANT CONFERENCES ATTENDED BY COUNCIL MEMBERS

Annual Scientific Meeting Of The FSA - Perth, 2-5 November 2003

Council Member: Professor Jim Cummins

The annual meeting of the Fertility Society of Australia was held in Perth for the first time in 13 years. Despite distance and the competing attractions of the rugby World Cup, 380 delegates attended, mostly from Australia and New Zealand. The general opinion was that it was one of the best-organised and most interesting meetings ever. As one of the Organising Committee, I can attest that this was largely due to the energy and dedication of the Chair, Dr Anne Jequier. The Serono Symposium held the day before the FSA meeting itself was entitled 'The Disappearing Male' with an attendance of 166. Speakers included Peter Schlegel and Steven Ward from the USA, Jenny Graves, Roger Short, David Handelsman, David Cram and Brian Setchell from Australia. The papers from this meeting will appear in a special edition of the journal Reproduction, Fertility and Development, and I was very pleased with the meeting. Anonymous feedback from delegates to Serono was also very positive.

From the perspective of the Reproductive Technology Council, one highlight of the FSA was a talk by Magdalena Zernicka-Goetz from Cambridge on the establishment of embryonic axes in the mouse. This is a hotly debated topic: some evidence suggests that the planes of division of the early mammalian embryo are predetermined by factors laid down in the cytoplasm of the oocyte before fertilization, yet can be modulated by the position of sperm entry. This in turn can bias or influence which of the cells in the early embryo are more likely to develop into the embryo proper as against the extraembryonic tissues such as the placenta. While such early positional signals can influence the fate of embryo cells, it is also evident from experimental embryology that mammalian cells retain totipotency until around days 3–4 of development when the embryo can split to form identical twins, or when two or more embryos can fuse to form a mosaic individual. Thus, the embryo retains considerable plasticity and can recover its capacity to self-organise despite manipulation or loss of a part. This has profound implications for techniques such as ICSI and embryonic cell biopsy for pre-implantation genetic diagnosis: how can we minimise the potential harm caused by such interventions? This is a challenging area for science, ethics and the law.

In a related area, the Most Reverend Dr Peter Carnley AO, Archbishop of the Anglican Diocese of Perth discussed the relationship between fertilisation and the beginning of life. His suggestion that individuation (not 'life') begins when the foetus assumes a recognisable shape and a central nervous system at around two weeks of age was based on traditional views of ensoulment going back to Aristotle, which are still held by Judaism and Islam. I should point out here that the Catholic Church's view on fertilization as the 'beginning' of individual life was finalised only in 1854 as the Doctrine of the Immaculate Conception. The Archbishop's comments caused a storm of protest from various 'right to life' protagonists in the media following the conference. However, this view accurately reflects much current legislation around the world including Australia, which generally sets a limit of two weeks of age for approved embryo experimentation.

Dr Gulam Bahadir discussed the ethical problems relating to posthumous conception, a topic that will almost certainly involve the Council at some stage. Monika Ward from the University of Hawaii spoke on the damage to sperm DNA that can arise among infertile men or in response to sperm manipulations *in vitro*. This is also especially relevant to the Council as ICSI is now more commonly used to treat infertility than classical IVF. On a related issue, Michelle Hansen of the TVW Telethon Institute for Child Health Research gave an update on the land-breaking research from Western Australia showing a significantly increased risk of major birth defects for children born out of assisted reproductive technology. While not welcomed by many in the 'IVF Industry' it is clear that vigilance and ongoing monitoring of these children should be a high priority perspective of the Council. I thank the Council for supporting and encouraging me to attend.

Annual Scientific Meeting Of The FSA - Perth, 2-5 November 2003 and satellite meetings

Dr Sandy Webb Senior Policy Officer, Reproductive Technology

Scientists in Reproductive Technology Meeting

Included in presentations to scientists who attended this meeting was a session on 'Perspectives on New Embryo legislation'. Speakers were Professor Jock Findlay (long-time member of the FSA and current Chair of Victoria's Infertility Treatment Authority (ITA) and Chair of the new National Health and Medical Research Council's Embryo Research Licensing Committee), Ms Helen Szoke (CEO of ITA) and Dr Sandy Webb. Dr Findlay provided a summary of the processes to be gone through by applicants for embryo research approval and Ms Szoke spoke about regulatory processes and the role of regulation more generally. Dr Webb discussed a number of practical aspects of the new regulatory regime where those in the clinics will need to pay particular attention to the development of and adherence to, protocols, such as in relation to the use of apparently unfertilised eggs or dead embryos for research and in carrying out diagnostic tests on embryos that are biologically unsuitable for transfer.

Dr Adrienne Pope gave a presentation on the incoming new requirements under the Therapeutic Goods Act, which will have a significant impact upon the use of culture media and artificial insemination procedures. Dr Pope will assist clinics in obtaining the appropriate approvals from the TGA and is liaising with the TGA to obtain a reasonable compromise in the requirements, so that daily work in the clinics is minimally compromised by the changes.

Serono Symposium: The Disappearing Male.

This one-day symposium focussed on aspects of male reproductive health, from a population and evolutionary perspective. All speakers provided up to date reviews of their areas of expertise, which included clinical papers on the causes and evaluation of male infertility, as well as some cutting edge areas of research into mammalian sperm chromatin structure and the causes and effects of oxidative stress in the testis.

Jenny Graves' presentation on 'The Disappearing Y Chromosome: Can conversion save it?" was an exciting and fascinating review of the evolution of the human male Y chromosome, which now contains very few of its original genes. Much valuable information comes from comparative genetics.

Dr Roger Short gave and inspiring and controversial talk on 'The HIV pandemic: Preventing infection in men'. Although not yet accepted by the South African Cochrane Review (in the absence of randomised controlled trials), there is evidently a strong epidemiological association between male circumcision and the prevention of HIV. In support of this finding, histological studies of the foreskin show that the inner aspect of the foreskin is relatively thin and non-keratinised, compared with the glans and the outer foreskin. It is also well supplied with Langerhans cells, which have specific receptors for HIV. Dr Short was also promoting another simple and effective measure that may also prove suitable for promotion in developing countries to prevent infection - that is using lemon juice as a microbicidal wash or douche after intercourse. Further research is required in both these areas, but the work and its potential public health implications are exciting.

Peter Schlegel gave a interesting paper on 'Causes of Azoospermia and their management', which may be obstructive or non-obstructive and the importance of medical history, a physical examination and hormone analysis in making the appropriate diagnosis. One important point made was that men with congenital obstructive azoospermia should be tested for the cystic fibrosis (CF) mutation because of the high risk of the male being ad CF carrier. He reported that sperm retrieval success rates vary from 30-70% of men with non-obstructive azoospermia, with pregnancy rates ranging from 20-50%. Techniques being used range from fine needle aspiration, testicular biopsies and micro-dissection of the testis, with the most successful approach being micro-dissection.

FSA meeting

Among the most interesting of the papers was that of Magdalena Zernicka-Goetz, on 'Developing polarity in the mouse embryo'. Her work may have significant implications for ICSI, which she will

begin to explore soon, as it is now evident that polarity is initiated in the mouse embryo from its earliest stages. There are two spatial cues in the mouse blastocyst: one is the animal pole, which is defined by the site of female meiosis and the other is associated with the site of sperm entry. The first cleavage plane is influenced by both of these planes, and one blastomere contributes mainly to the embryonic part of the blastocyst and the other half contributes mainly to the foetal membranes. The interaction of the developing embryo and the uterus is also of interest, as the antero-posterior axis of the embryo is found to be almost perpendicular to the long axis of the uterus.

A presentation by Monash IVF on 'Pre-implantation genetic diagnosis: current and future applications' was of relevance for those of us in WA, where amendments that would allow PGD to be carried out here were before Parliament. This presentation indicated the currently wide range of applications for PGD in practice. Testing for single gene disorders has been carried out there since 1999, and conditions tested for include cystic fibrosis, Huntingdon's and thalassemia. Requests have also been made for testing for pre-disposition to cancer, familial early onset Alzheimer's disease, profound deafness and HLA tissue matching, although approval for this latter condition is only given in Victoria on a case by case basis where there is also a risk of transmission of a genetic disease. Aneuploidy testing is also being carried out, with the main indications being advanced maternal age, repeated IVF failure, repeated miscarriages and known translocations. It was reported that to date there have been 1000 successful PGD's carried out world-wide, with 25% successful pregnancies and 200 healthy babies born.

A presentation from the Fertility Centre in New Zealand outlined a system being used to assess eligibility for the single IVF cycle that is funded by the NZ government to infertile couples, based on a point score which gives priority access to women under 40 years of age, with normal FSH levels and a BMI of <32.

Of great relevance to those of us from WA working towards amendment of the HRT Act was the presentation by Archbishop Carnley, on "fertilisation and the beginning of life'. Dr Carnley set out a detailed argument as to the status of the entity in the test tube, based in part on its genetic uniqueness. Fertilisation and conception are now no longer synonymous and conception must now be considered a process, which is only completed with successful implantation into the uterus. He pointed out that the latin word 'conceptio' means 'I hold on to or retain'. Dr Carnley holds that the developing embryo in the test tube may be considered as human genetic material and he would not rule out using it for research up to 14 days' development.

Debra Gook of Royal Women's Hospital and Melbourne IVF gave an update on experience there with oocyte maturation in xeno-grafted, cryo-preserved human ovarian tissue, based on experience with three patients whose ovarian tissue was grafted into mice. Histological evidence of a response to injected HCG was observed in all cases, indicating that follicles cryopreserved at the primordial stage are capable of developing to the peri-ovulatory stage following xeno-grafting.

Dr Peter Burton of Concept Fertility Centre gave a presentation on assisted hatching (AH), which concluded that the clinical effectiveness of assisted hatching is still questioned, as 370 published studies gave no consensus on the matter. Their own study did not have an appropriate control group but overall their treatment cycles with AH had significantly higher clinical pregnancy rates. Dr Burton reported that there is a need to collect birth outcome data, as an improvement in clinical pregnancy rate does not necessarily flow through to live birth rate.

Michael Davies from SA's reproductive medicine Unit reported on a study of maternal size in pregnancy and its mediation of foetal growth. His conclusion was that a variety of factors contribute to the inter-generation growth of women and that maternal factors need to be considered when interpreting associations between size at birth and adult health.

Dr Bahadur of the Royal Free & University College Medical School, UK, spoke on 'Posthumous conception: the ethics and practicalities'. He spoke on the motivating factors and some of the surrounding legal and ethical issues. He predicted that in the UK it is only a matter of time before there is a case that will clarify the property status of gametes and embryos.

REPRODUCTIVE TECHNOLOGY IN THE PRESS

Assisted Reproductive Technology and Legislation

Western Australian Law

The West Australian newspaper reported on the introduction of the Human Reproductive Technology Amendment Bill 2003, into Parliament on 1 July 2003. The legislation was introduced to bring WA into line with new Commonwealth laws. The Bill included a prohibition on human cloning and amendments that would allow people to consent to research on embryos considered surplus to their IVF requirements. The Bill also included proposed amendments, which would permit the screening of embryos before they are implanted into the uterus. The Bill made clear that their had to be a significant risk of a serious genetic disease, such as Huntington's disease or muscular dystrophy, being present in the embryo before permission would be granted to test embryos. A conscience vote will be allowed which means politicians will not have to vote on party lines.

On 14 October 2003, a small group of MPs revealed amendments their proposed amendments to the Human Reproductive Technology Amendment Bill which would mean that women in IVF programs would be told which life-threatening disease they could screen their embryos for. The MP's from across the political spectrum believed diseases, which could be tested for, needed to be specified to stop widespread screening, which they believe could lead to creation of designer babies. However, Health Minister Jim McGinty said that the aim of the Bill was to provide consistency between pre-implantation testing of embryos and prenatal testing of foetuses at 12 to 15 weeks. This particular amendment was defeated 30 votes to 12 in the Legislative Assembly. However, two major amendments were passed, one to ban human embryos from being used in the testing or manufacture of cosmetic products and the other allowing scientists and medical staff to refuse to participate in research involving embryos.

Italian Law

Italy now has Europe's most restrictive laws on assisted reproduction. The law restricts fertility treatment to heterosexual couples that live together and exclude homosexuals and grandmothers. They ban sperm and egg donation, surrogate motherhood, freezing embryos, pre-implantation genetic diagnosis, experiments with embryos and cloning of any kind. Fertility doctors are forbidden to create more than three embryos at a time and all must be implanted in a woman's womb. After a woman's eggs have been fertilised, she cannot refuse to have all the embryos implanted. The 24,000 frozen embryos which already exist in Italy will be put up for "adoption" and frozen embryo banks will be closed.

German Law

Germany has some of the strictest laws in Europe in reproductive medicine. However, an overview of contemporary German bioethics in the latest issue of the journal the New Atlantis reports that pressure is building for a less restrictive view of bioethics to allow Germany to compete in biotechnology. Currently, pre-implantation genetic diagnosis, freezing embryos, embryo experimentation, surrogacy, egg donation, and therapeutic cloning are all banned.

"Egg-Giving" Banned in UK

IVF clinics in the UK have been told not to offer women cheap treatment if they are prepared to go through egg retrieval twice and donate half the resulting eggs. The Human Fertilisation and Embryology Authority says that "egg giving", as the practice is called, cannot be justified because women are being asked to risk their health for a financial inducement. There is a one per cent chance of an adverse reaction to ovary-stimulating drugs and occasionally it is fatal. The HFEA says that "egg sharing", in which eggs from a single cycle are divided between two women, is acceptable. "Altruistic" egg giving, in which a woman donates her eggs without undergoing fertility treatment, is also acceptable. There is a nation-wide shortage of donor eggs for women in IVF programs whose own eggs are not suitable.

UN Cloning Resolution

The US government is backing a UN resolution to ban all forms of cloning. Last year a key UN committee was forced to postpone for one year a Franco-German proposal for a treaty which would have banned reproductive cloning but allowed research cloning. With the year nearly up, American diplomats are lobbying for a resolution proposed by Costa Rica, which would ban all forms of cloning. On the domestic US scene, a stem cell coalition lobbying for Federal funding for embryonic stem cell research is being cobbled together for the 2004 elections.

In November 2003, the Costa Rica resolution was blocked for the time being, with a motion put forward by Iran to defer consideration of the drafting of a treaty on cloning for two years. The vote for the motion was accepted 80 to 79 with 15 abstentions in the General Assembly's legal committee, one of the closest votes in recent UN history. A month later the United Nations General Assembly agreed to overturn the legal committee's decision and instead delay discussion on a global treaty for one year, until the end of 2004.

Posthumous Use of Gametes and Embryos

In the UK, Diane Blood, the widow who fought to have children using her husband's sperm, has won a long legal battle to have him recognised as the father of his posthumous sons. A new bill has amended the UK's Human Fertilisation and Embryology Act 1990, which stipulates that a man is not considered a child's legal father if the child has been conceived from frozen sperm or a frozen embryo after his death.

In Israel, doctors will be allowed to harvest the sperm of dead Israeli men without their consent if their wives or partners request it, according to guidelines announced by Attorney-General. However, a man's explicit instructions that his sperm should not to be used for artificial insemination would have to be followed. Guido Pennings, of the European Society of Human Reproduction and Embryology ethics committee, says that no other country allows sperm to be used without written consent.

Regulative Authority Proposed for USA

A leading American bioethics think-tank, The Hastings Center, has proposed that the US Government set up a national authority to regulate reproductive medicine. The "Reprogenetics Technologies Board", which would resemble the UK's Human Fertilisation and Embryology Authority, would make policy on experiments with human gametes, set a code of practice for IVF practitioners, and promote public debate about embryo research. The report reflects concerns in the US that the market is currently the only regulator of reproductive science.

Tighter Control of IVF Industry Proposed in USA

The US President's Council on Bioethics wants to rein in the American IVF industry. Members reached consensus on several practical measures in a discussion paper. If adopted, these would force the IVF industry to disclose more about its practices and impose "interim prophylactic measures". The procedures that could be restricted or banned are animal-human hybrid embryos, the creation of embryos with genetic material from more than two parents and possibly surrogate motherhood. The Council also supports the need for government-funded studies of the health of children born from assisted reproductive technology (ART), the health of women who use ART, and the effects of reproductive genetic technologies. IVF clinics would be told to provide more user- friendly reporting of data, the side effects and risks of procedures and their cost. All embryos created would have to be accounted for.

UK Authority Rules Out Sex Selection

Parents should not be allowed to choose the sex of their babies, the UK's IVF regulator has recommended after a year-long public consultation. The Human Fertilisation & Embryology Authority reports that there was a "huge public consensus" against selection, except for medical reasons. The HFEA's recommendations need to be underpinned by government legislation, as the sorting of fresh, non-frozen, sperm is not currently covered by its remit. If this happens, the three centres operating in the UK, which offer sperm sorting as a means of sex selection, will be forced to restrict their services. Couples who want to choose the sex of their child for "family balancing" reasons will be forced to go abroad for treatment.

WA Donor Contact

In April 2004, The West Australian newspaper reported on the case of an egg donor and recipient who under WA's current legislation were being denied access to identifying information on each other. The egg donor and the recipient of her eggs had been exchanging letter with each other and wished to have contact. The donor had donated her eggs to the recipient in 2001 after reading a newspaper interview about the recipient's search for an egg donor. The subsequent procedure had been successful with a baby boy born in July 2002. After the story was published the newspaper arranged for the egg donor to meet with the recipient family. Subsequently, the Attorney General Jim McGinty introduced amendments to the law that would allow consenting parties to meet prior to the child turning 18. The amendments also allow donor offspring to access identifying information on their donor once they reach 16 years of age. These provisions were not retrospective.

NSW Sperm Donors

Sperm donors would be able to veto pregnancies under a proposed law in New South Wales to regulate aspects of IVF treatment not covered by Federal laws. The law would also prevent a woman from using frozen embryos after a broken relationship, unless her former partner consented. Legal advisers to the NSW health department said that there were conflicting views on whether donors should have the right to control the fate of embryos.

European Parliament Bans Sale of Eggs and Sperm

The European Parliament has approved a ban on the sale of eggs, sperm and other human tissue. Donors will be able to claim expenses, but not payment, for the tissues that they donate. It will be up to member states to set the dividing line between reimbursement and inducement. The new rules also set quality standards for donated tissue. The regulations are almost sure to be approved by the EU's Council of Ministers, which they need before becoming EU law.

ART Risks

Source of Defects may be IVF Culture Medium

There is more study needed on the effects of culture medium life upon how an IVF embryo's genes are expressed. German veterinary researchers in the Institute for Animal Science in Neustadt compared IVF embryos and cloned embryos with embryos, which had been conceived normally and found "numerous aberrations" in the former. Reproductive BioMedicine Online published at least 2 articles on this matter during the year.

Increased Pressure for Follow Up of IVF Children in USA

Increasing pressure is being brought to bear in the USA for a national register to track the health of IVF children as there is mounting evidence that IVF treatment is related to birth defects. The Wall Street Journal reported that there have been at least a dozen papers published in the last year, which suggest a link to increased health risks. Confidentiality concerns, privacy laws and a fear of stigmatising the children hamper the idea of a massive follow-up study. In the US there are some attempts under way to collect information, but all of them have serious limitations, either because many parents do not cooperate or because the data relies on parents' recollections. In France, the IVF industry has been more successful with patient compliance. A program called Follow Up involves more than 20 IVF centres, with 95% of parents participating.

IVF Multiple Births

Multiple pregnancies and related premature births are associated with increased mortality and morbidity, both for mothers and babies and are considered the most frequent and most serious complication concerning IVF. In the USA the latest statistics show that multiple births made up more than half of the children born in five states (California, Florida, New York, Illinois and Texas) where almost half of the 100,000 IVF procedures in 2000 were performed. Australian IVF specialists succeeded in lowering the number of embryos transferred some time ago and generally do not transfer more than two embryos. In the UK fertility doctors have been told to implant a maximum of two embryos. The new HFEA guidelines apply only to women under 40. Women over 40 have so much difficulty in conceiving that doctors will still be allowed to transfer three embryos. This is in line with recommendations made by an expert meeting of international fertility experts convened early last year by the Bertarelli Foundation. In Scandinavia, doctors regularly transfer only one embryo, while in the US they often transfer as many as five.

Lower Birth Weight and Prematurity Associated with ART

A study published in the British Medical Journal revealed that children conceived by assisted reproduction are more likely to be born early and have a lower birth weight than naturally conceived babies. The ART babies are also more likely to be born by caesarean section, be admitted to neonatal intensive care units and suffer fatal complication. The results applied specifically to singleton births. It is well known that twins are more likely to be born premature, at low birth weight and to suffer complications, however the study found that IVF twins generally fared better than naturally conceived twins.

Social Trends

IVF's 25th Birthday

25 July 2003 marked the 25th birthday of Louise Brown the first person born through IVF. The world media reported on the advances in reproductive technology over time. As reported in the Daily Telegraph assisted reproduction has produced 45,000 Australian babies. The number of Australian IVF babies is increasing each year with about 4500 born in 2002. It was also noted that Australian scientists were the first in the world to achieve a pregnancy using frozen embryos. The Sunday Times reported that the use of IVF in WA had doubled in the last ten years.

A study published in the Medical Journal of Australia indicated that the public's attitude toward reproductive technology had changed considerable over time with the public today being more accepting of the technology. Support for IVF use by infertile married couples had increased from 77% in 1981 to 86% in 2001. Support of use of donor insemination for both single women and lesbian women had increased markedly. For single women the increase was from 18% in 1993 to 38% in 2000 and for lesbian women from 7% in 1993 to 31% in 2000.

Sperm Shortage

Sperm shortage is an issue for countries like Australia, UK and India. Most states in Australia are facing diminished numbers of men willing to donate sperm. An IVF clinic in Albury NSW has been offering Canadian university students a free holiday in Australia. About 15 men have expressed an interest in the deal. One of the reasons given for the shortage of Australian donor sperm is that potential donors' fear that they might have to face paternity claims by their offspring. In the UK the shortage is forcing the IVF regulatory body to consider bulk imports from overseas. Fewer British men are donating to sperm banks because they fear that the right to anonymity may be scrapped in the future. The shortage is particularly severe for patients with ethnic backgrounds,

especially those from India and Pakistan. Importation has not been allowed in the past because of concerns over quality control and how much overseas donors are paid.

Donor – Conceived Children

Children born from sperm donors seldom find out anything about their biological fathers, according to a Melbourne symposium. Furthermore, surveys indicate that only about 20% of children conceived with donor sperm are told the truth by their parents, according to the CEO of the Victorian Infertility Treatment Authority, Helen Szoke. Only since 1988 have Victorian donors been required to give limited information about themselves. A voluntary register at the ITA has attracted only 37 donors, six offspring and 22 recipient parents -- even though about 150 children are born every year in Victoria through donor-assisted reproduction. The situation is similar in the US. Its 100 sperm banks are all anonymous to protect donors against claims for child support and parents against demands for custody of a biological child.

Most Embryo Donated Children Not Told of Origins

Only a third of parents whose child began life as a donated embryo tell them about their origins, compared with 100% of parents of adopted children and 90% of parents who used their own eggs and sperm. Fiona MacCallum, a psychologist at City University in London, told the ESHRE conference that parents believed that knowledge of their origins would upset the child and that since the mother bore the child, she was in fact the real mother.

Number of Childless Women Doubled in Last 25 Years in USA

The proportion of American women who finish their reproductive years without bearing children has nearly doubled in the last 25 years, according to recent statistics from the US Census Bureau. In 2002, about 18% of women between 40 and 44 were childless, compared to 10% in 1976. The average number of children for this age bracket was 1.9 in 2002, compared to 3.1 in 1976.

British Women Having Fewer Children and Later in Life

British women are having fewer children and having them later in life to hang on to a comfortable lifestyle, says the Institute of Public Policy. A report sponsored by Lever Faberge, the detergent company, reveals that "later maters" regard children as a mixed blessing with clear penalties for parents, especially women. The report found that many women in their 30s were not desperate for children. The current British birth rate is 1.64 children per female, marginally higher than the European average of 1.53.

PGD in Australia

Six out of every 10 patients at one of Australia's leading IVF clinics are using pre-implantation genetic diagnosis (PGD) to select the sex of an embryo rather than to test it for a medical condition. The Daily Telegraph reports that the number of parents using PGD for sex selection has increased four-fold in three years. More than 250 couples have had sex selection done at Sydney IVF since 1995, with 120 of them in 2002. About one-third resulted in a pregnancy. Details of the procedure are outlined on the clinic's website. Despite fears that parents would choose only boys, the director of PGD at Sydney IVF, Dr Kylie de Boer, says that 64% wanted a girl and that when only one parent wanted to select the sex, it was nearly always a mother who wanted a daughter.

A Westpoll survey, conducted by The West Australian March 2004, indicated that 88% or people supported genetic testing and only 9% believed it should be banned in all circumstances. The survey found that young people and men (rather than women) were more likely to believe that screening should not be subject to restrictions. Additionally, people living in the country were more likely to be opposed to all screening than those living in the metropolitan area.

PGD is currently not permitted in WA therefore WA couples who have sought this treatment have been required to travel east for treatment. The local newspaper reported that government funds had been used for interstate PGD through the Interstate Procedure Transfer Scheme, which provides assistance to people requiring medical procedures not available in WA. The article drew attention to the fact that it was illegal to have the procedure conducted in WA, however the Department of Health was willing to pay airfare and accommodation costs for a couple to go to Sydney for the procedure. In April 2004, The West Australian, reported that the WA couple provided with the assistance had given birth to a boy.

In June 2004 the Daily Telegraph reported that Sydney IVF was planning a trial where people undergoing IVF treatment would routinely have their embryos diagnostically screened prior to implantation. The aim of the trial was to identify those embryos with chromosomal abnormalities, which are less likely to implant and lead to a pregnancy. Several hundred women aged under 37 would take part in the clinics trial which would run for a year. The rates of pregnancy, miscarriage and live birth would be compared to a control group of women whose embryos would not be screened. If the trial was successful embryo diagnostic screening could become a routine part of the clinics IVF practice.

Embryo Testing for Tissue Matching

The use of PGD for the purpose of tissue matching an embryo to an existing offspring was also highlighted in the media this year. Reports indicated that seven couples from Australia and overseas had sought help from specialists at Sydney IVF to provide embryos that would also be a match to existing offspring to provide bone marrow. A Perth couple who had a daughter with the rare genetic disorder, Diamond Blackfan Anaemia, were hoping that embryo tissue matching would help them have a child who would also be able to provide bone marrow for their ill daughter. The couple had two attempts at using IVF with tissue matched embryos, however, neither attempt was successful.

Embryo Research in Australia

Newspapers nationally reported on the first licenses to be approved allowing embryo research in Australia. In 2002 laws were passed by Federal Parliament permitting embryo research. Under the law, only those embryos created before 5 April 2002 and declared "excess" by the parents of the embryos may be used in research. A committee of the National Health and Medical Research Council would oversee the applications for embryos research. Five licenses were approved in April 2004, four of these will provide the opportunity to discover better ways to perform IVF and will research development of human embryonic stem cells. Four of the five licences approved were granted to Sydney IVF.

It was later reported, in June 2004, that researchers at Sydney IVF had succeeded in growing their first stem cell line as part of their embryo research licence. The couple who had donated their embryos to this research project told about their decision to donate their three excess embryos to research. The couple had felt uncomfortable about donating their embryos to another family and did not want to just throw them out as they would be wasted, therefore they chose to donate them to research. The Daily Telegraph reported that at least six other families have given consent for Sydney IVF to use their excess embryos to try and create more stem cells.

In May 2004, it was reported that a study by Dr Burton, a Perth IVF researcher, had found that 27% of couples surveyed indicated they would donate surplus It was reported that only 15% of couples surveyed would donated their surplus embryos to another childless couple.

"Fertility Tourism" in USA and Europe

American women desperate for a child are going to Mexico, the Middle East and Eastern Europe for untested fertility technologies, which have been banned in their own country. SELF, a US women's magazine, has reported that until three years ago, there was "virtually zero government oversight" of fertility medicine. But in 2001 and 2002 the Food and Drug Administration instructed clinics to stop procedures like cytoplasmic transfer, lymphocyte immune therapy, animal co-culture and nuclear transfer until they had been thoroughly investigated. As a result, the "FDA crackdown has spawned a scary form of medical tourism," SELF claims.

The expansion of the European Union will result in couples in Western Europe travelling to countries like Slovenia and Hungary for IVF treatment, which is cheaper but still comparable in quality. According to data presented to the ESHRE conference by Dr Anders Nyboe Andersen, of Copenhagen University Hospital, in Denmark, Denmark is still the country where IVF was most popular, with 1,923 cycles per million people. There were 1,133 cycles per million in Sweden, 1,122 in Slovenia, 963 in the Netherlands, 593 in the UK, and 578 in Hungary.

New Technologies

Artificial Sperm Created by Japanese Scientists

Japanese scientists have transformed mouse embryonic stem cells (ESCs) into sperm cells for the first time. Researchers at the privately funded Mitsubishi Kagaku Institute of Life Sciences in Tokyo nurtured ESCs in a Petri dish and then injected them into the tissue surrounding the testes. The sperm matured and successfully fertilised mouse eggs. Although the results are only preliminary, the experiment led Professor Lee Silver, of Princeton University, to forecast a future in which "you could have human sexual reproduction without people. You could generate a human being who never had any parents." It would also be possible to engineer sperm with specific genetic traits. In May, scientists at the University of Pennsylvania discovered that it was possible to create eggs from either male or female stem cells. It appears that sperm, however, can only be created from male ESCs.

Synthetic Embryos

Japanese and Korean researchers were able to produce the world first mouse derived from two mothers and no fathers. By modifying two genes in the mouse's egg the researchers were able to "masculinise" the egg allowing it to fulfil the role normally taken by sperm. This egg was then fused with another egg and treated with chemicals to mimic fertilisation and start embryo development. This lead to a successful pregnancy and the birth of "Kaguya" the mouse with the DNA of two females and no males.

Chimeras

Researchers in the US have created the first mixed sex hybrid human embryos. The embryos had been created during an experiment where cells from male IVF embryos were injected into female embryos. The researchers cultured the embryos for 6 days. In more than half of those created, the embryos appeared to be developing normally. The aim of the research was to investigate whether healthy cells could be implanted into defective embryos to prevent genetic diseases. However, a number of experts indicated they thought the experiment was unethical and unnecessary.

Alternative to IVF Developed in Auckland

Auckland researchers say that they have proven the effectiveness of a low-cost treatment for unexplained fertility without the ethical complications of IVF. Dr Neil Johnson, of Auckland University, says that flushing a liquid called lipiodol through the womb and fallopian tubes gives women a significantly higher chance of becoming pregnant. In a study of 73 women who received the treatment, 38% became pregnant, compared to 16% in a control group. An IVF cycle costs at least NZ$5,000, compared to several hundred dollars for the lipiodol flushing.

Cloning Errors Could Affect Cure Potential for Embryos

Cloning creates potentially dangerous abnormalities in embryos, scientists from Cornell University told the ESHRE conference. Only 30% of cloned mouse embryos reached the blastocyst stage of development, while the proportion of parthenogenetic and ICSI embryos was about the same as naturally conceived embryos, Takumi Takeuchi and Gianpiero Palermo found. The reason for this, they think, is that the gene activity in the cloning process is abnormal. Although the researchers' take-home message was that reproductive cloning is unsafe, the executive director of ESHRE, Professor Andre van Steirtegheim, also warned that these problems had to be solved before therapeutic cloning could be used to treat human diseases. "It would be a grave mistake, if there was something wrong with the epigenetics of these stem cell lines, to transfer them back into patients," he said.

Cloning

In January 2004, Dr Panos Zavos announced he had implanted a cloned human embryo into a woman. However, it would be a few weeks before he knew if the embryos had implanted. The embryo had been derived using eggs from an infertile 35 year old women fused with a skin cell from her husband. Dr Zavos indicated that if the procedure was successful DNA tests on the mother, father and child would be presented to prove the procedure was genuine. The claims from Dr Zavos were greeted with condemnation and scepticism form around the world. Dr Reik, a cloning expert from the Babraham Institute Cambridge, said that in cloning experiments 99% of clones die in the womb and the remaining 1% have problems (Mercury: 19/01/2004). Therefore he suggested it would be irresponsible to do human cloning. There were no further announcements from Dr Zavos indicating that the cloned embryo had implanted.

Therapeutic Cloning

In February 2004, a paper was published in the leading journal Science, documenting the first procedure where stem cells had been extracted from a cloned human embryo. Scientists from the Seoul National University carried out the procedure. Although this was not the first time a human had been cloned it was the first time a cloned embryo had grown to blastocyst stage where stem cells can be extracted. As described in the Age, 242 oocytes were obtained from 16 women who had volunteered for the research. Cumulus cells from the ovary were used to provide the DNA for the enucleated oocytes. The team was able to grow 30 embryos to blastocyst stage. The inner cell mass, the embryonic stem cells, which can turn into any cell in the human body, were isolated in 20 of these embryos. From these, one stem cell line was successfully cultured until they began to differentiate into specialist types of cells.

Creating Twins for Spare Parts

Two IVF experts on opposite sides of the Atlantic have teamed up for a startling experiment. Dr Panos Zavos, a Kentucky-based scientist who wants to create the world's first clone, and British sex-selection specialist Paul Rainsbury have announced that they will launch an embryo- splitting program to cater for couples who want spare parts for their baby. The idea is that an embryo would be split into twins. One half would be allowed to develop into a baby and the other half would be frozen and used for stem cells, spare tissue or organ parts for its sibling. Theoretically, since the donor cells and the recipient have the same genetic make-up, there will be no danger of rejection. However, using half an embryo to produce a baby has not been clinically proven. This radical proposal was not welcomed in the UK and the Human Fertilisation and Embryology Authority indicated that it would not grant the required licence for such a procedure. Both doctors are used to finding overseas venues for their treatment therefore this will not hamper their plans. They are also working together to find a surrogate mother for a cloned embryo purportedly created by Dr Zavos. British authorities reminded them, however, that implanting a cloned embryo is a criminal offence in the UK.

Clone Embryos – UK

HFEA, the government fertility regulator, announced in June 2004 that they were considering the UK's first application to clone embryos. The application from Newcastle University is seeking to extract stem cells from cloned embryos to treat diabetes. Researchers are hoping they can grow stem cells into insulin producing islet cells, which when returned to the patient would end the need for insulin injections. The application was put on hold because HFEA wanted further information. Professor Alison Murdoch, of Newcastle University, says that once a license is granted, the first cloned embryo in the UK could be created by the end of the year.

Screening for Genetic Diseases - Monash University

Researchers at Monash University have used gene chip technology to develop a 100% accurate test for one of the most common mutations for cystic fibrosis. Within two or three years, it will be possible for parents to test their embryos for many of the 1000 mutations which cause CF. The technology was developed by Chelsea Salvado, a PhD student working with Professor Alan Trounson at the Institute of Reproduction and Development at Monash. She foresees that gene chips -- or microarray technology -- will make possible a uniform, single, quick test for genetic mutations. Pre- implantation genetic diagnosis could be offered for all genetic diseases in the future.

First Natural Pregnancy from Frozen Ovarian Tissue

In November 2003 scientists came a step closer to achieving a pregnancy from frozen ovarian tissue after they were able to develop a normal embryo from transplanted tissue. Previously researchers had been able to derive eggs from ovarian tissue grafted under a woman's forearm but were not able to fertilise these eggs. In this experiment ovarian tissue had been removed and frozen from one of the ovaries of a 30 year old women prior to commencing chemotherapy. Test results confirmed that after the chemotherapy the woman had become menopausal. Six years later doctors thawed the pieces of ovarian tissue and transplanted them beneath the skin of the woman's abdomen. The woman was given hormones to stimulate growth of oocytes. After three months the woman noticed a lump at the transplant site and tests confirmed the ovarian function had returned. Scientists were able to retrieve 20 eggs from the transplanted tissue of which 8 were suitable for fertilisation and one of these fertilised normally after ICSI. The embryo was transferred but did not implant.

Then in June 2004, the ESHRE conference heard that a woman who underwent aggressive chemotherapy and radiotherapy has become pregnant naturally after fertility doctors reimplanted strips of her frozen ovarian tissue. The woman is now 24 weeks pregnant with a girl after treatment at the Catholic University of Louvain in Brussels, Belgium. This landmark technique offers the hope of renewed fertility for cancer patients, many of whom become infertile and menopausal after treatment for their illness. Frozen ovarian tissue has produced embryos before, but only through IVF. This is the first time that a natural pregnancy has been achieved. Although researchers presented the technique as a way for younger women to beat cancer, it also prompted media speculation about women bypassing menopause by freezing ovaries in their 20s and having children in their 50s or 60s.

Test to Detect Woman's Biological Clock

A South Australian IVF researcher has developed a test, which will tell women how many more years of fertility they have left. Professor Robert Norman, of Adelaide University, told a menopause conference in Hobart that it would help women to fit babies into their plans for careers and relationships. Women would no longer experience the shock of discovering that they had delayed motherhood too long and were unable to have children naturally. The diagnostic service combines blood tests, which measure hormones produced by the ovaries, indicating the number and quality of eggs, and ultrasound scans which pick up the number of developed eggs. Although the tests have already been used with some IVF patients, further refinements are still needed.

World Record for Frozen Sperm

The world record was broken in 2004 for the longest period that sperm had been stored before being successfully used. A healthy baby boy was born to a British man who had been diagnosed with testicular cancer at 17 and had had his sperm in frozen storage for 21 years. The baby boy was conceived after four cycles of IVF.

Research Finding

Ovarian Stem Cells

In March 2004, groundbreaking findings that researchers had found stem cells in mouse ovaries were published in the medical journal Nature. For more than half a century it has been believed that women are born with a fixed number eggs that that supply eventually runs out by menopause. But this research suggests that stem cells in the mouse ovaries may generate new eggs well into adulthood. To test this, researchers transplanted ovaries from a normal mouse into a genetically modified one with cells that glow green. The transplanted ovary tissue then developed new green follicles indicating that the transplanted tissue had contained stem cells. The researchers considered that the decline in a woman's fertility may be a result of the depletion of stem cells rather than an exhaustion of egg reserves.

Embryo Implantation

A study by US researchers has revealed how embryos attach themselves to the uterine lining. The findings suggest that at approximately day 6 after fertilisation, molecules on the surface of the embryo excrete a sticky protein called L-selectin. At the same time the uterine wall becomes rich in carbohydrates. This interaction between the uterine lining and embryo enables the embryo to stop wandering and come to a stop. Once the embryo stops it is able to attach to the uterine wall where it develops links to the mothers blood supply. Failure of the embryo to attach itself to the uterus is believed to cause 75% of miscarriages.

Single Embryo Transfer

This year the progress of single embryo transfer was further highlighted. Data from Sydney IVF showed that transferring a single embryo during an IVF cycle was just as likely to result in a live birth pregnancy as transferring two embryos. The study included 382 IVF patients under the age of 38 years who had at least two five day embryos that could be transferred. Of those who choose single embryo transfer there were 3 sets of twins, whereas among those 275 women who choose to transfer two embryos there were 90 twins. The live birth rate was 36% for single embryo transfer and 35% for two embryo transfer.

Sperm Counts

There appears to be a growing concern worldwide that sperm counts are decreasing, although it should be noted that many experts consider that there have been no accurate studies to support these claims. Many articles were published this year suggesting factors contributing to the "plummeting" sperm counts such as general exposure to pollutants like fertilisers, pesticides and cigarette smoke.

Chemical substances called phthalates, which can be found in many common household products, such as shampoo, skin lotions, make up and plastic, may be contributing to male infertility. A two year study by Edinburgh Medical Research Council found that exposure to high levels of phthalates in rats disrupts testosterone at a crucial stage of foetal development, doubling the rate of defects and leading to low sperm counts.

The anti-impotence drug Viagra may actually be decreasing male fertility. Researchers from Belfast found that although sperm exposed to Viagra became more active they also "fired" prematurely. This relates to the acrosome reaction a mechanism whereby sperm release digestive enzymes that help the sperm to penetrate the egg wall. If the sperm releases these acrosome enzymes too early, before reaching the egg, the sperm will not be able to penetrate the egg. The acrosome reaction usually occurs after three hours in untreated sperm, however, in sperm exposed to Viagra the reaction occurs after only one hour.

Hungarian researchers have found that men who carry mobile phones in their pockets or on their belt have 30% less sperm than men without mobile phones or those who keep them turned off. It was believed that the electromagnetic radiation emitted by the phone may have negative effects on spermatogenesis leading to lower sperm counts and less motile sperm.

The sperm of heavy marijuana users was also the subject of a study by researchers from the University of Buffalo. When compared to sperm from fertile men it was found that the sperm from marijuana users was less likely to achieve fertilisation due to early "hyperactivation". This impedes the sperm's progress to meet the egg.

APPENDIX 1

LICENCES AND EXEMPTIONS

LICENCES CURRENT UNDER THE HUMAN REPRODUCTIVE TECHNOLOGY ACT AT 30 JUNE 2004

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 2004

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
E031	Dr PD Green	Australind	WA 6233
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
E051	Dr WD Patton	Rockingham	WA 6168
E015	Dr BD Roberman	Subiaco	WA 6008
E017	Dr C Russell-Smith	Kwinana	WA 6167
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
June 2004

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
	C/- South West Mental Health Services PO Box 1993 Bunbury WA 6231	(08) 9791 4355 Fax (08) 9791 4385
Ms Rosemary Keenan*	69 Clontarf St, Sorrento WA 6020	(08) 9447 8365
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 Fax (08) 9446 9860
		(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	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	Lot 124 Hibbertia Court Jarrahdale WA 6124	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 2003/2004

OPERATIONS OF LICENSEES FOR THE FINANCIAL YEAR 2003/2004

BACKGROUND

This summary was put together from information submitted, as required by the *Human Reproductive Technology Act 1991* (Act), about five Storage Licences and four 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 2004. 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.

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 2002.

Semen storage and donation

During the 2003/04 financial year, semen was donated to WA Storage Licensees by 48 men. Of these, 27 were new donors. This is a further increase in the total number of donors from 2002 when the lowest numbers of donors was recorded (illustrated in figure 1). The age distribution of donors (Table 1), indicates that the majority (62.5%) were 30 years of age or older. This continues the general trend seen over the last twelve years, towards a greater number of older donors (figure 2). Table 3 indicates there were substantially more single donors (85.4%) than donors in a married/de facto relationship (14.6%).

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. In the course of submitting their Annual Reports two Exempt practitioners requested revocation of their Exemptions, leaving 19 exempt practitioners, as detailed in Appendix 1.

Embryo storage

Table 3 shows that the total number of embryos in storage at the end of the year was 12,529. The total number of embryos in storage has continued to increase since 1993 (as illustrated in figure 3), in recent years by just over 1000 per year. Therefore the increase in embryos of 432 this financial year is considerably less than that of previous years. This may indicate greater use of stored embryo through frozen embryos transfer (FET) cycles, with the proportion of FET cycles on the increase since 1993 and now approaching fifty percent (48.9%) of all cycles with embryo transfer. Under the Act (Direction 8.4) where participants have more than two embryos in storage, the licensee must not allow the creation of any further embryos.

A total of 4646 embryos were stored following treatment and 3926 stored embryos were used in treatments during the year. In all 307 embryos were allowed to succumb at the request of the participants.

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

Table 4 shows that during the last financial year 1164 women began oocyte retrieval cycles for IVF, 723 began FETs and 2 began GIFT procedures.

A total of 3092 cycles were begun for IVF, frozen embryo transfer or GIFT, again slightly more than in the previous year (3020). As illustrated in figure 4, of all cycles begun, 1678 (54.3%) were for IVF and 1412 (45.7%) were for frozen embryo transfer. GIFT cycles accounted for only 2 of the cycles begun.

Of the 1680 cycles begun for fresh IVF or GIFT with ovarian stimulation, 88.1% proceeded to oocyte retrieval and 76.2% proceeded to transfer fresh embryos or gametes (figure 5). Of the 1412 frozen embryo transfer cycles begun, 1225 (86.8%) proceeded to transfer.

Overall, donated human reproductive material was involved in 6.0% of all IVF or GIFT cycles with oocyte retrieval during the year. In 4.5% of cycles donor semen was used (66 cycles); donor eggs were used in 1.6% of cycles (23 cycles) and there were no IVF cycles with fresh embryos donated. A higher proportion of frozen embryo transfer cycles (11.1%) involved used of donated gametes or embryos. Donor embryos were used in 2.6% of all FET cycles with transfer (32 cycles); donor eggs in 3.8% (47 cycles) and donor semen in 4.7% (57 cycles).

Of all 1478 IVF treatment cycles with successful oocyte retrieval, 629 (42.6 %) used intra-cytoplasmic sperm injection (ICSI). As illustrated in Figure 6, use of ICSI appears to be levelling off with the proportion of IVF cycles in which ICSI is used remaining relatively stable for the past 6 years. Fresh or frozen sperm retrieved from the epididymis or testis was used in 51 of the ICSI treatment cycles.

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 5, 65 women were treated with fresh IVF transfer and 27 with frozen transfer. The results for this year indicate the number of public patients treated is similar to that of

last year. During the year 82 fresh IVF and 104 FET treatment cycles were conducted. This year 23 of the IVF cycles involved micro-manipulation (ICSI). There was no use of donated reproductive material among the IVF public patients. In addition, Concept reported 58 artificial inseminations (6 DI, 52 AIH) patients between 1 July 2003 and 30 June 2004.

Intra-uterine insemination (IUI)

The Council is continuing to monitor IUI carried out by licensees and Exempt practitioners. A total of 1236 IUI cycles were reported by five Practice licensees and two Exempt practitioners. The overall ongoing clinical pregnancy rate per treatment cycle carried out was 9.5% (117 ongoing pregnancies), and of the pregnancies, 105 were singleton (89.7%), 10 were twin (8.5%) and two were triplet (1.7%).

The information provided showed that 83.3% of the IUIs used the partner's sperm and 16.7% used donor sperm. Of all cycles carried out, the majority (58.6%) did not involve the use of ovulation induction. Clomid was used in only 6.1% of the cycles, and gonadotrophins were used in 35.3% of the cycles.

The two sets of triplets reported followed gonadotrophin stimulation in two separate clinics, one using the partner's sperm (AIH) and the other using donor sperm (DI). Of the ten sets of twins reported, one set followed ovulation induction by clomid, 8 followed ovulation induction by gonadotrophins and one set of twins occurred following a natural cycle. Two sets of twins were a result of DI and the remaining 8 were AIH.

Serious morbidity and mortality in women undergoing treatment

Overall the four clinics reported a total of 23 cases of severe ovarian hyper-stimulation relating to 1680 IVF and GIFT stimulation cycles (1.4% stimulation cycles, with a clinic range of 0–3.1%). The average number of follicles above 12cm for women who were affected by severe ovarian hyperstimulation was 18.2 (with a median of 14).

There were no reports of severe pelvic infection, and no reported cases of mortality in association with fertility treatment during the year. There were eight cases of other serious morbidity reported at two separate clinics. Seven of these cases were readmitted to hospital.

Counselling

There were 1025 counselling sessions provided by the licensed clinics during 2003-2004 according to the annual reporting forms. This is an increase of 20% from the previous year. Almost eighty eight per cent (87.7%) of participants who had counselling had one session of counselling. Of those seeking treatment that had a single session of counselling almost eighty two per cent had information counselling while 17.5 per cent of participants accessed support or therapeutic counselling. This was consistently the case in all the licensed clinics.

Most counselling was conducted on site at the clinics. The majority of clinics did not charge a separate fee for counselling. However at one clinic 39.5 per cent of participants paid a fee for counselling. One clinic reported conducting telephone counselling sessions during the year.

Counselling concerning issues of donation for donors or recipients made up 32.5% of all counselling compared to 38.4 per cent in the previous year. For one IVF clinic over 73% of all counselling offered for the year was pertaining to issues of donation.

Approved research and innovative practices

Three clinics with approval to carry out assisted hatching provided data that showed this procedure had been used in a total of 303 fresh and 315 frozen embryo cycles. The use of the procedure ranged from being used in 15% to 32.7% of all cycles (fresh and frozen) with transfer.

Data from the three clinics with approval to carry out blastocyst culture indicated the procedure was used in 278 fresh and 174 frozen embryo cycles. The use of the procedure between clinics varied greatly from 1.7% to 51.5% of cycles (fresh and frozen) with transfer. In total, most of the cycles (91.4%) were carried out in one clinic. A variety of factors, including patient selection, may explain this considerable range in use of blastocyst culture. Council will be particularly interested in monitoring the number of embryos transferred in each cycle of blastocyst culture especially with the greater risk of multiple births when more than one embryo is transferred. This data (including multiple birth rates) will be available from the RT Register at a later date.

- Current approved research and innovative practices.

Research

R001 Use of granulosa cell co-culture in assisted reproduction procedures
PIVET Medical Centre
Approved 20/05/93.
These research procedures were not performed in the last financial year.

R005 Comparison of culture media in human in vitro fertilisation
PIVET Medical Centre
Approved 14/12/95.
In abeyance.

R007 The impact of Tobacco and Caffeine consumption on the outcomes of *in* v*itro* Fertilisation-embryo transfer
PIVET Medical Centre
Approved 28/02/95.
Completed in July 2003.

R016 Does ICSI increase the risk of major birth defects?
TVW Telethon Institute for Child Health Research
Approved 24/11/98.
Second phase of study now underway with expanded study group and measurements of outcome.

R019 Phase III, Multicentre open label randomised trial to assess the efficacy

and convenience of orgalutron
PIVET Medical Centre
Approved 08/08/00
Initial data analysis of the study group was completed in 2003, however ongoing data is still being collected from frozen embryos generated in the study cycles.

R020 ASSET multicentre trial on single embryo transfer
PIVET Medical Centre
Approved 10/09/02.
This study was abandoned in January 2004 due to poor patient recruitment.

R021 Ovarian hyperstimulation: a pathophysiological study
Fertility North
Approved 28/04/03.
This study was cancelled this year as the chief investigator retired from the clinic.

Innovative clinical/laboratory practices

I 001 Improvement of IVF in severely oligospermic patients using partial zona dissection (PZD) and subzonal spermatozoal injection (SUZI)
PIVET Medical Centre
Approved 20/05/93.
These micromanipulation techniques were not used in the last financial year.

I 002 Use of SAIZAN (Growth Hormone) in ovulation induction
PIVET Medical Centre
Approved 23/11/93.
Report 2004 indicated use in 19 cycles for 18 women, leading to 16 cycle with oocyte collection and 5 ongoing pregnancies.

I 008 Assisted Hatching
PIVET Medical Centre
Approved 13/11/00
Report 2004 indicated use in 178 cycles: 69 fresh cycles and 109 cycles FET.

I009 Assisted hatching
Concept Fertility Centre
Approved 06/02/01.
Report 2004 indicated use in 320 cycles: 85 IVF, 86 ICSI and 149 FET.

I010 Blastocyst transfer
Concept Fertility Centre
Approved 20/03/01.
Report 2004 indicated use in 17 cycles: 7 IVF and 10 FET

I011 In vitro culture of human embryos to Blastocyst stage
Pivet Medical Centre
Approved 19 /06/01.
Report 2004 indicated use in 22 cycles: 12 fresh cycles and 10 cycles FET.

I012 Assisted Hatching
Hollywood Fertility Centre
Approved 20/03/01.
Report 2004 indicated use in 120 cycles: 63 fresh cycles and 57 cycles FET.

I013 Blastocyst Transfer
Hollywood Fertility Centre
Approved 23/09/03.
Report 2004 indicated use in 413 cycles: 259 fresh cycles and 154 cycles FET.

I014 ART treatment for couples where the male is HIV positive
Concept Fertility Centre
Approved 08/06/04.
No data as yet as study only approved in June 2004.

There were a number of research projects conducted at clinics during the year, which did not require specific approval. These projects met the criteria for 'general approval' research. The studies included the following:

- Concept Fertility Centre: The influence of psychosocial factors on the success of Assisted Reproductive Technology.
- Concept Fertility Centre: Attitudes towards the storage and destiny of supernumeracy cryopreserved embryos.

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, predominantly to patient information sheets were received through the year.

Complaints

A total of 13 formal complaints were reported by clinics for issues including accounting, clinical and ultrasound services, patient management and general practice organisation.

Figure 1: Semen Donors in WA

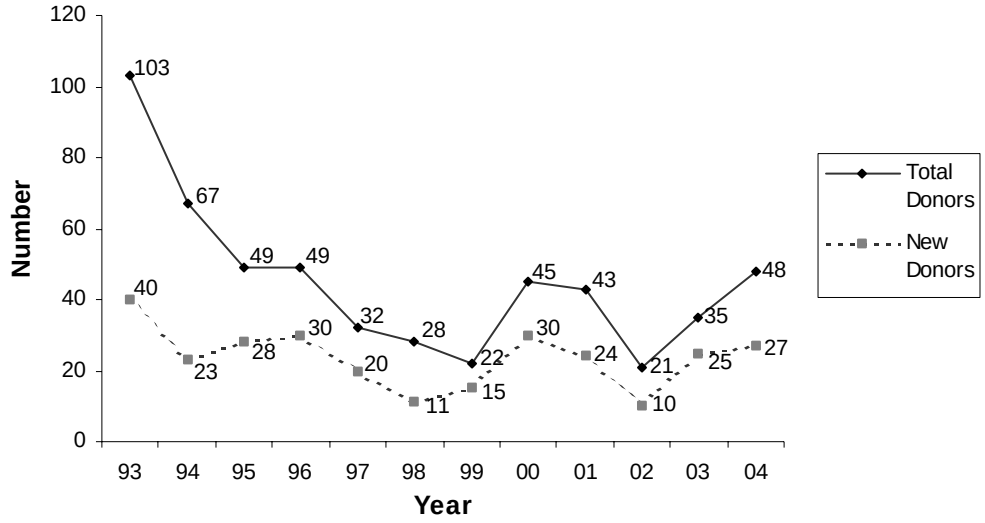


Figure 2: Ages of Semen Donors

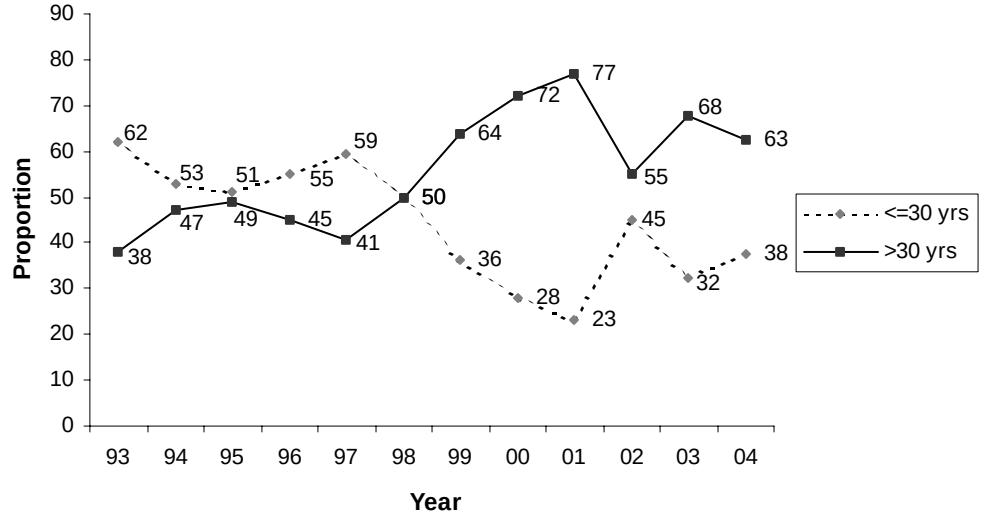


TABLE 1: 2003/4 SEMEN DONOR AGES STATUS

Age of Donor (years)	Number (%)
18-25	8 (16.7)
26-30	10 (20.8)
31-35	14 (29.2)
36-40	10 (20.8)
41-49	5 (10.4)
50 +	1 (2.1)
Total	**48 (100)**

TABLE 2: 2003/04 MARITAL STATUS OF SEMEN DONORS

Marital Status	Number (%)
Single	39 (81.2)
Married/ De Facto	7 (14.6)
Divorced/ Sep	2 (4.2)
Total	**48 (100)**

Figure 3: Trends in Embryo Storage

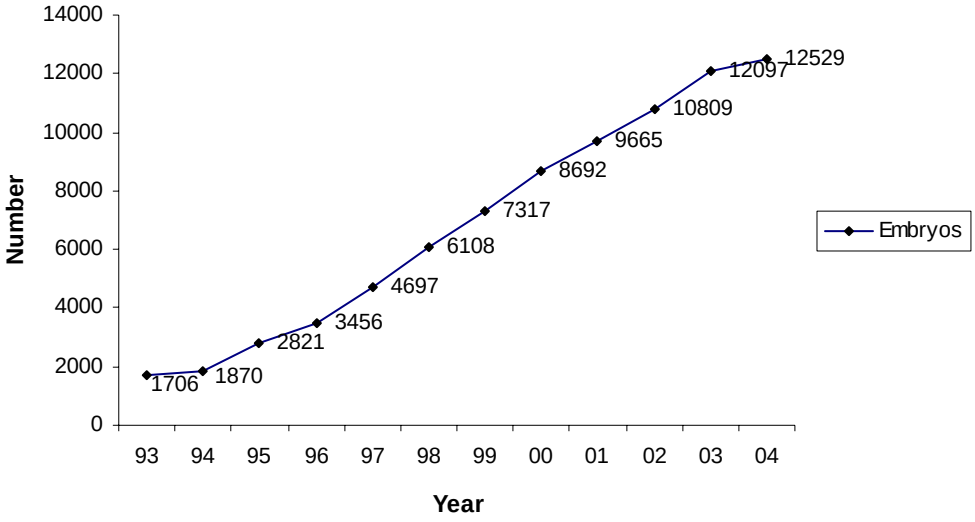


TABLE 3: DISPERSAL OF STORED EMBRYOS 2003/2004

	No of embryos
Embryos in storage 30/06/03	**12097**
Embryos created from IVF	4646
Transferred into WA clinics from interstate	82
Transferred between clinics in WA	179
Transferred to clinics outside WA (Patients moving interstate/overseas)	63
Used in frozen embryo transfer treatments	3926
Allowed to succumb with consent of couples	307
Embryos in storage 30/06/04	**12529**

Figure 4: ART Treatment Trends

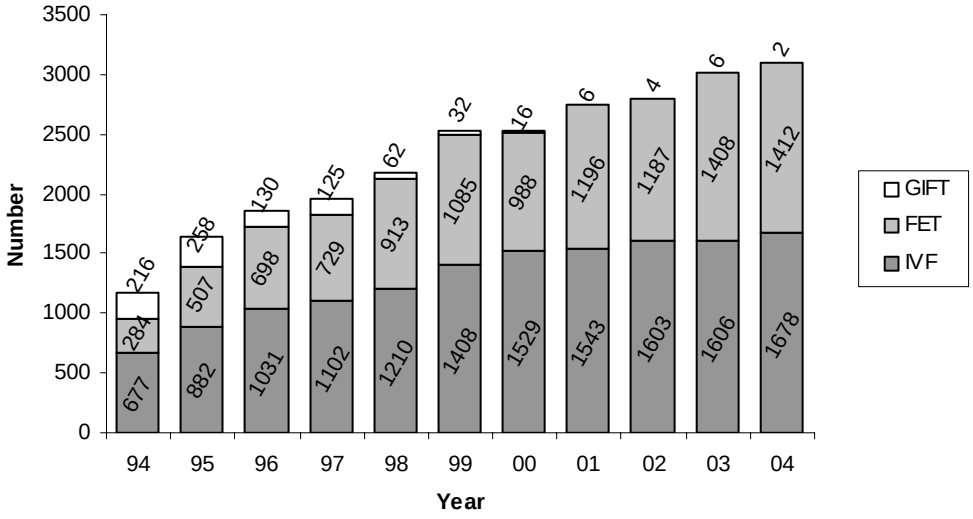


Figure 5: IVF (fresh) and GIFT Treatments

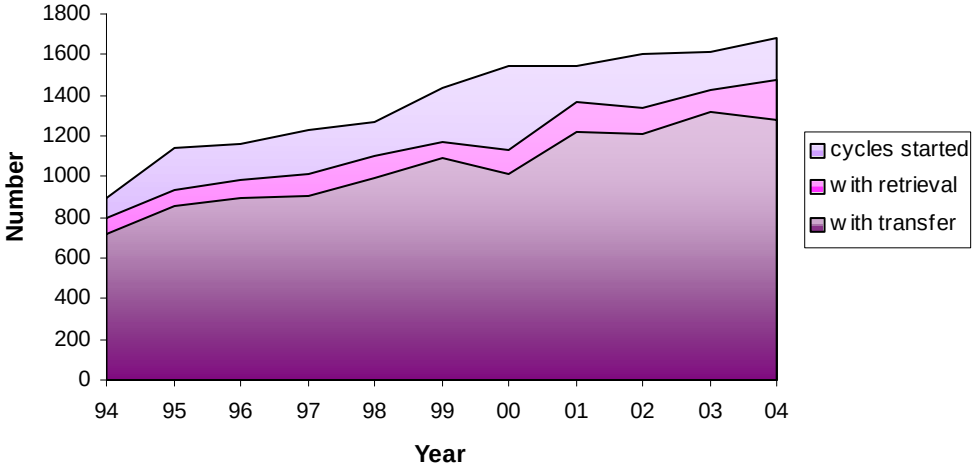


Figure 6: IVF cycles using ICSI

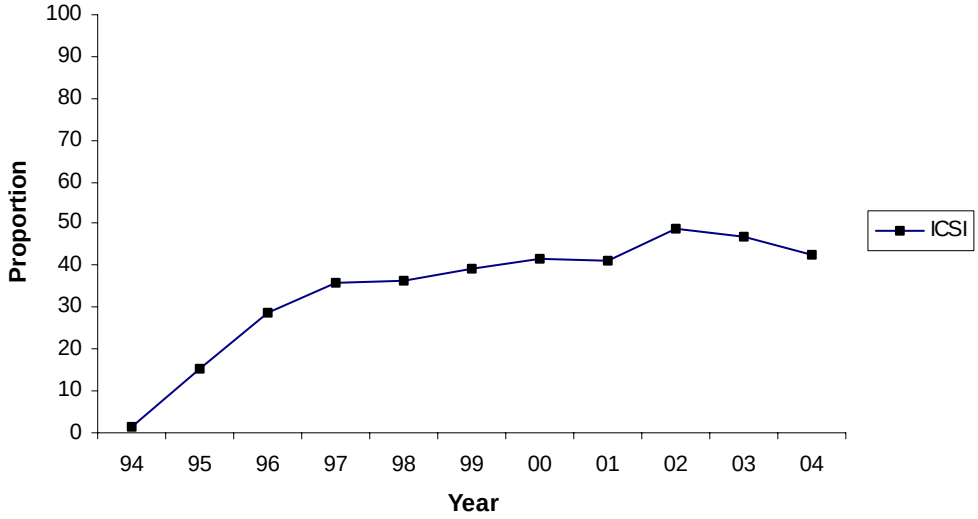


TABLE 4: 2003/04 IVF and GIFT TREATMENTS

	IVF (fresh)	IVF (frozen)	GIFT	TOTAL
Women treated	1164	723	2	1889
Cycles begun	1678	1412	2	3092
Cycles with egg retrieval	1478	-	2	1480
Cycles with gamete or embryo transfer	1279	1225	2	2506
Cycles with embryos storage	888	-	1	889
Number of cycles using donor:				
Semen	66	57	0	123
Eggs	23	47	0	68
Embryos	0	32	-	35
Total	89	136	0	226
Number of cycles from which human reproductive material was donated:				
Eggs donated	26	-	0	26
Embryos donated	-	-	0	0
Breakdown of treatment cycle details				
Cycles with IVF/GIFT same cycle	0	0	0	0
Cycles with surgical sperm aspiration	51	-	0	51
Cycles with ICSI*	629	-	0	629
Cycle with Fallopian embryo/egg transfer	2	1	0	3

* ICSI is Intra Cytoplasmic Sperm Injection, a form of microinjection.

TABLE 5: IVF AND RELATED TREATMENT OF PUBLIC PATIENTS

	No. of Patients				No. of Treatment Cycles			
	2000/01	2001/02	2002/03	2003/2004	2000/01	2001/02	2002/03	2003/2004
IVF	87	77	50	65	126	114	71	82
GIFT	0	0	0	0	0	0	0	0
FET	19	64	39	27	101	142	127	104
TOTAL	**106**	**141**	**89**	**92**	**227**	**256**	**198**	**186**

APPENDIX 4

REPORT FROM THE REPRODUCTIVE TECHNOLOGY REGISTER: JANUARY 1 TO DECEMBER 31 2002

REPORT FROM THE REPRODUCTIVE TECHNOLOGY REGISTER: 1 JANUARY TO 31 DECEMBER 2002

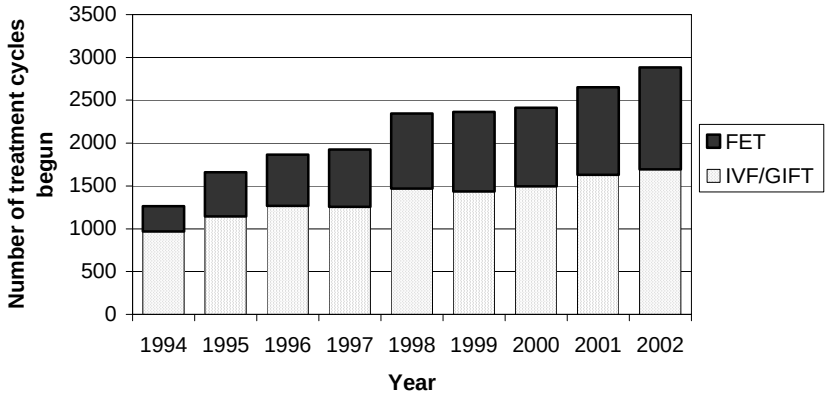
This is the tenth report from the Reproductive Technology Register established from 8 April 1993 under the WA *Human Reproductive Technology Act 1991*. This report summarises information about artificial fertilisation procedures undertaken in Western Australia between 1 January and 31 December 2002. 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 1 exempt practitioner.

Comparisons are made throughout the summary to data reported in previous years[1-8] 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)[9]. 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 2002 data on the Reproductive Technology Register.

There was a total of 2884 treatment cycles begun for IVF and related procedures (GIFT and frozen embryo transfer (FET)) in 2002, an increase of 8.80% compared to the previous year (2651). The majority of these (1694) were stimulation cycles for IVF or GIFT (see Table 2), and 1190 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. The number of FET procedures in 2002 (1190) represented the largest number of FET cycles commenced since the procedure was established and 171 more cycles than last year. In 2002 treatment cycles begun for frozen embryo transfer represented 41.3% of all treatment cycles begun.

Figure 1: Number of treatment cycles begun for IVF/GIFT and FET, 1994-2002



During 2002, 1198 women (23 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 12.8% of cases, which is slightly lower than last year (2001: 15.7%). A wide clinic range was also evident (0%-23.4%), which may in part reflect the different ovulation induction regimes used by the clinics. Of those egg retrievals attempted, only 0.5% were performed by laparoscopy while 99.5% 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 (10.0, median = 9) than by laparoscopy (6.8, median = 8). The overall mean and median for both techniques combined were 10.0 and 9 respectively. This is a slight decrease in the mean number of eggs retrieved compared to the last two years (2001: 10.5 and 2000: 10.8). Attempted egg retrievals were almost all successful (98.0%) with a narrow clinic range (97.5%-98.8%).

Eggs were donated in 2.3% of successful egg retrievals, and 31.5% 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, Humegon, and Metrodin, 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, Saizen (growth hormone) and Cetrotide were used in a limited number of cases.

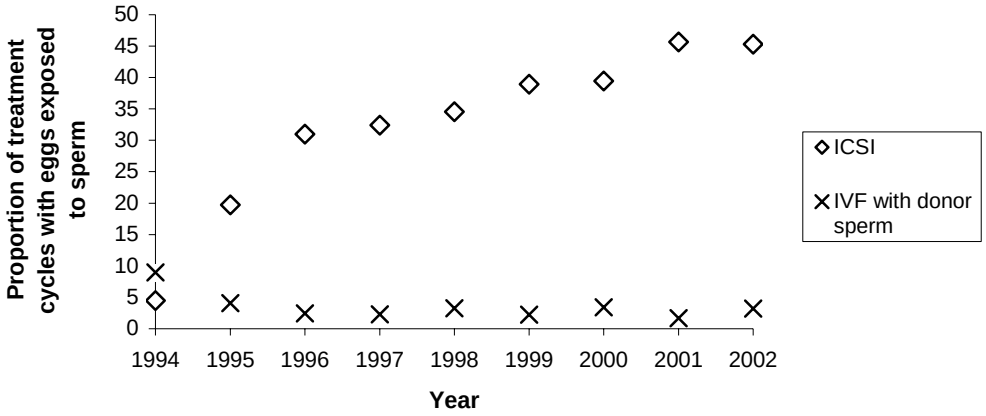
Between 1 January and 31 December 2002, 1415 women had embryo transfers (fresh or frozen) or egg transfers (GIFT) (see Table 3). This represents a 6.2% increase compared to the 1333 women having embryo transfers in 2001, and more than double the women treated in 1994 (687: the first year complete data was collected). The majority of these women (45.3%) had only fresh embryo transfers, although 28.7% had only frozen embryo transfers, and 25.8% had both IVF and FET transfers. Of the 1415 women treated in 2002, table 4 shows most had only one transfer during the year (57.1%), although 25.0% had two transfers and 10.4% had three. One hundred and seven women had more than three transfers, the highest being 2 woman who had 7 transfers during the reporting period. The mean number of transfers per woman in this period was 1.7 and the median 1.

Table 5 summarises the fertilisation and embryo dispersal data for treatment cycles commenced between 1 January and 31 December 2002. There were 1453 cycles with eggs exposed to sperm, a further increase on 2000 where there were 1360 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 9.2 (median 8) with a clinic range from 8.3 to 10.4 (and the median varied between the clinics from 7 to 9).

Use of Intra-cytoplasmic sperm injection (ICSI) to achieve fertilisation was used in 45.4% of treatment cycles with eggs exposed to sperm, with a wide clinic range (39.2%-52.9%). This is the first time since its introduction that use of ICSI has not increased

from the previous last year. 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, 1994-2002



Fertilisation of one or more eggs occurred in 96.4% of treatment cycles with eggs exposed to sperm (Table 5). The range between clinics for successful fertilisation per egg exposed to sperm was narrow (69.8%-74.4%), and for all clinics combined was 72.4%. Donor sperm was only used in 3.2% of treatment cycles, an increase from 2001 when it was used in 1.7% of cycles (see Figure 2 above). There was a marked difference in fertilisation rates using husbands' sperm compared to donor sperm (72.8% vs 62.2%). It is difficult to determine the reason for this variance and it is probably a random occurrence. There appears to be no consistent pattern over the years regarding fertilisation rates for donor compared to husbands' sperm. In 2002, 2000, 1998 and 1997 husband's sperm had higher fertilisation rates then donor sperm (2002: 72.8 vs 62.2, 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 90.3% of treatment cycles with successful fertilisation, with a wide clinic range from 82.5% to 94.5% (see Table 5). These proportions do not appear to reflect the effectiveness of fertilisation and embryonic development (as the clinic with the lowest number of cycles leading to fresh transfer had the best rate of fertilisation). 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 64.4% of treatment cycles with successful fertilisation (see Table 5), and some embryos were allowed to succumb in 58.5% of treatment cycles. The majority of embryos that were allowed to succumb were reported by clinics to have been abnormal or to be degenerating (93.6%).

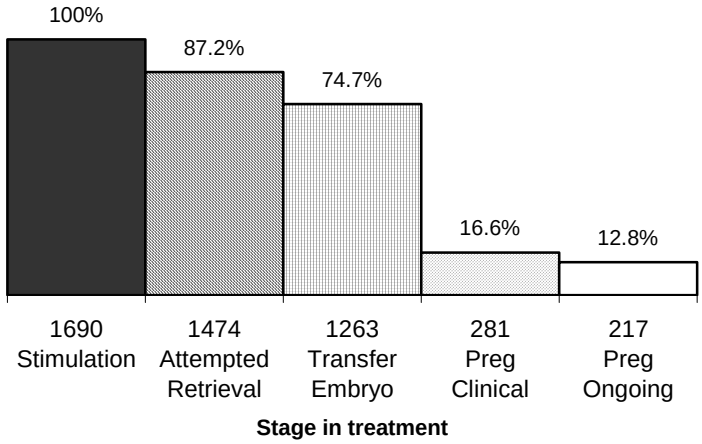
Fresh Embryo Transfer (IVF-ET):

There were 1263 fresh embryo transfers in 2002, only 97 more than the previous year (see Table 6). Donor egg embryos and donor sperm embryos were used in 0.8% and 2.9% of fresh embryo transfers respectively. In one case (0.1%) both donor eggs and donor sperm were used in the embryos. There were 281 clinical pregnancies resulting from IVF embryo transfer (19.1 per 100 egg retrieval cycles) and 216 ongoing (14.7 per 100 egg retrieval cycles, with a clinic range of 11.9-18.5). These pregnancy rates were slightly lower than in 2001 when there were 22.7 clinical pregnancies per 100 egg retrieval cycles and 16.8 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 16.6 clinical pregnancies per 100 stimulation cycles begun, and 12.8 ongoing pregnancies per 100 stimulation cycles.

Figure 3: Results in subsequent phases of IVF-ET treatment, in 2002



Of the confirmed 211 pregnancies with live births, 81.0% were singleton, 18.5% were twin and there was one set of triplets. 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 252 live births in 2002, 3 stillbirths and 1 neonatal death. This represents a perinatal mortality rate of 15.7per 1000 total births. There was one singleton stillbirth and both twins from a twin pregnancy were stillborn. The neonatal death was one baby from a set of twins. The 2002 perinatal mortality rate for *all* babies born in Western Australia was 9.2 per 1000 total births.[10]

As the numbers of embryos transferred influences the proportion of multiple births, 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 1.8, and the median 2 (clinic range 1.6-2.0 with a median of 2 for all clinics). In WA the percentage of cycles where more than two oocytes or embryos were transferred was 7.7%. This is slightly lower than that observed for all Australian and New Zealand IVF clinics combined (15.4%).[9] 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 1.4% to 16.9% of fresh embryo transfer cycles. This difference may influence the overall proportion of multiple births in each clinic (range 5.9%-24.5% 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 2002. 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 (46.2% vs. 21.0%). There was only one case of live born triplets in IVF fresh embryo transfers in 2002, which was a consequence of a three embryos transfer. There were only 3 transfers where 4 embryos were replaced.

An analysis of the implantation rate (the proportion of embryos replaced at fresh transfer which resulted in a birth) varied between the clinics from 7.5% to 14.8%. The implantation rate for all clinics was 11.0%. Implantations rates were highest for single embryo transferred (1 embryo: 12.3%; 2 embryos: 11.4%; 3). The implantation rate for cycles where three embryos were transferred was significantly lower than when one or two embryos are transferred (3 embryos: 7.1%).

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	301	36	36	12.0	0	0	1	37.0
Two	865	162	196	18.7	21.0	0	3	15.2
Three	94	13	20	13.8	46.2	7.7	0	0
Four	3	0	0	0	0	0	0	0
Total	1263	211	252	16.7	19.0	0.5	4	15.7

Gamete Intra Fallopian Transfer (GIFT):

GIFT transfers accounted for only 0.1% of all assisted conception transfer procedures performed in 2002. Only two clinics carried out GIFT treatments only an estimated* 3 treatment cycles begun for GIFT which represented 0.2% of egg retrieval cycles attempted (Table 7). GIFT has been in steady decline since 1994 (2001: 4, 2000: 7, 1999: 25, 1998: 26, 1997: 74, 1996: 90, 1995: 140, 1994: 286). It is 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 2.3 (median 2).

Two of the GIFT cycles resulted in ongoing pregnancies, indicating a 67% success rate per GIFT cycle for 2002. Both of these pregnancies resulting in three live born babies, one singleton and one set of twins. 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 774 women who undertook frozen embryo transfer procedures in the reporting period. This represents a further increase in the number of women undergoing FET (2001: 708, 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 2002 (1190), from that of 2001 (1019). The 1190 treatment cycles begun for FET accounted for 32.0% to 52.7% of all transfer procedures (for IVF, GIFT and FET) in the different IVF clinics. Embryo transfer occurred in 96.8% of treatment cycles begun for FET, and 11.5% of these involved donated material. Donor eggs were used in 5.4% of transfers; donor sperm in 2.4%; both sperm and donor egg in 0.3% and donor embryos were used in 3.4%.

The mean number of embryos transferred at FET was 1.8 (and the median 2). There were 219 clinical pregnancies (19.0 per 100 embryo transfer cycles) and 167 ongoing pregnancies (14.5 per 100 embryo transfer cycles with a clinic range of 12.7-18.2). The ongoing pregnancy rate in 2001 was slightly higher (18.9 per 100 embryo transfer cycles). There were 161 pregnancies with confirmed live births, 86.3% were singleton, 13.7% twins and there were no triplets. There was 1 stillbirths and no neonatal deaths following FET treatment in 2002.

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.[9]

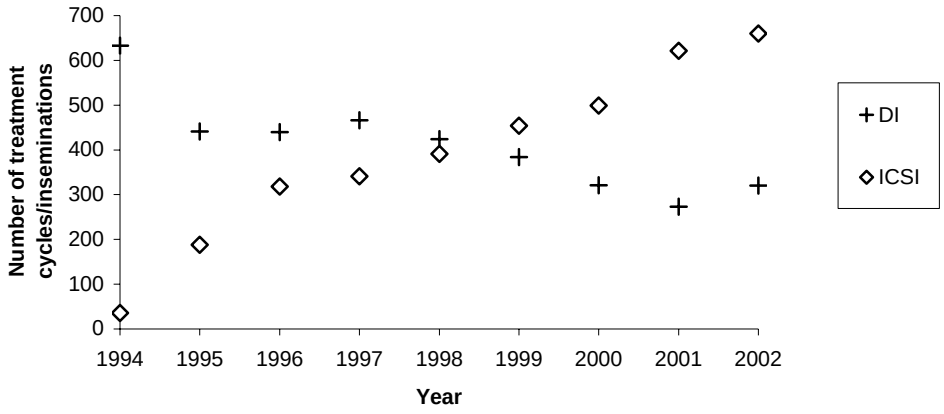
A large number of factors may be important in determining the difference between clinics in live birth pregnancy rates seen for FET (12.7-16.7 per 100 embryo transfer cycles). The average number of eggs collected per retrieval in each clinic will influence the number of embryos developed, in turn influencing 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 320 DI treatments undertaken by 105 women in 2002, slightly more than the 273 DI treatments undertaken in 2001. 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 undertaken was less than the number of ICSI treatments.

Figure 4: Number of treatment cycles using ICSI and number of donor inseminations, 1994-2002



The mean number of inseminations per woman treated in 2002 was 3.0 (median 3), with a clinic range of 2.0 to 3.8 (and a median range of 2-3.5). There were 26 clinical pregnancies as a result of DI treatment (8.1 per 100 insemination treatments) and 22 ongoing pregnancies (6.9 per 100 insemination treatments). Twenty one percent of women treated during the year had an ongoing pregnancy. Of 21 pregnancies with confirmed live births, 85.7% were singleton and 14.3% were twin. These resulted in 24 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 2003/04 earlier in this report and this 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 2002. Forty-eight egg donors, 113 sperm donors and 23 embryo donor couples all donated material used in this period. There were 13 babies born of treatment cycles involving donor eggs, 30 babies through treatment involving donor sperm, 5 babies were born from donated embryos and one baby born from combined donor egg and donor sperm embryos.

Notes:

Comparisons to national data relate to the 2001 calendar year as the 2002 results had not yet been published at the time of printing. These results are due to be published in October 2004.

Multiple birth comparisons are made to national data for the 2000 calendar year as 2001 and 2002 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; for their assistance in providing information on confinements and neonatal deaths and implementation of an internal linkage of the Reproductive Technology Register.

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TABLE 2: IVF/GIFT egg retrievals and dispersals between 1 January and 31 December 2002

	Treatment Cycles				Women
	N	%	%	%	N
IVF/GIFT treatment begun:	1694 (160-595)	100.0			1198
No. cycles begun per woman - Mean: (range[1])					1.4 (1.3-1.5)
Median: (range[1])					1 (1-1)
Cancelled: (range[1])	217 (0-139)	12.8 (0-23.4)			
Total egg retrievals attempted[2] - (range[1])	1477 (160-456)	87.2	100.0		
Laparoscopy:	7		0.5		
Trans Vaginal Ultrasound:	1470		99.5		
Failed retrievals: (range[1])	29 (2-11)		2.0 (1.3-2.5)		
Successful egg retrievals: (range[1])	1448		98.0 (97.5-98.8)	100.0	
Mean number of eggs per successful retrieval -					
All: (median)	10.0 9				
Laparoscopy: (median)	6.8 8				
Trans Vaginal Ultrasound: (median)	10.0 9				
With eggs exposed to sperm:	1438[3]			99.3[2]	
With eggs transferred at GIFT:	3			0.2[2]	
With eggs donated:	33			2.3[2]	
With eggs used for experimentation:	0			0.0[2]	
With eggs discarded:	456			31.5[2]	

Footnotes:
1) (range[1]) gives the range of results from the four IVF clinics.
2) These categories are not exclusive.
3) 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 2002

Transfer Type	N	%
IVF-ET only	641	45.3
FET only	406	28.7
GIFT only	3	0.2
IVF-ET & FET	365	25.8
GIFT & FET	0	0.0
IVF-ET & GIFT	0	0.0
IVF-ET, GIFT & FET	0	0.0
TOTAL	**1415**	**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 2002

No. of Transfers[1]	N	%
1	808	57.1
2	354	25.0
3	147	10.4
4	63	4.5
5	35	2.5
6	6	0.4
7	2	0.1
TOTAL	**1415**	**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 2002

	Treatment Cycles			Eggs/Embryos			Women
	N	%	%	N	%	%	N
Eggs exposed to sperm:	1457	100.0		13319	100.0		1136
(range[1])	(156-451)						
Mean number of eggs exposed to sperm per treatment cycle:				9.1			
(range[1])				(8.3-10.3)			
Median:				8			
(range[1])				(7-9)			
Using husband sperm:	1410	96.8					
(range[1])		(93.6-97.4)					
Using donor sperm:	47	3.2					
(range[1])		(2.6-6.4)					
Using micro-manipulation -	660	45.3					
(range[1])		(39.2-52.5)					
ICSI:	660	45.3					
SUZI:	0	0.0					
PZD:	0	0.0					
PZD/SUZI:	0	0.0					
Failed fertilisation:	54	3.7					
(range[1])		(2.4-4.6)					
Fertilisation occurred:	1403	96.3	100.0	9643	72.4	100.0	
(range[1])	(150-440)						
Using husband sperm:				9340	72.8[2]		
(range[1])					(70.8-74.8)		
Using donor sperm:				303	62.2[2]		
(range[1])					(60.7-62.9)		
Fresh embryo transfer	1264		90.1	2324	17.4	24.1	
(range[1])			(82.1-94.5)				
Embryo freezing	905		64.5	5086	38.2	52.7	
(range[1])			(50.0-73.6)				
Embryo donation	0		0.0	0	0.0	0.0	
Embryos discarded	819		58.4	2233	16.8	23.2	

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 (2090) and 143 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:	1474[2]	100.0				
(range[1])	(160-454)					
With embryos transferred -	1263[3]	85.7	100.0		1006	100.0
(range[1])	(140-415)					
Donor -						
Egg:	10		0.8			
Sperm:	36		2.9			
Egg+Sperm:	1		0.1			
Embryo:	0		0.0			
Number embryos per transfer -						
Mean:	1.8					
(range[1])	(1.6-2.0)					
Median:	2					
(range[1])	(2-2)					
Clinical pregnancy -						
Yes:	281	19.1	22.2		276	27.4
(range[1])		(15.6-22.5)	(17.9-24.6)			
No:	982	66.6	77.8		730	72.6
Blighted ovum:	14	0.9	1.1			
Missed abortion:	34	2.3	2.7			
Spontaneous abortion:	8	0.5	0.6			
Ectopic:	9	0.6	0.7			
Therapeutic abortion:	1	0.1	0.1			
Ongoing clinical pregnancy at 20 weeks:	216	14.7	17.1		216	21.5
(range[1])		(11.9-18.5)	(13.6-20.2)			
Pregnancies with live births:	211[4]	14.3	16.7	100.0	212	21.1
(range[1])		(11.9-18.3)	(13.6-20.0)			
Plurality:						
1	171	11.6	13.5	81.0		
(range[1])		(8.8-15.2)	(11.2-16.6)	(74.0-94.7)		
2	39	2.6	3.1	18.5		
(range[1])		(0.6-3.1)	(0.7-3.9)	(5.0-26.0)		
3	1	0.1	0.1	0.5		
(range[1])		(0-0.2)	(0-0.3)	(0-1.7)		
Live Births:	252	17.1	20.0			
Still Births:	3[5]	0.2	0.2		2	0.2
Neonatal deaths (within 28 days of birth):	1[6]	1.0	0.1			

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) One baby was a singleton and the other two were twins from the same pregnancy

6) One baby from a twin pregnancies

Note: Three women gave birth outside WA. In each case the treating clinic reported a birth outcome,

TABLE 7: GIFT transfers and outcomes between 1 January and 31 December 2002

	Treatment Cycles				Women	
	N	**%**	**%**	**%**	**N**	**%**
Egg retrievals attempted for GIFT*:	3	100.0				
(range[1])	(0-2)					
With eggs transferred -	3	100.0	100.0		3	100.0
(range[1])	(0-2)					
Donor -						
Egg:	0		0.0			
Sperm:	0		4.0			
Egg+Sperm:	0		0.0			
Number eggs per transfer -						
Mean:	2.3					
(range[1])	(0-3.0)					
Median:	2					
(range[1])	(0-3)					
Clinical pregnancy -						
Yes:	2	66.7	66.7		2	66.7
(range[1])			(50-100)			
No:	1	33.3	33.3		1	33.3
Blighted ovum:	0	4.0	4.0			
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:	2	66.7	66.7		2	66.7
(range[1])						
Pregnancies with live births:	2	66.7	66.7	100.0	2	66.7
(range[1])						
Plurality:						
1	1		33.3	50.0		
(range[1])						
2	1		33.3	50.0		
(range[1])						
Live Births:	3	100.0	100.0			
Still Births:	0	0.0	0.0		0	0.0
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.

TABLE 8: Frozen Embryo Transfers between 1 January and 31 December 2002

	Treatment Cycles				No. of Embryos		Women	
	N	%	%	%	N	%	N	%
Treatment cycles begun for FET:	1474	100.0						
(range[1])	(160-454)							
Cancelled:	22	1.8						
Number embryos thawed:					3349	100.0		
Number embryos flawed:					1286	38.4		
Totally failed thaw:	16	1.3						
Embryos transferred -	1152	96.8	100.0		2063	61.6	761	98.3
Own:	1020		88.5		1822			
Donor -								
Egg:	62		5.4		118			
Sperm:	28		2.4		52			
Egg + Sperm:	3		0.3		6			
Embryo:	39		3.4		65			
Number embryos per transfer -								
Mean:					1.8			
(range[1])					(1.5-2)			
Median:					2			
(range[1])					(1-2)			
Clinical pregnancy -								
Yes:	219	18.4	19.0				214	27.6
(range[1])		(15.1-24.3)	(15.1-25.0)					
No:	933	78.4	81.0				547	70.7
Blighted ovum:	11	0.9	1.0					
Missed abortion:	27	2.3	2.3					
Spontaneous abortion:	6	0.5	0.5					
Ectopic:	7	0.6	0.6					
Therapeutic abortion:	1	0.1	0.1					
Ongoing clinical pregnancy at 20 weeks:	167	14.0	14.5				167	21.6
(range[1])		(11.7-17.7)	(12.7-18.2)					
Pregnancies with live births:	161[2]	13.5	14.0	100.0			161	20.8
(range[1])		(11.7-16.2)	(12.7-16.7)					
Plurality:								
1	139	11.7	12.1	86.3				
(range[1])		(10.2-13.0)	(11.2-13.4)	(80.4-91.5)				
2	22	1.8	1.9	13.7				
(range[1])		(1.1-3.2)	(1.1-3.3)	(8.5-19.6)				
3	0	0.0	0.0	0.0				
(range[1])								
Live Births:	182	15.3	15.8					
Still Births:	1[3]	0.1	0.1				1	0.1
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) Six women were lost to follow up and their birth details were unavailable therefore they are excluded from confinement data.

3) One baby from a twin pregnancy

TABLE 9: Donor Insemination treatments and outcomes carried out between 1 January and 31 December 2002

	Treatment Cycles			Women	
	N	**%**	**%**	**N**	**%**
DI carried out:	320	100.0		105	100.0
(range[1])	(3-178)				
No. DIs per woman treated -					
Mean:				3	
(range[1])				(2.0-3.8)	
Median:				3	
(range[1])				(2-3.5)	
Clinical pregnancy -					
Yes:	26	8.1		25	23.8
(range[1])	(0-9)	(0-21.1)			
No:	294	91.9		80	76.2
Blighted ovum:	1	0.3			
Missed abortion:	1	0.3			
Spontaneous abortion:	1	0.3			
Ectopic:	1	0.3			
Therapeutic abortion:	0	0.0			
Ongoing clinical pregnancy at 8 weeks:	22	6.9		22	31.0
(range[1])		(0-18.4)			
Pregnancies with live births:	21[2]	6.6	100.0	21	20.0
(range[1])		(0.0-18.4)			
Plurality:					
1	18	5.6	85.7		
(range[1])		(0.0-15.8)	(77.8-100)		
2	3	0.9	14.3		
(range[1])		(0.0-2.6)	(0.0-22.2)		
3	0	0.0	0.0		
(range[1])					
Live Births:	24	7.5			
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 4 holders of Practice Licenses and from 1 Exemptee who performed 1 or more DI's during the period.

2) One woman was lost to follow up and her birth details were unavailable therefore they are excluded from confinement dat

TABLE 10: Donation of Human Reproductive Material between 1 January and 31 December 2002

	IVF-ET	GIFT	FET	DI	TOTAL
Number of Treatment Cycles -					
Donor Egg:	10	0	62	-	72
Donor Sperm:	36	0	28	320	384
Donor Egg+Sperm:	1	0	3	-	4
Donor Embryo:	0	-	39	-	39
Number of Babies Born -					
Donor Egg:	3	0	10	-	13
Donor Sperm:	2	0	4	24	30
Donor Egg+Sperm:	0	0	1	-	1
Donor Embryo:	0	-	5	-	5
Number of Donors Used -					
Donor Egg:	11	0	39	-	48
Donor Sperm:	32	0	21	79	113
Donor Embryo[2]:	0	-	23	-	23

Footnotes:

1) The total number of egg and sperm donors is not equivalent to the sum of 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

INFORMATION

Interim Information: Proposed Changes To The *Human Reproductive Technology Act 1991* - Release Of Identifying Information About Donation.

TO: PERSONS RESPONSIBLE AT ALL CLINICS LICENSED UNDER THE *HUMAN REPRODUCTIVE TECHNOLOGY ACT 1991*

FROM: Con Michael
Chair
Reproductive Technology Council

DATE: 14 May 2004

RE: Interim information concerning proposed changes to the *Human Reproductive Technology Act 1991* (HRT Act) relating to the release of identifying information about donation.

As reported in the West Australian on Wednesday 12 May 2004, the Government has now decided to include amendments relating to the release of identifying information about donation along with the amendments currently under debate in the Legislative Council that arose from the Council of Australian Governments (COAG) agreement of 5 April 2002 on human cloning and embryo research.

These amendments (attachment 1) address two separate aspects of the issue of access to identifying information about donation. It is anticipated that, prior to proclamation of the amendments, the Commissioner of Health will issue relevant Directions. These will set explicit and detailed standards for practice in this area. It is anticipated that the Directions will generally rule out any use of donated material where a donor has not consented to the material being used in the knowledge that the law provides that identifying information may be released to a donor offspring aged 16 or over. There will be scope for exceptions to this prohibition in some circumstances.

Background

The impetus for the change was highlighted by the case that has had media attention recently, where neither the clinic nor the Reproductive Technology Register could release identifying information to an egg donor and recipients who requested this. The HRT Act requires, in addition, the consent of the donor offspring for this sharing of information. As in most other aspects of family life there is scope for parents to consent on behalf of their minor children and therefore it is appropriate that this right be extended to cover these circumstances. The proposed amendments however do set in place a requirement for any sharing of identifying information to follow approved counselling to address, in particular, what may be in the best interests of the child.

The second proposed change will put in place a significant recommendation of the Select Committee, which carried out an extensive review of the HRT Act and reported in 1999. These recommendations followed extensive public consultation by the Committee, including with the clinics. The Committee recommended amendment of the HRT Act to provide a right for mature donor offspring to obtain identifying information about their donors, although this right was not to be made retrospective.

You should also be aware that although the HRT Act in WA is to bring in these explicit requirements for this state, similar standards are likely to be set throughout the country when the National Health and Medical Research Council's (NHMRC's) revision of the 1996 *Ethical*

guidelines on assisted reproductive technology is completed. These guidelines are currently undergoing revision and their final form not yet known, but the draft revision released for public consultation in February 2003 (draft *Ethical guidelines on the use of assisted reproductive technology in clinical practice and research*) contained similar requirements to those being proposed by the amendments to the HRT Act. These would allow the release of identifying information to mature donor offspring and rule out the use of donated reproductive material unless the donor is aware that identifying information may be released to mature offspring born as a result of the donation. Both the Commonwealth's *Research Involving Human Embryos Act 2002* and an amended HRT Act include a requirement that use of non-excess ART embryos occurs in a Reproductive Technology Accreditation Committee (RTAC) accredited ART clinic. A requirement for RTAC accreditation is compliance with the NHMRC's current ethical guidelines.

Summary

In summary, it is anticipated that the overall effect of the changes proposed through amendment of the HRT Act and new Directions will be as follows:

- There should be no use of donated human reproductive material where a donor is not aware that identifying information can be provided to mature donor offspring.
- All new donors should be recruited on this understanding.
- All donors who donated prior to the changes coming into effect should be contacted and their consent to the use of the donated material be renewed in the knowledge that identifying information about them may be released to mature donor offspring conceived in future treatments sought. Where they cannot be found or they do not consent their donated material should not be used again, except in circumstances that may be established under Directions.
- There will be no retrospective right to identifying information for offspring conceived prior to the amendments using this donated material. It is only where the donation was made with the knowledge that identifying information may be provided or with the consent of these donors that this information may be shared.

Although this is not explicitly set out in the amendments, it is anticipated that prior to proclamation of the amendments Directions will be issued that will rule out use of donated material where the donor has not consented to the release of identifying information to mature offspring, with several compassionate exceptions. Anticipated exceptions are where embryos have been developed and stored using donated material, or a woman wishes to undergo a further donor treatment with the aim of having a full sibling to an existing donor child and the donor who donated prior to the amendments coming into force cannot be found or refuses to give consent to the release of identifying information.

Con Michael

14 May 2004

Con Michael AO — Date
Chair, Reproductive Technology Council

Attachment 1.

Amendments to Section 49 of the *Human Reproductive Technology Act 1991* to be moved by the Parliamentary Secretary in the Legislative Council.

The Parliamentary Secretary to the Minister for Health: To move -

19/33 Page 34, after line 7 - To insert -

"

(2) Section 49(2)(d) is amended by inserting before "with" —

" subject to subsections (2a) to (2c), ".

(3) After section 49(2) the following subsections are inserted —

"

(2a) Information that would identify a child born as a result of the relevant procedure who has not reached 16 years of age cannot be divulged or communicated under paragraph (d) of subsection (2) unless each person who has given consent for the purposes of that paragraph has completed approved counselling before giving that consent.

(2b) Except as provided in subsection (2c), a child who has not reached 16 years of age cannot consent for the purposes of paragraph (d) of subsection (2).

(2c) A person who has parental responsibility (as defined in section 68 of the *Family Court Act 1997*) for the child may, after completing approved counselling, consent for the purposes of paragraph (d) of subsection (2) on behalf of that child and in that case the child is to be taken to have consented for the purposes of that paragraph.

(2d) Subject to subsection (2e), information to which subsection (1)(a) applies may be divulged or communicated to a child resulting from the donation who has reached 16 years of age and who has completed approved counselling.

(2e) Information cannot be divulged or communicated under subsection (2d) unless —

(a) the donation was made on or after the day on which the *Human Reproductive Technology Amendment Act 2003* came into operation (the **"commencement day"**); or

(b) the donation was made before the commencement day and —

(i) was used with the effective consent of the donor given on or after the commencement day; or

(ii) the Commissioner of Health is satisfied that the donor was, before the donation, adequately informed that future changes in legislation might enable the information to be divulged or communicated to the child without the donor's consent.

(2f) In subsections (2a), (2c) and (2d) —

"approved counselling" means counselling approved by the Commissioner of Health in relation to the divulging or communication of information to which subsection (1) applies.

Identifying Information Amendments – Introduction

These amendments are to Section 49 of the *Human Reproductive Technology Act 1991*.

Section 49 deals with confidentiality of identifying information about donors of reproductive material, participants in procedures involving reproductive technologies, or children born as a result of any such procedure.

Section 49(1) is a general prohibition on the releasing identifying information obtained by reason of the Act except in circumstances that are set out in section 49(2). The prohibitions apply to both licensees, and the Department of Health, which maintains the register of identity established by Section 45.

Section 49(2)(d) currently provides that identifying information can be provided with the consent of each donor, participant or child, but only insofar as it does not identify a person who has not given consent.

The child's consent would be required to give information that would identify a birth parent to a donor, as the identity of the parent would identify the child. In the case of a young child, it was not possible for a parent to consent on behalf of the child.

The new subsection (2c) introduced by this amendment makes clear that a parent can consent on behalf of a child under the age of 16. Because of the possible impacts on the child and the adults concerned it is important that proper support is provided to ensure that all the issues have been considered before consent is given. The new subsection (2a) provide that before a person can consent either in their own right or on behalf of a child, to the release of identifying information in a case that involves a child under the age of 16 they must have completed approved counselling. The new subsection (2b) provides that a child under the age of 16 cannot consent to the release of identifying information. The new subsection (2f) provides that the form of counselling is to be approved by the Commissioner of Health, who will obtain advice from the Reproductive Technology Council about what counselling is appropriate.

This amendment does not change the limitation in section 49(2)(d) and will only allow the exchange of identifying information in relation to a child under the age of 16 with the consent of all the parties, that is, the birth parents, the donor and a parent on behalf of the child.

The new subsections (2d) and (2e) introduce a new category of exception to the prohibition on the divulging of identifying information.

This exception is when a donor offspring aged 16 years of age or over wants to find out the identity of the donor who contributed eggs or sperm to their conception. Subsection (2d) provides that the donor offspring will be able to be given the information provided that he or she has undertaken approved counselling. The explicit consent of the donor to the provision of the identifying information will not be required at the time of the release of the information where the circumstances in subsection (2e) apply.

Subsection (2e)(a) provides that the identifying information may be provided in cases where the donation of reproductive material (ie eggs, sperm or embryos) is made after the commencement of the provisions in the Bill. Subsection (2e)(b)(i) means that identifying information may also be provided where the donor has provided consent to the use after the date the amendments come into effect. Subsection 2(b)(ii) means that this information may also be provided in situations where there is clear evidence that the donor was aware at the time of the donation that information may later be provided to any resulting child. This latter provision of information will be a matter of evidence, based on the records of the clinic at the time the donation was made.

The provision in subsections (2d) and (2e) to give donor offspring a right to information about their genetic parentage was a recommendation of the Select Committee that reviewed the *Human Reproductive Technology Act 1991* and reported in 1999. In making its recommendation, the Select Committee gave careful consideration to balancing the rights of a child to know the identity of a biological parent with the rights of donors who only donated on the understanding that their donation would be anonymous.

Any past donors who are willing for their identity to be disclosed to a child already born as a result of the donation will be able to register with the Voluntary Donor Register that has been established by the Department of Health in accordance with another of the Select Committee recommendations.

APPENDIX 6

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."*