WESTERN AUSTRALIAN REPRODUCTIVE TECHNOLOGY COUNCIL

ANNUAL REPORT

1 JULY 2001- 30 JUNE 2002

WESTERN AUSTRALIAN

Reproductive T*echnology* C*ouncil*

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This Report may be found on the Council's web site or may be obtained free of charge from:

The **R***eproductive* **T***echnology* **C***ouncil*
189 Royal Street, East Perth WA 6004

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Editor: Sandra M Webb

ISBN 0 7307 0098 4
2002: Perth, Australia

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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 an Annual Report of the Reproductive Technology Council. This Report is for the financial year 2001-2002. 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 September 30 2002 and also, as is required, to be laid by the Minister before each House of Parliament.

The last year has again been one during which politics has significantly impacted upon the area of assisted reproductive technology (ART), at both the state and national levels. These developments have also impacted significantly on the work of the Council.

At the national level the Coalition of Australian Governments worked to achieve consistent national legislation to ban human cloning and other unacceptable practices; and regulate certain activities involving the use of human embryos. It introduced the *Research Involving Embryos and Prohibition of Human Cloning Bill 2002* on 27 June 2002, and plans to debate that in the 2002 Spring Session of Federal Parliament. Indirectly, these developments have placed significant demands on the time of the Executive Officer and Deputy Executive Officer. The State Government has not finalised its response to many recommendations of the Select Committee that reviewed the Act, which may be in concert with the development of legislation consistent with that of the Commonwealth. Implementation of a number of other recommendations of the Select Committee were progressed or finalised during the year.

Significant changes to the HRT Act flow from *the Acts Amendment (Lesbian and Gay Reform) Bill 2001*. When implemented, these changes will require advice from the Council as to the changes necessary to patient information and consent forms; advice to clinics about the changes to the eligibility criteria for IVF treatment. Treatment will no longer be limited to married couples or de facto couples who have co-habited for an aggregate of five years in the previous six years.

Review of the operations of the Council was included in the Terms of Reference of the Select Committee that reviewed the Act and tabled its report in April 1999. Recommendations of the Select Committee generally endorsed the Council's current functions and operations. Some changes to the functions and relationships of the Council may however flow from the June 2001 report of the taskforce that was established to review the machinery of WA's Government (Government Structures for Better Results). The functions of each statutory authority in the State were reviewed during this financial year and a report is expected in December 2002. In the meantime the Council continued to improve the effectiveness of its decision making and to clarify the relationship between the Council and the Department of Health.

I would like to commend current and past Council members for their contributions to the challenging matters we face. I would also, on behalf of all members of the Council, like to acknowledge the provision of ongoing legal, financial and administrative support by the Department of Health, which are all essential for it to carry out its statutory duties.

Yours sincerely

Professor Con Michael AO
CHAIR
Reproductive Technology Council
Date:

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 2001- 2002, 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 2001 - 2002. Information reported by clinics licensed under the HRT Act, gives summary information about their activities during the financial year 2001 – 2002. 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 2000. In addition the report includes information from a variety of sources about various matters of significance to the public interest in reproductive technology.

At the national level the most significant development during the year was the April decision by the Coalition of Australian Governments (COAG) to work towards consistent national legislation to ban human cloning and regulate the use of 'spare' human embryos, such as for stem cell research. Passage of legislation introduced into Federal Parliament on 27 June will impact significantly on operations of assisted reproductive technology services in Western Australia. Changes to the HRT Act will be required to ensure consistency and to remove requirements for dual licensing for embryo research in WA which is not intended.

During the year, the Council had input into the review of the National Health and Medical Research Council's *Ethical guidelines on assisted reproductive technology*. The revised Guidelines, when finalised, will give leadership in shaping policies and practices in Western Australia.

At the state level, the most significant change to assisted reproductive services will be as a result of the *Acts Amendment (Lesbian and Gay Law Reform) Bill 2001*. This Bill received Royal Assent on 17 April 2001 and a proclamation date of 20 September 2002 set. Included in these amendments are some to the HRT Act. Most significantly, these amendments will be to allow single women or women in a lesbian relationship, where they are infertile or whose children risk being affected by a genetic abnormality or disease, to access in vitro fertilisation procedures.

The budget allocation for the Reproductive Technology Unit, which includes funding of all operations of the Council, was $38,000, an increase of $7,000 to meet the costs of higher sitting fees. The Annual Report sets out the financial statement for the year.

This year is the first since 1996, that is when the HRT Act was amended to allow extensions to the embryo storage limit, where the number of applications made by *clinics* has exceeded the number of applications made directly by the *couples*. The Council expressed concern about this situation. A major concern was whether

participants were given sufficient support in their difficult decision about their remaining embryos. This decision may be made more difficult still when one option for future use of 'spare' embryos may be donating them for research. The Minister for Health asked the Council to consider what supports and counselling should be available to couples in these situations. The Council gave this matter a lot of consideration. It plans to discuss it further at its next workshop (in November 2002) and get input from participants.

During the year several studies were published regarding the risks of assisted reproduction on infants born. One of these studies, published in the New England Journal of Medicine in March 2002, was based on data from the Western Australian Reproductive Technology Register, and conducted by Hansen *et al*. It found infants conceived through assisted reproductive technology (ART) were more than twice as likely as naturally conceived infants to be diagnosed with a major birth defect by one year of age. 8.6% of infants conceived with through Intra-cytoplasmic Sperm Injection (ICSI) and 9.0% of infants conceived with standard *in vitro* fertilisation (IVF) were diagnosed with major birth defects. The investigators pointed out that the overall risk of infants conceived with ART being diagnosed with major birth defects was relatively low.

As the research demonstrated that there was no difference in the risk of birth defects in infants conceived through standard IVF compared to those conceived through ICSI, the Council informed clinics that ICSI could now be considered a routine procedure, therefore no longer requiring specific approval.

MEMBERSHIP OF THE COUNCIL

30 June 2002

Professor Con Michael, Chair (Nominee of the Royal Australian College of Obstetrics and Gynaecology);
Ms Antonia Clissa, (Nominee of the Women's Policy Development Branch);
Professor Alan Harvey, (Nominee of the Minister for Health);
Mr Philip Matthews, (Nominee of the Minister for Health);
Dr Mark McKenna, Deputy Chair (Nominee of the Department of Obstetrics and Gynaecology, University of WA);
Ms Sue Hudd, (Nominee of the Minister for Community Development);
Dr Kaye Miller, (Nominee of the Health Consumers' Council);
Dr Beverly Petterson, (Nominee of the Minister for Health); and
Dr Sandra Webb, (Executive Officer, Senior Policy Officer Reproductive Technology, Department of Health, *ex officio*).

Resignations:
Dr Sue Cherry, (Nominee of the Australian Medical Association); and
Dr Gaye Lansdell, (Nominee of the Law Society of WA).

DEPUTY MEMBERS

A/Professor Jim Cummins, (Nominee of the Department of Obstetrics and Gynaecology, University of WA);
A/Professor Jeanette Hacket, (Nominee of the Law Society);
Ms Sue Midford, (Nominee of the Women's Policy Development Branch); and
Fr Joe Parkinson, (Nominee of the Minister for Health);
Mr Peter Grey Searle, (Nominee of the Minister for Community Development);
Ms Amalia Burmas, (Research Officer Reproductive Technology, Department of Health, *ex officio*);

Resignations:
Mrs Christine Lemon, (Nominee of the Health Consumers' Council); and
Rev Tess Milne, (Nominee of the Minister for Health).

COMMITTEES OF THE COUNCIL

TERMS OF REFERENCE AND MEMBERSHIP

30 June 2002

COUNSELLING COMMITTEE

Terms of Reference:
In relation to counselling-

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

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

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

d) convening training programs for counsellors if required;

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

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

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

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

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

Membership:
Ms Sue Midford (Chair); Ms Antonia Clissa; Mrs Stephanie Knox (Patient representative); Mrs Christine Lemon (Patient representative); Mr Peter Grey Searle; Ms Iolanda Rodino; Ms Patrice Wringe, Executive Officer (SPO, Department of Health).

SCIENTIFIC ADVISORY COMMITTEE

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

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

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

Membership:
A/Professor Jim Cummins (Chair); A/Professor Jeanette Hacket; Professor Alan Harvey; Dr Mark McKenna; Mr Philip Matthews; Dr Beverly Petterson; and Dr Sandra Webb (*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; Ms Sue Midford; Professor Con Michael; Ms Sue Hudd; and Dr Sandra Webb (*ex officio*). (Chair of the Committee, Dr Cherry, resigned during the year)

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; Ms Antonia Clissa; A/Professor Jeanette Hacket; Dr Kaye Miller; and Dr Sandra Webb (*ex officio*).

STAFF OF THE REPRODUCTIVE TECHNOLOGY UNIT

Dr Sandra Webb, Senior Policy Officer (Reproductive Technology) and Executive Officer of the Council;

Ms Patrice Wringe, Senior Policy Officer (Surrogacy).

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

Ms Kim Gifkins, Project Officer (0.25FTE for the Unit).

REPRODUCTIVE TECHNOLOGY COUNCIL 2001/2002: FINANCIAL STATEMENT

- The Department of Health funds the administration of the HRT Act, particularly operations of the Council, provided Infrastructure and Workforce Development funding of $38,000 (per annum).

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

	Expenditure ($)	Income ($)
Staff or Council:		
Training/Registration/Course Fees	$102.27	
Travel/Accommodation intrastate		
Travel interstate		
Airfares	$1,464.00	
Accommodation	$2,754.52	
Motor vehicle/Taxis	$399.43	
TOTAL	**$4720.22**	
Food supplies/catering	**$1090.63**	
Purchase of external services:		
Sessional fees:		
Reproductive Technology Council	$9475.00	
Council Committees:		
Counselling	$4819.00	
Scientific Advisory	$881.00	
Embryo Storage	$169.00	
Licensing and Administration	1349.00	
Approved counsellors		
Subsidy of FPA Workshop		
External consulting fees and advertising	$3481.29	
Administration and clerical		
TOTAL	**$20,174.29**	
Other expenses:		
Books/magazines/subscriptions	$1742.23	
Freight and cartage/ postal	$38.20	
Printing and stationery incl. Annual Report	4999.86	
Telecommunication expenses	$506.93	
Entertainment expenses	$173.91	
TOTAL	**$7,461.13**	
Licence applications		**800.00**
Donations from seminar attendance 17.11.01		**$295.00**
Reimbursement from IFFS Conference		**$110.00**
TOTAL	**$33,446.27**	**$1,205.00**
Budget Allocation	**38,000.00**	

OPERATIONS OF THE COUNCIL
1 JULY 2001 TO 30 JUNE 2002

MEETINGS, MEMBERSHIP AND STAFFING

Meetings

The Council met on nine occasions during the year, with an average attendance of 76 per cent. The Counselling Committee met on eight occasions; the Scientific Advisory Committee on one occasion; the Licensing Committee on two occasions (there was also a site visit by this committee); and the Embryo Storage Committee on two occasions.

Membership

There was stable membership during the past year, with the only change to the committee members being the resignation of Dr Sue Cherry in December 2001. Dr Cherry's successor has not been appointed. Pending the report on the Review of Statutory Bodies no new appointments have been made. A/Professor Hacket, who took over as the Law Society nominee, when Dr Lansdell took extended leave, has continued in that role.

The Minister for Health approved an increase in the sitting fees of eligible members on 24 July 2002. The following rates apply from that date: Chairperson $323 per day and $213 per half day; and members $215 per day and $142 per half day.

Staff assisting the work of the Council

During the year Ms Amalia Burmas was awarded the permanent appointment as Research Officer and continues to be the deputy Executive Officer.

Ms Patrice Wringe took on more integral roles in relation to the Council during the past twelve months, including a number of responsibilities of the Executive Officer, especially in relation to the psychosocial aspects of ART. She continued to support the work of the Counselling Committee. She had a key role in the organisation of two seminars during the year. Ms Wringe continued preparatory work towards the development of the Voluntary Donor Register, which is likely to be launched later in this calender year. She finalised the Audit of Infertility Counselling Services and worked towards the implementation of its findings. She is still responsible for work on surrogacy matters.

Ms Kim Gifkins, Project Officer (0.25FTE), continued to provide some administrative support to the Council, up to one day a week.

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

During the year the Council considered its functioning and its interface with the Department of Health. A draft document, entitled *'Functioning of Council: Operational changes and clarification of roles and responsibilities'*, was discussed at the Council meeting in July 2001. At that meeting the review of statutory bodies being undertaken by the Government was noted. The need to clarify the lines of responsibilities for statutory authorities to ensure independence of their statutory roles and clear responsibilities and accountabilities was identified. It was agreed that there should be discussion with the Commissioner of Health with regard to proposals for interaction with the Department and disbursement of its budget. That discussion took place in early February 2002, and clarified a number of issues.

LICENSING MATTERS

New and current licences and Exemptions

- On Council advice, the Fertility West Practice and Storage licences were annotated to include a new 'transport IVF' clinic at Joondalup Hospital, until the end of December 2001 when Fertility West closed. On 31 January 2002, Practice and Storage Licences were granted to Joondalup IVF for a period of six months.

- Licenses at the Public Fertility Clinic at King Edward Memorial Hospital for Women, which expired in May 2001 were not renewed, but referrals from that clinic for IVF and artificial insemination to Concept Fertility Centre continued.

- Nine medical practitioners requested revocation of their Exemptions from the requirement to be licensed to carry out artificial insemination (Dr LM Farrell, Dr DN Spence, Dr AM Cooney, Dr PH Faulkner, Dr GL White, Dr P McAllister, Dr SR Turner, Dr JH Payne, Dr NP Silberstein). During the year there were no new applications for Exemptions.

Information circulated to Licensees

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

The matters covered were:

- The *Privacy Act 1988* (January 2002)
- Proposed changes to the reporting to the Reproductive Technology Register (March 2002)
- Minimum standards for ICSI use, screening, patient information and follow-up in WA fertility clinics (April 2002).

Contraventions of the Act

The Commissioner of Health disciplined one licensee during the year. On 8 November 2001 Licensee Fertility West Administration Services Pty Ltd submitted to a summary determination made by the Commissioner of Health on 31 October 2001. This summary determination was that the licensee and the person responsible had stored three sets of embryos beyond the permitted storage period, in contravention of section 24(1)(b) of the HRT Act.

The Commissioner imposed penalties, as provided for in section 40(1)(d) of the HRT Act. These involved the licensee and person responsible entering into a formal

written undertaking to develop an effective and documented system identifying embryo storage periods; develop a management structure which provides for appropriate communication and reporting between the person responsible and other members of staff as to the impending expiries of storage periods of all embryos held in storage; and provide evidence of implementation and effectiveness of the new system and management structure, to the reasonable satisfaction of the Council.

Complaints

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

EMBRYO STORAGE

Introduction

When the *Human Reproductive Technology Act 1991* (HRT Act) became operational on 8 April 1993, it permitted the storage of frozen embryos for a maximum of three years. Early in the operation of the HRT Act the Council recognised that this storage limit was too restrictive as many couples were seeking to store embryos for a longer time period, for example to allow for family spacing. Therefore urgent recommendations were made to the Minister for Health requesting amendments to the HRT Act to allow embryos to be stored for more than three years. In April 1996 the HRT Act was amended to allow the Council to grant extensions to the permitted storage period, where there are special reasons for doing so in a particular case.

The HRT Act does not specify who is to apply for these extensions to storage. In practice there are two methods whereby embryo storage extension applications may be made, namely:

1. through a **Form 8** application - the participants for whom the embryos are stored and who have the right to make decisions about them may apply for an extension; or
2. through a **Form 9** application - where the licensee may apply for an extension when any instruction or consent required for a Form 8 application cannot be obtained.

Applications for extensions from July 2001 – June 2002

During the year the Council received 340 applications for extension to the permitted storage period of frozen embryos. Of these applications 162 were made by couples for whom the embryos were stored, and 178 were made by clinics on behalf of couples with whom they could not make contact or the couples had not responded to the clinic contact. Extensions were granted to all applications. This is the first year since 1996, when the HRT Act was amended to allow extensions to the storage limit, that the number of applications made by *clinics* has exceeded the number of applications made directly by *the couple*.

Of all applications received, 134 extensions (39.7%) were for people who had previously had extensions to permitted storage of their embryos. The majority of these (132) were repeat extensions for a set of embryos that had previously been granted an extension.

The reasons that were provided by couples seeking extensions to the permitted storage period have been classified into a number of categories. The majority of couples

applying intended to use the embryos in the future for their own use (89.5%). In 4.3 percent of cases the couples were planning to or in the process of donating embryos to another eligible couple. In the remaining 6.2 percent of cases the couple were undecided and applied for an extension to allow them more time to consider available options.

Nearly half (47.2%) of the extension applications made by clinics, rather than by the couple for whom the embryos are being extended, were in cases where the clinic had lost contact with the couples. Another two fifths (40.4%) of applications made by clinics were cases where the clinic had been able to contact the couples, but the couples had not sent in their application forms, and the clinic had then applied on their behalf.

In 9.0 percent of cases clinics applied for extensions on behalf of couples who had consented to the donation of their embryos, but a suitable recipient couple had yet to be found. The clinics applied for extensions in 3.4% of cases where the participants were unable to decide what they wanted to do with their embryos.

It was necessary to convene two meetings of the Embryo Storage Committee during the year. Both of these were necessitated by changes to the Council's meeting schedule which could not have been anticipated by the clinics.

Patterns in relation to embryos storage

During the year the Council has been reviewing the pattern of embryo storage extensions. From October 1996 to 30 June 2002, 1280 applications for extension to the permitted storage period were received. These applications involved 4748 embryos. Of these only four (4) applications were not approved for extension. In most cases extensions were for a two-year period. In over 70 per cent of cases to date only **one** application was made to extend the storage period. However, based on trends in recent years it is likely that a further application to extend that storage period may be made in some of these cases. Approximately one per cent were extended **four** times.

Overall, couples made applications for extensions (through a **Form 8**) more often than clinics making the applications on behalf of couples (through a **Form 9**). However a trend has been observed since 1997 that **Form 9** applications have increased at a greater rate than **Form 8** applications. And in 2002 for the first time, the number of **Form 9** applications has exceeded the number of **Form 8** applications. This trend is disturbing as it may suggest that increasingly it is **not** the persons for whom the embryos were stored who are making decisions about the ongoing storage of their embryos.

The Council continues to be concerned about the increasing numbers of embryos in storage, particularly those extended through **Form 9** applications made by the clinics. It will continue to monitor and explore these trends in applications for extension to storage. The Council is also to investigate ways in which to support participants and the clinics, such that participants will be more encouraged to take responsibility for decisions about their own embryos.

The Council recognises the need for implementation of recommendations relating to embryo storage made by the Select Committee that reviewed the HRT Act and reported in 1999. Most importantly, these recommendations would clarify ambiguities in the HRT Act relating to dealing with embryos where participants fail to give instructions.

DONOR ISSUES

Information provided by donors at time of donation

The Counselling Committee examined whether the information currently provided by donors at the time of donation should be reviewed. Copies of information from other places were considered. One clinic in Victoria has a comprehensive form that has the potential to obtain greater information from donors than that currently provided by donors on WA. It has been decided to discuss that matter at a workshop planned for November 2002. It is hoped to get input from donors, recipients and donor offspring before considering changes to current practices here.

Establishment of the Voluntary Donor Register

The Select Committee recommended the establishment of the Voluntary Donor Register to assist parties to donation obtaining information about each other. This Register will provide a service for donor offspring who wish to find out about their genetic origins. Donors who are willing to provide information to any donor offspring, or perhaps have contact with them, may also join the Register.

Work towards the establishment has continued during the year. It is hoped that it will be launched later in 2002.

Production of a new pamphlet

A pamphlet on '*Talking to children about Donor Conception*' was prepared by the Counselling Committee and circulated to relevant organisations and groups during the year. This was well received. It provides practical assistance to parents of donor offspring in telling their child about the method of his/her conception. See Appendix 6 for a copy of the text of the pamphlet.

Limits to the use of donated sperm

The Directions under the HRT Act stipulate that the Licensee of a clinic must ensure that for each donor of gametes there are no more than five known donee families, including families that may be outside Western Australia (section 8.1).

The Council re-considered this Direction during the year. The consideration at the time the Direction was made related to how all parties involved could deal with having people to whom they had a genetic relationship in a number of other families. Although there is still no empirical evidence to base this decision on, it was considered reasonably likely that children could deal with the notion of having such a genetic relationship with people in up to five families as well as their own family. Any more would most likely be difficult for them to accommodate.

Also expected to be difficult for the children, and other parties, would be to accommodate the situation where children in the same family have been born as a result of donations from different men, so the use of the same donor within a family should be supported. Therefore, deciding the number of **families**, instead of the

number of **offspring** was considered to be relevant. Other places have stipulated that one donor should have a limit of 10 donor offspring. Theoretically that could mean one donor offspring in ten different families. That could be very difficult for the offspring to deal with.

Although the Council considered making the five family limit applicable to use of donated sperm only within Australia, after discussion it was decided to retain the section 8.1 of the Directions as it is currently. If sperm is to be imported from outside of the state, clinics must ensure that this Direction can be adhered to.

RESEARCH AND INNOVATION

General issues

At the end of the year the Council was provided with preliminary information from researchers at Adelaide University about a national multi-centred trial which aims to investigate the overall success rates in single embryo transfer compared to multiple embryo transfer. The Council agreed the research project was well designed and would provide vital information on the appropriate number of embryos to transfer. The researchers hoped that the WA clinics would participate in this research.

In light of the growing amount of research demonstrating that there was no difference in the risk of birth defects in ICSI compared to standard IVF infants, including the research from WA, the Council considered that ICSI could be regarded as a routine procedure and therefore no longer required specific approval.

Specific approvals granted during the year

There were no completed applications for specific approval received this year.

The Council received information about a study to be performed at Joondalup IVF which was subject to general approval. This study entitled "Treatment adherence in IVF treatment cycles" would look at patients' understanding of information they are given regarding their treatment.

Current Specific Approvals

Concept Fertility Centre
Innovative Practice-

- Blastocyst transfer
- Assisted hatching

Pivet Medical Centre
Research-

- Multicentre open label randomised trial to assess the efficacy and convenience of orgalutron
- The impact of tobacco and caffeine consumption on the outcomes of in vitro fertilisation – embryo transfer

Innovative Practice-

- In vitro culture of human embryos to blastocyst stage
- Assisted hatching
- Use of Saizan (Growth Hormone) in ovulation induction

Hollywood Fertility Centre
Innovative Practice-
- Assisted hatching

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

Seminars, workshops and other Council initiatives

- **Seminar – Life after ART – Developing Families**

  The Counselling Committee organised a seminar, held on 17 November 2001, on *Life after ART – Developing Families*. Professor Eric Blyth, Professor in Social Work at Huddersfield University in the UK addressed the seminar on 'Current issues in assisted conception in the UK'. Nine consumers gave a moving insights into the impact of ART on their lives. They included a donor offspring, a sperm donor, three mothers who had formed their families through IVF treatment (one of whom chose to donate spare embryos to another couple), a parent of a child born as a result of sperm donation, a surrogate mother, a commissioning mother and person born as a result of a surrogacy arrangement. Small group discussions on a number of pertinent topics provided messages to Council. The Council is considering these messages at its meetings in 2002. A booklet of proceedings has been prepared and is available free of charge from the Council.

- **Pre-implantation genetic diagnosis**

  The Select Committee recommended that pre-implantation genetic diagnosis (PGD) should be allowed to occur under restrictions determined by the Council. PGD is a technique that combines genetic testing and IVF in order to offer those who are at risk of passing on a serious genetic condition the choice of selecting embryos that are unaffected before a pregnancy is begun. As is evidenced in the Reproductive Technology in the Press (p29), it is clear that there was much public interest in this topic during the year. The Council discussed PGD at a number of meetings. Following these discussions, the Council felt it would be in a position to provide advice to the Government, if requested to do so.

- **Counselling services**

  The Council also considered counselling issues during the year. This included examining the findings of the audit of counselling as well as making sure processes will be in place that will provide information, support and counselling to people considering donating their spare embryos for stem cell research, when legislation is in place to allow this. It has been decided to consider this matter further at the next Council workshop in November 2002.

- **Seminar on Cloning, Stem Cell Research and Transgenics**

  With the cooperation of Murdoch University and the excellent coordination of Dr Jim Cummins from the School of Anatomy, Division of Veterinary & Biomedical Sciences at that University, a very successful seminar was held on 24 May 2002, on Cloning, Stem Cell Research and Transgenics. Over 250 people attended the seminar. The participants included students and lecturers from Murdoch and Curtin Universities and the University of WA, medical personnel, scientists, nurses, allied health professionals, and members of the public. The talks covered

the scientific, legal, medical and ethical issues involved and were balanced and easily understood by a lay audience. A booklet of proceedings will be available later in the year.

Relevant presentations and publications by Council members and staff

Council members

Professor Alan Harvey-
Hypothetical 3 August 2001
"Stem cells and central nervous tissue repair", RTC Seminar, Cloning, stem cell research and transgenics 24 May 2002

Mr Philip Matthews
"Cloning ethics: evolution of moral philosophy", RTC Seminar, Cloning, stem cell research and transgenics 24 May 2002

Ms Antonia Clissa
Talk back radio, Liam Bartlett show, November 2001, re access to information for donor parties

Ms Sue Midford
Talk Back radio, Verity James Show, hosted by John McNamara, re psychosocial aspects of ART, 16 November 2001
Sunday Times article, Price of IVF, 18 November 2001

Staff

Dr Sandra Webb-
Presentations:
"Human Cloning" Curtin University Lunchtime Forum on Bioethics, 15 September 2001.
"At the control panel of life" Panel member in the Curtin University Forum, 27 September 2001
"IVF ethical issues" Curtin University Human Biology lecture, 10 October 2001
"WA's ART Legislation: what is going on and why?" Murdoch University Veterinary Studies lecture, 24 May 2002
"Towards the national regulation of cloning and embryo research" Cloning, Stem Cell Research and Transgenics, Murdoch University/Reproductive Technology Council Seminar, 24 May 2002

Ms Patrice Wringe and Ms Amalia Burmas-
"Emerging issues in Assisted Reproductive technology", Population Health Conference, Department of Health, May 2002.

Publication:
M. Hansen, JJ Kurinczuk, C Bower and S Webb (2002). The risk of major birth defects after intra cytoplasmic sperm injection and in vitro fertilisation. New England Journal of Medicine, 346 (10), 725-730.

Attendance at relevant meetings by Council members with Council support

The Council supported the attendance of the Executive Officer and two Council members to attend the 17th World Congress of Fertility and Sterility in November 2001 in Melbourne. Ms Wringe and other Council members attended symposia to the Congress with the support of the Council.

OPERATIONS OF THE COUNSELLING COMMITTEE
1 JULY 2001 – 30 JUNE 2002

Meetings and membership

During the year the Counselling Committee met on eight occasions. Membership of the Committee was well equipped to deal with relevant issues. Membership this year included two consumer representatives (Mrs Knox – Genesis and Mrs Lemon – Donor Conception Support Group); two clinic counsellors, one of whom is a member of the Council (Ms Clissa and Ms Rodino); and the Deputy Council member for the Department for Community Development (Mr Searle). Ms Midford again ably chaired the Committee. She attended most Council meetings (on which she is Deputy to Ms Clissa) to discuss matters arising from the Counselling Committee. Ms Patrice Wringe continued as Executive Officer of the Committee during the year. Ms Amalia Burmas attended all meetings, especially providing information on the scientific aspects of ART.

During the year Ms Lemon resigned her membership. The Committee expressed its appreciation for her hard work on the Committee over many years.

Ms Lemon's resignation left a vacancy for a consumer on the committee. Because of the gender imbalance it was agreed to try to recruit a male member and preferably one with the experience of donation.

When the *Acts Amendment Lesbian and Gay Reform Bill 2001* becomes operational law, single and lesbian women, who are infertile, will be able to access IVF treatment. The Committee was keen to recruit a single or lesbian woman to represent this group and make sure their viewpoint is considered. The Council agreed to make this appointment for 12 months.

A number of nominations were made for these positions and three candidates put in expressions of interest. On the Counselling Committee's recommendation, the Council endorsed the appointment of Mr Peter Fox to the Counselling Committee and Mr Robert Sterry as deputy member. Ms Colleen Brown was appointed for 12 months to represent the interests of single and lesbian women.

These new members attended their first meeting on 24 July 2002.

Key focus areas

The Committee continued the implementation of a number of the recommendations of the Select Committee, including the finalisation of the Audit of Counselling Services provided by clinics, and establishing the Voluntary Donor Register. The Committee worked on a procedure manual for approved counsellors.

It prepared a pamphlet to assist in telling children about their conception when donation is involved (a copy of the text of the pamphlet is available at Appendix 6).

It organised the seminar – *Life after ART Developing Families* on 17 November 2002 and prepared a booklet on proceedings. It assisted in the organisation of the Seminar – *Cloning, Stem Cell Research and Transgenics* in May 2002. It reviewed and updated the booklet – *Questions and Answers about the Donation of Human*

Reproductive Material. It begun the revision of other Council pamphlets; the finalisation of this revision will await the legislative amendments. It examined literature on the psychosocial effects of ART, and in this regard, Ms Wringe commenced an MA (Social Work) at the University of Western Australia to research the journeys of people who have sought assisted reproductive technology treatment.

Audit of counselling services

A preliminary report on the audit was made in the previous Annual Report. The audit was conducted in two phases – the first and major phase surveyed patients, staff and clinic counsellors and the second phase surveyed counsellors providing counselling services in community agencies. The response rate to both phases was lower than hoped for.

In ***phase one*** of the consumers who were given a questionnaire, only 36 per cent returned a completed questionnaire. This low response rate may have skewed the results. Reasons for non-participation in the survey were not canvassed, nor was there any follow-up on non-respondents. Clinic staff respondents had a higher participation rate, at 47.4 per cent; and all eight approved counsellors who were given a questionnaire returned it completed.

The results showed that 71.4 per cent of consumer respondents had counselling through the clinic, and of those - 24 per cent had two or more sessions of counselling. Therefore 82.9 per cent had either no counselling through the clinic or only one session. That is despite 83.1 per cent being past their first IVF treatment.

A total of 14 respondents were involved in donation, four as donors and 10 as recipients of donated human reproductive material. All donors had counselling, and eight recipients had counselling, with two who received sperm donation not having counselling. Both of these patients had a number of treatment cycles and stated that they were not informed about, nor encouraged to attend counselling. They agreed that people involved in donation should have access to counselling.

Tentative conclusions, only, may be drawn because of the poor response rate from consumers. However, a number of assumptions can be made. It is clear that the counselling by approved counsellors being provided through the clinics is limited, and it appears that most IVF patients are not receiving their full counselling entitlement. The precise reasons for this are not known, but a combination of factors are likely to apply. These could include the availability of counsellors; the promotion of counselling by the clinics; and the preparedness of patients to have counselling. For example, the survey results pointed out that:

- counselling may be perceived as being necessary for people with 'problems', and patients may not want to be perceived as having problems, in case this jeopardises their treatment;
- patients want to maintain their privacy as much as possible;
- a significant number of patients do not know about the availability of counselling services, nor about their counselling entitlement; some patients stated that they were charged for counselling services provided through the clinic;
- some clinic counsellors spend less than half a day in the clinic, so may not have a strong visible profile in the clinic;

- counsellors may not be available to do follow-up work with patients – what patients seem to need most;
- counsellors are not in the clinics to educate staff on the role of counselling, and to promote counselling as a 'normal' and integral part of treatment, rather than a service for those with specific problems;
- clinic staff provide 'informal' counselling; and
- some clinic staff are perceived as not promoting counselling services.

Areas that could be considered further include: the greater promotion of counselling; clarification of the method for payment for counselling services; counsellor availability; and the types of counselling services provided, as well as the timing of the these services.

Phase Two looked at the counselling that is being provided by counsellors in community agencies and in private practice, to find out if people who are coping with fertility/infertility issues are seeking counselling services, that may or may not be associated with fertility treatment.

In this phase, the views of a wide group of counsellors were canvassed. Included were approved counsellors who have less involvement in the clinic work and other counsellors who provide generic and specific counselling to individuals and families.

A total of 231 community service agencies, 20 women's health centres, six employee Assistance Program organisers, and all approved counsellors were sent questionnaires. Managers of agencies were invited to copy the questionnaire and circulate to relevant staff. The Australian Association of Social Workers and the Australian Psychologists Association included information on the survey in their September 2001 newsletter, canvassing counsellors to fill in a questionnaire.

A total of 53 completed questionnaires were returned. Over 47 per cent of the respondents stated that they had ***not*** provided infertility counselling, either in the last 12 months or in the past. From the results it appears that very few people are accessing counselling for infertility issues from counsellors working in community agencies and in private practice.

It is planned to discuss counselling services further at the next Council workshop in November 2002 to try to ascertain how best to meet patients' needs in relation to support and counselling.

Articles on the audit were prepared for the Genesis and Donor Conception Support Group newsletters.

Establishment of a Voluntary Donor Register

The Select Committee recommended the establishment of a voluntary register for persons involved in past donation. The Voluntary Donor Register is to provide a service for donor offspring who wish to find out about their genetic origins. Donors who want to know if a child has been born as a result of their donations(s) and/or are willing to provide information to any donor offspring may also join the Register.

During the past couple of years preparatory work has been undertaken towards the establishment of this Register. It is likely to be established before the end of the 2002 calender year.

Procedure Manual for Approved Counsellors

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

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

The Counselling Committee has progressed the development of this manual during the past year and hopes to finalise it after discussion with other infertility counsellors in Western Australia and in other states. Because of the constant developments in this area, the need for regular amendments has been identified. When completed, the manual will be placed on the Council website and amended on a regular basis.

The manual will contain information on stem cell research and the counselling services that may be required to people considering donating spare embryos for such research.

Re-recognition of 'approved counsellors'

As the terms of 24 approved counsellors were to expire on 30 June 2002, they were invited to seek re-recognition. In seeking re-recognition, counsellors had to show that they had provided some infertility counselling and engaged in related professional development. A proforma seeking this information was sent to the relevant counsellors.

Sixteen counsellors returned completed forms. The Committee recommended to Council that all sixteen be granted re-recognition as approved counsellors, two of them with conditions on that recognition.

New 'approved counsellor' applications

The Committee reviewed applications by four new applicants who sought to be recognised as approved counsellors. On recommendations from the Committee, the Council approved them as 'approved counsellors' under the HRT Act. These were Ms Lisa McCombe; Ms Kate Tudor Owen; Mr John Bluntschli; and Ms Jane Irvine.

REPRODUCTIVE TECHNOLOGY REGISTER

Research involving Register data by staff of the RT Unit

In March 2002 an article "The risk of major birth defects after ICSI and IVF" was published in the New England Journal of Medicine. This research, conducted by Ms Michele Hansen, involved linkage of data from the Reproductive Technology (RT) Register to the Midwives' Notification of Birth System and the Western Australian Birth Defects Registry to identify infants conceived through ART who had birth defects.

In early 2002, a follow-up study to the above-mentioned research commenced. The aim of this project was to study further aspects of morbidity, including hospitalisations, cerebral palsy and intellectual disability in infants conceived through ART; and compare this to the rates in naturally conceived infants. This research would also expand the previous research by studying a larger cohort, with an additional two years of data, which will be obtained from the RT Register.

The report of 2000 data from the RT Register may be found in Appendix 4.

Updates to the RT Register

Nationally work began on the establishment of the Australia and New Zealand Assisted Reproduction Database (ANZARD). This initiative was a result of the Working Party on National Data Collection, which was established by the Fertility Society of Australia to review the process of data collection from ART units to the National Perinatal Statistic Unit. ART Clinics in Australia were provided with a data structure for the ANZARD. Clinics will be required to collect all information in the data structure electronically, so that it can be forwarded to the NPSU for inclusion in the ANZARD. Information is required to be provided on all treatments from January 2002.

Many of the fields in the ANZARD are the same as those collected on the RT Register, therefore the aim of the RT Register is to streamline data collection so that a single database in each clinic can be used to collect the data for all required reporting by clinics. Work is currently in progress reviewing data collection for the RT Register.

Early in the year clinics were informed they were required to provide data, in their regular reporting to the Register, on any treatments where blastocyst culture or assisted hatching were used.

Requests for information from the Register

There were six requests for information from the Register. Two were for information about embryos in storage. Another two were for information on women accessing treatments, one related to age and the other to marital status. There was one request for the number of multiple births born in WA who were conceived through ART. The final request was from a participant who wanted information on their own ART treatment.

SIGNIFICANT DEVELOPMENTS IN REPRODUCTIVE TECHNOLOGY DURING THE YEAR

Research and innovation

During the year a number of studies were published examining the risks of ART to children conceived through these procedures. A Swedish study, published in February 2002, found that in their study group children born after IVF had an increased risk of developing neurological problems, especially cerebral palsy. They found the increased risk was present even when only singleton IVF births were studied.

In March, the New England Journal of Medicine published results of two studies on infants conceived through ART. One of these was based on Western Australia data collected through the Reproductive Technology Register. This study, by Hansen et al, found infants conceived through ART were more than twice as likely as naturally conceived infants to be diagnosed with a major birth defect by one year of age. 8.6% of infants conceived with ICSI and 9.0% of infants conceived with standard IVF were diagnosed with major birth defects. The investigators pointed out that the overall risk of infants conceived with ART being diagnosed with major birth defects was relatively low.

The second study investigated the risk of low birth weight associated with the use of ART. It is well known that multiple births are associated with low birth weight, and in ART there is a much higher rate of multiple births than in the general population. Therefore the study compared ART singletons to singletons in the general population. They found singleton conceived through ART were more likely to be low (<=2500g) and very low (<=1500g) birth weight babies, with 13.2% being low birth weight and 2.6 being very low birth weight.

Progress towards the development of national legislation relating to ban human cloning and regulate embryo research

On Thursday 27 June 2002 the *Research Involving Embryos and Prohibition of Human Cloning Bill 2002* was introduced into the Commonwealth House of Representatives.

This Bill is the Commonwealth's response to the Council of Australian Government's (COAG) agreement of 5 April 2001, that the Commonwealth, States and Territories would introduce nationally consistent legislation to ban human cloning and some other unacceptable practices associated with ART, and put in place a strict regulatory regime that would allow approved research to go ahead on excess ART (IVF) embryos.

Following the birth of Dolly the cloned sheep in 1997, the Commonwealth Minister for Health requested advice from the Australian Health Ethics Committee (AHEC). In December 1998 AHEC presented the Minister its Report on *Scientific, ethical and regulatory considerations relevant to the cloning of human beings.* This report recognised existing bans on cloning in SA, WA and Victoria and recommended that

all States and Territories introduce such a ban. It also recommended that the Minister should promote public debate on therapeutic cloning, in relation to which research had advanced rapidly during the preparation of the report.

In August 1999, the Minister for Health (Cwlth) commenced the process of consultation with all states and territories about the development of uniform national standards for ART and a ban on the cloning of human beings. Then in September 1999 the Minister for Health also referred the AHEC report to the House of Representatives Standing Committee on Legal and Constitutional Affairs (the Andrews Committee) for review.

In July 2001 the COAG agreed to introduce nationally consistent legislation to ban human cloning, and a nationally consistent approach to regulate ART and related emerging technologies. The aim was that a nationally consistent approach should be in place by June 2002. The Australian Health Ministers were requested to prepare a report on the technical aspects of the decision for consideration by COAG.

The report on technical matters produced with assistance of officials from all jurisdictions was considered by COAG on 5 April 2002, along with the Report on Human Cloning prepared by the House of Representatives Standing Committee on Legal and Constitutional Affairs (the Andrews Committee), which was released in August 2001.

At this time COAG agreed that all jurisdictions would introduce nationally consistent legislation to ban human cloning and other unacceptable practices and regulate research on excess ART embryos (including research directed at the derivation of embryonic stem cells) through a licensing regime to be administered by the NHMRC.

The *Research Involving Embryos and Prohibition of Human Cloning Bill 2002* was developed by the Commonwealth government in consultation with all other jurisdictions. There was targeted public consultation on an exposure draft of the Bill in May and June 2002. Members of the Reproductive Technology Council attended consultation briefings in Perth along with other invited experts.

Review of the NHMRC's 1996 *Ethical guidelines on assisted reproductive technology*

The statutory five-year review of these guidelines (required under the *National Health and Medical Research Council Act 1992)* commenced during the year with the formation of a working party of the Australian Health Ethics Committee and a call for public submissions. The Reproductive Technology Council made a detailed submission to this first phase of consultation of this review.

Lesbian and gay law reform

The *Acts Amendment (Lesbian and Gay Law Reform) Bill 2001* received Royal Assent on 17 April 2002 and a proclamation date of 20 September 2002 set. Included in these amendments are some to the *Human Reproductive Technology Act 1991.* The effect of these amendments will be to allow access to IVF for single or lesbian women

who are infertile or whose children risk being affected by a genetic abnormality or disease.

STATUS OF IMPLEMENTATION OF RECOMMENDATIONS OF THE SELECT COMMITTEE THAT REVIEWED THE *HUMAN REPRODUCTIVE TECHNOLOGY ACT 1991.*

The Select Committee, that reviewed the Human Reproductive Technology Act 1991 (HRT Act) and tabled its response in 1999, made 95 recommendations. The former Government's response to the Select Committee Report was tabled on 24 November 1999 and implementation of a number of the recommendations commenced. The current Government is still to finalise its position on many of the recommendations. However, progress made in implementation of the Select Committee recommendations is summarised below.

Surrogacy policy development

A draft policy paper has been submitted to the Minister for Health (WA) and is being considered. The Reproductive Technology Council has provided advice to the Minister on some matters relevant to the administration of legislation. As yet the Government has not finalised its position on whether to develop surrogacy legislation.

Recommendations referred to the Council for implementation.

Twenty-two recommendations, in six broad categories, were referred to the Council. The broad categories and the action to date are set out below.

Recommendations requiring liaison by the Council with licensees to encourage and facilitate follow up research and donor recruitment

The Council is currently reviewing policies that impact on the availability of donor sperm, in particular in relation to the import of donor semen.

Recommendations requiring liaison by the Council with the new Family and Children's Policy Office in relation to child and family welfare

During the past year the Family & Children's Policy Office was amalgamated with other functions. Advice has been received that it is no longer the appropriate liaison body to progress this recommendation. It is planned to liaise with other sections of the Department for Community Development in ensuring that the principles of the best interests of children and their families are identified and policy development is consistent with these principles.

Recommendations requiring modification of consent forms so that the Council may make appropriate recommendations to the Commissioner of Health regarding revision of the current forms

Considerable work reviewing the consent forms has been carried out in consultation with the clinics and with advice from Legal and Legislative Services (Department of Health). Further work has been put on hold, pending amendment of the HRT Act that may impact on the consent forms in many ways.

Recommendations about record keeping and reporting so that the Council may make appropriate recommendations to the Commissioner of Health regarding revision of existing standards and directions

The RT Unit is currently involved in consultation with a working party of the Reproductive Technology Accreditation Committee (RTAC) that is also reviewing reporting requirement for clinics. The ultimate aim is to better coordinate the multiple reporting requirements for clinics providing fertility services and to achieve submission of data electronically.

The establishment of a Voluntary Register of donors

As noted in the section of this report detailing the operations of the Counselling Committee, work towards the establishment of a Voluntary Donor Register, as recommended by the Select Committee has progressed. In January 2001, the then Minister for Health and the Commissioner of Health approved that the Commissioner of Health should establish the Voluntary Donor Register, as the Commissioner holds and maintains the Reproductive Technology Register. Work towards the commencement of operations has continued since that time. It is likely to be established before the end of the calender year 2002.

Recommendations about counselling standards and services

As noted in the section of this report detailing operations of the Counselling Committee, the audit of counselling, as recommended by the Select Committee, is now complete and work towards implementing its recommendations have progressed with clinics.

Liaison with the Attorney General regarding amendment of the *Artificial Conception Act 1985* (AC Act).

The Select Committee recommended amendment of the AC Act to ensure that no donors of human reproductive material have unintended legal responsibilities for offspring resulting from procedures such as artificial insemination. The *Acts Amendment (Lesbian and Gay Law Reform) Act 2002* amended the AC Act to clarify the position of donors of human reproductive material.

Communication with the Minister for Health and Aged Care (Cwlth) with regard to recommendations with Commonwealth implications.

WA has participated in a working group, coordinated by the National Health and Medical Research Council, to develop a framework for a national ban on human cloning and a working group to develop a consistent approach to the regulation of ART.

REPRODUCTIVE TECHNOLOGY IN THE PRESS

Fertility

The Herald Sun reported on an article in the Journal *Nature Genetics* (16 July 2001) on fertility risks of smoking. Jonathan Tilly at Boston's Massachusetts General Hospital made the find. It claimed that the chemicals known as polycyclic aromatic hydrocarbons, in high concentrations in tobacco smoke, can trigger the death of ovarian cells. Associate Professor Euan Wallace at Monash University's Centre for Women's Health Research said 'the study unlocked the key to how smoking could cause lower fertility and ovarian failure'.

A 'chilling' report in the Sunday Times (4 November 2001) stated that men could be in danger of extinction, due to sperm banks, fertility treatment and human cloning. They had higher death rates on all leading causes of death and their life expectancy is about seven years shorter than women's, and this could worsen.

'Sperm count alone is no predictor for men facing fertility problems'. A US study, reported by the Herald Sun (10 November 2001), of 1461 men from nine US clinics found that sperm count alone is not a predictor of fertility. The shape of the sperm and how well they swam were also important indicators. An expert on male infertility, Dolores Lamb, admitted that whilst the study provided some useful information, alone it could not be used to distinguish fertile from infertile men. A sperm count of zero is the only way to be sure a man is infertile. She said some men with discouraging semen analysis have treatable problems, such as reproductive tract blockage, but they rarely saw a urologist who could diagnose this condition.

A letter to the Editor in the Age on 17 November 2001 questioned whether the 'psychologically infertile' would jump the queue at fertility clinics ahead of the 'truly biologically infertile'. IVF used to be seen as a practical technology to mitigate biological infertility.

The Daily Telegraph (29 November 2001) reported that the Director of the Monash Institute of Reproduction and Development, Professor David de Krester, told an international conference that Australia's national DNA database will hold 5000 samples from infertile males to help international research into the "Y chromosome deletion condition". Up to 10 per cent of infertile men who had nil or low sperm counts had Y chromosome deletions.

A study reported in the Journal of Occupational Medicine found that male teachers were nearly eight times more likely to be infertile than other men. Finance analysts and engineering technicians were also at higher risk than men in other occupations. It was admitted that this was a small study. Dr Stephen Steigrad, director of the Department of Reproductive Medicine at the Royal Hospital for Women in Randwick said that he doubted that there was a connection between employment and male infertility, as the main cause is genetic (Sun-Herald, 2 December 2001).

The Weekend Australian gave an explanation of the screening process for sperm donors on 8 December 2001. A battery of tests and diagnostic semen analysis as well as at least one session with the counsellor is followed by a quarantine period of six months, then

further interviews and tests. The article did not state where this screening process is followed.

It was reported in the Sunday Telegraph on 27 January 2002 that a study conducted at Monash University found that almost one quarter of women in Australia have an abnormality of the ovaries, called polycystic ovaries, which is a common cause of irregular menstrual periods and can affect their fertility. But a reproductive endocrinologist at Sydney's Royal Women's Hospital, Associate Professor John Eden said that moderate lifestyle changes can normalise the menstrual cycle and hormonal imbalance.

In January 2002, the Sunday Times, the Daily Telegraph and Adelaide Advertiser reported on a study by the Queensland Fertility group that found exposure to chemicals could increase the risk of infertility in hairdressers. In IVF treatment, hairdressers' eggs tended to fertilise at a slower rate. It was agreed that further work would be necessary before a link could be proved.

The Sydney Morning Herald reported that Sydney men are as fertile as ever (20 February 2002). A study over 18 years showed that on average men produced 180 million sperm per ejaculation – anything above 60 million was considered normal. This result differs from other data provided in the article. It states that globally sperm concentration fell more that 40 per cent between 1940 and 1990 (from a 1992 study). Danish army recruits, men in Paris and Scottish men were all found to have reduced sperm counts.

The Courier Mail ran an article in March 2002 about the shortage of sperm donors in Queensland. Dr Warren De Ambrosis, the Director of Queensland Fertility Group, said he believed the shortage could be related to men being scared of their names going on a national register. At the moment Queensland donors can remain anonymous.

The Kalgoorlie Miner reported in April 2002 that a presentation by Leonie Batson, Perth family planning nurse, gave women wanting to get pregnant a number of suggestions about the impact of diet, weight, and stress on their ability to conceive. She also stated that men need to take some responsibility and examine their workplace, for example, looking for high levels of chemicals in the workplace or stress related to work.

The Sunday Times (28 April 2002) reported on research on professional women who delayed pregnancy as they pursued their careers. Thirty three per cent of these women aged between 40 and 45 years were childless. The researcher stated that the pregnancy success rates for women in their 40s is only about five per cent. She suggested that women consider having their children before they are thirty-five years. The Sunday Times quoted that research again in May, when the results of another study were released. This later study of 872 healthy couples showed that female fertility begins to drop in their late 20s, but it also noted that fertility rates differed widely between the couples studied. 'The chances of pregnancy from intercourse at peak times ranged from 20 per cent to 60 per cent'. The Australian ran this story also. The West Australian (23 November 2002) gave figures from the report by the Australian Institute of Health and Welfare, which showed that couples using assisted reproductive technology were getting older. The age range for the male partners of

women being treated during 1999 was from early 20s to 70s; 156 men were 50 years or older. The oldest woman was 53 years, seven others were over 50. The Institute statistics unit member Michael Chapman stated that the technology was getting better but reminded women that 'to delay conception can result in disappointment and frustration – despite continuing improvements in assisted reproductive technology'.

The Daily Telegraph (23 April 2002) reported on research on 500 women over a five-year period. They had given birth naturally or by emergency caesarean. It showed that a significant proportion of women having emergency Caesarean procedures reported later long term infertility problems while others were simply too frightened by the experience to go through childbirth again. About half did not have another child.

On 24 April 2002 the Financial Review ran an article entitled 'A productive low fertility" based on research conducted at Griffith University by Ross Guest and Ian McDonald. Their key findings, based on economic modelling, were that the decline in Australia's fertility rates will lead to higher, not lower, living standards.

Preimplantation genetic diagnosis

Preimplantation genetic diagnosis (PGD) is a technique that combines genetic testing and IVF in order to offer those who are at risk of passing on a serious genetic condition the choice of selecting embryos that are unaffected before a pregnancy is begun. Such testing is not allowed under the *Human Reproductive Technology Act 1991* (HRT Act), but the Parliamentary Select Committee that reviewed the HRT Act recommended that this testing be allowed with restrictions. To date, the HRT Act has not been amended to reflect this.

Twenty-four media reports on PGD were collected during the year. They related to testing to prevent implantation of an embryo that had a genetic disease; creating an IVF embryo to produce children that could save the life of an existing sibling; PGD for sex selection; PGD to detect Down's Syndrome; and PGD to detect deafness.

Articles about PGD appeared in all major papers across Australia. The debate was generally polarised, with some (often those wishing to use this test), wanting facilitating legislation and others against the practice as it involves the destruction of unwanted embryos.

Many articles were written during March and April 2002, when the Victorian Infertility Treatment Authority made an interim policy to allow a couple to use IVF to create an embryo that could be tissue-type matched to help an existing child with Fanconi's anaemia, a rare genetic blood disease. There were reports that other families would also seek this test in Victoria to help an exiting child. A Queensland couple had travelled to America in December 2001 after being rejected in Melbourne, to create the 'perfect match' embryo (reported in the Sunday Herald Sun on 23 December 2001).

At about the same time it was reported that the Human Fertilisation and Embryology Authority in the UK had allowed a couple to create an IVF embryo to help save a sibling with a rare blood disease, and in the UK also

other families were likely to ask for the tests.

Comments made by bio-ethicists include:

- "the basic principle … is one of respect for creative autonomy, respect for people's own decision about the kind of children they want to have' (Professor Savulescu, as reported in the Sunday Age, 21 April 2002);
- "I condemn out of hand that selection is allowed for anyone" (Mr Nicholas Tonti-Filippini, ibid);
- Concern that a significant number of embryos would be created and destroyed in the search for the 'perfect match' (regarding creating a child to help save the life of an existing child: Norman Ford, Caroline Chisholm Centre for Health Ethics, Canberra Times, 17 April 2002).
- Restricting parents' choices about having the tests makes them feel like criminals, according to the medical director of Sydney IVF, Robert Jansen (Sydney Morning Herald, 17 April 2002). He stated that Sydney IVF readily conducts the type of treatment sought by the Melbourne couple (who wanted to create a child to help save the life of an existing child).

Two articles reported on parents seeking to use PGD for deafness; one Victorian family to screen out embryos that have the gene that causes deafness (Sunday Mail, 30 June 2002); and a profoundly deaf lesbian couple who wanted a child that was also profoundly deaf (Australian, 19 April 2002).

The Weekend Australian (18 May 2002) ran a Supplement entitled 'On Our Selection', discussing couples who wanted embryos screened so they could choose the sex of their baby. The article reported that about 100 couples across Australia have used IVF to select the sex of their baby; some of whom wanted to avoid a gender-linked hereditary disease.

The West Australian (2 March 2002) reported that Genetic Services WA Director Jack Goldblatt criticised the State Government for not legislating to allow PGD – the only Australian state that he was aware of where this is not allowed. Dr Goldblatt felt that legislating for PGD was of greater importance than for stem cell research. The Weekend Australian (11 May 2002) again criticised the WA legislation that forced people who required PGD to go interstate for the test. A Perth woman travelled to Sydney in order to select an embryo without an abnormal chromosome that had led to four miscarriages.

Donor issues

Seven articles related to donor issues. These included a search for an egg donor, whether egg donors should be paid; and seeking information about donor parties.

A 40-year old woman in the South West of WA advertised for an egg donor after two miscarriages and two unsuccessful IVF attempts. She had been told her eggs were not viable (West Australian 9 July 2001). A Queensland woman hired a public relations company to help her to find an egg donor (West Australian 16 June 2002).

On 8 and 9 June 2002 the West Australian, the Sydney Morning Herald and the Sunday Age ran articles debating whether payment should be

made to egg donors. John McBain, chairman of Melbourne IVF believed the Victorian legislation should be changed to allow payment to egg donors. Mr Nicholas Tonti-Filippini found it 'un-Australian to talk about trading in human tissue and making a profit'. Carol O'Shea of the Australian Red Cross, stated that it is contrary to the principles of the Red Cross. "There is no evidence to suggest that if you pay donors you're going to get any more of them", she said.

The Sunday Times (18 November 2001) stated that a fourteen-year old donor offspring said 'she felt lost and was fighting to find her genetic history'. On 26 November 2001 the West Australian reported on a speaker at the World Congress on Fertility and Sterility who believed that parents should retain the right not to tell IVF children how they were conceived. It was stated that 85 per cent of parents did not tell their children they were the result of sperm donation, when that had been the case.

IVF treatment

Articles on IVF treatment related to three main issues – treatment for a woman who is HIV positive; a widow accessing embryos created before the death of her husband; and risks of treatment. Other issues raised related to costs of treatment; treatment success and treatment being stigma-free.

An HIV positive woman, who is also infertile, asked that Monash IVF consider her application for IVF. The Standards Committee agreed to examine each case on its merits where advice from clinicians is that there is low risk of infection to the child.

In July 2001 it was reported that a young widow had embryos created using her husband's sperm before he died. She had two implanted before he died but she had a miscarriage. She wanted to use the remaining three embryos, but found that she could not do so under Victorian legislation, which banned the use of embryos when a gamete donor was deceased. In September the Victorian Minster for Health announced that the legislation would be changed to remove the ban on embryo use where a donor is dead. (Articles in the Sunday Times and Sunday Telegraph on 1 July 2001, and in Sunday Times on 16 September 2001)

"The IVF industry must rebuild public trust" was a heading in the Australian on 29 November 2001. The article discusses the likelihood of multiple pregnancy following IVF and the small number of women who seek selective reduction. The author hopes that the need for selective reduction would be a rarity and the IVF industry would work hard to reduce the incidence of multiple births and ensure that parents are not put in a position of having to consider selective reduction. The Adelaide Advertiser (24 June 2002) reported on a study by fertility specialists to convince couples to have just one baby at a time. The Australian Study of Single Embryo Transfer (ASSET) trial is currently being conducted across Australian clinics. The trial hopes to show good results from single embryo transfer in order to reduce the risk of multiple births. There is a 21 per cent chance of having twins following assisted conception compared to a 1.2 per chance in natural pregnancy (reported by the Canberra Times, 23 June 2002). These are all high-risk pregnancies. The ASSET trial was also reported in the Daily Telegraph on 29 November 2001.

Reports in many papers across the country on an article in the New England Journal of Medicine in March 2002 told that IVF babies are twice as

likely to have a serious birth defect as normally conceived children, according to a WA study. Examples of birth defects observed were Down's syndrome, cleft lip and palate and heart abnormalities. The underlying cause of infertility, medications used to induce fertility, and the procedures, such as freezing and thawing, may have contributed to the higher rate of birth defects, according to Ms Michele Hansen, the lead author. Papers in most states ran articles on this study.

Two articles, both in WA newspapers, discussed costs of IVF. Pivet Medical Centre general manager Max Keyt said the clinic was becoming increasingly concerned about using donated eggs and sperm because the expectations of parents may be beyond what can be provided. Increasing costs of indemnity and public liability insurance meant that costs would need to be passed on to patients. A letter to the Editor in the South West Times (20 June 2002) stated that IVF was for the rich, and that it should be provided through the public system. A Queensland woman who wanted to 'change an unfair system' wrote the letter.

During the year there were a number of articles on Professor Carl Wood, the founding father of IVF. For example, he is reported as advocating for a change in technique in human fertility programs, to allow embryo splitting, a technique used in animals. He said it would minimise the woman's exposure to powerful IVF drugs. The embryo is split at the five to seven day blastocyst stage. It re-forms as two embryos in about an hour. Professor Wood said one embryo could be implanted and the other frozen for future use. That may mean twins would be born years apart. Embryo splitting is a form of cloning, but the article states that it is distinct from cloning. (Sydney Morning Herald, 18 July 2001). The West Australian ran an article on 7 June 2002 celebrating 21 years of IVF success, as the world's first non-identical IVF twins turned 21. That article also reports Professor Wood's promotion of embryo splitting. The article states that embryo splitting is outlawed under Victoria's Infertility Treatment Act. An article in the Australian Financial Review on 12 June 2002 reported on other areas of interest for Professor Wood. These include looking for a cure for endometriosis, which affects 10 per cent of women, and uterine fibroids, which affect 40 per cent of women over 35. He is reported to have said that 'women are seven times more likely than men to suffer reproductive organ-related disease'.

The Sunday Mail (24 March 2002) reported that women who had IVF treatment had lower death rates than women in the same age group. However, it was stated that there are likely to be other factors contributing to the finding, more social than medical. The study can provide some reassurance about the safety of IVF, but it also indicates that the selection process deter unhealthy women for pregnancy and infertility treatment.

Advances in IVF technology have doubled viable pregnancy rates in a decade, according to the report of the Australian Institute of Health and Welfare, as reported in the Age on 23 November 2001. Monash IVF stated that all its profits are donated to Melbourne's Monash University for research and development in reproductive medicine. Success rates are constantly being improved (Sunday Mail 28 October 2001). The Canberra Times (18 January 2002) reported that several clinics say IVF produces higher

pregnancy rates that the traditional methods – 36 per cent for IVF compared to 25 per cent for 'plain old-fashioned sex'. However, 'IVF is expensive and intrusive' and is likely to remain the last resort for couples, according to Keith Harrison Queensland Fertility Group spokesperson.

The Albury Reproductive Medicine Clinic has boosted its pregnancy rate from the Australian average of 18 per cent to 36 per cent in the past five months, as reported in the Australian on 7 January 2002. The clinic attributed its success to better handling of embryos and keeping them warm at all stages of treatment. Taping a humidifier to the side of the microscope allowed warm air to flow continuously over the embryo. Dr Giltrap said the breakthrough was simple and cheap. The clinic had also noticed an increase in twin pregnancies – from using the humidifier together with more stable incubators and better laboratory cultures, allowing embryos to grow for longer before implantation. Dr Giltrap planned to advise younger couples to have single embryo transfers to avoid the risk of multiple pregnancies. This small IVF clinic in Albury had doubled the national average IVF pregnancy rate to 36 per cent, according to the Daily Telegraph on 1 February 2002.

A number of articles reported on how the stigma associated with IVF in the 1980s no longer exists, eg in the Sun Herald on 25 November 2001. The West Australian reported on 12 June 2002 that the term 'test tube baby' is no longer used; people are more open about discussing their treatment. With the fine-tuning of techniques there are fewer multiple births. Yet it still seems more acceptable in the community to attribute infertility to the woman or an unknown cause rather than to the man. The article went on to discuss lifestyle factors that could affect fertility.

Discrimination

Whether to provide IVF services to single and lesbian women continued to receive attention in the press during the past year. In 2000, the Federal Court upheld the challenge that the Victorian *Infertility Treatment Act 1995*, that stated that restricting access to assisted reproductive technology treatment to a woman who lives with her husband on a genuine domestic basis or lives with a man in a de facto relationship breached the Commonwealth Sex Discrimination Act and was therefore constitutionally invalid. The Prime Minster responded by stating that he intended to amend the Sex Discrimination Act and allow States to legislate to limit access to assisted reproductive technology treatment to heterosexual couples only. The Australian Catholic Bishops Conference also responded and took the matter to the High Court in October 2000. The Bishops Conference argued that the Commonwealth Sex Discrimination Act does not stop the Victorian Government from banning single and lesbian women from accessing IVF treatment. The Commonwealth Government backed the Bishops stance. The Attorney General stated that if the Catholic Bishops won the High Court challenge the Government would drop the proposed amendments to the Sex Discrimination Act. He also stated that the Government did not support the Catholic Bishops' argument that preventing discrimination on the grounds of marital status was unconstitutional. He said the implications of that would be quite significant, for example, it could allow landlords to discriminate against single

people (Adelaide Advertiser, 15 August 2001).

During the last financial year, as the Full Court of the High Court considered the Catholic Bishops' appeal and the amendment to the Sex Discrimination Act was introduced into Federal Parliament, the media reported on views in the community. Again the views were polarised. The Canberra Times (6 September 2001) reported that there was a two-faced stance on IVF. Justice Mary Gaudron was reported as accusing the Attorney General Daryl Williams as having 'two goes at the cherry', by granting a fiat to the Catholic Bishops Conference and then intervening in the court case between the Church and feminists. It was stated that 'the Coalition is obviously afraid of both the considerable Catholic lobby and the feminists and those who support this particular part of their cause'.

On 18 April 2002, the High Court dismissed the Catholic Bishops' challenge, as reported in the Sydney Morning Herald on 19 April 2002. Chief Justice Murray Gleeson was quoted, "people who are not parties to litigation do not have a claim of right to have judicial decisions quashed because they are erroneous". Other papers also ran articles on the High Court decision. The Australian (19 April 2002) reported that the Prime Minister planned to move ahead with amendments to the Sex Discrimination Act. The Courier Mail (20 April 2002) stated that the amendments may be defeated in the Senate. The Sydney Morning Herald and other papers (22 April 2002) reported that the Health Minister Kay Patterson had urged that Government MPs be given a conscience vote on this matter. After Cabinet discussed this it was decided that Government MPs would not have a conscience vote (Daily Telegraph, 23 April 2002). Simon Crean ruled out a conscience vote for Labor MPs and said the Opposition would oppose the amendments (Canberra Times 22 April 2002).

The Australian Medical Association denounced the Government's decision to alter the Sex Discrimination Act as being discriminatory and claimed 'the flimsiest of excuses were being used' (Sydney Morning Herald, 23 April 2002).

At 30 June 2002, the amendment to the Sex Discrimination Act had not been passed in the Commonwealth Parliament.

Cloning

The media reported widely on reproductive cloning and therapeutic cloning during the year.

Many articles discussed the dangers of cloning, for example a report in Science, conducted by the Whitehead Institute and the University of Hawaii, found stem cell clones to have hidden abnormalities which are difficult to detect until after the clone is born (Weekend Australian 7 July 2001). A British study by Professor Ian Wilmut of the Roslin Institute in Edinburgh called for a moratorium against copying people because the outcome is so unpredictable (Sunday Times, 8 July 2001).

Other articles called for the ban on cloning. The Canberra Times (1 August 2001) reported on the debate in the US on whether to allow or ban therapeutic and/or reproductive cloning. Mr Bush had said that he supported the ban on somatic cell nuclear transfer, the process used for creating "Dolly". The Daily Telegraph reported the following day that the US

House of Representatives voted to ban the cloning of human embryos for scientific purposes.

The work of the 'controversial' Italian embryologist, Severino Antinori, received media attention during the year. Earlier in the year he said he planned to make the world's first attempt to produce a human clone. Many Australian experts condemned this move (Age, 6 August 2001). 'A fiery symposium' in Washington on 8 August 2001 debated the production of a human clone, with many condemning it and a few, including Antonori, planning to go ahead (Daily Telegraph & The Age). Antinori announced his intention to move to the UK (Age, 17 November 2001). He announced in April 2002 that he had successfully used a cloned egg to help a woman to become pregnant (Canberra Times 7 April 2002). Other papers ran this story too.

The UK Parliament passed regulations in January 2001 under *the Human Fertilisation and Embryology Act 1990* to permit cloning to create embryos for stem cell research, but producing cloned babies was outlawed (Canberra Times 20 January 2002). A High Court decision in November 2001 ruled that an organism created by cloning was not an embryo, and so was not covered by the Human Fertilisation and Embryology Act, hence human cloning was beyond the UK law, according to a report in the West Australian on 17 November 2001. However, the UK government announced its intention to introduce legislation to outlaw cloning to make babies (Adelaide Advertiser, 20 November 2001). That legislation was passed in both Houses and became law on 5 December 2001 (West Australian 6 December 2001). On 18 January 2002, the Court of Appeal upheld cloning regulations passed in Parliament in 2001. The decision overturned a High Court ruling that invalidated the government-sponsored legislation designed to regulate human cloning.

The Australian Financial Review reported on 27 November 2001 that a Massachusetts company had created human embryos through cloning, but the aim was to help to treat disease, not create a human being. Professor Alan Trounson, the medical director of the Monash Institute of Reproduction and Development said that cloning was a 'small useful step'. The Courier Mail reported on the Massachusetts finding and also stated that there was a second breakthrough in the Massachusetts laboratory, when the researchers took a human egg and by treating it, got it to progress to the embryo stage without fertilisation, either by sperm or outside genetic material. A number of articles in various papers stressed the difference between therapeutic cloning that may help to treat disease and reproductive cloning which would create a human clone, and the need to consider the ethical issues in both.

The Canberra Times (10 August 2001) called for Australia to have informed consultation on the matter. The West Australian (11August 2001) insisted on the need for ethicists, moral philosophers and theologians to try to keep up with the genetic and scientific advances. The Age on the same day stated that the 'clamour around the world for bans on reproductive cloning' should be heeded.

The Sunday Times (12 August 2001) provided information on the 18-month project titled Genomics, Society and Human Health that was seeking public opinion on how best the evolving technologies can be used. This was an opportunity for the public to consider

the ethical dilemmas. A series of seminars, lectures and debates were planned.

The Federal Parliamentary Committee, chaired by Mr Kevin Andrews released its report, entitled '*Human cloning: scientific, ethical and regulatory aspects of human cloning and stem cell research'* in August 2001. The West Australian (21 September 2002) reported on its conclusions.

The Daily Telegraph (28 November 2001) reported that cloning is just another frontier, and that human knowledge and achievements are always being extended. 'Cloning offers undreamed-of opportunities to harness the powers within us for healing a wide range of our disabilities', diabetes being one. The Herald Sun (6 December 2001) reported that there was potential to treat 3000 people a day if therapeutic cloning is allowed, according to scientists in Massachusetts. The Sunday Mail on 9 December 2001 reported on an 11-month old boy who had received a stem cell transplant to treat leukaemia. The Sydney Morning Herald ran a story written by a man with a motor neurone disease, where he claims that there are some means that can never justify the ends and some ends that can never justify the means. He also states that therapeutic cloning is scientifically, ethically and morally different from reproductive cloning.

On 29 November 2001, the Canberra Times editorial claims that the history of human society shows that if the technology is there, it is likely to be used, and that ultimately cloned human beings will be produced. Religious leaders again urged a ban on cloning.

The Daily Telegraph reported on 4 January 2002 that the creators of Dolly had cloned genetically modified piglets. This was seen as a huge leap towards developing animal organs for transplantation into humans. This could address the shortage of human organ donors. The Age reported on 8 January 2002 that Dolly had arthritis at a young age. The head of the team who had created her was not sure if the arthritis was linked to the cloning.

The Queensland Parliament planned to introduce human cloning legislation in December 2001, but the Australian reported on 10 December 2001 that the wording of the Bill was ambiguous and might encourage the destruction of human embryos instead of preventing this. There was concern that it might undermine the COAG agreement. It also differed from the position of the Australian Health Ethics Committee.

Cc – carbon copy cat was created by a team in Texas A&M University, backed by a business man John Sterling whose company planned to offer cloning to dog and cat owners (Sydney Morning Herald, 16 February 2002). In March 2002 a team of French scientists unveiled the world's first cloned rabbits (Sunday Age, 31 March 2002).

The COAG decision on 5 April 2002 which proposed uniform State and Federal legislation including a ban on therapeutic cloning and allowed the use of 'spare' embryos from IVF programs was reported upon by the Australian on 8 April 2002 and other papers. On 27 June 2002 the *Research Involving Embryos and Prohibition of Human Cloning Bill 2002* was introduced into Federal Parliament. It bans cloning and other unacceptable practices like growing a foetus outside a woman's body and strictly controls research on human embryos. It allows the use of

excess IVF embryos for research. It includes penalties for breaches.

Stem cell research

The number of media reports on stem cell research outstripped all other topics in assisted reproductive technology during the year. Many of the stories went hand in hand with reports on cloning. As noted earlier, the federal parliamentary committee that looked into this area handed down its report, entitled '*Human cloning: scientific, ethical and regulatory aspects of human cloning and stem cell research'* in August 2001. The committee recommended banning human reproductive cloning but allowed research on excess IVF embryos. Following the release of the report many articles discussed the possible therapeutic benefits of stem cell research and the ethical issues involved.

The Herald Sun (18 July 2001) reported on a four-country survey of people's views on conducting embryo research. Australians were more open-minded about this matter than residents of the other three countries, namely New Zealand, the UK, and the US. 72 per cent of Australians backed the use of embryonic stem cells for medical treatments compared to 66 per cent in New Zealand, 63 per cent in the US and 62 per cent in the UK. Incidentally Australians were also more likely to support IVF treatment. Opposition to the use of IVF for childless couples was greatest in the US where 20 per cent of respondents said that childless couples should not be able to use medical technology to have children.
The Australian (25 July 2001) reported on advances made by Bresagen, an Adelaide-based US research facility, on isolating four stem cell lines. It stated that this put that facility in a strong position with regard to growing these lines in the laboratory.

Use of human embryonic stem cells for growing heart cells was a scientific breakthrough to help in regenerating tissue damaged by cardiac failure. This advancement was made in Haifa at the Faculty of Medicine and Rambam Medical Centre (Advertiser, 2 August 2001).

Commentaries on stem cells provided regular reports on their status in the US. In August 2001 President Bush announced in an address to the nation that he would allow research only on existing stem cell lines already taken from embryos. Scientists felt this was a very conservative approach. The decision could be overturned by Congress (Age 11 August 2001). The West Australian stated that the approach brought sharp criticism from both sides of the debate (11 August 2001).

The Canberra Times (17 August 2001) reported on Melbourne scientists, who had shown that stem cells in mammalian brains supply a continuous supply of brain cells, were considering going overseas because of funds shortage. Their research was in adult stem cells.

On 22 August 2001, the West Australian stated that embryonic stem cell research got a financial boost when the federal government gave $5.5 million to Melbourne's Monash University. On 1 December, Monash Institute of Reproduction and Development and the Hadassah University in Isreal became the first to grow the full range of human brain cells from embryonic stem cells, as reported in the Age.

State and federal legislation was hindering the advance of stem cell research according to scientists and medical experts. The ethical concerns need to be balanced with the enormous benefits to society (eg treatment of diabetes, cardiac, liver and Alzheimer's diseases), said Dr Mudge, who chairs the Australian Medical Association's ethics committee. (Sydney Morning Herald, 27 November 2001).

Pursuing adult stem cell research is recommended by Dr Amin Abboud, an assistant lecturer in medical ethics and health law at the University of NSW. He quotes Dennis Steindler, a professor in neuro-science and neurosurgery at the University of Tennessee, Memphis 'these adult tissues don't appear to be as restricted in their fate as we thought they were'. (Sydney Morning Herald, 17 August 2001).

Embryonic stem cell research will become the Holy Grail of medicine, according to Julian Savulescu, an associate professor at the Murdoch Children's Research Institute. He points out the potential of stem cell research to cure diseases. He claims that it is hypocritical to allow abortion and post-coital contraception and not allow the use of about 1000 spare IVF embryos for research, when these embryos are destroyed each year. (Daily Telegraph, 16 August 2001).

On 30 August 2001, Robert Jansen, medical director of Sydney IVF stated that he had been extracting stem cells from donated excess IVF embryos. The aim was to provide stem sells for doctors at the Prince of Wales Hospital to help treat juvenile diabetes. He had got approval from Sydney IVF's independent ethics review committee. Two ethical centres condemned the destruction of life (Sydney Morning Herald).

Umbilical cord blood can be collected after a baby's birth, the stem cells extracted and stored in liquid nitrogen. These cells will be a perfect match for the child. The Sydney Morning Herald (18 December 2001) reported on a couple who used this technology. Their first child had a rare form of leukaemia. A worldwide search for a stem cell donor for this child was unsuccessful and he had subsequently died. Storing the stem cells for their second child will mean a perfect match will be available if required. It cost an initial fee of $2,000 and a yearly fee of $150 to store the tissue.

Another report in the same paper on 8 January 2002 gave information about a London-based Australian scientist who had made a breakthrough that could result in a cancer vaccine. Dr Monk, head of molecular embryology at the Institute of Child Health at London's Great Ormond Street Hospital, found that the genes present in human embryos are also present in cancer tumours. In an embryo the cells proliferate to create all the cells in the human body. Their presence in cancer cells suggested that they 'forgot' their programming and reverted to their state as embryos and proliferate into a lump. Dr Monk hopes the genes specific to cancer cells can be targeted in therapy and drugs used to knock them out or develop a vaccine. The Peter McCallum Cancer Institute is also working on growing stem cells to offer hope to cancer sufferers especially such as leukaemia and lymphoma. Trials had been deemed successful. "It's not a cure, but it's a step, but it's an exciting step", said research leader Miles Prince. (West Australian 3 June 2002).

At the end of February 2002, federal Cabinet deferred its decision on allowing embryonic stem cell research,

ahead of the COAG decision in April 2002. The community was divided and people either supported or opposed this stance (West Australian 27 February 2002). Some papers claimed that if there is a ban imposed on embryonic stem cell research, it could drive scientists off shore to conduct their research. The following day it was reported that the UK is expected to establish the first bank of human embryonic stem cells. Doctors hope to use these cells to repair the ravages of old age, damage and disease.

A survey by the Melbourne Institute of Applied Economic and Social Research in late 2001 showed that 73 per cent of Australians approve of the use of foetal cells for research. This result reinforced an earlier poll in the US which showed that 72 per cent of Australians supported such research (Australian, 4 March 2002). The Premier of NSW Bob Carr supported this research. So too did the peak scientific and research bodies, including the Australian Research Council (Australian Financial Review, 4 March 2002). WA State Cabinet approved the use of leftover embryos for medical research on 5 March 2002 (West Australian, 6 March 2002). It was seen as important that doctors did not stockpile or over-create embryos for research, according to Dr Webb, executive officer of the Reproductive Technology Council. Ms Michele Kosky of the Health Consumer's Consumers Council said there needed to be community discussion about how regulation would be tightened. Dr Rosanna Capolingua federal executive member of the Australian Medical Association said the ethical issues were being discussed by the federal ethics committee. Mr Ted Watt, secretary to the Coalition for the Defence of Human Life, opposed the use of embryos for medical research, as this is destroying a human being. (West Australian, 11 March 2002). On 16 March 2002 the West Australian reported that the head of the Anglican Church Dr Peter Carnley went against the views of other church leaders and claimed that harvesting stockpiled human embryos did not amount to destroying human life. He claims conception occurs when the embryo is embedded in the uterus wall several days after fertilisation takes place.

Federal ALP members will be allowed a free vote on stem cell research. Simon Crean said he wanted full consideration of the issue within the party before the COAG meeting on 5 April 2002 (Daily Telegraph, 13 March 2002, many other papers ran similar stories). WA Premier Geoff Gallup said ALP members would get a free vote in WA State parliament also. On 6 April 2002 the Advertiser reported that every Australian politician – federal, state and territory - had a conscience vote as the nation moved towards uniform legislation on allowing human embryos for research.

Leading up to the COAG decision many articles discussed the use of stem cell research from various positions. On 4 April 2002 the Australian Financial Review reported that all Premiers supported the use of surplus IVF embryos for research. On 5 April the papers reported that the Prime Minister would back using embryos for stem cell research, with some applauding and others opposing the move. However, some Premiers, scientists and churches challenged the planned restrictions.

The COAG decision on 5 April was to allow scientists to use for research spare embryos already in storage but **not** those created after 5 April 2002. After three years that ban may be

lifted. It was also made easier for scientists to get consent to use the embryos. (Courier Mail 6 April 2002).

The ACT MLAs were polled in the Canberra Times on their support for embryo research: nine supported it; five were undecided and three opposed it. A Westpoll showed overwhelming support in WA for embryo research. Eighty per cent supported the decision to allow human embryos to be used for medical research; 15 per cent objected to the decision. (West Australian 15 April 2002). On 31 May 2002, the Prime Minister announced a 46 million-dollar package over five years to the Monash-based Centre for Stem Cells and Tissue Repair, headed by Alan Trounson.

On 6 June 2002, the Gnowangerup Star reported on a recent seminar run by the Reproductive Technology Council on stem cell research. The seminar was to inform and educate members of the public and provide information about the moves towards nationally consistent regulation of this work.

On 18 June 2002 the papers reported on the discovery of a special stem cell that could be used to rebuild the organ called the thymus that is crucial to the human immune system. This discovery will open the way for treatment of patients suffering form AIDS and cancer. This discovery was made at Monash University. On 21 June 2002 the West Australian reported on another discovery of the rare stem cell found in adult bone marrow that can turn into all types of tissue needed to repair damaged bodies.

As the legislation was being prepared for introduction in Federal Parliament, the possibility of splitting the Bill into two was discussed in the papers on 26 June 2002. One Bill would deal with the ban on human cloning and the other with embryonic stem cell research.

The *Research Involving Embryos and Prohibition of Human Cloning Bill 2002* was introduced into Federal Parliament on 27 June 2002. The Sydney Morning Herald (28 June 2002) reported that heated debate looms as the stem cell Bill was launched.

Evolving technologies

Three articles in different papers discussed hope for the infertile male as a body cell could be taken from the man to fertilise the egg. Monash University researcher Orly Lacham Kaplan is working on this. The Sunday Telegraph ran this article on 8 July 2001. The Sun-Herald reported on a similar program in a London based clinic that is working on a project to produce artificial sperm. (18 November 2001). The Assisted Reproduction and Gynaecology Centre is investigating how to take a body cell and remove one set of chromosome to create the artificial sperm, which can then be used to fertilise an egg by conventional IVF methods. Unlike cloning where the offspring are genetically identical to the parent, the artificial sperm technique would allow the creation of babies who are a natural mix of genes from the mother and the father. The technique had been successful using a mouse egg and a cell taken from the body of the male. The West Australian (12 July 2001) reported how anti-abortion and medical ethicists 'had slammed' the technique whereby a woman's egg could be fertilised with a cell from any part of the human body, including from another woman. Margaret Tighe from Right to Life denounced the scientific ways to make babies and that they all disrespected the right to life for every embryo created.

Nick Tonti-Filippini said the technique was dangerous and akin to cloning. Gay and lesbian groups welcomed the development.

The West Australian reported on 26 June 2002 on a 'fertility gel' applied during intercourse that could help women, who suffer from miscarriages, to conceive and carry their pregnancy to full term. Dr Sarah Robertson at the University of Adelaide stated that 50 per cent of women who had problems becoming pregnant or carrying a child did so because their immune system was rejecting the embryo. This was because of a protein in their partner's semen that caused the woman to treat the embryo as a foreign object. Another protein also in the man's semen could moderate the woman's immune system and make her more tolerant of the foreign protein and less likely to reject the embryo. Dr Robertson said it could be 10 years before the gel came on the market.

Australian and British researchers have joined in the search for the gene linked to endometriosis that can cause infertility. The Australian Gene Cooperative Research Centre has joined with Oxford University to speed up the identification of the gene that predispose to the condition, get earlier diagnosis and develop a drug treatment. (West Australian 12 September 2001).

Monash University IVF head Professor Gab Kovacs had treated three Victorian men who had contracted AIDS through blood transfusions in the 1980s, with an IVF micro-injection technique whereby a single checked sperm was inserted into an egg. Twenty healthy babies had been born through this technique in France and it was recently used in Japan. There is a one per cent risk of passing on the HIV virus. (Canberra Times 26 November 2001)

The technique of freezing healthy eggs to be used later has not yet been developed. Sperm can be stored and frozen successfully, but so far the technology to freeze eggs is still experimental. This is because the chromosomes in the egg are fragile and freezing can cause breakdown and survival is low. Dr Stephen Junk from Pivet Medical Centre predicted that it would be five years before the technology was available for all clinics to be able to stimulate, collect and freeze a woman's egg. He claimed that under WA law, it is currently illegal for single women to have eggs collected for storage as it is considered part of an IVF cycle. The article also discussed women having their children later in life. (West Australian 12 June 2002).

Another procedure that could prolong fertility by 10 years was discussed at a conference on 24 March 2002. Alan Trounson of Melbourne's Monash University said Australia was well advanced in the technique that causes a woman's eggs to 'sleep' in her ovaries. This was based on restricting the number of eggs a woman released during her fertile years so she is left with a stockpile of eggs as she grows older. (West Australian 25 March 2002).

A menopause expert advocated saving ovarian tissue to guard against infertility in young women with breast cancer. Dr Rod Baber, head of the menopause clinic at Sydney's Royal North Shore Hospital, told the Young Breast Cancer Forum in Sydney that it was possible to freeze tiny slices of the ovary and implant them later in case chemotherapy triggered early menopause. He said ovarian biopsies successfully grafted on to a patient's

arm had stimulated egg production in the US. (Australian 22 October 2001).

Surrogacy

One article was collected on surrogacy during the year. The West Australian reported on 15 June 2002 that a search of a US website found a number of Australian women using a service to offer themselves as surrogate mothers or find potential surrogate mothers. This included a Perth couple who was willing to pay $20,000 for a surrogate mother to help them have a child. The advertisement came to light as a Victorian woman faced charges over attempting to sell her baby to a New York couple for $10,000.

APPENDIX 1

LICENCES AND EXEMPTIONS

LICENCES CURRENT UNDER THE HUMAN REPRODUCTIVE TECHNOLOGY ACT AT 30 JUNE 2002

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

J.L. Yovich Pty Ltd, *LEEDERVILLE* –
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.

Anne Marie Jequier trading as Joondalup IVF, JOONDALUP –
Practice and Storage Licences.

MEDICAL PRACTITIONERS WITH AN EXEMPTION FROM THE REQUIREMENT TO BE LICENSED TO CARRY OUT ARTIFICIAL INSEMINATION: AUGUST 31 2002

Exemptee No	Name	Suburb	Post Code
E023	Dr PK Bairstow	Bunbury	WA 6230
E042	Dr LD Brett	West Leederville	WA 6007
E034	Dr RT Chapman	Katanning	WA 6317
E011	Dr M J Cohen	Cottesloe	WA 6011
E041	Dr RJ Cooper	Kelmscott	WA 6111
E014	Dr TW Cottee	Bunbury	WA 6231
E027	Dr DP Day	Kelmscott	WA 6111
E001	Dr ZN Dorkhom	Bunbury	WA 6230
E057	Dr LG Green	Newman	WA 6753
E031	Dr PD Green	Australind	WA 6233
E040	Dr MC Hamdorf	Dunsborough	WA 6281
E012	Dr JT Jeffery	West Perth	WA 6005
E050	Dr R Kirk	Carnarvon	WA 6701
E046	Dr TP Knight	Mandurah	WA 6210
E024	Dr DN Lawrance	Kelmscott	WA 6111
E025	Dr HH Leslie	Exmouth	WA 6707
E016	Dr KA McCallum	Kalgoorlie	WA 6430
E003	Dr KT Meadows	Collie	WA 6225
E032	Dr D Mildenhall	Albany	WA 6330
E051	Dr WD Patton	Rockingham	WA 6168
E015	Dr BD Roberman	Subiaco	WA 6008
E017	Dr C Russell-Smith	Kwinana	WA 6167
E039	Dr T Silbert	Morley	WA 6062
E022	Dr BGA Stuckey	Nedlands	WA 6009
E029	Dr JM Vujcich	West Perth	WA 6050
E028	Dr RJ Watt	Mandurah	WA 6012
E049	Dr M Zafir	Albany	WA 6330

APPENDIX 2

APPROVED COUNSELLORS

LIST OF APPROVED COUNSELLORS
31 August 2002

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	FPWA Roe Street Centre for Human Relationships, 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 Antonia Clissa*	FPWA Roe Street Centre for Human Relationships, 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 9380 6387
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 or 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	FPWA Roe Street Centre for Human Relationships, 70 Roe St, Northbridge WA 6003	(08) 9228 3693 Fax (08) 9227 6871
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*	Suite 7 - 126 Grand Boulevard, Joondalup WA 6027	(08) 9300 0460 Fax (08) 9300 0459
Ms Lisa McCombe	C/- Advanced Personnel Management 58 Ord Street, WEST PERTH WA 6005	(08) 9486 1244 Fax (08) 9486 1344
Ms Sue Midford*	Suite 8/19 York Street, Subiaco WA 6008	(08) 9446 9860 Fax (08) 9446 9860
	2/36 Ormsby Tce, Mandurah WA 6210	(08) 9446 9860 (Appointments) Mobile 0411 590 566
Dr Kaye Miller	Palm Springs Medical Centre, 3 Halliburton Drive, Warnbro WA 6169	(08) 9593 2033 Fax (08) 9593 1913
Ms Helen Mountain	C/ Genetic Services of WA King Edward Memorial Hospital Centre for Women's Health Bagot Road, Subiaco 6008	(08) 9340 1525 Fax (08) 9340 1678
Ms Kate Orr	1974 Wannerup Road, Neerabup WA 6031	(08) 9407 4545 Fax (08) 9407 4500
	PO Box 607, Joondalup WA 6919	Mobile 0417 905 395
Ms Prue-Anne Reynalds*	5 Klenk Road, Attadale WA 6156	(08) 9330 7340
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, 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

*** 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.

APPENDIX 3

OPERATIONS OF LICENSEES FOR THE FINANCIAL YEAR 2001/2002

OPERATIONS OF LICENSEES FOR THE FINANCIAL YEAR 2001/2002

BACKGROUND

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

All information was submitted in a collated form and referred to the financial year which ended at 30 June 2002. While it is not possible to provide any data on outcomes of treatments undertaken during the financial year just ended because of the necessary lag time required for reporting, this summary shows the scale and type of activities carried out under the licences.

The Practice and Storage licences held by Fertility West terminated when that clinic closed down in December 2001 and Practice and Storage licences issued to Joondalup IVF commenced in January 2002. Owing to the closure during the year of Fertility West and unforeseen difficulties encountered at Joondalup IVF at the end of the reporting period, not all the data required for the Annual Report could be obtained in time for inclusion in the annual report. Where data are missing this is noted. It should be noted that in spite of difficulties in obtaining some data for the Annual Report, these difficulties will not affect submission of data required by the Reproductive Technology Register.

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 2000.

SUMMARY

Semen storage and donation

From Table 1 it can be seen that semen was donated to WA Storage Licensees by 21 men during 2001/2002. Of these 10 were new donors. This indicates a decline in both the total number of donors and the number of new donors when compared to the previous year. The age distribution of donors (Table 2), indicates that this year the proportions of donors under and over 30 year of age were similar, suggesting relatively greater recruitment of younger donors in comparison with the last couple of years. Table 3 indicates similar numbers of married and single (never married) donors, suggesting more effective recruitment of married donors this year.

Reporting by Exempt practitioners and the Sperm Banks indicated that during the year only one Exempt practitioner had been supplied with donor sperm. Five Exempt

practitioners who failed to submit an Annual Report (including any 'zero return') will be followed up. In the course of submitting their Annual Reports nine other Exempt practitioners requested revocation of their Exemptions.

Embryo storage

Table 4 shows that the total number of embryos in storage at the end of the year was 10,815. This was 1150 more than at the same time last year. The total number of embryos in storage has continued to increase dramatically since 1993. A total of 5143 embryos were stored following treatment and 3476 stored embryos were used in treatments during the year. In all 515 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 6 shows that during the last financial year 961 women began oocyte retrieval cycles for IVF, 561 began FETs and 3 began GIFT procedures.

A total of 2794 cycles were begun for IVF, frozen embryo transfer or GIFT, again slightly more than in the previous year. It can be seen that of all cycles begun, 1603 (57.4%) were for IVF and 1187 were for frozen embryo transfer. Overall frozen embryo transfer cycles made up 42.5% of all cycles begun. GIFT cycles (4) made up only 0.1% of all cycles begun.

Of the 1607 cycles begun for fresh IVF or GIFT with ovarian stimulation, 83.5% proceeded to oocyte retrieval and 75.1% proceeded to transfer fresh embryos or gametes. Of the 1187 frozen embryo transfer cycles begun, 1016 (85.6%) proceeded to transfer.

Overall, donated human reproductive material was involved in 2.2% of all IVF or GIFT oocyte retrieval cycles begun during the year, and 10.0% of all frozen embryo transfer cycles. In 1.2% of all oocyte retrieval cycles begun donor semen was used (19 cycles); donor eggs were used in 0.6% of all IVF cycles begun (10 cycles). Three IVF cycle involved the use of fresh donor embryos (0.2%), and donor embryos were used in 2.6 % of all FET cycles begun (31 cycles).

Of all 1341 IVF treatment cycles with successful oocyte retrieval, 656 (48.9 %) used intra-cytoplasmic sperm injection (ICSI), compared with 41.0 % in the previous year. Data from one clinic was unavailable, but other clinics reported that fresh or frozen sperm retrieved from the epididymis or testis was reported to have been used in 53 of the ICSI treatment cycles.

- *Summary reports on Council approved research and innovative practices*

Although data collected through the RT Register continues to allow follow-up of outcomes after ICSI, clinics performing ICSI are no longer required to report on its use with their Annual Reports as during the year the Council agreed that ICSI should no longer be considered an innovative practice. ICSI is now an accepted part of routine IVF around the world and, as noted above in the 1341 treatment cycles where egg collection occurred during the year in WA, ICSI was performed in 48.9 per cent.

The three clinics with approval to carry out assisted hatching reported on its use during the year. Assisted hatching was used in a total of 341 treatment cycles, 186 for fresh embryo transfer and 155 for frozen embryo transfer. The clinics reported a total of 64 ongoing pregnancies (plus 10 unknown outcomes), that is at least 18.8 ongoing pregnancies per 100 transfers following assisted hatching.

The two clinics with approval to use blastocyst transfer reported a total of 65 cycles and 16 ongoing pregnancies, that is 24.6 ongoing pregnancies per 100 blastocyst transfers. Data reported for both assisted hatching and blastocyst transfer did not provide information on the numbers of embryos transferred.

Current special approvals-

- Research:

R001 Use of Human Granulosa cell co-culture in Assisted Reproduction Techniques
Pivet Medical Centre
Approved 25.05.93: in abeyance

R 005 Comparison of culture media in human IVF
Pivet Medical Centre
Approved December 1994: in abeyance

R007 The impact of Tobacco and Caffeine consumption on the outcomes of in Vitro Fertilisation-embryo transfer.
Pivet Medical Centre
Approved 28 February 1995: in process of writing up.

R016 Does ICSI increase the risk of major birth defects?
TVW Telethon Institute for CHR
Approved 24/11/98: Finalised and published data 2002.

R019 Multicentre open label randomised trial to assess the efficacy and convenience of orgalutron etc
Pivet Medical Centre
Approved 8/8/00: report ongoing, finalisation delayed.

- Innovative clinical/laboratory practices:

I 002 Use of SAIZAN (Growth Hormone) in ovulation induction
Pivet Medical Centre
Approved 23.11.93: ongoing reported July 2002.

I 008 Assisted hatching
Pivet Medical Centre
Approved 13/11/00:

I009 Assisted hatching
Concept Fertility Centre
Approved 27/12/01: Report provided 2002

I010 Blastocyst transfer
Concept Fertility Centre
Approved 20/3/01: Report provided 2002

I011 In vitro culture of human embryos to Blastocyst stage
Pivet Medical Centre
Approved 18/01/01:

I012 Assisted Hatching

Hollywood Fertility Centre
Approved 20/3/01: Report provided July 2002.

- *Serious morbidity and mortality in women undergoing treatment*

These data were provided by three out of four clinics licensed to carry out IVF and related procedures.

Overall these three clinics reported a total of 32 cases of severe ovarian hyper-stimulation relating to 1506 IVF and GIFT stimulation cycles (2.0% stimulation cycles, with a clinic range of 1.1 –3.8%). The average number of follicles above 12cm for women who were affected by severe ovarian hyperstimulation was 21.2, and 15 women with OHSS were admitted to hospital for 1-10 days.

Two women undergoing intra-uterine insemination in licensed clinics were also severely affected.

There were no reports of severe pelvic infection or other serious morbidity, and no reported cases of mortality in association with fertility treatment during the year.

- *Intra-uterine insemination (IUI)*

The Council is continuing to monitor IUI carried out by licensees and Exempt practitioners. A total of 923 IUI cycles were reported by four Practice licensees and four Exempt practitioners. Data was not available from one Licensee as indicated above. The overall ongoing clinical pregnancy rate per treatment cycle carried out was 8.1% (75 ongoing pregnancies), and of the pregnancies, 66 were singleton (88.0%), 7 were twin (9.3%) and two were triplet (2.7%).

The information provided showed that 70.2% of the IUIs used husbands' sperm and 29.8% used donor sperm. Of all cycles carried out, 43.9% did not involve the use of ovulation induction. Clomid was used in only 14.0% of the cycles, and gonadotrophins were used in 42.1% of the cycles.

The two sets of triplets reported followed gonadotrophin stimulation in AIH. Of the six sets of twins reported, one set followed ovulation induction by clomid and the other five sets by gonadotrophins.

- *Counselling*

As reported last year, the Council introduced improved forms for reporting about the use of counselling services in the clinics. This is the first year when data was supplied on the new forms. As clinics did not fill in forms in exactly the same way, there may be discrepancies in the conclusions reached. There will be discussions with clinics as to whether the form needs adjusting or altering in the future. No data was supplied by one clinic.

Based on the reporting forms it was found that 956 sessions of counselling were conducted during the year. 83.5 per cent of patients who had counselling had one

session of counselling. The majority of patients had counselling for clarifying information and this was consistent across all clinics, with the exception of the one clinic that does not perform IVF services. That clinic had a higher number of therapeutic counselling sessions.

Of the patients that had more than one session of counselling (77 across all clinics), in the clinics that provide IVF services, patients had two or less than two sessions on average. The most frequent stated reason for having more than one session was for a 'matter related to infertility, followed by 'seeking support'. Just over 12 per cent of these patients had support or therapeutic counselling.

Most counselling was conducted on the clinic site. Clinics did not generally charge a separate fee for counselling; one clinic did not provide any information on 'method of payment'.

Counselling for people affected by donation – either as donors or recipients - made up 39 per cent of all counselling, but there was a wide range between clinics. For example, in one clinic 74.4 per cent of counselling was to donors and recipients. This contrasted with another where 20.1 per cent was to people affected by donation.

The figures obtained this year will be compared with like figures in the future.

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

Three clinics submitted amendments to their protocol manuals for the approval of Council during the year. At the time of Annual Reporting one clinic indicated the following changes to their routine procedures: the use of the Puregon Pen; the use of HSA in culture media; culture under oil; sperm morphology; use of the mixed anti-globulin reaction (MAR) test.

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

During the year a number of patients from the King Edward Memorial Hospital (KEMH) Infertility Clinic were referred for treatment at the Concept Fertility Centre, which reported on the treatments and their outcomes. As can be seen from Table 7, the results for this year indicate another increase in the number of public patients when compared to previous years. During the year 256 IVF and FET treatment cycles were carried out for 111 public patients. This year 38 of the IVF cycles involved micro-manipulation (ICSI). One patient underwent two treatment cycles using donated ova.

In addition, Concept reported 51 artificial inseminations (26 DI, 25 AIH) for 17 public patients between 1 July 2001 and 30 June 2002.

Complaints

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

TABLE 1: NUMBER OF SEMEN DONORS

	1993/94	1994/95	1995/96	1996/97	1997/98	1998/99	1999/00	2000/01	2001/02
No. current Donors	67	49	49	23	28	22	45	43	21
No. new donors in last year	23	28	30	20	11	15	30	24	10

TABLE 2: SEMEN DONOR AGES

Age of Donor (years)	Frequency (%)							
	1994/95	1995/96	1996/97	1997/98	1998/99	1999/00	2000/01	2001/02
18-25	15 (30.6)	19 (38.8)	11 (34.3)	6 (21.4)	8 (36.4)	7 (16.3)	8 (18.6)	6 (30.0)
26-30	10(20.4)	8 (16.3)	8 (25.0)	8 (28.6)	0 (0)	5 (11.6)	2 (4.7)	3 (15.0)
31-35	10 (20.4)	13 (26.5)	7 (21.9)	4 (14.3)	6 (27.3)	4 (9.3)	7 (16.3)	3 (15.0)
36-40	5 (10.4)	3 (6.1)	4 (12.5)	6 (21.4)	1 (4.5)	12 (27.9)	13 (30.2)	6 (30.0)
41-50	9 (18.3)	6 (12.2)	2 (6.3)	3 (10.7)	7 (31.3)	12 (27.9)	11 (25.6)	0 (0)
>50	0 (0)	0 (0)	0 (0)	1 (3.6)	0 (0)	3 (7.0)	2 (4.7)	2 (10.0)
Total	49[1] (100)	49 (100)	32 (100)	28 (100)	22 (100)	43[2] (100)	43 (100)	20[3] (100)

[1] ,[3] age missing for one donor
[2], age missing for two donors

TABLE 3: MARITAL STATUS OF SEMEN DONORS

	Frequency (%)							
Status	1994/95	1995/96	1996/97	1997/98	1998/99	1999/00	2000/01	2001/02
Single	36 (73.5)	34 (69.4)	25 (78.1)	20 (71.4)	14 (63.6)	28 (62.2)	23 (53.5)	10 (47.6)
Married/de facto	11 (22.4)	13 (26.5)	6 (18.8)	6 (21.4)	5 (22.7)	12 (26.7)	14 (32.6)	9 (42.9)
Divorced/sep.	2 (4.1)	2 (4.1)	1 (3.1)	2 (7.1)	3 (13.6)	5 (11.1)	6 (14.0)	2 (9.5)
Total	49 (100)	49 (100)	32 (100)	28 (100)	22 (100)	45 (100)	43 (100)	21 (100)

TABLE 4: TOTAL NUMBER OF EMBRYOS IN STORAGE JUNE 30

YEAR	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002
No Embryos	1706	1870	2821	3456	4697	6108	7317	8692	9665*	10,815

*updated information from 2001 Annual Report

TABLE 5: DISPERSAL OF STORED EMBRYOS 2001/2002

	No of embryos
Transferred between clinics in WA	410
Transferred to clinics outside WA (Patients moving interstate/overseas)	30
Transferred into WA clinics from interstate or overseas	28
Used in frozen embryo transfer treatments	3476
Allowed to succumb with consent of couples	515

TABLE 6: IVF/GIFT TREATMENTS: Four year data

	IVF Fresh embryo transfer				IVF Frozen embryo transfer				GIFT				Total			
	1998/99	**1999/2000**	**2000/01**	**2001/02**	**1998/99**	**1999/2000**	**2000/01**	**2001/02**	**1998/99**	**1999/2000**	**2000/01**	**2001/02**	**1998/99**	**1999/2000**	**2000/01**	**2001/02**
No of women treated	802	977	1047	961	511	510	667	561	18	12	5	3	n/a	n/a	n/a	n/a
No of cycles begun	1408	1529	1543	1603	1085	988	1196	1187	32	16	6	4	2525	2533	2745	2794
No of cycles with oocyte retrieval	1143	1114	1357	1341	-	-	-	-	24	14	6	1	1167	1128	1363	1342
No of cycles with gamete or embryo transfer	1069	1003	1209	1206	917	832	980	1016	25	14	6	1	2011	1849	2195	1207
No of cycles using donor:																
Semen	33	37	25	19	16	19	25	14	1	0	1	0	50	56	51	33
Ova	11	10	11	10	34	22	60	74	0	0	0	0	45	32	71	84
Embryo	1	1	0	3	30	36	20	31	-	-	0	0	31	37	20	34
Total	45	48	36	32	80	77	105	119	1	0	1	0	126	125	142	151
No of cycles where embryos stored	641	670	763	841	-	-	-	-	10	9	4	0	651	679	767	841
No of cycles from which human reproductive material was donated:																
Ova donated	11	21	33	30	-	-	-	-		0	0	0	11	21	33	30
Embryos donated	1	0	0	6	-	-	-	-		0	0	0	1	1	0	6
Breakdown of treatment cycle details																
No of cycles with IVF/GIFT same cycle	2	0	0	1	-	-		-	-	-	-	-	2	0	?	-
No of cycles with sperm retrieval	106	102	90	53[+]	-	-		-	-	-	0	0	106	102	90	53[+]
No of cycles with ICSI*	466	463	556	656	-	-		-	-	-	-	-	450	466	556	656
No of cycles with Fallopian embryo transfer	6	6	2	1	3	3	2	1	-	-	0	0	9	9	4	1

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

TABLE 7: IVF AND RELATED TREATMENT OF PUBLIC PATIENTS

	No. of Patients				No. of Treatment Cycles			
	1998/99	**1999/2000**	**2000/2001**	**2001/2002**	**1998/99**	**1999/2000**	**2000/2001**	**2001/2002**
IVF	43	46	87	77	53	62	126	114
GIFT	1	0	0	0	1	0	0	0
FET	14	20	19	64	60	42	101	142*
TOTAL	**58**	**66**	**106***	**141****	**114**	**104**	**227**	**256**

* 2 Cycles used donated ova.

**Collated information showed that a total of 111 women underwent one or more IVF/FET treatment cycles.

2002 EMBRYO STORAGE

1. Embryos in storage 30th June 2001

Concept: 4313
Pivet: 3497
Fert West: 1154*
Hollywood: 701

2. Embryos stored (1 July 2001 to 30 June 2002

	Concept	Pivet	Fert West/ Joondalup IVF	Hollywood	Total
Frozen after retrieval	1604	1954	469	1116	5143
From WA clinics	19	100	41	250	410
From interstate	15	12	1	0	28
From overseas	0	0	0	0	0
Total	1638	2066	511	1366	5581

3. Embryos removed from storage (1 July 2001to 30 June 2002)

	Concept	Pivet	Fert West	Hollywood	Total
Thawed for FET	1190	1377	373	536	3476
Thawed to succumb	96	283	121	15	515
To WA clinics	45	77	283	5	410
To interstate	8	20	0	2	30
To overseas	0	0	0	0	0
Total	1339	1757	777	558	4431

4. Total embryos in storage at 30th June 2002

	Concept	Pivet	Fert West	Hollywood	Total
In storage 30th June 2001	4313-	3497	1154*	701	9665
30 June 2002	4612	3806	888	1509	10,815

*on later information have upgraded the number for embryos at the end of June 2001.

APPENDIX 4

REPORT FROM THE REPRODUCTIVE TECHNOLOGY REGISTER: JANUARY 1 TO DECEMBER 31 2000

REPORT FROM THE REPRODUCTIVE TECHNOLOGY REGISTER: 1 JANUARY TO 31 DECEMBER 2000

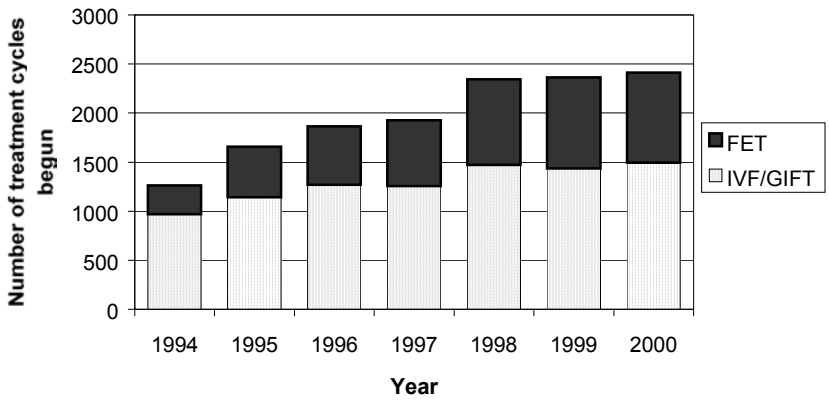
This is the eighth report from the Reproductive Technology Register established from 8 April 1993 under the WA *Human Reproductive Technology Act 1991*. This report summarises information about artificial fertilisation procedures undertaken in Western Australia between 1 January and 31 December 2000. 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 6 exempt practitioners.

Comparisons are made throughout the summary to data reported in previous years[1-6] 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)[7]. 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 2000 data on the Reproductive Technology Register.

There was a total of 2412 treatment cycles begun for IVF and related procedures (GIFT and frozen embryo transfer (FET)) in 2000, an increase of only 2.0% compared to the previous year (2365). The majority of these (1496) were stimulation cycles for IVF or GIFT (see Table 2), and 916 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 procedures carried out each year appears to have stabilised over the last three years (1998-2000) after a steady increase until 1998. The number of FET procedures in 2000 (916) was less than that of the previous year (930), which is the first time the number of FET cycles has not increased from the previous year. In 2000 treatment cycles begun for frozen embryo transfer represented 38.0% of all treatment cycles begun.

Figure 1: Number of treatment cycles begun for IVF/GIFT and FET, 1994-2000



During 2000, 1115 women (81 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 1.3, with a median of 1.

Cancellation of stimulation cycles for IVF or GIFT occurred in 15.6% of cases, which is slightly lower than in recent years (1999: 18.1%; 1998: 22.3%). A wide clinic range was also evident (1.6%-26.1%), which may in part reflect the different ovulation induction regimes used by the clinics or different definitions of cancelled cycle, which the Reproductive Technology Council will review. Of those egg retrievals attempted, 1.0% were performed by laparoscopy and 99.0% 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 (10.9, median = 9) than by laparoscopy (6.1, median = 6.0). The overall mean and median for both techniques combined were 10.8 and 9 respectively. This is the first year since 1994 that the mean and median number of oocytes retrieved has decreased compared to the previous year. Attempted egg retrievals were almost all successful (99.3%) with a narrow clinic range (97.5%-100%).

Eggs were donated in 1.9% of successful egg retrievals, and 28.5% 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, Metrodin, Progynova and Saizen were also used in ovulation induction but in a smaller proportion of cycles. As part of Down Regulation prior to ovulation induction the two drugs Lucrin and Synarel were commonly used, Orgalutron was used in a limited number of cases as part of a clinical trial.

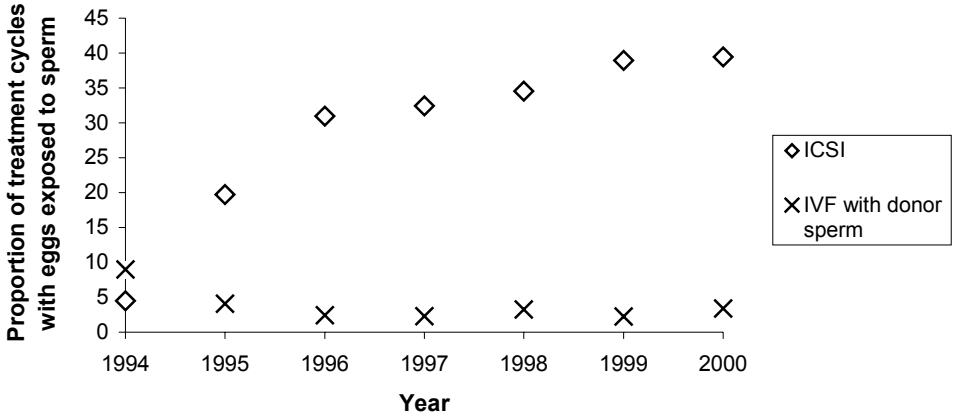
Between 1 January and 31 December 2000, 1253 women had embryo transfers (fresh or frozen) or egg transfers (GIFT) (see Table 3). This represents a 5.1% increase compared to the 1192 women having embryo transfers in 1999, and a 82.4% increase compared to 1994. The majority of these women (47.6%) had only fresh embryo transfers, although 27.0% had only frozen embryo transfers, and 24.9% had both IVF and FET transfers. Of the 1253 women treated in 2000, table 4 shows most had only one transfer during the year (59.2%), although 27.0% had two transfers and 8.5% had three. Sixty-six women had more than three transfers, the highest being 1 woman who had 6 transfers during the reporting period. The mean number of transfers per woman in this period was 1.6 and the median 1.

Table 5 summarises the fertilisation and embryo dispersal data for treatment cycles commenced between 1 January and 31 December 2000. There were 1265 cycles with eggs exposed to sperm, a further increase on 1999 where there were 1166 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 9.8 (median 9) with a clinic range from 9.5 to 10.1 (and the median varied between the clinics from 8 to 9).

Micro-manipulation to achieve fertilisation was used in 39.4% of treatment cycles with eggs exposed to sperm, with a wide clinic range (30.8%-55.3%). Intra-cytoplasmic sperm injection (ICSI) was the only micro-manipulation technique used in 2000, as it

has been since 1996. The rapid increase in the proportion of ICSI treatment cycles since 1994 seems to have levelled off however, with only small increases over the last few years (38.9% treatment cycles using ICSI in 1999, 34.5% in 1998, 32.4% in 1997 and 31.1% in 1996). 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, 1994-2000



Fertilisation of one or more eggs occurred in 96.9% of treatment cycles with eggs exposed to sperm (Table 5). The range between clinics for successful fertilisation per egg exposed to sperm was narrow (72.3%-76.8%), and for all clinics combined was 74.1%. Donor sperm was only used in 3.4% of treatment cycles, an increase from the 2.2% of 1999 but on par with the rate of 3.3% in 1998 (see Figure 2 above). The fertilisation rate using husbands' sperm was slightly higher than that using donor sperm (74.1% vs 73.8%). There appears to be no consistent pattern over the years regarding fertilisation rates for donor compared to husbands' sperm, as in 1998 and 1997 husbands sperm had higher fertilisation rates then donor sperm (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 90.0% of treatment cycles with successful fertilisation, with a wide clinic range from 82.9% to 96.5% (see Table 5). These proportions do not just reflect the effectiveness of fertilisation and embryonic development. They will also be affected by the proportion of GIFT cycles in which eggs were also exposed to sperm for embryo storage rather than being used in the GIFT procedure, although in 2000 there were only a small total number of treatment cycles in which eggs were replaced at GIFT. When these are excluded, fresh embryo transfer occurred in 90.5% of all IVF treatment cycles with successful fertilisation, still with a substantial clinic range of 83.3% to 96.5%. This may be a consequence of clinic preference in fresh transfer vs. freezing of higher quality embryos and/or differences in medication regimes between clinics and/or patient factors

Embryos were frozen in 61.2% of treatment cycles with successful fertilisation (see Table 5), and some embryos were allowed to succumb in 64.2% of treatment cycles. The majority of embryos that were allowed to succumb were reported by clinics to have been abnormal or degenerate (87.8%).

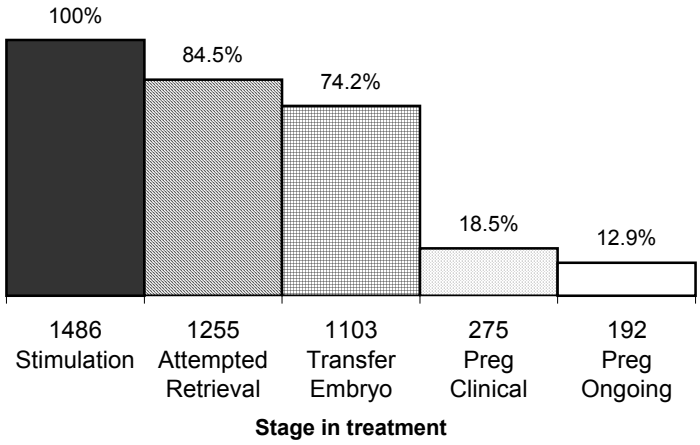
Fresh Embryo Transfer (IVF-ET):

There were 1103 fresh embryo transfers in 2000, only 85 more than the previous year (see Table 6). Donor egg embryos and donor sperm embryos were used in 1.0% and 3.1% of fresh embryo transfers respectively. There were 275 clinical pregnancies resulting from IVF embryo transfer (21.9 per 100 egg retrieval cycles) and 192 ongoing (15.3 per 100 egg retrieval cycles, with a clinic range of 14.6-16.7). These pregnancy rates were slightly lower than in 1999 when there were 20.5 clinical pregnancies per 100 egg retrieval cycles and 16.4 ongoing pregnancies per 100 egg retrieval cycles.

The 2000 fresh embryo transfer (including ICSI) pregnancy rates reported for all Australian and New Zealand clinics combined were similar to those observed for the WA clinics (21.3 clinical pregnancies per 100 oocyte retrieval cycles, and 17.5 ongoing pregnancies at 20 weeks per 100 oocyte retrieval cycles).[7]

The clinical pregnancy rate based on all treatment cycles with stimulation begun for IVF-ET was lower than the rate per egg retrieval attempted. These lower rates can be attributed to the relatively high number of cycles which were cancelled prior to retrieval. Figure 3 illustrates that there were 18.5 clinical pregnancies per 100 stimulation cycles begun, and 12.9 ongoing pregnancies per 100 stimulation cycles.

Figure 3: Results in subsequent phases of IVF-ET treatment, in 2000



Of the confirmed 188 pregnancies with live births, 78.2% were singleton, 20.7% were twin, and 1.1% were triplet (i.e. 21.8% of live births were multiple). The proportion of multiple births is marginally lower that that observed in 1999 when they represented 21.9% of live births. National data for 1999[#] indicated that 21.5% of 'IVF pregnancies' following fresh *or* frozen embryo transfer resulted in multiple births (the data do not distinguish between fresh and frozen transfers).

There were 229 live births in 2000, 6 stillbirths and 3 neonatal death. This represents a perinatal mortality rate of 38.3 per 1000 total births. In 2000, all perinatal deaths after IVF-ET occurred in multiple births. The 2000 perinatal mortality rate for *all* babies born in Western Australia was 10.7 per 1000 total births.[8]

As the proportion of multiple births is influenced by the numbers of embryos transferred, the Reproductive Technology Accreditation Committee (RTAC) encourages the transfer of no more than 2 oocytes or embryos in most circumstances. The mean number of embryos replaced per fresh embryo transfer in WA was 2.0, and the median 2 (clinic range 1.9-2.2 with a median of 2 for all clinics). In WA the percentage of cycles where more than two oocytes or embryos were transferred was 16.5%. This is slightly lower than that observed for all Australian and New Zealand IVF clinics combined (18.8%).[7] 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 9.6% to 25.9% of fresh embryo transfer cycles. This difference may influence not only the overall proportion of multiple births in each clinic (range 14.7%-28.1% of pregnancies with live births) but also the proportion of higher order multiple births (clinic range 0-1.6% 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 2000. Multiple births only occurred in treatments where either two or three embryos were transferred. The overall proportion of multiple births was similar for 2 and 3 embryo transfers (24.5% vs. 21.7%), however, the proportion of higher order multiple births (triplets) was higher for 3 embryo transfers. There were only 5 transfers where 4 embryos were replaced.

An analysis of the implantation rate (the proportion of embryos replaced at fresh transfer which resulted in a live birth) varied between the clinics from 9.2% to 11.1%. The implantation rate for all clinics was 10.3%. Implantations rates where one embryo was transferred were slightly lower than for two embryo transfer (1 embryo: 10.2%; 2 embryos: 12.1%). As has been typical in previous years the implantation rate for cycles where three and four embryos are transferred are much lower than when one or two embryo are transferred (3 embryos: 5.5%; 4 embryos 5.0).

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 2000.

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	168	17	17	10.1	0	0	0	0
Two	753	147	182	19.5	24.5	0.7	7	37.2
Three	177	23	29	13.0	21.7	4.3	2	69.0
Four	5	1	1	20.0	0	0	0	0
Total	1103	188	229	17.0	21.8	1.1	9	38.3

Gamete Intra Fallopian Transfer (GIFT):

GIFT transfers accounted for only 0.3% of all assisted conception transfer procedures performed in 2000. Only two clinics carried out GIFT treatments with the majority of treatments (71.4%) carried out by one clinic. There were an estimated* 7 treatment cycles begun for GIFT which represented 0.6% of egg retrieval cycles attempted (Table 7). The number of GIFT treatments in 2000 (7) was eighteen less than the number in 1999 (25). GIFT has been in decline since 1994 (1998: 26, 1997: 74, 1996: 90, 1995: 140, 1994: 286), currently being used only in special circumstances such as where a couple has ideological reasons not to participate in IVF. Donor sperm was used in 1 case (14.3%) of the GIFT procedures, and the mean number of eggs replaced at transfer was 2.3 (median 2).

There were 2 clinical pregnancies resulting from GIFT treatment in 2000 (28.6 per 100 egg retrieval cycles), but none of these resulted in ongoing pregnancies (at 20 weeks). These rates are not compared to national data due to the small number of GIFT transfers carried out in Western Australia in 2000.

Frozen Embryo Transfer (FET):

Table 8 summarises treatment cycle information for the 654 women who undertook frozen embryo transfer procedures in the reporting period. This represents a further increase in the number of women undergoing FET (1999: 636, 1998: 590, 1997: 476, 1996: 419, 1995: 372, 1994: 232). However, the number of FET cycles during 2000 (916) decreased from that of 1999 (930). This is the first decrease in FET cycles since the commencement of the Register. The 916 treatment cycles begun for FET accounted for 31.8% to 48.7% of all transfer procedures (for IVF, GIFT and FET) in the different IVF clinics. Embryo transfer occurred in 97.3% of treatment cycles begun for FET, and 10.7% of these involved donated material. Donor eggs were used in 4.6% of transfers, donor sperm in 2.6%, both sperm and donor egg in 0.3% and donor embryos were used in 3.3%.

The mean number of embryos transferred at FET was 2.0 (and the median 2). There were 196 clinical pregnancies (22.0 per 100 embryo transfer cycles) and 156 ongoing pregnancies (17.5 per 100 embryo transfer cycles with a clinic range of 13.6-22.1). The ongoing pregnancy rate in 1999 was slightly lower (17.0 per 100 embryo transfer cycles). There were 156 pregnancies with live births, 78.8% were singleton, 18.6% twins and 2.6 were triplets. There were 0 still births and 2 neonatal deaths following FET treatment in 2000.

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, however, and the overall clinical pregnancy rate following FET in 2000 was 17.7 per 100 embryo transfers with an ongoing pregnancy rate at 20 weeks of 14.2 per 100 embryo transfers.[7]

A large number of factors may be important in determining the wide clinic range in live birth pregnancy rates seen for FET (13.6-22.1 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

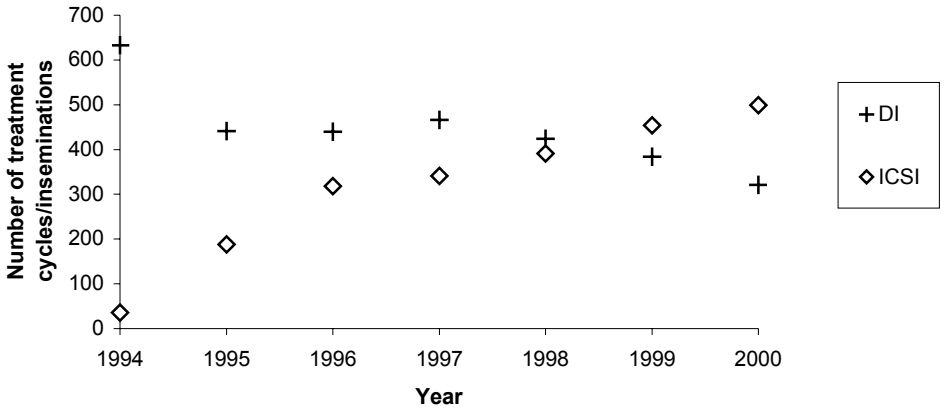
affect the quality of frozen embryos replaced and therefore the pregnancy rate in each clinic.

Drugs used in preparation for FET were: Gonal F, Metrodin, Primogyn, Puregon, Profasi, Progesterone Pessaries, Pregnyl, Progynova, and Proluton.

Donor Insemination (DI):

Donor insemination (DI) treatments and outcomes carried out in the reporting period are summarised in Table 9. There were 321 DI treatments undertaken by 122 women in 2000, slightly less than the 484 DI treatments undertaken in 1999. 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 two years, the number of donor insemination treatments was less than the number of ICSI treatments.

Figure 4: Number of treatment cycles using ICSI and number of donor inseminations, 1994-2000



The mean number of inseminations per woman treated in 2000 was 2.6 (median 2), with a clinic range of 1.5 to 3.6 (and a median range of 1-3). There were 30 clinical pregnancies as a result of DI treatment (9.3 per 100 insemination treatments) and 24 ongoing pregnancies (7.5 per 100 insemination treatments). The proportion of pregnancies with live births varied between the clinics, from 0 to 33.3 per 100 insemination treatments. This difference may be influenced by the differing patterns in the use of ovulation induction between clinics. Of 22 pregnancies with live births, 86.4% were singleton, 9.1% were twin and 4.5% were triplets. There were 26 live births, 1 still birth and 1 neonatal death. More up to date information on the use of intra-uterine insemination (IUI) by licensees and exemptees may be found in the summary report of clinic data for 2000/01 earlier in this report and these data. In addition to IUI using sperm from donors, includes information about IUI using sperm from the husbands/partners

Table 10 summarises the use of donated human reproductive material in 2000. Thirty-nine egg donors, 98 sperm donors and 19 embryo donor couples all donated material used in this period. There were 15 babies born of treatment cycles involving donor eggs, 47 babies through treatment involving donor sperm, and 9 babies were born from donated embryos.

Notes:

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

* As information reported to the register does not differentiate between egg retrievals attempted for IVF-ET 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; Ms Margo O'Neill, Research Officer for the WA Midwives' Notification System; Ms Carol Garfield, Database Administrator for the LinkData Project and Ms Lexie Stoney, Research Officer for the LinkData Project; for their assistance in providing information on confinements and neonatal deaths and implementation of an internal linkage of the Reproductive Technology Register.

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TABLE 2: IVF/GIFT egg retrievals and dispersals between 1 January and 31 December 2000

	Treatment Cycles				Women
	N	%	%	%	N
IVF/GIFT treatment begun:	1496 (154-614)	100.0			1115
No. cycles begun per woman - Mean: (range[1])					1.3 (1.2-1.5)
Median: (range[1])					1 (1-1)
Cancelled: (range[1])	234 (4-160)	15.6 (1.6-26.1)			
Total egg retrievals attempted[2] - (range[1])	1262 (132-454)	84.4	100.0		
Laparoscopy:	13		1.0		
Trans Vaginal Ultrasound:	1249		99.0		
Failed retrievals: (range[1])	9 (0-6)		0.7 (0.0-2.5)		
Successful egg retrievals: (range[1])	1253		99.3 (97.5-100)	100.0	
Mean number of eggs per successful retrieval -					
All: (median)	10.8 9				
Laparoscopy: (median)	6.1 6				
Trans Vaginal Ultrasound: (median)	10.9 9				
With eggs exposed to sperm:	1251[3]			99.8[2]	
With eggs transferred at GIFT:	7			0.6[2]	
With eggs donated:	24			1.9[2]	
With eggs used for experimentation:	0			0.0[2]	
With eggs discarded:	357			28.5[2]	

Footnotes:
1) (range[1]) gives the range of results from the three 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 2000

Transfer Type	N	%
IVF-ET only	596	47.6
FET only	338	27.0
GIFT only	2	0.2
IVF-ET & FET	312	24.9
GIFT & FET	4	0.3
IVF-ET & GIFT	1	0.1
IVF-ET, GIFT & FET	0	0.0
TOTAL	**1253**	**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 2000

No. of Transfers[1]	N	%
1	742	59.2
2	338	27.0
3	107	8.5
4	51	4.1
5	14	1.1
6	1	0.1
TOTAL	**1253**	**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 2000

	Treatment Cycles			Eggs/Embryos			Women
	N	%	%	N	%	%	N
Eggs exposed to sperm:	1265	100.0		12456	100.0		1029
(range[1])	(131-458)						
Mean number of eggs exposed to sperm per treatment cycle:				9.8			
(range[1])				(9.5-10.1)			
Median:				9			
(range[1])				(8-9)			
Using husband sperm:	1222	96.6					
(range[1])		(95.7-98.5)					
Using donor sperm:	43	3.4					
(range[1])		(1.5-4.3)					
Using micro-manipulation -	499	39.4					
(range[1])		(30.8-55.3)					
ICSI:	499	39.4					
SUZI:	0	0.0					
PZD:	0	0.0					
PZD/SUZI:	0	0.0					
Failed fertilisation:	39	3.1					
(range[1])		(2.6-3.8)					
Fertilisation occurred:	1226	96.9	100.0	9229	74.1	100.0	
(range[1])	(126-446)						
Using husband sperm:				8899	74.1[2]		
(range[1])					(72.3-76.9)		
Using donor sperm:				330	73.8[2]		
(range[1])					(73.0-87.5)		
Fresh embryo transfer	1104		90.0	2223	17.8	24.1	
(range[1])			(82.9-96.5)				
Embryo freezing	750		61.2	4763	38.2	51.6	
(range[1])			(45.8-70.9)				
Embryo donation	0		0.0	0	0.0	0.0	
Embryos discarded	787		64.2	2243	18.0	24.3	

Footnotes:

1) (range[1]) gives the range of results from the three 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 (1969) and 274 surplus embryos were discarded.

Note: Embryos from two separate fertilisations were used together in one fresh transfer so there were 1103 transfer procedures

TABLE 6: IVF-ET (fresh IVF embryo transfer) transfers and outcomes between 1 January and 31 December 2000

	Treatment Cycles				Women	
	N	%	%	%	N	%
Egg retrievals attempted for IVF-ET:	1255[2]	100.0				
(range[1])	(132-449)					
With embryos transferred -	1103[3]	87.9	100.0		909	100.0
(range[1])	(112-418)					
Donor -						
Egg:	11		1.0			
Sperm:	34		3.1			
Egg+Sperm:	0		0.0			
Embryo:	0		0.0			
Number embryos per transfer -						
Mean:	2.0					
(range[1])	(1.9-2.2)					
Median:	2					
(range[1])	(2-2)					
Clinical pregnancy -						
Yes:	275	21.9	24.9		272	29.9
(range[1])		(20.5-25.0)	(22.0-29.5)			
No:	828	66.0	75.1		637	70.1
Blighted ovum:	15	1.2	1.4			
Missed abortion:	29	2.3	2.6			
Spontaneous abortion:	21	1.7	1.9			
Ectopic:	15	1.2	1.4			
Therapeutic abortion:	3	0.2	0.3			
Ongoing clinical pregnancy at 20 weeks:	192	15.3	17.4		192	21.1
(range[1])		(14.6-16.7)	(16.0-19.6)			
Late pregnancy loss:	0	0.0	0.0		0	0.0
Pregnancies with live births:	188[4]	15.0	17.0	100.0	187	20.6
(range[1])		(14.6-15.9)	(16.0-18.8)			
Plurality:						
1	147	11.7	13.3	78.2		
(range[1])		(10.6-12.9)	(11.9-15.2)	(71.9-85.3)		
2	39	3.1	3.5	20.7		
(range[1])		(2.0-3.9)	(2.2-4.8)	(13.2-26.6)		
3	2	0.2	0.2	1.1		
(range[1])		(0.0-0.2)	(0.0-0.3)	(0.0-1.6)		
Live Births:	229	18.2	20.8			
Still Births:	6[5]	0.5	0.5		4	0.4
Neonatal deaths (within 28 days of birth):	3[6]	0.2	0.3			

Footnotes:

1) (range[1]) gives the range of results from the three 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) Two women were lost to follow up and their birth details were unavailable therefore they are excluded from confinement data.

5) Both babies from two twin pregnancies and one baby from another two twin pregnancies

6) Both babies from one twin pregnancy and one baby from another twin pregnancy

Note: Two women gave birth outside WA. In each case the treating clinic reported a birth outcome (two sets of twins), and these are included in the confinement data.

TABLE 7: GIFT transfers and outcomes between 1 January and 31 December 2000

	Treatment Cycles				Women	
	N	%	%	%	N	%
Egg retrievals attempted for GIFT*:	7	100.0				
(range[1])	(0-5)					
With eggs transferred -	7	100.0	100.0		7	100.0
(range[1])	(0-5)					
Donor -						
Egg:	0		0.0			
Sperm:	1		14.3			
Egg+Sperm:	0		0.0			
Number eggs per transfer -						
Mean:	2.3					
(range[1])	(0-3.5)					
Median:	2					
(range[1])	(0-2.5)					
Clinical pregnancy -						
Yes:	2	28.6	28.6		2	28.6
(range[1])		(0-40)	(0-40)			
No:	5	71.4	71.4		5	71.4
Blighted ovum:	0	0.0	0.0			
Missed abortion:	1	14.3	14.3			
Spontaneous abortion:	0	0.0	0.0			
Ectopic:	1	14.3	14.3			
Therapeutic abortion:	0	0.0	0.0			
Ongoing clinical pregnancy at 20 weeks:	0	0.0	0.0		0	0.0
(range[1])						
Late pregnancy loss:	0	0.0	0.0		0	0.0

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

TABLE 8: Frozen Embryo Transfers between 1 January and 31 December 2000

	Treatment Cycles				No. of Embryos		Women	
	N	%	%	%	N	%	N	%
Treatment cycles begun for FET:	916	100.0					654	100.0
(range[1])	(87-389)							
Cancelled:	7	0.8					6	0.9
Number embryos thawed:					3000	100.0		
Number embryos flawed:					1222	40.7		
Totally failed thaw:	18	2.0					18	2.8
Embryos transferred -	891	97.3	100.0		1778	59.3	642	98.2
Own:	796		89.3		1577			
Donor -								
Egg:	41		4.6		84			
Sperm:	23		2.6		49			
Egg + Sperm:	3		0.3		6			
Embryo:	29		3.3		65			
Number embryos per transfer -								
Mean:					2.0			
(range[1])					(1.8-2.2)			
Median:					2			
(range[1])					(2-2)			
Clinical pregnancy -								
Yes:	196	21.4	22.0				195	29.8
(range[1])		(17.0-28.1)	(17.0-28.7)					
No:	695	75.9	78.0				447	68.3
Blighted ovum:	7	0.8	0.8					
Missed abortion:	17	1.9	1.9					
Spontaneous abortion:	2	0.2	0.2					
Ectopic:	10	1.1	1.1					
Therapeutic abortion:	4	0.4	0.4					
Ongoing clinical pregnancy at 20 weeks:	156	17.0	17.5				156	23.9
(range[1])		(13.6-21.6)	(13.6-22.1)					
Late pregnancy loss:	0	0.0	0.0				0	0.0
Pregnancies with live births:	156	17.0	17.5	100.0			156	23.5
(range[1])		(13.6-21.6)	(13.6-22.1)					
Plurality:								
1	123	13.4	13.8	78.8				
(range[1])		(9.8-17.8)	(10.6-18.1)	(62.5-82.2)				
2	29	3.2	3.3	18.6				
(range[1])		(2.6-3.9)	(2.6-4.3)	(16.4-25.0)				
3	4	0.4	0.4	2.6				
(range[1])		(0.0-2.0)	(0.0-2.1)	(0.0-12.5)				
Live Births:	193	21.1	21.7					
Still Births:	0	0.0	0.0				0	0.0
Neonatal deaths (within 28 days of birth):	2[2]	0.2	0.2					

Footnotes:

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

2) One baby from a twin pregnancy and one singleton

TABLE 9: Donor Insemination treatments and outcomes carried out between 1 January and 31 December 2000

	Treatment Cycles			Women	
	N	%	%	N	%
DI carried out:	321	100.0		122	100.0
(range[1])	(3-200)				
No. DIs per woman treated -					
Mean:				2.6	
(range[1])				(1.5-3.6)	
Median:				2	
(range[1])				(1-3)	
Clinical pregnancy -					
Yes:	30	9.3		29	23.8
(range[1])	(0-15)	(0.0-33.3)			
No:	291	90.7		93	76.2
Blighted ovum:	1	0.3			
Missed abortion:	3	0.9			
Spontaneous abortion:	2	0.6			
Ectopic:	0	0.0			
Therapeutic abortion:	0	0.0			
Ongoing clinical pregnancy at 8 weeks:	24	7.5		24	19.7
(range[1])		(0.0-33.3)			
Late abortion (post 8 weeks):	0	0.0		0	0.0
Pregnancies with live births:	22[2]	6.9	100.0	23	18.9
(range[1])		(0.0-33.3)			
Plurality:					
1	19	5.9	86.4		
(range[1])		(0.0-33.3)	(0.0-100)		
2	2	0.6	9.1		
(range[1])		(0.0-6.7)	(0.0-100)		
3	1	0.3	4.5		
(range[1])		(0.0-1.3)	(0.0-11.1)		
Live Births:	26	8.1			
Still Births:	1[3]	0.3		1	0.8
Neonatal deaths (within 28 days of birth):	1[4]	0.3		1	0.8

Footnotes:

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

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

3) 1 singleton

4) 1 singleton

TABLE 10: Donation of Human Reproductive Material between 1 January and 31 December 2000

	IVF-ET	GIFT	FET	DI	TOTAL
Number of Treatment Cycles -					
Donor Egg:	11	0	40	-	51
Donor Sperm:	34	1	23	321	379
Donor Egg+Sperm:	0	0	3	-	3
Donor Embryo:	0	-	29	-	29
Number of Babies Born -					
Donor Egg:	3	0	12	-	15
Donor Sperm:	12	0	8	27[3]	47[3]
Donor Egg+Sperm:	0	0	0	-	0
Donor Embryo:	0	-	9	-	9
Number of Donors Used -					
Donor Egg:	11	0	31	-	39[1]
Donor Sperm:	26	1	19	73	98[1]
Donor Embryo[2]:	0	-	19	-	19

Footnotes:

1) There were 98 individual sperm donors and 39 individual egg donors whose sperm and eggs were used in 2000. These total donor numbers are not equivalent to the sum of donors in the IVF-ET, GIFT, FET and DI categories for these fields as the same donor may be used in more than one type of transfer eg for DI inseminations as well as in an IVF treatment cycle.

2) Embryo donors are considered as a couple

3) This number includes one stillbirths

APPENDIX 5

INFORMATION CIRCULATED TO LICENSEES

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

30 JANUARY 2002

THE PRIVACY ACT 1988.

Background

Amendments to the *Privacy Act 1988* that bring certain aspects of your operations into the ambit of that Act came into operation from 21 December 2001.

As you know RTAC now requires all clinics to have a Privacy Policy.

The Reproductive Technology Register (RT Register) is established under the *Human Reproductive Technology Act 1991* (HRT Act). Under the HRT Act some participant information is forwarded to the RT Register which is located at the Department of Health. Although this is a statutory register it is important that participants are fully informed about its existence.

The attached excerpt from the Directions given by the Commissioner of Health under the Act set out the information that is required to be given to participants prior to consenting for treatment.

SANDRA M WEBB
Executive Officer, Reproductive Technology Council

SECTION 4: INFORMATION

Part 3, Division 2 of the Act, section 22 in particular.

INFORMATION TO BE PROVIDED PRIOR TO CONSENT

4.1 Prior to participants giving effective consent to any artificial fertilisation procedure, the **person responsible must ensure that they are given oral explanations supported by relevant written material in a form approved by Council, including:*

- *information about the effects of the consents given, and the ability to place **conditions** and to vary or withdraw consents;*
- *accurate, objective information about the **options** that may be elected during treatment and the likely and **relevant success rates** for the procedure (national and for the clinic in question, as well as what is likely for the couple concerned);*
- *the potential risks, side effects, longer term outcomes, and limitations to current knowledge, for the participants and any child born;*
- *information about the **Registers** being kept for the purpose of monitoring and evaluating the procedures undertaken, including evaluation of the safety of those procedures in both the short and the long term, and **limitations to the research uses of the Registers,** namely-*

  the only research done will involve linkage to existing public health data bases and will be bona-fide medical and public health research, that follows the stringent guidelines set by the Health Department's Confidentiality of Health Information Committee (CHIC);
  there will be no publication of information that identifies any individual;
  in the event that a legitimate need for further medical or public health research arises, approved by CHIC on the advice of the Reproductive Technology Council, any consent requested for any further involvement in research may be refused; and

- *information about the status of any **innovative procedure** being consented to, with its likelihood of success, the potential risks and side effects and longer term outcomes, known and unknown, for the participants and any child born;*
- *information about counselling, including-*

  counselling requirements and entitlements under the Act;
  the availability of counselling through the licensed practice;
  that counselling service is provided to assist decision-making and provide emotional and therapeutic support, such as grief/loss counselling; and
  encouraging counselling from an 'approved counsellor'.

- *information that the Act does not permit the use of gametes in an artificial fertilisation procedure where the provider of the gametes is known to be dead.*

ADDITIONAL INFORMATION TO BE GIVEN IN RELATION TO THE USE OF DONATED REPRODUCTIVE MATERIAL

4.2 Prior to consent being given to **donation or use of donated human reproductive material, the **person responsible** must ensure that all donors and recipients are given oral explanations, supported by relevant written information in a form approved by Council, including information:*

- *drawing attention to the **Artificial Conception Act 1985,** in particular to the effect of sections 6 and 7 of that Act in relation to semen donation and section 60B of the **Family Law Act;***

- *where a donor consents to use by a woman who does not have the consent of a husband or de facto partner, information about uncertainty in the application of the **Artificial Conception Act 1985 or Family Law Act**;*

- *about **the Donor Register** and inclusion of information about biological parentage, and access to non-identifying information under the Human Reproductive Technology Act 1991 to children born or to donors;*

- *about the possibility of developments in policy and legislation making **identifying information** about their biological parentage available to children of donors;*

- *about the medical, social (rearing) and secrecy implications in relation to donation and the rearing of donor children.*

TO: **PERSONS RESPONSIBLE**
ALL CLINICS LICENSED UNDER THE HRT ACT 1991

FROM: **SENIOR POLICY OFFICER**
REPRODUCTIVE TECHNOLOGY UNIT
DEPARTMENT OF HEALTH

DATE: **15 MARCH 2002**

RE: PROPOSED CHANGES TO REPORTING TO THE REPRODUCTIVE TECHNOLOGY REGISTER

BACKGROUND

Currently clinics are required to report individual treatment data to the Reproductive Technology Register as well as a summary statistical report of the previous financial year to the Reproductive Technology Council (RTC). Additionally, reporting of treatment data and birth details to the National Perinatal Statistic Unit (NPSU) is required.

Previously data provided to the NPSU was an annual summary of treatment data as well as individual information on each pregnancy. However, under changes being implemented the NPSU will now require individual treatment cycle information provided in an electronic format.

With the impetus from the NPSU to change their reporting format to an individual treatment cycle basis the RT Register considers it an appropriate time to alter its reporting format to streamline the reporting process.

PROPOSED PROCESS

To streamline the reporting requirements of clinics it has been proposed that all data reporting be directed to the Reproductive Technology Register. From there the register will provide the required data to the NPSU and summary data to the RTC. An integrated data collection based on the fields provided by the NPSU with additional field for the RT Register.

Steps in the process:

- Combined data reported by clinics to the RT Register
- Validation of all data by the RT Register
- Communication between the RT Register and clinics to clarify any data queries
- Data is extracted for the NPSU and RTC from the RT Register
- RT Register is linked to Midwives' Notification of Birth System to provide details of all births in Western Australia
- Communication between the RT Register and clinics for details of any ongoing pregnancies not reported on Midwives' Notification of Birth System

- Birth details extracted from RT Register for clinics and NPSU

DATA TO BE COLLECTED

All the NPSU fields contained in the data structure which have already been provided to clinics will be included in the data to be collected along with a number of additional fields for the RT Register which will be provided to clinics shortly.

There are a number of fields collected by both the NPSU and the RT Register, where the definitions or criteria differ between the two data sets. For these fields the RT Register will match the definition/ criteria provided by the NPSU. These fields include: causes of infertility, husband or donor sperm use and final outcome.

IMPLEMENTATION / TIMEFRAME

Shortly, clinics will be provided with additional fields to be collected under the combined NPSU and RT Register data collection. We are hoping that 2003 treatment data will be reported through the new system. Any field not already collected will need to be added (note- clinics will find their databases already include most of the additional fields). Extraction programming will need to be altered to include the additional fields.

Data is to be reported to the NPSU in six month reporting intervals (ie January-June and July-December). With the data to be transferred electronically three months after completion of the reporting interval. However as the RT Register is to act as an intermediary between clinics and the NPSU these reporting times will need to be altered for WA clinics. It is anticipated that clinics will be required to report to the RT Register in three monthly reporting intervals (ie January-March, April-June, July-September, October to November). For each reporting period data would be required three months after the completion of the period. The RT Register would then report the data to the NPSU in their required six month reporting intervals once validation of the data is complete, approximately four to five months after the completion of the reporting interval. The receipt of the first three months of data (in the 6 month reporting interval) prior to the rest of the data will allow this data to be validated earlier enabling the data to be reported to the NPSU earlier.

ADVANTAGES

Clinics will benefit from this system as their amount of reporting will be reduced. Instead of reporting to several sources all reporting will be through the RT Register. Communication of queries regarding the data will also only be through one source. Clinics will be required to perform three steps:

- Report data in three monthly batches to the RT Register
- Follow up on any queries received from the RT Register
- On request provide birth details for any ongoing pregnancies not born in Western Australia or whose information is not available through the Midwives' Notification of Births System or the Hospital Morbidity Data System.

Provision of birth information to clinics through the Midwives' Notification of Birth System will also reduce the workload in collecting birth information.

Additionally clinics may be able to adopt an integrated database into their clinic operations incorporating a number of applications, which hopefully will benefit clinics in the longterm.

The advantages for the RT Register and the NPSU are the benefits associated with electronic transfer. That would include reduced time spent on data entry and increased accuracy of data include checking mechanisms within their database. The NPSU will also benefit from getting data that has already been validated and consistent birth record details.

Minimum standards for ICSI use, screening, patient information and follow-up in WA fertility clinics

April 2002

BACKGROUND

The Reproductive Technology Council (Council) wishes to inform clinics licensed under the *Human Reproductive Technology Act 1991* (HRT Act) that it has resolved that treatment by intra-cytoplasmic sperm injection (ICSI) should no longer be considered to be an 'innovative practice'. Specific approval of the Council is therefore no longer required for a clinic to carry out this procedure and previously granted specific approval and the conditions placed on them no longer apply.

In making its decision the Council noted that in WA ICSI is now used in 51.4% of IVF fertilisation procedures. The Council also noted that the procedure has been shown to be effective and to date no major health problems have been found specifically in association with ICSI.

The Council however noted recent evidence from a WA study (Hansen et al, 2002, attached), in particular that this study has shown that infants born following ICSI and IVF were more than twice as likely to be diagnosed with a major birth defect compared with naturally conceived infants. These infants were also more likely to have multiple major birth defects. The excess risk remained significant when only singleton births were considered and after correction for maternal age, parity, infant sex and correlation within sib-ships. It did not appear to be due to differential diagnostic vigilance. The study did not allow separation of excess risk that may be associated with infertility treatment and that which may be related to the underlying causes of the infertility.

The Council remains concerned to see that clinics address these risks, and the yet unknown potential for longer term adverse outcomes for ICSI offspring, in counselling with all couples considering IVF and ICSI treatment, to ensure that they are well informed about the procedures they are undertaking.

It also remains vital that clinics continue to clearly identify all ICSI fertilisations in the required reporting to the RT Register, to enable ongoing monitoring and study of ICSI outcomes.

The Council will advise the Commissioner of Health to issue revised directions to ensure that the current reporting requirements that provide this information continue and that the following standards continue to apply to ICSI treatments.

The Council will continue to request that the Reproductive Technology Unit (RT Unit) routinely monitor birth outcomes through data linkage, at the time of annual reporting. The Council will also request that the RT Unit monitor longer term outcomes from time to time, where this may be carried out through linkage to other databases available in the health system, and do what it can to promote and endorse this research.

RECOMMENDATIONS

Please note the above changes to the status of ICSI under the HRT Act and matters to be raised with couples considering IVF and ICSI.

Please note the attached *Minimum standards for ICSI* which will continue to apply through directions to be issued by the Commissioner of Health.

Please consider carefully whether any changes should now be made to your patient information sheets for IVF and ICSI, and make available the most up to date version of this information to the Council as soon as possible.

CA Michael
Chair, Reproductive Technology Council
April 2002

Minimum standards for ICSI use, screening, patient information and follow-up in WA fertility clinics

April 2002

1. Currently acceptable minimum standards for ICSI use (including the use of retrieved sperm)

1.1 Given the range of concerns, current knowledge of ICSI does not support its use in all cases of IVF for the time being.

1.2 The HRT Act does not permit the use of ICSI to avoid transmission of a disease other than a genetic disease.

1.3 ICSI may be used in the treatment of severe male factor infertility and including cases with -

- Very low numbers of motile sperm with normal appearance
- Unexplained azoospermia; azoospermia due to ejaculatory disorders (eg retrograde ejaculation, aspermia); or acquired testicular failure (eg mumps, orchitis, radiotherapy or chemotherapy)
- Problems with sperm binding to and penetrating the egg
- Antisperm antibodies of sufficient quantity and /or quality to prevent fertilisation
- Prior repeated low fertilisation rate or fertilisation failure with standard IVF culture and fertilisation methods
- Frozen sperm collected prior to cancer treatment that may be limited in number and quality
- Absence of sperm secondary to blockage or abnormality of the ejaculatory ducts.

1.4 ICSI should be a clinical decision made in advance and it is not appropriate for the matter to be raised with the patients for the first time in the emergency situation, especially by laboratory staff on the day of oocyte retrieval. Emergency ICSI should be allowed only if this possibility has been foreshadowed and discussed at the time of clinical examination and counselling, so that the patients are able to give effective consent to the procedure.

1.5 Use of immature sperm

The current requirement that any surgically retrieved sperm from the epididymis or testis that is to be used in ICSI by a WA clinic should be independently motile sperm, that have been released from the seminiferous epithelium by spontaneous spermiation, which have normal head morphology (regular oval shape lying within the parameters 3-5 microns long and 2-3 microns wide)

1.6 'Rescue ICSI'

At present, because of the risk of undetected polyspermia and an increased risk of cytogenetic abnormalities it is not appropriate to use ICSI to re-fertilise eggs that have failed to fertilise by conventional IVF.

1.7 'Split fertilisation'

Where a clinic is to carry out 'split fertilisation', with some oocytes being subjected to standard IVF and some to ICSI, this should be indicated on the fertilisation form in response to the question about micro-manipulation, including comments on why this is being carried out. Where an embryo transfer involves mixed ICSI and non-ICSI embryos these should be left out of any follow-up of ICSI outcomes carried out by the RT Unit.

1.8 Any clinic seeking to vary these limitations should make a specific application for approval by the Council.

2. Minimum standards for required screening prior to ICSI

2.1 For all cases where there is an unexplained low sperm count (below WHO guidelines for normality), because of the potential link between male infertility and other genetic conditions, every effort should be made to obtain a three generation genetic history from the client. The privacy of others involved must be respected during this process.

2.2 For all cases where there is unexplained azoospermia or severe oligozoospermia (<1 million sperm/ml) patients should be strongly advised to have karyotyping and testing for micro y deletion and CFTR testing. The outcome of these tests will assist the couple in giving informed consent prior to undergoing ICSI.

2.3 For all cases where ICSI is considered and the participants are of advanced age, participants should be informed of the desirability of undergoing pre-natal genetic testing should a pregnancy result, and consider the implications of complications associated with these tests in multiple pregnancies. Genetic counselling should be routinely offered.

3. Follow-up by licensees.

3.1 The clinics should continue to report to the Council any matters of concern arising from their own experience or from the literature.

3.2 Clinics are also encouraged to design and carry out their own additional follow-up studies.

APPENDIX 6

PAMPHLET: TALKING TO CHILDREN ABOUT DONOR CONCEPTION

TALKING TO CHILDREN ABOUT DONOR CONCEPTION: INFORMATION FOR PARENTS RAISING CHILDREN BORN AS A RESULT OF THE USE OF DONATED EGGS, SPERM OR EMBRYOS

Donated eggs, sperm or embryos are sometimes used in artificial fertilisation procedures. Parenting a child born as a result of such a treatment includes telling about his/her biological origins.

Deciding to tell or not to tell

All parenting is both a rewarding and a challenging process. People who have had difficulty in conceiving and giving birth to a child and finally achieve parenthood then discover that the challenges of having children are replaced with the challenges of raising them. One such challenge is if, when, and how to tell them about their origins, especially when the child/ren are genetically related to another person/s.

Parents can be confused about whether or not it's best to tell a child about biological origins. It appears that, in the past, parents were encouraged not to tell, as anonymity was often thought to be best for all involved in this conception process.

Now, based on research and information obtained from offspring directly, it is known that keeping children's origins a secret from them is generally not in their best interests. All people should be able to find out about how they were conceived and about their genetic history. Many now believe that open communication as early as possible is the best protection for children.

The best preparation parents can bring to raising their children, including telling them about their origins, is to have tried to resolve their own feelings towards their infertility. The way they do this will be as individual as each family. Dealing with their grief at not being able to have their 'own' children, their sense of guilt and failure, anger at self and each other, are some issues with which many grapple. These issues may take years to be addressed and this may delay the process of telling children.

The timing of the telling will vary from family to family. Some parents want to tell as soon as possible and build on the initial information as the child matures. Other parents may be concerned that telling their child/ren may place an added burden on them and delay the telling. It is very reasonable and understandable if parents have not told their children in their early years. However, they need to prepare well before telling an adolescent or adult, as that usually requires more sensitivity and skill.

It is very important that the parent/s do the telling rather than relying on another relative or a professional. They may seek advice or support before proceeding to check out that they have considered most of the issues.

Telling a child usually means that grandparents and other relatives are also made aware of the child's origins (if this was not known already). And this could involve redefining the kinship network and accepting the children as part of that network, even though they are 'not fully related'.

Why it is best to tell

A person's life story begins with their genetic history. Knowing this history helps in understanding who one is and in developing a personal identity. Knowing his/her genetic history can enhance a person's level of self-esteem.

Protecting secrets of such magnitude for a long time is also very difficult. It is possible that the secret will be divulged at some stage, and in a way that is distressing. Indeed, the sense of trust and stability of family relationships could be damaged if important personal information is inadvertently obtained through medical tests, through other documentation, or through other people.

There are compelling medical reasons why it is best to tell. Prevention or early diagnosis of diseases or medical conditions could be facilitated if one knows of inherited tendencies to these conditions. Through DNA or blood group testing, people could find out about genetic relatedness or lack of such relatedness.

There is also a small risk of intermarrying of donor offspring and accidental incest. This is not of great importance for a population the size of WA. The possible personal and social factors associated with a person coming to terms with the likelihood of having half-siblings in *different* families could be of greater concern for children. The Directions under the Human Reproductive Technology Act stipulate that the donations from any **one** donor must only be used for a maximum of five (5) recipient families.

When to tell

It is best to tell children the truth. At a very early age, even before they understand, a photo album of the child's earliest days can be shared with the child and the word 'donor' can be introduced into that conversation. Then, when they start asking questions, like 'where did I come from', at three or four years, they can be given honest answers in simple language that they can understand. As children grow older they can be given further information as their level of understanding and maturity grows.

How to tell

It is best if the child is told by the parent/s, rather than from careless whispers or through overhearing a conversation. They should be told in a loving and caring way, rather than by accident or in anger. If the telling is in response to a child's question, it is best if the parent has prepared a simple answer. Then a more detailed follow-up can be given at a more convenient time.

The telling is a dual process. Whilst explaining the existence of the child's biological parent/s, parents must also reinforce the child's place - physically and emotionally – with them as loving parents, thereby strengthening rather than undermining the stability of the child within the family.

The telling should be as relaxed as possible and discussed as a normal part of the life of the child and family. Using the word 'donor' from as early as possible in normal conversation helps the child to become familiar with the word long before they understand what it means.

It is best for parents to become comfortable with words they plan to use before they decide to tell, so that when the time comes they are prepared and comfortable. Having an understanding of the child's development stages can also help in deciding which words to use and how much information to tell. Alexina McWhinnie's booklet, referenced below, has a useful chart of child development phases and the kind of questions children may ask during these phases. For example, a three to four year old may ask, 'how was I made?' or 'how was I born?' The five to seven year old will ask, 'what was the exact time of my birth?' and 'what hospital was I born in?' The eight to ten year olds may fantasise that they are a prince/princess, and that these people are not really my parents. The older child will be concerned with 'who am I?' as they form their personal identity.

Simple explanations of the way families are formed are important for all children, like 'to be born there is a joining of woman's egg and man's sperm/seed, and then the baby grows in the woman's body'. Then parents can talk about the different ways families are made, like families with lots of children, families with one child, families with adopted children, foster children, and so on. Then the parents can add, 'in our case we needed a doctor to help us for our family to come together'. Then they can add that another man or woman helped by giving us an egg or sperm/seed, as applicable. The article by Suzanne Midford, referenced below, suggests keeping a photograph album with the baby's beginnings. For example, it would be good to have a photo of the clinic that assisted in conception, and then the hospital, as well as the usual baby photographs and birth details.

Preparing the child for dealing with insensitive comments from others is useful too. Just as many parents help their children who are hurt by thoughtless comments relating to their race, religion, colour, etc., preparing the child for dealing with donor issues is useful too. It might be wise to remind young children that other young children may not understand about donors, so may make an insensitive or hurtful response if the information is shared with them.

It is important to be prepared for the children's responses, which could range from no interest, to specific questions. They may say that they had a sense that something was different. It is also important to know where and how much information is available about the donor/s, if and when the child requests to know more. If there is likely to be no or very little information, make this clear to the child and explain why.

Human Reproductive Technology Act 1991 (WA)

Under this Act, the Commissioner of Health must establish and maintain registers of information about all assisted reproductive technology treatments, including when donated eggs, sperm or embryos are used. These must include named information about donors and recipients. The Act gives an unfettered right of access to non-identifying information held on the Donor Register. Where all parties to the donation give their consent, nothing in the Act would rule out access to identifying information about each other, or contact between the participants to the donation.

The information held on the Donor Register dates back to 8 April 1993, when the Act came into operation. Before that date, any information about donor treatments is *only* held by the doctor or clinic that provided the treatment.

Comments that have been made by donor offspring

"*Parents who have told their children ought to be commended. They now have no secrets in their family and can proceed to have an open, honest and healthy relationship*" Lauren, Victoria, Keeping Secrets and Telling Stories – SA Council on Reproductive Technology – May 1998

"*It wasn't my choice to be born through artificial insemination by donor, I'm only the product of it, although I'm a real human. It marvels me how science made this possible, but what really marvels me is how a man donated his gametes to help infertile couples despite all of the complications of artificial reproductive methods, and make me*" Bridgitte, WA, Life after ART, Developing Families, Perth, November 2001.

"I sometimes sit in coffee shops and gaze at men who would be old enough to be my father….. I fantasise about being told that the man sipping the short black, with the beard and the glasses, reading a paper, is my father". Nicky, Let the Offspring Speak, Discussions on Donor Conception, 1997

References Used for this Pamphlet and Useful Reading for Parents

Donor Conception – Telling your Child, South Australian Council on Reproductive Technology, Supported by Department of Human Services, 2001
Families Following Assisted Conception What do we Tell our Child? Alexina M. McWhinnie, University of Dundee, Department of Social Work, 1996
Let the Offspring Speak: Discussions on Donor Conception, Donor Conception Support Group of Australia, Inc. 1997
Talking to Children about Adoption, Suzanne Midford, 1988

APPENDIX 7

PUBLICATIONS: REPRODUCTIVE TECHNOLOGY COUNCIL

PUBLICATIONS:
REPRODUCTIVE TECHNOLOGY COUNCIL

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

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

3. Donor Insemination: The facts (leaflet);

4. Semen Donation: The facts (leaflet);

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

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

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

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

9. Life after ART Developing Families: Proceedings from Seminar convened by the Western Australian Reproductive Technology Council, 2001

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

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

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

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

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

15. Discussion paper on Human Embryo Experimentation (Booklet) (1990).

APPENDIX 8

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."*