



# **WESTERN AUSTRALIAN REPRODUCTIVE TECHNOLOGY COUNCIL**

## **ANNUAL REPORT**

**1 JULY 2000- 30 JUNE 2001**

**WESTERN AUSTRALIAN**

**Reproductive Technology Council**

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**1 JULY 2000 – 30 JUNE 2001**

**This Report may be found on the following web site:**  
**<http://numbat.murdoch.edu.au/RTC/rtchome.html>**

**Copies of this report may be obtained free of charge from:**

**The Reproductive Technology Council**  
189 Royal Street, East Perth WA 6004

**For further information please contact-**

The Council's web site at  
**<http://numbat.murdoch.edu.au/RTC/rtchome.html>**

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Professor Bryant Stokes AM  
A/ Commissioner of Health  
Health Department of Western Australia  
189 Royal Street  
EAST PERTH WA 6004

Dear Professor Stokes

It is with pleasure that I once again submit to you an Annual Report of the Reproductive Technology Council. This Report is for the financial year 2000-2001. 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* (Act). It is in a form suitable for submission by you to the Minister for Health by September 30 2001 and also, as is required, to be laid by the Minister before each House of Parliament.

The last year has 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 there have been major developments with regard to discrimination in the provision of ART services and a decision by the Coalition of Australian Governments to achieve consistent national legislation to ban human cloning and regulate ART around the country. Indirectly, these developments have placed significant demands on the time of the Executive Officer and Deputy Executive Officer. Although the new Government is still to finalise its response to many recommendations of the Select Committee that reviewed the Act, implementation of other recommendations progressed during the year.

As you know, the Reproductive Technology Council (Council) is established under the Act. It has been in operation since 31 March 1992, with broadly based membership largely appointed from nominations made by various relevant bodies. The Act sets out clearly functions and duties for the Council and its relationships with the Minister for Health and Commissioner of Health. The Act also establishes considerable independence for the Council.

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 are to be reviewed before 1 July 2002.

However, during the year the Council embarked on a review of its own operations, which is still being finalised. This was carried out with a view to improving the effectiveness of its decision making and clarifying 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  
CHAIR  
Reproductive Technology Council  
Date:

## EXECUTIVE SUMMARY

- **Statutory requirements for the Annual Report**

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* (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 2000 - 2001, and is in a form suitable for the Minister to lay before both Houses of Parliament as required by the Act.

The Report details the activities of the Council in the financial year 2000 - 2001. Information reported by clinics licensed under the Act, giving summary information about their activities during the financial year 2000 - 2001 and there is also detailed, collated information from the IVF and Donor Registers which were established under the Act when it came into operation on 8 April 1993. This information relates to treatments carried out in the calendar year 1999. In addition the report includes information from a variety of sources about various matters of significance to the public interest in reproductive technology.

- **Significant national and local political developments relating to reproductive technology**

At the national level there have been major developments during the year in relation to discrimination in the provision of ART services and a decision by the Coalition of Australian Governments to achieve consistent national legislation to ban human cloning and regulate ART around the country. Information about these developments is set out in this Report at pages 30 and 31 respectively, and Appendix 7 provides some up to date information about cloning and stem cell research.

Although the new Government is still to finalise its response to many recommendations of the Select Committee that reviewed the Act, implementation of other recommendations progressed during the year. The development of policy on surrogacy is ongoing. More information about the status of the review of the Act may be found in the Report at page 27.

A summary of reproductive technology issues in the local media is included in the body of the Report.

- **Review of Council operations**

During the year the Council embarked on a review of its own operations, although recommendations of the Select Committee that reviewed the Act and tabled its report in April 1999 generally endorsed the Council's current functions and operations. Some changes to the functions and relationships of the Council may also 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).

- **Council meetings, membership and staffing**

The Council met on 9 occasions during the year; The Counselling Committee met on six occasions; the Scientific Advisory Committee on five occasions; and the Embryo Storage Committee on 7 occasions.

The budget allocation for the Reproductive Technology Unit, which includes funding of all operations of the Council, was \$31,000 and the Annual Report sets out the financial statement for the year. In July 2001 the Minister for Health approved an increase in sitting fees for members.

Professor Harvey was re-appointed by the Minister for a further term; Mr Mildern retired and his deputy, Ms Sue Hudd, was appointed as nominee of Department of Family and Children's Services, with Mr Grey Searle as her new deputy. Two other new deputy members were appointed by the Minister: Reverend Tess Milne and Father Joe Parkinson. Dr Lansdell took extended leave when she moved interstate and her deputy (A/Professor Hackett) took over as the Law Society nominee. Deputy Executive Officer Ms Hansen took one year's leave, but it was not until July 2001 that Ms Burmas was formally appointed as Deputy Executive Officer. Members whose terms of office expired on 31 March 2001 continued in office, as until the review of all statutory bodies is complete new appointments will not progress.

Ms Amalia Burmas was appointed as Research Officer (RT). Ms Wringe continued her primary work as Senior Policy Officer (Surrogacy), however, through her appointment to the Counselling Committee, she also took over support of that Committee. A new position of Project Officer (0.5FTE) included functions for Ms Kim Gifkins providing some administrative support to the Council, up to one day a week.

The Council gratefully acknowledges secretarial support from Ms Phil Valladares; Administrative support early in the year from Ms Pat Webster; Data linkage by Ms Di Rosman and her staff in the Data Linkage Group; the provision of data about birth outcomes by Ms Vivien Gee and her staff who manage the Midwives' Notification System; and the continuing legal support of Ms Deborah Andrews of Legal and Legislative Services.

- **Licensing matters**

Some clarification is being sought with State Treasury, but for the present Council has been advised that licence application fees are not subject of GST.

The Fertility West Practice and Storage licences were annotated to include a new 'transport IVF' clinic operating from the Joondalup Hospital. The Council was satisfied with the outcome of its six-month review of the newly licensed Hollywood Fertility Centre. Licenses at the Public Fertility Clinic at King Edward Memorial Hospital for Women terminated in May 2001, but referrals from that clinic for IVF and artificial insemination continued.

Because of concerns about the adequacy of systems in two clinics with regard to information about permitted storage periods, the Council reviewed these systems in

all clinics. Advice was provided on improvement of the systems to ensure that applications for extension are made in a timely manner.

During the year one medical practitioner was granted an Exemption from the requirement to be licensed to carry out artificial insemination and seven medical practitioners requested revocation of their Exemptions.

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

- The position regarding IVF procedures under the HRT Act in connection with surrogacy arrangements;

- The position regarding parental rights and responsibilities of donors of human reproductive material for children born as a result of artificial fertilisation procedures under certain circumstances pursuant to the *Artificial Conception Act 1985*;

- General approval under the *Human Reproductive Technology Act 1991* of some reproductive technology research involving participants;

- Assisted Hatching: Standards and conditions for approval as an innovative practice under the *Human Reproductive Technology Act 1991* (Act);

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

- Import of donated human reproductive material.

Information concerning the following was also sent out to those Licensees who made relevant inquiry-

- That the Reproductive Technology Council has now been advised that the *Human Reproductive Technology Act 1991* does not provide any power to regulate the removal and storage of ovarian tissue.

No disciplinary proceedings were commenced by the Council during the year and the Council received no formal complaints from participants during the year.

### • Embryo storage

During the year there were 293 applications to the Council for extension to permitted storage. Of these applications 162 were made by couples for whom the embryos were stored and 131 were made by clinics on behalf of couples with whom they could not make contact. Three applications could not be considered as they came after the expiry of permitted storage, but all other applications were approved.

Table 5 in Appendix 3 shows that at the end of the year there were 9661 embryos in storage in WA, a further increase over the previous year. Table 7 shows a further increase in demand for frozen embryo transfer, which may account in large part for the increasing storage of embryos. The number of frozen embryo transfer cycles carried out and the number of IVF cycles where embryos were stored during the year also both increased.

- **Donor issues**

Council considered in depth two instances where it was possible that a sperm donor may, subsequent to donation, have developed a mental illness. The Council concurrently began to review standards for donor screening and other broad issues relating to the recruitment of donors. This was put on hold pending conclusion of a similar review being carried out by the Reproductive Technology Accreditation Committee (RTAC), whose guidelines for screening are those currently adopted under the Act.

The Council also commenced a review of importation of donor semen, in light of an apparently increasing trend for importation of donor semen by the WA clinics. Clinics were notified of concerns relating to such importation (as set out in Appendix 5) and the Council's review of these matters is ongoing.

- **Research and innovation**

Early in the year, following lengthy deliberations based primarily on the results of published research into the effectiveness and safety of assisted hatching, the Council issued its agreed standards that would apply to approvals to carry out assisted hatching. These are set out in Appendix 5. Following a review of the published literature, the Council also agreed on the circumstances where it may approve applications for approval of extended culture of embryos.

Following considerable discussion the Council issued a notice setting out several types of research involving participants that would be granted general approval under the Act, and conditions to be placed on such approval. The relevant notice may be found in Appendix 5.

The Council granted approval for three clinics to introduce assisted hatching as an innovative procedure and for two clinics to introduce extended (blastocyst) culture as an innovative procedure. Approval was granted for one research project during the year and this was for a multicentre, randomised trial to assess the efficacy and convenience of the drug 'Orgalutron'.

The Council is keeping Intra cytoplasmic sperm injection (ICSI) under review in four clinics as an innovative practice, and the birth outcomes continue to be followed up in a comprehensive manner. Research Officer Ms Hansen completed her thesis for the Master of Public Health: 'Intra-cytoplasmic sperm injection and major birth defects'.

Prior to the State Election the Council, at the request of the then Minister for Health, embarked on the development of guidelines that it may apply in considering approval for the application of pre-implantation genetic diagnosis. Considerable progress was made.

- **Council's role in the promotion of public debate on reproductive technology issues**

Council member A/Professor Cummins developed a web site for the Council and Murdoch University has generously allowed the Council free access to the University

site. Development of the site is ongoing, but it may be found at <http://numbat.murdoch.edu.au/RTC/rtchome.html>.

In July 2000, the Health Department held two focussed community fora as part of the development of a policy on the regulation of surrogacy. The Council contributed significantly to these sessions, providing speakers and engaging in the discussion at each forum. Council members also participated in a number of special meetings organised by the Project Management Committee that managed the process of policy development.

In August 2000, members of the Counselling Committee participated in a seminar run by Genesis, discussing the best interest of children born as a result of assisted reproductive technology treatments. Twenty counsellors attended a seminar in May 2001, organised and facilitated by the Counselling Committee. This was a lively, interactive and productive seminar. The information collected at the seminar will form the basis of a procedure manual for counsellors.

#### • **Operations of the Counselling Committee**

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 Family and Children's Services (Mr Searle). Ms Midford again ably chaired the Committee. When necessary she also attended meetings of the Council (on which she is Deputy to Ms Clissa) to discuss matters arising from the Counselling Committee. Halfway through the year Ms Patrice Wringe took over as Executive Officer of the Committee.

Phase One of the Audit of Counselling Services recommended by the Select Committee was conducted at the beginning of 2001 with the support of all clinics, surveying patients of fertility clinics, clinic staff and approved counsellors who provide regular counselling services to clinic patients. A separate questionnaire was prepared for counsellors working in government and non-government agencies as well as in private practice, for implementation in the latter part of 2001. A summary of findings from Phase One of the Audit may be found in the body of the report and at Appendix 6.

In November 2000, the Counselling Committee made recommendations to Council on policy to guide the establishment of the Voluntary Donor Register recommended by the Select Committee. Work towards the commencement of operations has continued since that time.

The Committee continued its review of the current Directions for counselling in situations where the donor and recipient(s) are known to each other, and recommended to Council that the Directions be amended to clarify the extent and nature of counselling required for participants. The Council accepted the recommendations and the Directions will be amended to reflect the changes.

The Committee provided Council with recommendations to improve reporting of

counselling services by clinics. Council endorsed the revised format and all clinics have been asked to commence its use on 1 July 2001. The reporting form will be trialed for one year and then reviewed and modified if required.

The Committee reviewed applications and recommended that the Council recognise two women who met all criteria as 'approved counsellors' under the Act, Ms Lisa Hamilton and Ms Helen Mountain.

### • **Reproductive Technology Registers**

The Specific Approvals Registers has been transferred to an ACCESS database and the Exemptee and Licensee Registers have been upgraded.

Register staff provided comments to a Working Party on National Data Collection, with the aim of streamlining data collection so that a single database in each clinic can be used to collect the data for all required reporting by clinics (WA Register, Annual reporting to the Commissioner of Health, NPSU and RTAC). During the year, Register staff liaised with two clinics about developing compatibility between the existing clinic computer databases and the Register which would enable electronic transfer in the future to both the Register and the NPSU.

Two applications for funding for research involving Register data have been submitted-

Hospital admission, cerebral palsy, intellectual disability and birth defects in assisted conception infants - a record linkage study (Ms Hansen to be principal investigator); and

Eight-year follow-up of mental health and hospital morbidity outcomes in women treated using Assisted Reproductive Technology (ART) in Western Australia (Professor D'Arcy Holman to be principal investigator, with Dr Webb).

There were 17 requests for information from the Register. None were for access to personal, non-identifying information about donations from donors or offspring.

The Report of 1999 data from the RT Register may be found in Appendix 4.

### • **Information about treatments carried out in Western Australia and their outcomes.**

Operations of Licensees for the financial year 2000-2001 may be found in Appendix 3.

Of interest from this information –

A slight decline in the number of new sperm donors

9661 embryos in storage at 30 June 2001

Compared with last year, relatively steady numbers of fresh IVF treatments, frozen embryo transfers, GIFT transfers and the proportion of cycles involving ICSI

An apparent slight increase in the number of ovum donations

A doubling of public patients being treated at King Edward Memorial Hospital

As noted above, the Report of 1999 data from the RT Register may be found in Appendix 4.

Of interest from this information-

- Very similar numbers of treatment cycles begun for IVF and related procedures compared with 1998

- Discrepancy between clinics in the proportions of cycles cancelled which requires review, and may be related to differing definitions rather than clinical differences

- Mean and median numbers of eggs collected at each retrieval were 11.7 and 10 respectively

- Mean and median numbers of transfers (fresh or frozen IVF or GIFT) per woman treated during the year were 1.6 and 2 respectively

- 38.9% of IVF procedures involved ICSI, compared with 34.5% in 1998

- Ongoing pregnancy rates per transfer were 18.6 (17.8-19.3) per 100 transfers for fresh IVF transfer, 24.0 (0-25.0) per 100 transfers for GIFT and 17.3 (20.0-26.3) per 100 transfers for FET

## MEMBERSHIP OF THE COUNCIL

30 June 2001

**Professor Con Michael**, Chair (Nominee of the Royal Australian College of Obstetrics and Gynaecology)\*;  
**Dr Sue Cherry**, (Nominee of the Australian Medical Association)\*;  
**Ms Antonia Clissa**, (Nominee of the Women's Policy Development Branch)<sup>+</sup>;  
**Professor Alan Harvey**, (Nominee of the Minister for Health)\*\*;  
**Dr Gaye Lansdell**, (Nominee of the Law Society of WA)\*;  
**Mr Philip Matthews**, (Nominee of the Minister for Health)<sup>+</sup>;  
**Dr Mark McKenna**, (Nominee of the Department of Obstetrics and Gynaecology, University of WA)<sup>+</sup>;  
**Ms Sue Hudd**, (Nominee of the Minister for Family and Children's Services)\*\*;  
**Dr Kaye Miller**, (Nominee of the Health Consumers' Council)<sup>+</sup>;  
**Dr Beverly Petterson**, (Nominee of the Minister for Health)<sup>+</sup>; and  
**Dr Sandra Webb**, (Executive Officer, Senior Policy Officer Reproductive Technology, Ex Officio).

## DEPUTY MEMBERS

**A/Professor Jim Cummins**, (Nominee of the Department of Obstetrics and Gynaecology, University of WA)<sup>+</sup>;  
**A/Professor Jeanette Hackett**, (Nominee of the Law Society)\*;  
**Mr Peter Grey Searle**, (Nominee of the Minister for Family and Children's Services)\*\*;  
**Mrs Christine Lemon**, (Nominee of the Health Consumers' Council)<sup>+</sup>;  
**Ms Sue Midford**, (Nominee of the Women's Policy Development Branch)<sup>+</sup>;  
**Rev Tess Milne**, (Nominee of the Minister for Health)\*\*;  
**Fr Joe Parkinson**, (Nominee of the Minister for Health)<sup>+</sup>; and  
**Ms Michele Hansen**, (Deputy Executive Officer, ex-officio) (on leave).

\*Terms of office expired at 31 March 2001: members continue in office

<sup>+</sup>Terms of office expire at 18 October 2002

\*\*Terms of office expire on 31 March 2003.

<p style="text-align: center;"><b>COMMITTEES OF THE COUNCIL</b></p> <p style="text-align: center;"><b>TERMS OF REFERENCE AND MEMBERSHIP</b></p> <p style="text-align: center;"><b>30 June 2001</b></p>
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## **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, (SPO Surrogacy, Health Department).

## **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* (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 Hackett; 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* (Act), the Reproductive Technology Council (Council), by resolution under s 11(1) of the 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:**

Dr Sue Cherry (Chair); Mr Philip Matthews; Professor Con Michael; Ms Sue Hudd; and Dr Sandra Webb (ex officio).

## LICENSING AND ADMINISTRATION ADVISORY COMMITTEE

### **Terms of Reference:**

1. Advise the Reproductive Technology Council (Council) on matters relating to licensing under the *Human Reproductive Technology Act 1991* (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 Act, particularly disciplinary matters.
3. Advise the Council as to suitable standards to be set under the Act, including clinical standards.
4. Advise the Council on any other matters relating to licensing, administration and enforcement of the Act.

**Membership:** Dr Mark McKenna (Chair); Professor Con Michael; Dr Sue Cherry; Ms Antonia Clissa; A/Professor Jeanette Hackett; Dr Kaye Miller; and Dr Sandra Webb (ex officio).

<b>STAFF OF THE REPRODUCTIVE TECHNOLOGY UNIT</b>
--

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

**Ms Patrice Wringe**, Senior Policy Officer (Surrogacy).

**Ms Michele Hansen**, Research Officer (Reproductive Technology) and Deputy Executive Officer of the Council to December 2001;

**Ms Amalia Burmas**; Research Officer (Assisting with implementation of the Government Response to the Report of the Select Committee on the *Human Reproductive Technology Act 1999*) (.5 FTE) to December 2000, then A/Research Officer (Reproductive Technology); and

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

<b>REPRODUCTIVE TECHNOLOGY UNIT 2000/2001:</b> <b>FINANCIAL STATEMENT</b>
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- The Health Department of Western Australia to fund the administration of the Act, particularly operations of the Council, provided Infrastructure and Workforce Development funding of \$31,000 (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 (\$)
<b>Staff or Council:</b>		
Training/Registration/Course Fees	1,075.00	
Travel/Accommodation intrastate		
Travel interstate		
Airfares	1923.84	
Accommodation	304.09	
Motor vehicle/Taxis	260.81	
<b>TOTAL</b>	<b>3563.74</b>	
<b>Food supplies/catering</b>	<b>553.81</b>	
<b>Purchase of external services:</b>		
Sessional fees:		
Reproductive Technology Council	4,929.00	
Council Committees:		
Counselling	1963.00	
Scientific Advisory	1260.00	
Embryo Storage	169.00	
Licensing and Administration	0.00	
Approved counsellors	922.00	
Subsidy of FPA Workshop	3,360.00	
External consulting fees and advertising	5712.43	
Administration and clerical	1,418.09	
<b>TOTAL</b>	<b>19,733.52</b>	
<b>Other expenses:</b>		
Books/magazines/subscriptions	493.85	
Freight and cartage/ postal	219.55	
Printing and stationery incl. Annual Report	4,327.72	
Motor vehicle expenses	60.02	
Computer equipment	2,696.00	
<b>TOTAL</b>	<b>7,797.14</b>	
<b>Exemptions</b>		<b>50.00</b>
<b>TOTAL</b>	<b>31,648.21</b>	<b>50.00</b>
<b>Budget Allocation</b>	<b>31,000.00</b>	

<b>OPERATIONS OF THE COUNCIL</b> <b>1 JULY 2000 TO 30 JUNE 2001</b>
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## **MEETINGS, MEMBERSHIP AND STAFFING**

### **Meetings**

The Council met on 9 occasions during the year, with an average attendance of 78%. The Counselling Committee met on six occasions; the Scientific Advisory Committee on five occasions; and the Embryo Storage Committee on 7 occasions.

### **Increase in sitting fees for Council members**

Sitting fees paid to Council members were set at \$96 per half day for a chairperson and \$73 per half day for members in 1991 when the Council commenced operations and have not been increased since that time. In July 2001, the Minister for Health approved an increase to \$213 per half day for a chairperson and \$142 per half day for members. The sitting fees will be increased accordingly for the next financial year.

### **Membership**

During the year Professor Harvey was re-appointed by the Minister for a further term. On the retirement of Mr Mildern, his deputy Ms Sue Hudd was appointed to the position as nominee of Department of Family and Children's Services with Mr Grey Searle as her new deputy.

Two other new deputy members were appointed by the Minister: Reverend Tess Milne as deputy to Professor Harvey and Father Joe Parkinson as deputy to Mr Matthews. Dr Lansdell took extended leave when she moved interstate and her deputy A/Professor Hackett took over as the Law Society nominee.

Deputy Executive Officer Ms Hansen took one year's leave, but it was not until July 2001 that Ms Burmas was formally appointed as Deputy Executive Officer. Members whose terms of office expired on 31 March 2001 continued in office. The change of Government was followed by a review of all statutory bodies and new appointments have not progressed.

### **Staff assisting the work of the Council**

Ms Michele Hansen completed her Master of Public Health with high distinction and embarked on a one year leave of absence, during which Ms Amalia Burmas was appointed in her place.

Ms Wringe continued her primary work as Senior Policy Officer (Surrogacy). However, through her appointment to the Counselling Committee, she also took over support of that Committee. Ms Wringe also coordinated the development of policy on the Voluntary Donor Register and carried out the Audit of Infertility Counselling Services.

A new position of Project Officer (0.5FTE) included functions for Ms Kim Gifkins providing some administrative support to the Council, up to one day a week.

The Council gratefully acknowledges-  
Secretarial support from Ms Phil Valladares;  
Administrative support early in the year from Ms Pat Webster;  
Data linkage by Ms Di Rosman and her staff in the Data Linkage Group;  
the provision of data about birth outcomes by Ms Vivien Gee and her staff who manage the Midwives' Notification System; and  
The continuing legal support of Ms Deborah Andrews of Legal and Legislative Services.

## LICENSING MATTERS

### Application fees for licences and GST

The Council examined the applicability of GST to licence application fees.

Under *A New Tax System (Goods and Services Tax) Act 1999* (GST Act), GST applies to the payment of fees, taxes and charges, except those that are excluded from GST. 'Regulatory fees for the licensing of IV(F) Clinics' under the *Human Reproductive Technology Act 1991* and the Human Reproductive Technology (Licences and Registers) Regulations 1993 are listed in the 'Western Australian Government Taxes, Fees and Charges that are **not subject to the GST**' by a determination of the Treasurer as provided for in Division 81 of the GST Act.

There is a little confusion on whether the exception provided by Treasury refers to 'licence fees' as opposed to 'regulatory fees'. Some clarification is required on this matter and that is being taken up with State Treasury. In the meantime, it is presumed that licence application fees are not subject of GST.

### New and current licences and Exemptions

- The Fertility West Practice and Storage licences were annotated to include a new 'transport IVF' clinic operating from the Joondalup Hospital.
- The Council was satisfied with the outcome of its six-month review of the newly licensed Hollywood Fertility Centre.
- Licenses at the Public Fertility Clinic at King Edward Memorial Hospital for Women terminated in May 2001, but referrals from that clinic for IVF and artificial insemination continued.
- During April the Council reviewed systems for keeping track of stored embryos at all four clinics holding licences authorising embryo storage. There had been concerns about the adequacy of these systems in two clinics, with regard to information about permitted storage periods. As a result of the review all clinics were provided with advice, which was both general and clinic-specific, about how their systems may be improved to ensure that applications for extension are made in a timely manner.
- During the year one medical practitioner was granted an Exemption from the requirement to be licensed to carry out artificial insemination (Dr LG Green, 28/08/2000). Seven medical practitioners requested revocation of their

Exemptions (Dr AR Yates, Dr JL Brockis, Dr JD O'Donovan, Dr QF Ho, Dr NP Bretland, Dr DF Hamilton, Dr MC Exley).

### **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 position regarding IVF procedures under the HRT Act in connection with surrogacy arrangements.
- The position regarding parental rights and responsibilities of donors of human reproductive material for children born as a result of artificial fertilisation procedures under certain circumstances pursuant to the *Artificial Conception Act 1985*.
- General approval under the *Human Reproductive Technology Act 1991* of some reproductive technology research involving participants.
- Assisted Hatching: Standards and conditions for approval as an innovative practice under the *Human Reproductive Technology Act 1991* (Act).
- Minimum standards for ICSI use, screening, patient information and follow-up in WA fertility clinics.
- Import of donated human reproductive material.

Information concerning the following was also sent out to those Licensees who made relevant inquiry-

- That the Reproductive Technology Council has now been advised that the *Human Reproductive Technology Act 1991* does not provide any power to regulate the removal and storage of ovarian tissue.

### **Contraventions of the Act**

No disciplinary proceedings were commenced by the Council during the year.

### **Complaints**

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

Although it received two written complaints from one 'person responsible' about activities at other licensed practices and the matters were raised in Council meetings, direct intervention by the Council was not thought to be appropriate. One matter was referred to the Reproductive Technology Accreditation Committee and the other had been dealt with previously in consultation with the Office of Health Review.

## **OTHER MATTERS WITHIN THE RESPONSIBILITIES OF THE COUNCIL**

### **Embryo storage decisions**

During the year the Council granted extensions in response to 293 applications. Of these applications 162 were made by couples for whom the embryos were stored and 128 were made by clinics on behalf of couples with whom they could not make contact.

Three applications, made on behalf of couples who had consented to the donation of embryos, could not be considered for extension as the applications were received

after the expiry of the permitted storage period. The Act does not allow the Council to grant extensions under these circumstances. Otherwise all applications for extension were granted.

Of all applications received, 121 extensions (41.3%) were for people who had previously had extensions to permitted storage of their embryos. The majority of these were (120) were repeat extensions for a set of embryos that had previously been granted an extension. There was only one instance where the extension was for a second set of embryos a couple had in storage.

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 (95.1%). In 2.4 percent of cases the couples were planning to or in the process of donating embryos to another eligible couple. In the remaining 2.4 percent of cases the couple were undecided and applied for an extension to allow them more time to consider available options.

Extension applications made by clinics, rather than the people for whom the embryos are being extended, are usually made in cases where the clinic has lost contact with the patients (58.1%). In 34.1 percent of applications the clinic had been able to contact the patients but the patients had not sent in their application forms and the clinic applied on their behalf.

In 7.8 percent of cases clinics applied for extensions on behalf of patients who had consented to the donation of their embryos, but for whom a suitable recipient couple had yet to be found. The Council is working with clinics to improve understanding of the ongoing responsibility of the donating couple for embryos they wish to donate, prior to acceptance by a recipient couple.

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

## **DONOR ISSUES**

### **Standards for donor screening: confidentiality and liability issues**

Council considered two instances where it was possible that a sperm donor may, subsequent to donation, have developed a mental illness. Issues raised included responsibilities to maintain confidentiality, consent to obtain medical information about the donor, heritability of certain mental illnesses, whether such sperm should be withdrawn from use and whether any recipient who achieved pregnancy from the use of such sperm and /or offspring should be informed.

The Council concurrently began to review standards for donor screening and other broad issues relating to the recruitment of donors. However, this was put on hold pending conclusion of a similar review being carried out by the Reproductive Technology Accreditation Committee (RTAC), whose guidelines for screening are those currently adopted under the Act.

## **Export and import of donor semen**

The Council commenced a review of importation of donor semen, in light of an apparently increasing trend for importation of donor semen by the WA clinics from “Cryos” in Denmark. It seems that this clinic has extremely high standards for screening and donor recruitment. Direction 8.1 however provides that licensees 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. Further, in the event the HRT Act is amended to provide a right of access by offspring to identifying information about the donor (as recommended by the Select Committee), sperm may not be imported from sources that are unable to release details of donor identity to participants. It appears that Danish Law does not limit the number of donor offspring born outside Denmark and would not permit export of the semen in the event the WA Act was amended to allow potential access by offspring to donor identity. Clinics were notified of these concerns (as set out in Appendix 5) and the Council’s review of these matters is ongoing.

Pursuant to Direction 6.2, approval was granted for the export of donor semen from Concept to CityWest IVF in Sydney, for a repeat pregnancy to the same donor.

A request for approval to import donor semen from South Africa was not granted as information required by the Register appeared likely to be unavailable. However, the clinic requesting approval was asked to provide more information to the Council in making any further request for approval of this case.

## **RESEARCH AND INNOVATION**

### **General issues**

- Early in the year, following lengthy deliberations based primarily on the results of published research into the effectiveness and safety of assisted hatching, the Council issued its agreed standards that would apply to approvals to carry out assisted hatching. These are set out in Appendix 5. The Council also agreed on the circumstances where it may approve applications for approval of extended culture of embryos. Again these were agreed following a review of the published literature. Subsequently, as set out below, in response to their applications the Council granted approval for assisted hatching in three clinics and extended (blastocyst) culture in two.
- Following considerable discussion the Council issued a notice setting out several types of research involving participants that would be granted general approval under the Act, and conditions to be placed on such approval. The relevant notice may be found in Appendix 5.

### **Specific approvals granted during the year**

- The Council granted approval to the one application for approval of research it received and to five applications for approval of innovative practices as listed below.

*Concept Fertility Centre:*

Innovative practices-

Blastocyst transfer

## Assisted hatching

### *Pivet Medical Centre:*

#### Research-

Multicentre open label randomised trial to assess the efficacy and convenience of orgalutron.

#### Innovative practices-

In vitro culture of human embryos to Blastocyst stage

Assisted hatching

### *Hollywood Fertility Centre:*

#### Innovative practice-

Assisted hatching

## **Other current specific approvals.**

### *Concept Fertility Centre-*

#### Innovative practice-

Intra cytoplasmic sperm injection (ICSI)

### *Pivet Medical Centre*

#### Research-

The impact of tobacco and caffeine consumption on the outcomes of in vitro fertilisation - embryo transfer

#### Innovative practices-

ICSI

Use of SAIZAN (Growth Hormone) in ovulation induction

### *Fertility West*

#### Innovative practice-

ICSI

### *Hollywood Fertility Centre*

#### Innovative practice-

ICSI

## **Pre-implantation genetic diagnosis**

Prior to the State Election the Council, at the request of the then Minister for Health, embarked on the development of guidelines that it may apply in considering approval for the application of pre-implantation genetic diagnosis. Considerable progress was made.

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

### **Establishment of a Council web site**

Council member A/Professor Cummins developed a web site for the Council and Murdoch University has generously allowed the Council free access to the University

site. Development of the site is ongoing, but it may be found at <http://numbat.murdoch.edu.au/RTC/rtchome.html>.

This facility is proving extremely useful when requests for information and documents are made. It is intended that the Annual Report will be available only via the web in future, in compliance with Government requirements and current tight budget restrictions.

### **Seminars, workshops and other Council initiatives**

- In July 2000, the Health Department held two focussed community fora as part of the development of a policy on the regulation of surrogacy. The Council contributed significantly to these sessions, providing speakers and engaging in the discussion at each forum. Council members also participated in a number of special meetings organised by the Project Management Committee that managed the process of policy development.
- In August 2000, members of the Counselling Committee participated in a seminar run by Genesis, discussing the best interest of children born as a result of assisted reproductive technology treatments.
- Twenty counsellors attended a seminar in May 2001, organised and facilitated by the Counselling Committee. This was a lively, interactive and productive seminar. The information collected at the seminar will form the basis of a procedure manual for counsellors.
- The Counselling Committee began planning for a seminar to be held on 17 November 2001 on *Life after ART – Developing Families*. Professor Eric Blyth, Professor in Social Work at Huddersfield University in the UK will address the seminar on 'Current issues in assisted conception in the UK'.

### **Relevant presentations and publications by Council members and staff**

#### **Council members**

*Ms Antonia Clissa-*

ART - Issues for Social Workers, Curtin Uni. Social Work School

*A/Professor Jim Cummins-*

Conference addresses:

- (1) British Fertility Society 24-27 April 2001 Belfast "Diagnostics of the future - the molecular approach"
- (2) Roger Short Symposium "From Elephants to AIDS" June 27-30 "Mitochondrial DNA and the Y chromosome: parallels and paradoxes"
- (3) ESHRE July 1-4 2001 Lausanne "Mitochondrial DNA in Mammalian Reproduction"
- (4) ALPHA 2001 September 8-11 2001 "The role of maternal mitochondria during oogenesis, fertilization and embryogenesis, Sheffield September 28-30 2001 "Mitochondrial DNA and sperm competition"
- (6) Two 2-hour lectures to Rockingham Campus students core unit A115 first and second semester; "Assisted Reproductive Technologies".

#### Papers:

- (1). Ahmed, F.A., Whelan, J., Jequier, A.M. *et al.* (2000) Torsion-induced injury in rat testes does not affect mitochondrial respiration or the accumulation of mitochondrial mutations. *International Journal of Andrology*, **23**, 347-356.
- (2). Cummins, J.M. (2000a) Fertilization and elimination of the paternal mitochondrial genome. *Human Reproduction*, **15**, 92-101.
- (3). Cummins, J.M. (2000b). Mitochondrial dysfunction and ovarian aging. In te Velde, E.R., Pearson, P.L., and Broekmans, F.J. (ed), *Female Reproductive Aging*. The Parthenon Publishing Group, New York, London, pp 207-224.
- (4). Cummins, J.M. (2001a) Cytoplasmic inheritance and its implications for animal biotechnology. *Theriogenology*, **55**, 1381-1399.
- (5). Cummins, J.M. (2001b) Mitochondria: potential roles in embryogenesis and nucleocytoplasmic transfer. *Human Reproduction Update*, **7**, 217-228.
- (6). Cummins, J.M. (In Press). Unresolved and basic problems in assisted reproductive technology. In de Jonge, C., and Barratt, C.L.R. (ed), *Assisted Reproductive Technology: Today and Beyond*. Cambridge University Press, Cambridge,
- (7). Mehmet, D., Ahmed, F., Cummins, J.M. *et al.* (2001) Quantification of the common deletion in human testicular mitochondrial DNA by competitive PCR assay using a chimaeric competitor. *Molecular Human Reproduction*, **7**, 301-306.

*Dr Kaye Miller-*

Emotional issues and infertility: Workshop fascilitator, Genesis Support Group.

#### Staff

*Dr Sandra Webb-*

Genetic Engineering: Catholic Education Conference.

*Ms Patrice Wringe-*

Surrogacy: Chaplaincy Forum, Curtin University.

*Ms Amalia Burmas*

[Congenital Hydrocephalus in Western Australia: Survival and Functional Outcomes in Western Australia, 1980-1996. Medical Genetics, UWA.](#)

#### **Attendance at relevant meetings by Council members with Council support**

The Council supported the attendance of the Executive Officer at two meetings of a working group convened by the National Health and Medical Research Council to develop consistent national standards to ban human cloning.

<b>OPERATIONS OF THE COUNSELLING COMMITTEE</b> <b>1 JULY 2000 – 30 JUNE 2001</b>
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During the year the Counselling Committee met on six 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 Family and Children's Services (Mr Searle). Ms Midford again ably chaired the Committee. When necessary she also attended meetings of the Council (on which she is Deputy to Ms Clissa) to discuss matters arising from the Counselling Committee. Halfway through the year Ms Patrice Wringe took over as Executive Officer of the Committee.

The Committee implemented a number of the recommendations of the Select Committee, including the Audit of Counselling Services provided by clinics, and establishing the Voluntary Donor Register.

### **Audit of counselling services**

It was decided to conduct the audit in two phases. Phase One was conducted at the beginning of 2001. In this phase, patients of fertility clinics, clinic staff and approved counsellors who provide regular counselling services to clinic patients, were asked to complete written questionnaires. Then, in order to determine the extent of counselling for fertility/infertility issues being provided in the community (independent of the clinics), a separate questionnaire was prepared for counsellors working in government and non-government agencies as well as in private practice. This latter phase (Phase Two) of the audit is being conducted in the latter part of 2001.

The first phase of the audit was conducted between January and March 2001. Separate questionnaires were sent to patients attending clinics during a one-month period; to all clinic staff and to approved counsellors working in clinics. The Counselling Committee appreciates the cooperation of the clinics in the implementation of this audit. Without their commitment and willingness to distribute questionnaires to both patients and clinic staff, the audit could not be completed. The Committee thanks everyone who took the time to complete the questionnaire.

A total of 150 completed questionnaires were returned: 105 from patients (36% of those distributed); 37 from clinic staff (47.4% of those distributed); and eight from approved counsellors who provide regular counselling services to clinics (100% of those distributed), with an overall response of 40 per cent. This response rate was somewhat lower than hoped for, but sufficient to get a picture of the counselling services being provided by clinics.

The results supported the assumption that a considerable number of patients are not attending counselling through the clinics. Out of a total of 105 completed patient questionnaires, 30 (28.6%) of patients did not attend any counselling through the clinic. A further 57 patients (54.8%) had only one counselling session. Hence 87 patients (82.9%) had either no counselling or only one session, despite one session of counselling per *in vitro* fertilisation (IVF) cycle, and one session when patients decide to discontinue treatment, being included in the overall fees paid.

A majority of patients stated that they had received verbal and written advice on their entitlement to counselling (69 received written advice; 80 had received verbal advice; and 63 had received both written or verbal information). Respondents who had received this information had a significantly higher uptake of counselling services than those who stated that they were not given information about their entitlement to counselling ( $p = 0.0015$ ).

Approximately 65 per cent felt they were encouraged by other clinic staff to participate in counselling. Again, respondents who stated that they felt encouraged to attend counselling had a significantly higher uptake of counselling services than those who did not receive this encouragement ( $p = 0.00000$ ).

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.

Suggested changes to the current system of counselling that consumer respondents gave highest responses to were '*the clinic to promote the importance of counselling*' (51, 48.6%), '*the counsellor to be available by telephone*' (62, 59%); and '*counsellor to be available after hours*' (47, 44.8%). Ten respondents did not respond to this question.

Part of the audit included patient awareness of and participation in Support Groups, eg Genesis and the Donor Conception Support Group. Even though nearly 77% of consumers were aware of Support Groups and listed a number of advantages of them, less than 13 per cent had contact with members of such groups. A number of respondents stated that infertility and its treatment is a private matter and they did not wish to discuss it with strangers. That was the main reason given for not participating, given by 31% out of a total of 64 people who responded to this question. (*Please refer to Appendix 6 for an outline of the project plan for the audit.*)

### **Establishment of a Voluntary Donor Register**

The Select Committee recommended the establishment of a voluntary register for persons involved in past donation. In November 2000, the Counselling Committee made recommendations to Council on policy to guide the establishment of this Register. These policy positions were endorsed with minor amendments. In January 2001, the 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.

### **Seminar for approved counsellors**

Recognising the need for ongoing development of approved counsellors, the Counselling Committee conducted an interactive seminar in May 2001. Twenty people attended this, 17 of whom are approved counsellors. Areas discussed were:

- 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.

A report was compiled following the seminar and circulated to participants. This will form a basis of a manual for counsellors in the future.

### **Counselling for participants in known donation**

The Committee continued its review of the current Directions for counselling in situations where the donor and recipient(s) are known to each other. It recommended to Council that the Directions be amended to clarify the extent and nature of counselling required for participants. The Council accepted the recommendations and the Directions will be amended to reflect the changes.

### **Annual reporting of counselling services**

The Committee examined the current reporting of counselling services from clinics and found that there are inconsistencies in the manner of reporting. The Committee prepared a reporting form for future use. Council endorsed the use of this form and all clinics have been asked to commence its use on 1 July 2001. The reporting form will be trialed for one year and then reviewed and modified if required.

### **Workshop on considering the best interests of the child**

Members of the Committee attended the Genesis meeting on 21 August 2000 and participated in a lively interactive workshop with Genesis members on promoting the best interests of children born as a result of artificial fertilisation procedures.

### **Visit of Professor Blyth**

Professor Eric Blyth, Professor in Social Work, University of Huddersfield, UK is visiting Perth in November 2001. Professor Blyth is interested in discussing the following two areas whilst he is in Perth: access to genetic origins information in third party assisted conception; and how well regulatory bodies are working, with a view to comparing these with UK's Human Fertilisation and Embryology Authority.

The Counselling Committee has prepared a program for Professor Blyth's visit, which includes a one-day seminar, on Saturday 17 November 2001, for consumers of artificial fertilisation procedures, clinicians, professional persons working and/or interested in the area, and interested members of the public. Other proposed meetings during Professor Blyth's visit, are his attending a Genesis meeting on 19 November 2001; and meeting with staff from the Department for Community Development.

### **New 'approved counsellor' applications**

The Committee reviewed applications and recommended that the Council recognise two women who met all criteria as 'approved counsellors' under the Act, Ms Lisa Hamilton and Ms Helen Mountain.

## REPRODUCTIVE TECHNOLOGY REGISTER

### **Renovation of the ACCESS database**

The Specific Approvals Registers has been transferred to an ACCESS database and the Exemptee and Licensee Registers have been upgraded.

The Register provided comments to a Working Party on National Data Collection. This Working Party, established by the Fertility Society of Australia, is reviewing the process of data collection from ART units to the National Perinatal Statistics Unit (NPSU) and the Reproductive Technology Accreditation Committee (RTAC).

Most of the data to be collected in the proposed model of the Working Party are already collected by the Register. Therefore the aim of the 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 (WA Register, Annual reporting to the Commissioner of Health, NPSU and RTAC).

During the year, staff from the Register liaised with two clinics about developing compatibility between the existing clinic computer databases and the Register which would enable electronic transfer in the future to both the Register and the NPSU.

### **Research involving Register data and staff of the RT Unit**

Two applications for funding for research involving Register data have been submitted-

- Hospital admission, cerebral palsy, intellectual disability and birth defects in assisted conception infants - a record linkage study (Ms Hansen to be principal investigator).
- Eight-year follow-up of mental health and hospital morbidity outcomes in women treated using Assisted Reproductive Technology (ART) in Western Australia (Professor D'Arcy Holman to be principal investigator, with Dr Webb).

### **Requests for information from the Register**

There were 17 requests for information from the Register. Five requests were for information regarding donations, such as the number of donors and numbers of treatments where donor material had been used. Another five requests were for information about numbers of offspring born from various ART treatments. Other requests included information on the number of women undergoing specific treatments, numbers of specific treatment types and information on fertility rates.

There were no requests for access to personal, non-identifying information about donations from donors or offspring.

## **SIGNIFICANT DEVELOPMENTS IN REPRODUCTIVE TECHNOLOGY DURING THE YEAR**

### **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* (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 change of Government has slowed the progress of implementation of the review, as the new 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**

##### **Background**

During 2000, work was undertaken to prepare a draft surrogacy policy in line with a Cabinet decision of the previous Government in November 1999.

Policy development was a joint initiative between the Health Department and Family and Children's Services, with the Health Department taking a lead role. A Project Management Committee, comprising officers from the Health Department and Family and Children's Services, directed the policy development, holding 14 meetings between May 2000 and February 2001.

A number of experts participated in three Project Management Committee meetings. Regardless of the personal or professional views of the experts, the majority recognised the need for careful regulation of surrogacy in order to protect the interests of all parties.

In May 2000, the Health Department commissioned Donovan Research to conduct a community attitudes survey on surrogacy to inform the policy development. A random sample of 600 West Australian adults was surveyed (400 residing in the metropolitan area and 200 residing in the country). The sample was comprised of varied respondents in terms of Aboriginality, ethnicity and religious denomination. Broad age, sex and location (country vs metropolitan) quotas were applied to reflect the current demographics of Western Australia.

The survey results showed that 72 per cent of those surveyed approved of surrogacy overall, with 76 per cent approval for altruistic surrogacy. Four-fifths of those surveyed approved of an arrangement where the child is created from the gametes of both of the commissioning parents. There was very strong support for limiting the practice of surrogacy to couples who are married (85% approval rate). The surveyed population's approval of surrogacy arrangements for *de facto* couples had a much lower approval rate, at 58 per cent.

Two focused forums were held, to which people and groups from the areas of surrogacy, adoption, reproductive technology, medicine, ethics, law, psychology and social policy were invited. A total of 89 people attended the forums (43 at the first forum and 46 at the second). A number of forum participants supported the development of carefully regulated policy and legislation. However, some questioned whether legislation was justified, given the small numbers of people who wish to practice surrogacy. A number of people voiced their opposition to the practice of surrogacy and to its regulation.

### **Draft policy**

A document outlining proposals for policy on surrogacy was forwarded to the Minister for Health for his consideration. The Government has yet to finalise its policy position in respect of surrogacy.

### **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.

The Executive Officer, Deputy Executive Officer and A/Deputy Executive Officer are members of two research teams that have applied for funding from the National Health and Medical Research Council to carry out two research projects that would follow up outcomes for IVF and ICSI offspring and women exposed to IVF.

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

The Executive Officer commenced discussion with the Family & Children's Policy Office, but this was put on hold due to the change of Government and the future role of the Office in relation to the new Department of Community Development.

#### **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 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.

### **Recommendations about counselling standards and services**

As noted in the section of this report detailing operations of the Counselling Committee, considerable progress has been achieved in reviewing counselling requirements for known donors and with the conduct of the audit of counselling recommended by the Select Committee.

### **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. Consultation with the Attorney General was ongoing, ultimately in conjunction with the implementation of recommendations of the Ministerial Reform Committee on Gay and Lesbian Law Reform.

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

The Minister for Health (WA) informed the Minister for Health and Aged Care of the recommended need to review the Medicare Benefits Schedule for ART services and of the Government's support for recommendations that there should be complementary national legislation of ART. Subsequently 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.

## **ACCESS TO ASSISTED REPRODUCTIVE TECHNOLOGY TREATMENTS**

### **Western Australian legislation**

The *Human Reproductive Technology Act 1991* (HRT Act) (s.23) sets out a number of eligibility requirements that must be satisfied in order for persons to access IVF procedures and prohibits such procedures where those requirements are not met. These include that the persons to be treated are members of a couple who are married to each other or are co-habiting in a heterosexual relationship as husband and wife and have done so for periods aggregating at least five years, during the previous six years. These persons must, as a couple, be infertile, or be at risk of transmitting a genetic abnormality or disease. The reason for infertility must not be age.

There are no explicit marital criteria under the Act that prohibit artificial insemination being carried out upon a woman for the purposes of assisted reproduction. Accordingly, any woman, whether married, in a de facto relationship, single, or in a lesbian relationship may undergo an artificial insemination procedure, providing it is carried out by or under the direction of a licensee or exempt practitioner. (Reg. 2(3)).

Permitting access to medically supervised artificial insemination for women who are not infertile reduces the risk of transmission of infectious and genetic diseases to their offspring. Also, these offspring will have access to information about their donor parent from the Reproductive Technology Register, established under the HRT Act.

### **Issues relating to who may access ART during the past year**

In July 2000, a Federal Court decision ruled that provisions in Victoria's *Infertility Treatment Act 1995*, which exclude single women and lesbians from access to IVF procedures and artificial insemination services, were inconsistent with the *Sex Discrimination Act 1984* (Cth) (SD Act). The decision has gone on appeal to the High Court. In August 2000 the Prime Minister, in responding to the Federal Court decision, proposed an amendment to the SD Act to allow states to make laws which would discriminate on the basis of marital status in the provision of assisted reproductive services. That amendment has not been enacted to date.

### **Current State Government position**

The Select Committee which reviewed the HRT Act and tabled its Report on 22 April 1999, made a number of recommendations that would impact on access to reproductive technology treatment in this State. The Government is currently finalising its position on recommendations in the Report.

Government policy does not support restriction of access to reproductive technology on the grounds of marital status or sexual orientation. In June 2001, a Ministerial Committee reported on *Lesbian and Gay Law Reform*. That Report included a number of recommendations relating to amendment of the HRT Act, intended to remove discrimination against lesbian couples in the provision of IVF services.

A review has been recommended concerning the issues of single women, genetic inheritance and limitations for the use of sperm by donors to ensure consistency between the *Equal Opportunity Act* and the *HRT Act*.

## **DEVELOPMENT OF A NATIONAL APPROACH TO THE BANNING OF HUMAN CLONING AND THE REGULATION OF ASSISTED REPRODUCTIVE TECHNOLOGY AND RELATED MATTERS: ISSUES FOR WESTERN AUSTRALIA (AUGUST 2001)**

In December 1998 the National Health and Medical Research Council (NHMRC) and the Australian Health Ethics Committee (AHEC) reported to the Minister for Health on 'Scientific, ethical and regulatory considerations relevant to the cloning of human beings'.

This Report recommended making a basic distinction between the cloning of a whole human being and the copying of component parts (such as DNA and cells).

The Report recommended that the cloning of individual humans be prohibited, but was referred to the House of Representatives Standing Committee on Legal and Constitutional Affairs (the Andrews Committee) for review in relation to the broad social and ethical implications of cloning technology. This Committee has not yet reported.

The Australian Health Ministers' Conference in July 2000 asked the NHMRC to facilitate the development of the national ban on the cloning of whole human beings recommended by AHEC. A report on implementation of this ban, prepared by the NHMRC, in consultation with State/Territory Health Authority representatives, has not yet been made public.

In June 2001 a provision in the Commonwealth *Gene Technology Act 2000* banning human cloning carried out by corporations, in what is widely thought to be an interim measure, came into operation.

The Council of Australian Governments (COAG) in June 2001 agreed that there should be a nationally consistent approach to the banning of human cloning and regulation of assisted reproductive technology (ART) and related emerging technologies in each State. [COAG sought a report on technical issues surrounding ART from the Health Ministers by the end of the 2001 with a view to regulation being in place by June 2002.](#)

The Western Australian *Human Reproductive Technology Act 1991* (HRT Act) already bans the cloning of whole human beings and strictly regulates human embryo research.

In addition the Select Committee that reviewed the HRT Act made several recommendations (April 1999) which would bring the Act into line with the standards for human embryo research established in the NHMRC's 'Ethical guidelines on assisted reproductive technology'.

The current WA Government has not finalised a position on these recommendations, but it appears unlikely there will be any significant difficulties for WA in complying with the proposals for consistent national regulation of cloning and regulation of ART, which are expected to be based on these guidelines.

## REPRODUCTIVE TECHNOLOGY IN THE PRESS

### Discrimination in Assisted Reproductive Technology

In July 2000, the Federal Court held that section 8 of the Victorian *Infertility Treatment Act 1995* is inoperative on the ground that it is inconsistent with section 22 of the *Sex Discrimination Act 1984* (SDA) (Clth). The Court held that the denial of IVF and DI to single women constituted direct discrimination pursuant to section 6(1) of the SDA. The Victorian Government accepted the Federal Court ruling. The ruling did not alter the present legislative position that only infertile women may be treated with ART. The *Australian* reported that the Bracks (Victorian) Government planned to send legal advice to practitioners that said the Federal Government ruling did not prevent the state banning fertile women seeking ART treatment (7 August 2001). The *Australian* also reported that a Melbourne scientist, who worked with Dr Ian Johnston to achieve the first IVF pregnancy, Alex Lopata criticised the Premier for taking this position.

Following the Federal Court ruling, the Prime Minister proposed an amendment to the SDA to allow states to make laws which would discriminate on the basis of marital status in relation to the provision of assisted reproductive services.

The decisions of the Federal Court and the Prime Minister's response led to an intense media debate on whether single and lesbian women should be allowed to access artificial insemination and *in vitro*

fertilisation treatments. Newspapers in all states contributed to this debate.

The debate was quite polarised, with one group claiming that laws regulating assisted reproductive technology that refused access to single and lesbian women were discriminatory against women. This group applauded the Federal Court decision. The second group was opposed to the Federal Court ruling and claimed that children had the right to be born into a family with a mother and a father, and they had a right to know of their biological origins.

It was claimed that children would be confused if they were not born into families with a father and a mother, they would constantly ask the question, 'why didn't I have a father?' On the other hand, it was claimed that women should not be discriminated against on the grounds of marital status and sexuality.

The issue of children's right to access information was covered in a number of media reports. On 17 August 2000, the Federal Health Minister, Dr Wooldridge made a strong plea for uniform regulation in relation to children having access to information about biological origins, as reported in the *Sydney Morning Herald*. Meg Lees stated that the Democrats would oppose the Government's amendment to the SDA, but would like the issue of the rights of children to be fully discussed. Anne Anderson stated that Victoria was the only state that permits IVF children (as adults) access to a central register where donors can be identified (*Australian*, 22

August 2000). The need for children to know all their parents, their heritage and genetic and health history is crucial. The effects of the secrecy in adoption had disastrous results (19 August 2000). The *Australian* reported that a very small number of women were affected by the IVF debates, as low as 150 women each year across Australia (5 August 2000).

Media attention was given on whether Labor MPs should have a conscience vote on the SDA amendment. It was suggested that some Members might not support the Party's position of opposing the amendment to the SDA. It was reported that the Leader of the Party, Mr Kim Beasley would not allow members to have a conscience on the matter, and that neither would Mr John Howard allow his Members to have a conscience vote on the matter.

The *West Australian* reported that the Greens Party planned to introduce a Bill into State Parliament giving single and lesbian women right of access to IVF treatment.

The *West Australian* conducted an opinion poll to gauge community opinion. The results were published on 15 August 2000. Four hundred people were surveyed. Forty three per cent were of the opinion that single women should have the same access to ART as married women. Forty nine per cent opposed this view. Fewer, 36 per cent were in favour of lesbians having access to treatment, with 56 per cent being against these women having access to treatment. Forty four per cent favoured single women having access to artificial insemination, and 47 per cent opposed such access.

The *Sydney Morning Herald* also conducted a poll, showing that 47 per cent of Australians opposed any ban on single women accessing ART treatment, and 42 per cent supported the ban, as reported on 15 August 2000.

The High Court challenge to the Federal Court ruling mounted by Catholic Church received mixed reactions in the press. The aim of this challenge, according to Archbishop Carroll, was 'to give children a voice, not to impose its (Church's) religious beliefs on a secular society', reported in the *Australian*, 27 October 2000. The Women's Electoral Lobby mounted a counter attack; reported in the *Australian*, 28 August 2000.

The *Sex Discrimination Amendment Act 2000* was introduced into Federal Parliament in August 2000. During the year the media reported on the Senate Committee that examined the proposed amendment. Membership of the Senate included three Liberal Members, one Labor member and one Democrat member, and chaired by Ms Marise Payne, from the Liberal backbench. The *West Australian* reported on the submission made by the Law Council, through its President, Ms Anne Trimmer. Ms Trimmer claimed that the proposed amendment breached Australia's international legal obligations, especially through breach of the *Convention on the Elimination of all forms of Discrimination against Women*. The Federal Attorney General's Department's submission claimed that 'the Government does not believe that the Bill is inconsistent with Australia's non-discrimination obligations'.

The Senate Committee's draft report did not make a recommendation either for or against the Federal Government's plan regarding IVF treatment, as reported in the *Australian* on 22 February 2001.

During the discussion about discrimination, there was discussion on the Western Australian legislative requirement that de facto couples must have co-habited for five years in the previous six years in order to access IVF treatment. This time stipulation was claimed to be inconsistent with the requirement in the SDA, which stipulates that de facto couples must live in a 'stable relationship'. The *West Australian* raised this issue on 23 August 2000. The Select Committee that reviewed the *Human Reproductive Technology Act 1991*, reporting in 1999, considered this inconsistency and recommended that the five-year stipulation be removed. The then Minister for Health, Mr John Day, indicated that the Government had not decided on this matter and may not do so in their term of government.

### Medicare funding for ART

A number of papers ran articles on 5 August 2000 on the Federal Health Minister's statement that doctors who perform Medicare-funded IVF treatments for fertile single women and lesbians could be breaching the law (*Kalgoorlie Miner*, *Courier Mail*, *West Australian*). It was reported that Dr Wooldridge made the clear distinction between services that were clinically or medically necessary and those that were elective. This applied

across the board for all medical procedures and not just IVF.

The *Age* reported that the Australian Medical Association urged the Federal Government to clarify the law on who is eligible for Medicare-funded infertility services. This would be preferable to 'trying to prosecute doctors' (5 August 2000).

Senator Lightfoot called for the cancellation of Medicare rebates for lesbian couples and to socially infertile single women accessing AI or IVF (*The West Australian*, 24 August 2000).

In letters to the Editor, the *Australian* published a letter objecting to public funding for IVF, as it was considered a non-health procedure, like cosmetic surgery (2 August 2000).

The opening of the Joondalup clinic was reported as making treatment cheaper, so that couples, regardless of their income, can have a chance to get pregnant (*The West Australian*, 12 September 2000).

### Risks in IVF

Babies born as a result of IVF often face greater risks than other babies, as published in the *Sunday Times* in May. Australian doctors have discovered IVF babies are three times more likely to be premature and require intensive care treatment after birth. IVF babies are more likely to be twins or triplets, and therefore face the risks of prematurity and low birth weight, but even with this taken into account they were still at greater risk compared to naturally conceived babies.

In the study, IVF babies who required intensive care stayed an average of 30 days in intensive care units (ICU's) which was nearly twice as long as naturally conceived babies (16 days). Of those babies in ICU's almost four percent were born through artificial reproduction techniques although these babies represent only one percent of all babies born.

### **Cloning and Stem Cells Research**

Cloning came into the spotlight in March 2001, when two doctors announced they were to start cloning humans, predicting they would create a human clone in two years. This announcement, which was widely covered by the media, resulted in much controversy regarding the ethical implications of human cloning. Difficulties which had been experienced with animal cloning were raised by *The Sunday Times* including oversized navels, neonatal deaths from heart and lung abnormalities and the hundreds of attempts required to clone just one offspring. A leading Australian scientist, Dr Hill, commented, in *The West Australian*, that the portrayal of cloning as a routine procedure was incorrect and there were still problems including low birth rates, high incidence of abnormalities, oversized young and premature aging.

Legislation on human and therapeutic cloning was also under review around the world as the techniques continued to evolve. In December, last minute amendments to the Gene Technology Act banned cloning of humans, that is any technology to create a duplicate or

descendant that is identical to the original human, as well as the combining of animal and human cells (*The Australian*). The ban applies only to research that involves commonwealth funds and complements laws already in place in Western Australia, where since 1991 all human cloning has been illegal under the Human Reproductive Technology Act.

At a meeting of state leaders and the Prime Minister, in June, it was agreed cloning of human beings would be banned under uniform and comprehensive state legislation (*Age*, June 2001). It was also anticipated a consistent approach to using stem cells for research would be developed, where it would be permitted as long as it did not involve the destruction of embryos.

Earlier in the year, in August, the *Canberra Times* reported that a British Government Committee had announced that stem cells could be taken from human embryos, less than 14 days old, for research. While only nine days later the United States Institute of Health announced that restrictions on the use of federal funds for research on stem cells derived from human embryos would be dropped.

The *Sydney Morning Herald* published an article in August detailing the potential of stem cell therapy and xenotransplantation. The techniques could provide tissues, including brain, liver or heart cells, or whole organs that would be useful in the repair of damaged body organs. Stem cells from human embryos could be cultured and programmed to become specific cells that were required, and through the use

of cloned embryos the problems of tissue rejection could be overcome. The ethical concern related to the use of stem cells is that the extraction of the stem cells destroys the embryo. Xenotransplantation is a technique whereby organs and tissues from animals, usually pigs, are transplanted to humans. To overcome the problem of rejection the animals would be genetically modified so the genes that cause humans to reject the tissue are removed.

Researchers at the Monash Institute for Reproduction and Development made a breakthrough in their research on stem cells, in August. PhD student, Megan Munsie, fused a mouse cell into a donor mouse oocyte with its genetic material removed to create a cloned mouse embryo. This embryo was grown and its stem cells, primordial cells with the capacity to become any cell in the body, removed and cultured. Ms Munsie was quoted, in *The West Australian*, saying “the stem cells have the same genetic make-up as the original target mouse and therefore if we were to program the cells to become a specific body type, theoretically they could be introduced to the target mouse to treat illness.” When the stem cells were returned to the original mouse, the researchers found there was no adverse reaction from the mouse’s immune system.

*The Australian* (August 2000) reported on two research teams who simultaneously announced they had successfully cloned pigs. A Japanese group was able to produce the world’s first cloned piglet and researchers from PPL Therapeutics had cloned five female pigs. The hope from such research was

that in the future organs from genetically modified cloned pigs would be used as human transplants. However, at the same time Scottish researchers said they would withdraw from research into cloning genetically modified pigs due to fears transplanted pig organs could transfer new diseases to humans. Scientists have been concentrating on pigs because they are a close genetic match to humans.

Concern was raised when it was discovered that three years ago Australian researchers had created an embryo that was part pig and part human. As reported in the *Herald Sun* (October 2000), the researchers used nuclear transfer where a nucleus from a human cell was inserted into a pig’s egg which had had its nucleus removed. The embryos were allowed to develop to the 32 cell stage before being destroyed. The experiment was conducted as the researchers hoped the transfer of the human cell into an egg would make the cell regress to become a stem cell. The research had been abandoned as researchers had since found effective ways of creating stem cells.

## **Evolving Technologies and Treatments**

**D**uring the year there were some interesting developments in assisted reproduction treatments. News of a new technique, referred to as cytoplasmic transfer, gained much media attention, as the babies born from the procedure were considered the first genetically altered humans. The treatment, developed by scientists at the Institute for Reproductive Medicine in

New Jersey, is being used in women who although their eggs can be fertilised the resulting embryos die prior to implantation. It is believed the problem in these cases is that the cytoplasm, the substance in the cell surrounding the nucleus, isn't providing an adequate environment for the embryo to survive. Therefore scientists took the cytoplasm from donor eggs and injected it into the eggs of infertile patients.

As reported in the *Australian* (May 2001), the treatment was used on 30 women, 12 of these had live born babies, one suffered a miscarriage and in 17 the treatment was not successful. Fifteen babies were born to the twelve women, of whom 13 were genetically unmodified and two were found to have additional genetic material. The added genetic material came from mitochondria in the donor's cytoplasm. The DNA within the mitochondria contributes only 0.03 percent of human DNA, and the scientists responsible for this technique believe this DNA plays no role in determining physical characteristics.

Later on in the month, the *Herald Sun*, published information that the scientists responsible for developing cytoplasmic transfer had failed to disclose that in two cases the treatment had lead to chromosomal anomalies. Two of the 17 fetuses created had suffered from the genetic condition of Turner's syndrome, one was miscarried and the other aborted when doctors found that an entire chromosome was absent. The results that the scientists published in the medical journal *Human Reproduction* had not mentioned the defect fetuses. Other researchers in the field criticised

the scientists for breaching high scientific standards.

Dr MacKellar, a lecturer in bioethics and biochemistry, believes the same technique, of nuclear transfer, which is used in cloning, could be used to conceive children without a biological mother. The intended use would be to provide a male homosexual couple with a child using their own DNA. The techniques, as described in the *Australian* (September 2000) would involve removing the nucleus of a donor egg and replacing it with the nucleus of a sperm from a male partner. This egg could then be fertilised in vitro with the sperm of another male, giving the created embryo two genetic fathers. However, women could not be taken completely out of the process as a surrogate mother would be required to carry the baby and a small percentage of donor DNA, found in the cytoplasm of the donor egg, would be present in any child.

Lord Robert Winston, one of Britain's leading fertility experts, has patented a technique to genetically alter sperm (*Australian*, December 2000). The technique involves injecting genetic material directly into the testes, using a virus to carry it directly to the developing germ cells, which generate the sperm. The main aim of this method would be to prevent children inheriting unwanted characteristics from their fathers, such as fatal diseases including cystic fibrosis. But critics fear the technology would be used inappropriately to create designer babies.

An article in the *Kalgoorlie Miner*, in December 2000, details the discovery, by

scientists in Colorado, of a way to identify the healthiest human embryos to be used in IVF. The scientists believe structures in the egg, called microtubules, may hold the key, as embryos with symmetrical microtubules are more likely to survive IVF attempts than other embryos. If embryologists were able to screen the embryos and then implant those with symmetrical microtubules, it may help improve the pregnancy rate in IVF.

A new method of storing sperm at room temperature, which could reduce costs, was developed by an Indonesian student. Currently the only way to store sperm is through freezing which requires expensive freezing equipment and also means sperm needs to be of high quality to survive thawing. The method, reported in the *Sunday Times* (March 2001), involves storing sperm in plastic drinking straws then adding compressed nitrogen gas through the straw to push the oxygen out and dry the material. The straws are then sealed and stored in Aluminium foil. More testing would be required to ensure sperm stored in this way retain all their necessary qualities.

### Male Fertility

Declining sperm counts were again the focus of research, with many Australian newspapers publishing stories on the latest research find, that disposable nappies may be contributing to low sperm counts and the rising incidence of testicular cancer. As detailed in *The Age*, in September, the researchers found that scrotal temperatures were significantly higher, by up to one degree, when children wore

disposable nappies compared to cotton nappies. They believed that the nappies could cause a build up in heat around the testes at an important time of development, and this could result in low sperm counts as adults, although a follow up study would be required to confirm this.

In September, *The Australian* reported results of a Danish study examining the risk of testicular cancer in males with fertility problems. The study found men in couples with fertility problems were 1.6 times more likely to develop testicular cancer when compared with the overall male population and specifically men with poor semen quality were two to three times more like to develop the cancer. However, the researchers did emphasise that as the number of cancer cases were very small, the statistical risk for a man with fertility problems developing testicular cancer was very low.

A British study of 8515 couples confirmed that a man's age affects his ability to have children. The *Sydney Morning Herald* reported, in August, that the likelihood of a couple conceiving within a twelve months period decreased by three percent for every year the male partner was over 24. By the time a man was 35 years of age the probability that it would take more than a year to conceive increased to fifteen percent. The study took into account other factors that could affect time to conception such as woman's age, period of living together, duration of the use of the pill and passive smoking. The researchers also discovered women whose partners were more than five years older than themselves had a

decreased likelihood of conception, within 6 or 12 months, when compared to women whose partners were the same age or younger.

### **Fertility Rates**

In February, the Herald Sun printed an article suggesting modern women may be more fertile than their predecessors. This claim was based on an Australian study of 6000 women, which revealed women were reaching menarche earlier and going through menopause later than their grandmothers. Previous studies have shown factors involved in delaying menopause are a tertiary education, higher cognitive ability at age eight and the number of children born to a woman.

Although, as the above study suggests there is the potential for fertility to increase, there are other factors that may decrease fertility and as was demonstrated by the latest report of the Australian Bureau of Statistics, birth rates have actually decreased. The rate of 1.73 births per woman in 1999, as reported in *The Herald Sun* in July, had fallen from 2.14 births in 1960. Additionally, it was expected that at the current rates 20 percent of women would remain childless in Australia.

As detailed in *The Australian* it was originally believed that the increase in the number of women reproducing in their 30's compensated for the women in their 20's who delayed childbirth. But new research found that since 1992 the fall had exceeded the increase.

"Kitchens may sink fertility" was the clever title of article in the November *West Australian* which reported results from an Italian study that had found electromagnetic fields in homes, from appliances such as washing machines and refrigerators, could reduce women's fertility. The scientists found, in mice exposed to extremely low frequency electromagnetic fields (ELF-EMF) the ovarian follicles, which contain the eggs, failed to develop properly. This raised concerns that exposure to ELF-EMF in women may impair their reproductive potential.

### **Pre-implantation Genetic Screening**

The birth of Adam Nash, who was considered the first baby to be genetically selected to help a sibling, was widely reported in the media (*The Australian*, *The West Australian*). Adam was an IVF baby who had been screened as an embryo to ensure he was free of Fanconi's anaemia, the life threatening disease suffered by his sister, and a compatible tissue donor. After his birth doctors collected cells from Adam's umbilical cord blood and infused them into his sister Molly, to function as Molly's bone marrow making platelets and white blood cells. Early results indicate the stem cell transplant is starting to reconstitute Molly's bone marrow. However, if the treatment were to fail the next step for the parents would be to consider Adam becoming a bone marrow donor, a much more painful and invasive procedure.

The controversy that surrounded Adam's birth was that any embryos that were not found compatible or not used were kept

frozen or allowed to succumb. Adam's mother said that had they not screened the embryos they would have waited until 20 weeks in the pregnancy at which stage they would have aborted the baby if it was diagnosed prenatally with Fanconi's anaemia.

An article in *The West Australian*, in June, reported that all IVF clinics in WA believed the Government needed to accept the recommendations of the Select Committee that reviewed the Human Reproductive Technology Act and abolish laws preventing genetic screening of embryos. Under the recommendations genetic tests could be used to screen for conditions such as Down's Syndrome and cystic fibrosis, but sex selection and determination of physical characteristics would not be allowed. Dr Matson, a WA IVF clinic director, indicated the screening would be used for couples with a genetic disorder in their families. Currently these patients were travelling interstate to partake in the treatment or were having an amniocentesis during pregnancy then aborting affected fetuses.

While at Monash IVF, in Victoria, approval was being sought from the Infertility Treatment Authority to allow screening of embryos for genes predisposing to cancer and other diseases. It was reported in the *Age*, in June, that there had only been one previous case in the world where screening for predisposition genes had occurred. This was an American couple who wanted to ensure their child had a functioning P53 gene, which helps protect against breast, brain, bone and soft tissue cancer.

## Embryo storage

**T**he *West Australian* reported (24 October 2000) that, according to the Annual Report of the Reproductive Technology Council, there were 8692 frozen embryos in storage. It stated that the Government had not implemented the recommendation of the State Parliament Committee on reproductive technology that there should be a limit on how long embryos should be stored.

## Donor Issues

**C**oncerns about a shortage of donor semen arose again as some fertility clinics around Australia indicated they were having difficulties finding semen donors. Professor Robert Jansen, director of Sydney IVF, was reported by the *Sydney Morning Herald* in August 2000, saying that fewer men were donating sperm and of those who did many were indicating that their donations were only to be used for heterosexual couples.

In March 2001, the *Australian Financial Review* interviewed Dr Anne Conway, an Andrologist at Sydney's Concord Hospital, who attributed the decline in semen donation to two factors. Firstly, the growing emphasis on the right of the child to know their biological parents, which meant donors could no longer be ensured their identity would remain anonymous. Secondly, additional screening of donors meant that fewer donors were being accepted. She also noted that these factors had led to a change in types of sperm donors, to slightly older men who were more

motivated by the idea of having genetic offspring. There were also more couples who were using known donors.

## **Surrogacy**

**I**n January 2001, the *West Australian* reported a Brisbane case where a 51 year old woman was put on a good behaviour bond after pleading guilty to paying a couple \$10,000 for their seven-week old son. She was prosecuted under the Surrogate Parenthood Act 1988. The couple was also charged under the Act.

The *Sydney Morning Herald* reported on a NSW Supreme Court case whereby a couple was allowed to adopt the two-year child who had been born as a result of a surrogacy arrangement. The surrogate mother, the commissioning mother's sister, was artificially inseminated with the sperm of her brother-in-law. The couple had cared for the child since birth (July 2000).

In a letter to the Editor in August 2000, *The West Australian* published a letter saying that the IVF debate had widened to include surrogacy. The similarities between surrogacy and adoption were raised. The 'ownership of' and 'secret kept from' children 'are the key issues and must not be condoned'.

**APPENDIX 1**

**LICENCES CURRENT UNDER  
THE HUMAN REPRODUCTIVE TECHNOLOGY ACT AT 30 JUNE 2001;  
COMPLETE LIST OF EXEMPT PRACTITIONERS 31 AUGUST 2001.**

<p><b>LICENCES CURRENT UNDER THE HUMAN REPRODUCTIVE TECHNOLOGY ACT AT 30 JUNE 2001</b></p>
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*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.

*Fertility West Administration Services Pty Ltd trading as Fertility West, PERTH* - Practice and Storage Licences.

*Fertility West Administration Services Pty Ltd trading as Fertility West, JOONDALUP* - Practice Licence.

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

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

<b>MEDICAL PRACTITIONERS WITH AN EXEMPTION FROM THE  REQUIREMENT TO BE LICENSED TO CARRY OUT ARTIFICIAL  INSEMINATION: AUGUST 31 2001</b>
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Exemptee No	Name	Suburb	Post Code
E023	Dr PK Bairstow	Bunbury	WA 6230
E055	Dr A Basell	Narrogin	WA 6312
E042	Dr LD Brett	West Leederville	WA 6007
E018	Dr JL Chaney	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
E020	Dr P Hugo	Murdoch	WA 6150
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
E007	Dr RD Mason	Bunbury	WA 6230
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
E030	Dr JH Payne	Booragoon	WA 6154
E015	Dr BD Roberman	Subiaco	WA 6008
E017	Dr C Russell-Smith	Kwinana	WA 6167
E053	Dr AK Shannon	Mt Claremont	WA 6010
E005	Dr NP Silberstein	Mt Barker	WA 6324
E039	Dr T Silbert	Morley	WA 6062
E056	Dr JS Singh	Woodvale	WA 6026
E022	Dr BGA Stuckey	Nedlands	WA 6009
E054	Dr ME Ure	Albany	WA 6330
E029	Dr JM Vujcich	West Perth	WA 6050
E028	Dr RJ Watt	Mandurah	WA 6012
E049	Dr M Zafir	Albany	WA 6330

## **APPENDIX 2**

### **LIST OF APPROVED COUNSELLORS AT 30 JUNE 2001**

**WESTERN AUSTRALIAN**  
**Reproductive Technology Council**  
**Approved Counsellors June 2001**

<b>Name</b>	<b>Professional Address</b>	<b>Telephone Number</b>
Ms Jill Bain*	Concept Fertility Centre, c/- KEMH Bagot Road, Subiaco WA 6008 57 Canning Beach Road, Applecross WA 6153	(08) 9382 2388 Fax (08) 9381 3603 Tel / Fax (08) 9364 3665.
Ms Bev Banovich	Park Street Centre, 203 Park Street, Subiaco WA 6008	0417 928 308
Mr George Burns	62 Churchill Avenue, Subiaco Western Australia 6008	(08) 9388 2733 Fax (08) 9388 3740
Ms Maxine Chapman*	Pivot Medical Centre 166-168 Cambridge St, Leederville WA 6007 Suite G10, Chelsea Village, 145 Stirling Hwy, Nedlands WA 6009	(08) 9382 1677 Fax (08) 9382 4576 Tel / Fax (08) 9386 2088
Ms Antonia Clissa*	Roe Street Centre for Human Relationships, 70 Roe St, Northbridge WA 6003 Keogh Institute for Medical Research SCG Hosp Nedlands WA 6009	(08) 9228 3693 Fax (08) 9227 6871 (08) 9346 2008 Fax 9380 6387
Ms Deborah Foster-Gaitskell*	62 Churchill Avenue, Subiaco WA 6008 Hollywood Fertility Centre, Hollywood Private Hospital Monash Avenue, Nedlands, WA 6009	(08) 9271 3582 Fax (08) 9388 3740 (08) 9346 7100 Fax (08) 9386 1463
Ms Elyse Frankel	Perth Division of General Practice, Mercy Medical Centre, Ellesmere Road, Mt Lawley 6050	(08) 9370 9778 Fax (08) 9370 9785
Ms Lisa Hamilton	Joondalup Health Campus, Shenton Avenue, Joondalup WA 6027	(08) 9400 9741 mob. 0411100255
Ms Alison Hay	Relationships Australia, PO Box 1206, West Leederville, WA 6901 Relationships Australia, 1 Ord Street, Fremantle WA 6010	(08) 9489 6363 Fax (08) 9489 6300 (08) 9336 2144
Ms Celine Harrison	KEMH Social Work Dept, Centre for Women's Health, Bagot Road, Subiaco WA 6008	(08) 9340 2777 Fax (08) 9340 2775
Mr Jeff Irwin	C/- PO Box 234, Capel WA 6271v C/- South West Mental Health Services PO Box 1993 Bunbury WA 6231	Tel / Fax (08) 9727 1197 (08) 9791 4355 Fax (08) 9791 4385
Ms Rosemary Keenan*	Grace House Suite 7 - 109 Grand Boulevard, Joondalup WA 6027	(08) 9300 0460 Fax (08) 9300 0459
Ms Libby Lloyd	KEMH Social Work Dept, Centre for Women's Health, Bagot Road, Subiaco WA 6008	(08) 9340 2777 Fax (08) 9340 2775
Ms Anne-Marie Loney	c/- York District Hospital, Trews Road, York WA 6302 2 Osnaburg Road, York WA 6302	(08) 96411 200 (08) 96411 469
Ms Sue Midford*	Suite 8/19 York Street, Subiaco WA 6008 2/36 Ormsby Tce, Mandurah WA 6210	(08) 9446 9860 Fax (08) 9446 9860 (08) 9446 9860 (Appointments) Mobile 0411 590 566
Dr Kaye Miller	Palm Springs Medical Centre, 3 Halliburton Drive, Warnbro WA 6169	(08) 9593 2033 Fax (08) 9593 1913
Ms Nada Murphy*	Suite 2, 324 Onslow Road, Shenton Park WA 6008	(08) 9381 7076 Fax (08) 9381 6021
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 Rona Murray	Community Mental Health Team Albany, PO Box 1411, Albany WA 6331 C/- North Road Family Practice, Cr North Road and Lyon Street, Albany WA 6331	(08) 9892 2440 (08) 9842 2727 Fax (08) 9842 8219
Ms Farley O'Dea*	PO Box 41, Mosman Park WA 6912	Tel (08) 9284 2586
Ms Kate Orr	Beldridge Medical Centre Beldon WA 6027 PO Box 607, Joondalup WA 6919	(08) 9407 4400 Fax (08) 9300 0799
Ms Marian Rawlins	Genetic Services of WA, KEMH Centre for Women's Health, Bagot Road, Subiaco WA 6008	(08) 9340 1525 Fax (08) 9340 1678
Ms Prue-Anne Reynolds*	5 Klenk Road, Attadale WA 6156	(08) 9330 7340
Ms Sally Robinson	73 Dickenson Way Booragoon WA 6154	Tel / Fax (08) 9364 8169
Ms Iolanda Rodino	64 Farrington Road, Leeming WA 6149	(08) 9389 7212 Fax (08) 9386 7564
Ms Kay Rosen	Private Practice, 36 Carnarvon Crescent, Mt Lawley WA 6050	(08) 9444 1617
Ms Jan Steel*	5/2690 Albany Highway, Kelmscott WA 6111	(08) 9495 4223
Ms Margaret van Keppel	267 Walcott Street NORTH PERTH WA 6006 Pivot Medical Centre 166-168 Cambridge St, Leederville WA 6007	(08) 9443 3655 Fax (08) 9443 8665 (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 2000/2001**

## **OPERATIONS OF LICENSEES FOR THE FINANCIAL YEAR 2000/2001**

### **BACKGROUND**

This summary was put together from information submitted, as required by the *Human Reproductive Technology Act 1991* (Act), about five Storage Licences and four Practice Licences authorising artificial fertilisation procedures including in vitro fertilisation (IVF) under the Act. In addition, one other Practice licensee, and medical practitioners who are Exempt from the requirement to be licensed to carry out artificial inseminations reported (as required), on their provision of intra-uterine insemination. Information from the public fertility clinic at King Edward Memorial Hospital, which held a Practice Licence until it terminated in May 2001, is also included but reported by Concept Fertility Centre where the procedures were carried out.

All information was submitted in a collated form and referred to the financial year which ended at 30 June 2001. While it is not possible to provide any data on outcomes of treatments undertaken during the financial year just ended because of the necessary lag time required for reporting, this summary shows the scale and type of activities carried out under the licences.

In Appendix 4 of this Report there is additional detailed information from the IVF and Donor Registers, including short term outcomes of all treatments, for the calendar year 1999.

### **SUMMARY**

#### **Semen storage and donation**

From Table 1 it can be seen that semen was donated to WA Storage Licensees by 43 men during 2000/2001. Of these 24 were new donors. This was a slight 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), as in the previous year, showed the majority (60.5%) were aged over 35 years. Table 3 suggests a further decline in donors who are single (never married).

The supply of donor semen by the sperm banks to external clinics or doctors is detailed in Table 4, indicating very few external recipients. Of interest is that one medical practitioner was supplied with donor semen on more than thirty occasions during the year. Also of interest is that one interstate medical practitioner was supplied with donor semen during the year, with the approval of the Council under Direction 6.2. This approval was based on an undertaking by that practitioner to ensure that all recipients were fully informed about requirements of the Act, and knew in particular that information about outcomes of treatments would be provided to the WA Reproductive Technology Register.

### **Embryo storage**

Table 5 shows that the total number of embryos in storage at the end of the year was 9661. This was 969 more than at the same time last year. The total number of embryos in storage has continued to increase since 1993.

As noted earlier in the Report, during the year 293 applications for extension to permitted storage were considered by the Council and all but three for which the permitted storage period had expired were approved.

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

Table 7 shows that during the last financial year 1047 women began oocyte retrieval cycles for IVF, 667 began FETs and 5 began GIFT procedures.

A total of 2745 cycles were begun for IVF, frozen embryo transfer or GIFT, slightly more than in the previous year. It can be seen that of all cycles begun, 1543 (56.2%) were for IVF and 1196 were for frozen embryo transfer. Overall frozen embryo transfer cycles made up 43.6% of all cycles begun. GIFT cycles (6) made up only 0.2% of all cycles begun.

Of the 1549 cycles begun for fresh IVF or GIFT with ovarian stimulation, 88.0% proceeded to oocyte retrieval and 78.4% proceeded to transfer of fresh embryos or gametes. Of the 1196 frozen embryo transfer cycles begun, 980 (81.9%) proceeded to transfer.

Overall, donated human reproductive material was involved in 2.4% of all IVF or GIFT oocyte retrieval cycles begun during the year, and 8.8% of all frozen embryo transfer cycles. In 1.7% of all oocyte retrieval cycles begun donor semen was used (26 cycles); donor eggs were used in 0.7% of all IVF cycles begun (11 cycles). No IVF cycle involved the use of donor embryos, however, donor embryos were used in 1.7% of all FET cycles begun (20 cycles).

Of all 1357 IVF treatment cycles with successful oocyte retrieval, 556 (41.0%) used intra-cytoplasmic sperm injection (ICSI), similar to 41.6% in the previous year. The proportion of IVF treatment cycles using ICSI for each year following the introduction of ICSI into the WA clinics in 1993/94 appears to have stabilised. Fresh or frozen sperm retrieved from the epididymis or testis was used in 90 of the ICSI treatment cycles, that is in 16.2% of all cycles using ICSI.

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

All four clinics with approval to carry out ICSI provided reports on the use and outcome of the procedure. Ongoing pregnancy rates per embryo transfer ranged from 16.0-24%.

Two of three clinics with approval to carry out assisted hatching reported on its use during the year in a total of 157 couples and 177 treatment cycles. The use of assisted hatching did not commence during the report period in the third clinic. The reported

ongoing pregnancy rates per embryo transfer were similar (14.4% in one clinic and 15.8% in the other).

Of the two clinics reporting on blastocyst culture, one reported only two treatment cycles with as yet unknown outcome and the other reported that the procedure had not yet commenced.

- *Serious morbidity and mortality in women undergoing treatment*

Overall clinics reported a total of 34 cases of severe ovarian hyperstimulation relating to IVF and GIFT cycles (2.2% stimulation cycles, with a clinic range of 0.7 to 3.9%). The average number of follicles above 12cm for women who were affected by severe ovarian hyperstimulation was 21.6.

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 906 IUI cycles were carried out during the year, by five Practice licensees and four Exempt practitioners. The overall clinical pregnancy rate was 7.8% (71 ongoing pregnancies), and of the pregnancies of known plurality (64), 53 were singleton (82.87%), 7 were twin (10.9%) and four were triplet (6.3%).

The information provided showed that 66.4% of the IUIs used husbands' sperm and 33.6% used donor sperm. Of all cycles carried out, 45.8% did not involve the use of ovulation induction. Clomid was used in only 13.0% of the cycles, and gonadotrophins were used in 41.2% of the cycles.

All sets of triplets followed gonadotrophin stimulation, two sets in donor insemination and two sets in AIH. Three of the four sets occurred in one clinic.

Once again the Council will be following up the failure of 9 of 50 (18%) Exempt practitioners to supply information required by the Directions. Five of these practitioners had moved and lost contact with the Register; none of these practitioners however received donated semen from a licensed Sperm Bank. Although it is likely that the others had not carried out any IUIs during the year, they are required to put in a zero return.

- *Counselling*

As noted elsewhere in this report the Council has now approved improved forms for reporting about the use of counselling services in the clinics. This is expected to improve the consistency and usefulness of information about counselling coming from the clinics in future years. Given the current variability of reporting about counselling, it is difficult to make comparisons between clinics or to ascertain the extent to which it is being taken up in the clinics. However, the clinic range in proportion of counselling sessions carried out in relation to the total number of cycles begun for IVF and related procedures (that is excluding DI, for which there is no information) did suggest significant differences in the uptake of counselling in the different clinics (range 26.1 to 48.7%).

The recently completed first phase of the audit of counselling services in the clinics should provide more information about this important area.

- *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. The most significant changes were the introduction of assisted hatching and blastocyst culture into several of the clinics.

- *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 8, the results for this year indicate another increase in the number of public patients when compared to previous years. More than double the number of treatment cycles were carried out for public patients in the last year (227 cycles begun, compared with 104 last year). This year 21 of the IVF cycles involved micro-manipulation (ICSI).

In addition, Concept reported 25 artificial inseminations (4 DI, 21 AIH) for 12 public patients between 1 July 2000 and 30 June 2001. These patients are managed through the KEMH Infertility Clinic, but Concept again reported on the treatments.

- *Complaints*

A total of twenty four formal complaints were reported from two 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
No. current Donors	67	49	49	23	28	22	45	43
No. new donors in last year	23	28	30	20	11	15	30	24

**TABLE 2: SEMEN DONOR AGES**

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

<sup>1</sup> Age missing for donor<sup>2</sup> Age missing for 2 donors

6

0

**TABLE 3: MARITAL STATUS OF SEMEN DONORS**

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

**TABLE 4: FREQUENCY OF SUPPLY OF SEMEN BY SPERM BANKS TO EXTERNAL CLINICS OR DOCTORS**

	Number of clinics or doctors supplied						
Number of times semen supplied	1994/95	1995/96	1996/97	1997/98	1998/99	1999/00	2000/01
1-5	18	16	14	7	7	5	3
6-10	2	1	4	4	3	3	1
11-15	1	1	1	1	1	0	0
16-20	0	0	2	0	1	0	1
21-25	3	0	0	1	0	0	1
26-30	2	0	1	0	2	0	0
>30	1	2	1	3	1	1	1
<b>Total</b>	27	20	23	16	15	9	7

**TABLE 5: TOTAL NUMBER OF EMBRYOS IN STORAGE JUNE 30**

<b>YEAR</b>	<b>1993</b>	<b>1994</b>	<b>1995</b>	<b>1996</b>	<b>1997</b>	<b>1998</b>	<b>1999</b>	<b>2000</b>	<b>2001</b>
<b>No Embryos</b>	1706	1870	2821	3456	4697	6108	7317	8692	9661

**TABLE 6: DISPERSAL OF STORED EMBRYOS 1999/2000**

	<b>No of embryos</b>
<b>Transferred between clinics in WA</b>	292
<b>Transferred to clinics outside WA (Patients moving interstate/overseas)</b>	79
<b>Transferred into WA clinics from interstate or overseas</b>	12
<b>Used in frozen embryo transfer treatments</b>	3582
<b>Allowed to succumb with consent of couples</b>	512

**TABLE 7: IVF/GIFT TREATMENTS: Four year data**

	IVF Fresh embryo transfer				IVF Frozen embryo transfer				GIFT				Total			
	1997/98	1998/99	1999/2000	2000/01	1997/98	1998/99	1999/2000	2000/01	1997/98	1998/99	1999/2000	2000/01	1997/98	1998/99	1999/2000	2000/01
<b>No of women treated</b>	900	802	977	1047	389	511	510	667	33	18	12	5	n/a	n/a	n/a	n/a
<b>No of cycles begun</b>	1210	1408	1529	1543	913	1085	988	1196	62	32	16	6	2185	2525	2533	2745
<b>No of cycles with oocyte retrieval</b>	1046	1143	1114	1357	-	-	-	-	56	24	14	6	1102	1167	1128	1363
<b>No of cycles with gamete or embryo transfer</b>	948	1069	1003	1209	757	917	832	980	44	25	14	6	1749	2011	1849	2195
<b>No of cycles using donor:</b>																
Semen	29	33	37	25	21	16	19	25	2	1	0	1	52	50	56	51
Ova	20	11	10	11	21	34	22	60	0	0	0	0	41	45	32	71
Embryo	0	1	1	0	5	30	36	20	-	-	-	0	5	31	37	20
<b>Total</b>	49	45	48	36	47	80	77	105	2	1	0	1	98	126	125	142
<b>No of cycles where embryos stored</b>	574	641	670	763	-	-	-	-	28	10	9	4	602	651	679	767
<b>No of cycles from which human reproductive material was donated:</b>																
Ova donated	19	11	21	33	-	-	-	-	0	0	0	0	19	11	21	33
Embryos donated	0	1	0	0	-	-	-	-	0	0	0	0	0	1	1	0
<b>Breakdown of treatment cycle details</b>					-											
No of cycles with IVF/GIFT same cycle	0	2	0	0	-	-	-		-	-	-	-	0	2	0	?
No of cycles with sperm retrieval	73	106	102	90	-	-	-		-	-	-	0	73	106	102	90
No of cycles with ICSI*	380	466	463	556	-	-	-		-	-	-	-	380	450	466	556
No of cycles with Fallopian embryo transfer	4	6	6	2	3	3	3	2	-	-	-	0	7	9	9	4

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

**TABLE 8: IVF AND RELATED TREATMENT OF PUBLIC PATIENTS**

	No. of Patients				No. of Treatment Cycles			
	1997/98	1998/99	1999/2000	2000/2001	1997/98	1998/99	1999/2000	2000/2001
<b>IVF</b>	45	43	46	87	56	53	62	126
<b>GIFT</b>	0	1	0	0	0	1	0	0
<b>FET</b>	12	14	20	19	46	60	42	101
<b>TOTAL</b>	<b>57</b>	<b>58</b>	<b>66</b>	<b>106</b>	<b>102</b>	<b>114</b>	<b>104</b>	<b>227</b>

## **APPENDIX 4**

### **REPORT FROM THE REPRODUCTIVE TECHNOLOGY REGISTER: JANUARY 1 TO DECEMBER 31 1999**

## REPORT FROM THE REPRODUCTIVE TECHNOLOGY REGISTER: 1 JANUARY TO 31 DECEMBER 1998

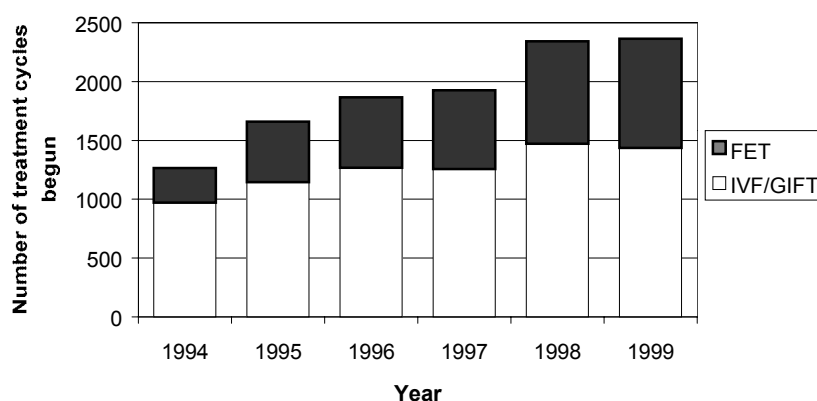
This is the seventh report from the Reproductive Technology Register established from 8 April 1993 under the *WA Human Reproductive Technology Act 1991*. This report summarises information about all assisted conception treatments undertaken in Western Australia between 1 January and 31 December 1999. The information for IVF/GIFT treatments was reported to the register by 3 licensees, and Donor Insemination treatments were reported by 4 licensees and 7 exempt practitioners.

Comparisons are made throughout the summary to data reported in previous years<sup>1-5</sup> 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)<sup>6</sup>. 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 1999 data on the Reproductive Technology Register.

There was a total of 2365 treatment cycles begun for IVF and related procedures in 1999, an increase of only 0.9% compared to the previous year (2344). The majority of these (1435) were stimulation cycles for in vitro Fertilisation (IVF) or Gamete Intra Fallopian Transfer (GIFT) (see Table 2), and 930 were for Frozen Embryo Transfer (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 rate of increase appears to have stabilised again after a 21.8% increase between 1997 and 1998. The proportion of treatment cycles begun for IVF/GIFT vs frozen embryo transfers continued the trend of an increase in the proportion of FETs relative to fresh embryo transfers. In 1994 treatment cycles begun for frozen embryo transfer represented 23.3% of all treatment cycles begun compared to 39.3% in 1999.

Figure 1: Number of treatment cycles begun for IVF/GIFT and FET, 1994-1999



During 1999, 1034 women (7 less than the previous year) underwent stimulation cycles for egg retrieval (Table 2). The average number of IVF/GIFT stimulation cycles commenced per woman was 1.4, with a median of 1.

Cancellation of stimulation cycles for IVF or GIFT occurred in 18.1% of cases, which is slightly lower than in 1998 (22.3%). A wide clinic range was also evident (0.8%-26.2%), which may in part reflect the different ovulation induction regimes used by the clinics or different definitions of cancelled cycle. Of those egg retrievals attempted, 1.9% were performed by laparoscopy and 98.1% 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 (11.7, median = 10) than by laparoscopy (6.9, median = 5.5). The overall mean and median for both techniques combined were 11.6 and 10 respectively. Attempted egg retrievals were almost all successful (99.7%) with a narrow clinic range (99.5%-100%).

Eggs were donated in 2.1% of successful egg retrievals, and 26.9% 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: Gonadotropin Releasing Hormone (GnRH) agonists, Gonadotropin Releasing Hormone (GnRH) antagonists, Gonadotropin Releasing Hormone (GnRH) agonists, Gonadotropin Releasing Hormone (GnRH) antagonists, Gonadotropin Releasing Hormone (GnRH) agonists, Gonadotropin Releasing Hormone (GnRH) antagonists. 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.

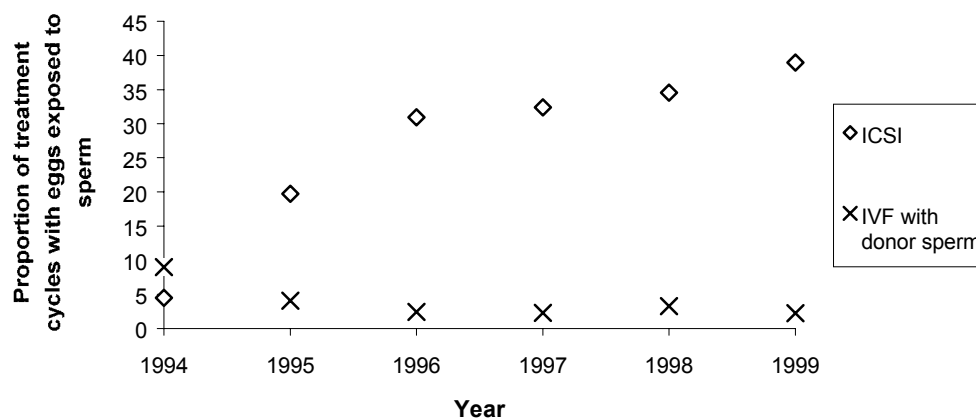
Between 1 January and 31 December 1999, 1192 women had embryo transfers (fresh or frozen) or egg transfers (GIFT) (see Table 3). This represents a 4.3% increase compared to the 1143 women having embryo transfers in 1998, and a 73.5% increase compared to 1994. The majority of these women (45.6%) had only fresh embryo transfers, although 28.7% had only frozen embryo transfers, and 24.2% had both IVF and FET transfers. Of the 1192 women treated in 1999, table 4 shows most had only one transfer during the year (58.8%), although 24.7% had two transfers and 11.2% had three. Sixty-two women had more than three transfers, the highest being 1 woman who had 9 transfers during the reporting period. The mean number of transfers per woman in this period was 1.6 and the median 2.

Table 5 summarises the fertilisation and embryo dispersal data for treatment cycles commenced between 1 January and 31 December 1999. There were 1166 cycles with eggs exposed to sperm, compared to 1132 in 1998, 1052 in 1997, 1027 in 1996 and 953 in 1995. The average number of eggs exposed to sperm per treatment cycle was 10.7 (median 9) with a clinic range from 9.5 to 11.8 (and the median varied between the clinics from 8 to 10).

Micro-manipulation to achieve fertilisation was used in 38.9% of treatment cycles with eggs exposed to sperm, with a wide clinic range (27.0%-63.1%). Intracytoplasmic sperm injection (ICSI) was the only micro-manipulation technique used in 1999, 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 (34.5% treatment cycles using ICSI 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, 1994-1999**



Fertilisation of one or more eggs occurred in 97.6% of treatment cycles with eggs exposed to sperm (Table 5). The range between clinics for successful fertilisation per egg exposed to sperm was narrow (71.7%-74.5%), and for all clinics combined was 73.6%. Donor sperm was only used in 2.2% of treatment cycles, a decrease from the 3.3% of 1998 but on par with the rate of 2.3% in 1997 and 2.4% in 1996 (see Figure 2 above). The fertilisation rate using donor sperm was slightly higher than that using husbands' sperm (75.2% vs 73.5%). 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 than donor sperm (1998: 74.2% vs 70.0% and 1997: 73.0% vs 67.6%), but the opposite was true in 1996 (71.3% vs 80.7%).

Fresh embryo transfer (IVF-ET) occurred in 89.5% of treatment cycles with successful fertilisation, with a wide clinic range from 82.3% to 97.0% (see Table 5). These proportions do not just reflect the effectiveness of fertilisation and embryonic development. They will also be affected by the proportion of GIFT cycles in which eggs were exposed to sperm for embryo storage rather than fresh transfer, although in 1999 there were only a small number of treatment cycles in which eggs were replaced at GIFT. When these are excluded, fresh embryo transfer occurred in 90.4% of all IVF treatment cycles with successful fertilisation, still with a substantial clinic range of 82.9% to 97.0%. 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.

Embryos were frozen in 62.3% of treatment cycles with successful fertilisation (see Table 5), and some embryos were allowed to succumb in 67.8% of treatment cycles. The majority of embryos that were allowed to succumb were abnormal or degenerate (85.3%).

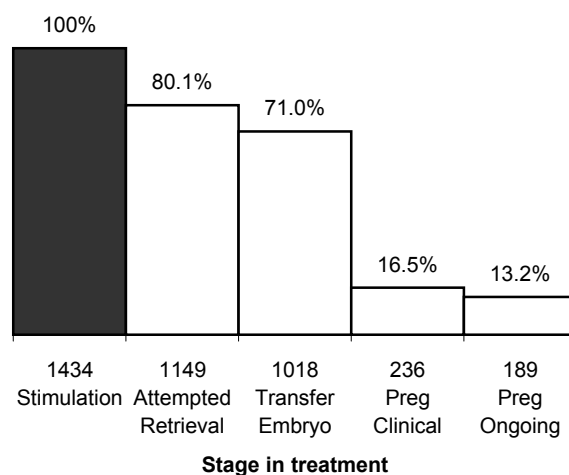
### Fresh Embryo Transfer (IVF-ET):

There were 1018 fresh embryo transfers in 1999, only 13 more than the previous year (see Table 6). Donor egg embryos and donor sperm embryos were used in 0.9% and 2.4% of fresh embryo transfers respectively. There were 236 clinical pregnancies resulting from IVF embryo transfer (20.5 per 100 egg retrieval cycles) and 189 ongoing (16.4 per 100 egg retrieval cycles, with a clinic range of 15.7-17.9). These pregnancy rates were slightly lower than in 1998 when there were 21.7 clinical pregnancies per 100 egg retrieval cycles and 17.1 ongoing pregnancies per 100 egg retrieval cycles.

The 1999 fresh embryo transfer (including ICSI) pregnancy rates reported for all Australian and New Zealand clinics combined were slightly lower than observed for the WA clinics (20.2 clinical pregnancies per 100 oocyte retrieval cycles, and 15.9 ongoing pregnancies at 20 weeks per 100 oocyte retrieval cycles).<sup>6</sup>

The clinical pregnancy rate based on all treatment cycles with stimulation begun for IVF-ET was lower than the rate per egg retrieval attempted. These lower rates can be attributed to the relatively high number of cycles which were cancelled prior to retrieval. Figure 3 illustrates that there were 16.5 clinical pregnancies per 100 stimulation cycles begun, and 13.2 ongoing pregnancies per 100 stimulation cycles.

**Figure 3: Results in subsequent phases of IVF-ET treatment, in 1999**



Of the confirmed 178 pregnancies with live births, 78.1% were singleton, 20.8% were twin, and 1.1% were triplet (i.e. 21.9% of live births were multiple). The proportion of multiple births is marginally lower than that observed in 1998 when they represented 23.3% of live births. National data for 1998<sup>#</sup> indicated that 19.4% 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 219 live births in 1999, 7 stillbirths and 1 neonatal death. This represents a perinatal mortality rate of 35.4 per 1000 total births. Most of the perinatal deaths

after IVF-ET occurred in multiple births. The 1998 perinatal mortality rate for *all* babies born in Western Australia was 9.1 per 1000 total births.<sup>7</sup>

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 2.1, and the median 2 (clinic range 1.9-2.4 with a median of 2 for all clinics). In WA the percentage of cycles with one or two embryos transferred was 80.8, which is slightly higher than that observed for all Australian and New Zealand IVF clinics combined (76.4%).<sup>6</sup> There appears to be variability in the number of embryos replaced at fresh transfer between the three Western Australian clinics. In two clinics one or two embryos were replaced in 90.7% and 85.3% of fresh transfers, while in the other clinic replaced <3 embryos in only 54.8% of transfers. This difference may influence not only the overall proportion of multiple births in each clinic (range 17.2%-30.0% of pregnancies with live births ) but also the proportion of higher order multiple births (clinic range 0-2.5% of pregnancies with live births).

Table 1 (below) compares the live birth pregnancy rate and the proportion of multiple births where one, two, three, and four fresh embryos were transferred in WA in 1999. These figures indicate that the live birth pregnancy rate was highest for two embryo transfers (19.8%). The overall proportion of multiple births was similar for 2 and 3 embryo transfers (23.2% vs. 21.7%), however, the proportion of higher order multiple births (triplets) was higher for 3 embryo transfers. There were only 3 transfers where 4 embryos were replaced.

An analysis of the implantation rate (or the proportion of embryos replaced at fresh transfer which resulted in a live birth) varied between the clinics from 9.7% to 11.4%. The implantation rate for all clinics was 10.4% and interestingly as the number of embryos transferred increased the implantation rate decreased (1 embryo: 15.2%; 2 embryos: 12.2%; 3 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 1999.**

<i>Number of embryos transferred</i>	<i>Number of fresh embryo transfers</i>	<i>Number of pregnancies with live births</i>	<i>Number of live births</i>	<i>Live birth rate (% of treatment cycles with embryos transferred)</i>	<i>Multiple birth rate (% of pregnancies with live births)</i>	<i>% higher order multiples (% of pregnancies with live births)</i>	<i>Number of stillbirths and neonatal deaths</i>	<i>Stillbirths and neonatal deaths (per 1000 total births)</i>
One	125	17	19	13.6	11.8	0	0	0
Two	698	138	171	19.8	23.2	0.7	8	39.3
Three	192	23	29	12.0	21.7	4.3	0	0
Four	3	0	0	0	0	0	0	0
Total	1018	178	219	17.5	21.9	1.1	8	35.4

**Gamete Intra Fallopian Transfer (GIFT):**

GIFT transfers accounted for only 1.3% of all assisted conception transfer procedures performed in 1999. Only two clinics carried out GIFT treatments with the majority of treatments (80.0%) carried out by one clinic. There were an estimated\* 25 treatment cycles begun for GIFT which represented 2.1% of egg retrieval cycles attempted (Table 7). The number of GIFT treatments in 1999 (25) was only one less than the number in 1998 (26). GIFT has been in decline (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 only 1 (4.0%) of the GIFT procedures, and the mean number of eggs replaced at transfer was 2.1 (median 2).

There were 7 clinical pregnancies resulting from GIFT treatment in 1999 (28.0 per 100 egg retrieval cycles), and 5 pregnancies with live births (20.0 per 100 egg retrieval cycles). All of these 5 were singleton live births. The live birth pregnancy rate was slightly higher than in the previous years (1998: 11.5; 1997: 9.5 per 100 egg retrieval cycles). These rates are not compared to national data due to the small number of GIFT transfers carried out in Western Australia in 1999.

**Frozen Embryo Transfer (FET):**

Table 8 summarises treatment cycle information for the 636 women who undertook frozen embryo transfer procedures in the reporting period. This represents an further increase in the number of women undergoing FET (1998: 590, 1997: 476, 1996: 419, 1995: 372, 1994: 232). There were 930 treatment cycles begun for FET, and they accounted for 26.0% to 52.1% of all transfer procedures (for IVF, GIFT and FET) in the different IVF clinics. Embryo transfer occurred in 97.8% of treatment cycles begun for FET, and 9.0% of these involved donated material. Donor eggs were used in 3.2% of transfers, donor sperm in 2.1%, both sperm and donor egg in 0.1% and donor embryos were used in 3.6%.

The mean number of embryos transferred at FET was 2.0 (and the median 2). There were 189 clinical pregnancies (20.3 per 100 embryo transfer cycles) and 155 ongoing pregnancies (16.7 per 100 embryo transfer cycles with a clinic range of 12.9-22.3). The ongoing pregnancy rate in 1998 was slightly lower (15.1 per 100 embryo transfer cycles). There were 149 pregnancies with live births, 84.6% were singleton and 15.4% twin. There were 4 still births and 1 neonatal deaths following FET treatment in 1999.

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 1999 was 15.7 per 100 embryo transfers with an ongoing pregnancy rate at 20 weeks of 12.1 per 100 embryo transfers.<sup>6</sup>

A large number of factors may be important in determining the wide clinic range in live birth pregnancy rates seen for FET (11.4-21.6 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.

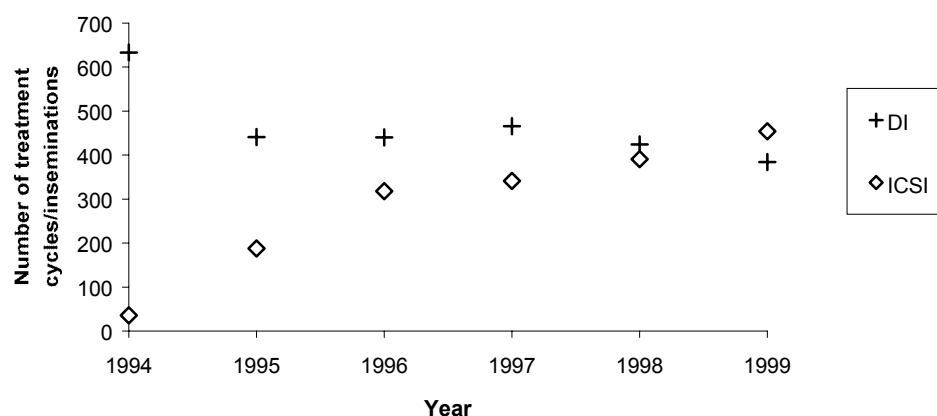
In addition, clinic preference in fresh transfer vs. freezing of higher quality embryos will affect the quality of frozen embryos replaced and therefore the pregnancy rate in each clinic.

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

### Donor Insemination (DI):

Donor insemination (DI) treatments and outcomes carried out in the reporting period are summarised in Table 9. There were 384 DI treatments undertaken by 137 women in 1999, slightly less than the 424 DI treatments undertaken in 1998. 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, for the first time since the introduction of ICSI in WA, the number of donor insemination treatments was less than the number of ICSI treatments, in 1999.

**Figure 4: Number of treatment cycles using ICSI and number of donor inseminations, 1994-1999**



The mean number of inseminations per woman treated in 1999 was 2.8 (median 2), with a clinic range of 1.7 to 3.4 (and a median range of 1-3). There were 36 clinical pregnancies as a result of DI treatment (9.4 per 100 insemination treatments) and 30 pregnancies (7.8 per 100 insemination treatments). The proportion of pregnancies with live births varied between the clinics, from 3.3 to 10.6 per 100 insemination treatments. This difference may be influenced by the differing patterns in the use of ovulation induction between clinics. Of 27 pregnancies with live births, 92.6% were singleton and 7.4% were twin. There were 29 live births, no still birth and 1 neonatal deaths. More up to date information on the use of IUI by licensees and exemptees may be found in the summary report of clinic data for 1999/00 earlier in this report.

Table 10 summarises the use of donated human reproductive material in 1999. Twenty-eight egg donors, 88 sperm donors and 19 embryo donor couples all donated material used in this period. There were 12 babies born of treatment cycles involving donor eggs, 40 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 1998 calendar year as 1999 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.

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**TABLE 2: IVF/GIFT egg retrievals and dispersals between  
1 January and 31 December 1999**

	Treatment Cycles				Women
	N	%	%	%	N
<b>IVF/GIFT treatment begun:</b>	1435 (248-692)	100.0			1034
<b>No. cycles begun per woman -</b>					
<b>Mean:</b>					1.4
<b>(range<sup>1</sup>)</b>					(1.3-1.5)
<b>Median:</b>					1.0
<b>(range<sup>1</sup>)</b>					(1.0-1.0)
<b>Cancelled:</b>	260 (2-181)	18.1 (0.8-26.2)			
<b>Total egg retrievals attempted<sup>2</sup> -</b>	1175 (246-511)	81.9	100.0		
<b>Laparoscopy:</b>	22		1.9		
<b>Trans Vaginal Ultrasound:</b>	1153		98.1		
<b>Failed retrievals:</b>	4 (0-2)		0.3 (0.0-0.5)		
<b>Successful egg retrievals:</b>	1171		99.7 (99.5-100)	100.0	
<b>Mean number of eggs</b>					
<b>per successful retrieval -</b>					
<b>All:</b>	11.6				
<b>(median)</b>	10				
<b>Laparoscopy:</b>	6.9				
<b>(median)</b>	5.5				
<b>Trans Vaginal Ultrasound:</b>	11.7				
<b>(median)</b>	10				
<b>With eggs exposed to sperm:</b>	1157			98.8 <sup>2</sup>	
<b>With eggs transferred at GIFT:</b>	25			2.1 <sup>2</sup>	
<b>With eggs donated:</b>	25			2.1 <sup>2</sup>	
<b>With eggs used for experimentation:</b>	0			0.0 <sup>2</sup>	
<b>With eggs discarded:</b>	315			26.9 <sup>2</sup>	

*Footnotes:*

1) (range<sup>1</sup>) gives the range of results from the three IVF clinics.

2) These categories are not exclusive.

3) Nine of these retrieval lead to two separate fertilisations, therefore there were 1166 fertilisations.

**TABLE 3: Number of women having different combinations of transfers<sup>1</sup>:  
IVF-ET, GIFT or Frozen Embryo Transfers (FET) between  
1 January and 31 December 1999**

Transfer Type	N	%
IVF-ET only	543	45.6
FET only	342	28.7
GIFT only	10	0.8
IVF-ET & FET	288	24.2
GIFT & FET	6	0.5
IVF-ET & GIFT	2	0.2
IVF-ET, GIFT & FET	1	0.1
<b>TOTAL</b>	<b>1192</b>	<b>100.0</b>

*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<sup>1</sup> between  
1 January and 31 December 1999**

No. of Transfers <sup>1</sup>	N	%
1	701	58.8
2	295	24.7
3	134	11.2
4	48	4.0
5	9	0.8
6	3	0.3
7	0	0.0
8	1	0.1
9	1	0.1
<b>TOTAL</b>	<b>1192</b>	<b>100.0</b>

*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 1999**

	Treatment Cycles			Eggs/Embryos			Women
	N	%	%	N	%	%	N
<b>Eggs exposed to sperm:</b> <b>(range<sup>1</sup>)</b>  <b>Mean number of eggs</b> <b>exposed to sperm</b> <b>per treatment cycle:</b> <b>(range<sup>1</sup>)</b>  <b>Median:</b> <b>(range<sup>1</sup>)</b>	1166 (244-503)	100.0		12506  10.7 (9.5-11.8)  9 (8-10)	100.0		948
<b>Using husband sperm:</b> <b>(range<sup>1</sup>)</b>  <b>Using donor sperm:</b> <b>(range<sup>1</sup>)</b>	1140  26	97.8 (96.9-98.4)  2.2 (1.6-3.1)					
<b>Using micro-manipulation -</b> <b>(range<sup>1</sup>)</b>  <b>ICSI:</b> <b>SUZI:</b> <b>PZD:</b> <b>PZD/SUZI:</b>	454  454 0 0 0	38.9 (27.0-63.1)  38.9 0.0 0.0 0.0					
<b>Failed fertilisation:</b> <b>(range<sup>1</sup>)</b>	28	2.4 (1.4-3.7)					
<b>Fertilisation occurred:</b> <b>(range<sup>1</sup>)</b>  <b>Using husband sperm:</b> <b>(range<sup>1</sup>)</b>  <b>Using donor sperm:</b> <b>(range<sup>1</sup>)</b>	1138 (235-490)	97.6	100.0	9205  8999  206	73.6  73.6 <sup>2</sup> (71.8-74.6)  75.2 <sup>2</sup> (67.3-82.4)	100.0	
<b>Fresh embryo transfer</b> <b>(range<sup>1</sup>)</b>  <b>Embryo freezing</b> <b>(range<sup>1</sup>)</b>  <b>Embryo donation</b>  <b>Embryos discarded</b>	1018  709  0  772		89.5 (82.3-97.0)  62.3 (42.1-70.0)  0.0  67.8	2107  4740  0  2358 <sup>3</sup>	16.8  37.9  0.0  18.9	22.9  51.5  0.0  25.6	

*Footnotes:*

- 1) (range<sup>1</sup>) 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 (2011) and 347 surplus embryos were discarded.

**TABLE 6: IVF-ET (fresh IVF embryo transfer) transfers and outcomes between 1 January and 31 December 1999**

	Treatment Cycles				Women	
	N	%	%	%	N	%
<b>Egg retrievals attempted for IVF-ET:</b> (range <sup>1</sup> )	1149 <sup>2</sup> (246-490)	100.0				
<b>With embryos transferred -</b> (range <sup>1</sup> )	1018 <sup>3</sup> (228-450)	88.6	100.0		834	100.0
<b>Donor -</b>						
<b>Egg:</b>	9		0.9			
<b>Sperm:</b>	24		2.4			
<b>Egg+Sperm:</b>	0		0.0			
<b>Embryo:</b>	0		0.0			
<b>Number embryos per transfer -</b>						
<b>Mean:</b> (range <sup>1</sup> )	2.1 (1.9-2.4)					
<b>Median:</b> (range <sup>1</sup> )	2 (2-2)					
<b>Clinical pregnancy -</b>						
<b>Yes:</b> (range <sup>1</sup> )	236	20.5 (20.0-22.0)	23.2 (21.8-24.7)		233	27.9
<b>No:</b>	782	68.1	76.8		601	72.1
<b>Blighted ovum:</b>	9	0.8	0.9			
<b>Missed abortion:</b>	18	1.6	1.8			
<b>Spontaneous abortion:</b>	6	0.5	0.6			
<b>Ectopic:</b>	14	1.2	1.4			
<b>Therapeutic abortion:</b>	0	0.0	0.0			
<b>Ongoing clinical pregnancy at 20 weeks:</b> (range <sup>1</sup> )	189	16.4 (15.7-17.9)	18.6 (17.8-19.3)		189	22.7
<b>Late pregnancy loss:</b>	0	0.0	0.0		0	0.0
<b>Pregnancies with live births:</b> (range <sup>1</sup> )	178 <sup>4</sup>	15.5 (14.0-16.3)	17.5 (17.1-17.8)	100.0	178 <sup>4</sup>	21.3
<b>Plurality:</b>						
<b>1</b> (range <sup>1</sup> )	139	12.1 (11.4-12.9)	13.7 (12.3-14.1)	78.1 (70.0-82.8)		
<b>2</b> (range <sup>1</sup> )	37	3.2 (2.4-4.5)	3.6 (2.9-4.8)	20.8 (17.2-27.5)		
<b>3</b> (range <sup>1</sup> )	2	0.2 (0.0-0.4)	0.2 (0.0-0.4)	1.1 (0.0-2.5)		
<b>Live Births:</b>	219	19.1	21.5			
<b>Still Births:</b>	7 <sup>5</sup>	0.6	0.7		5	0.6
<b>Neonatal deaths (within 28 days of birth):</b>	1 <sup>6</sup>	0.1	0.1			

*Footnotes:*

- 1) (range<sup>1</sup>) 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) Two treatments where both fresh and frozen embryos were transferred together in the same procedure are included in this table.
- 4) Six women were lost to follow up and their birth details were unavailable therefore they are excluded from confinement data.
- 5) Two sets of twins (ie 4 babies) and three singletons
- 6) One baby from a twin pregnancy

Note: Three women moved interstate prior to giving birth. In each case the treating clinic reported a birth outcome (three singletons), and these are included in the confinement data.

**TABLE 7: GIFT transfers and outcomes between 1 January and 31 December 1999**

	Treatment Cycles				Women	
	N	%	%	%	N	%
<b>Egg retrievals attempted for GIFT*: (range<sup>1</sup>)</b>	25 (0-20)	100.0				
<b>With eggs transferred - (range<sup>1</sup>)</b>	25 (0-20)	100.0	100.0		19	100.0
<b>Donor -</b>						
<b>Egg:</b>	0		0.0			
<b>Sperm:</b>	1		4.0			
<b>Egg+Sperm:</b>	0		0.0			
<b>Number eggs per transfer -</b>						
<b>Mean: (range<sup>1</sup>)</b>	2.1 (0-2.2)					
<b>Median: (range<sup>1</sup>)</b>	2 (0-2)					
<b>Clinical pregnancy -</b>						
<b>Yes: (range<sup>1</sup>)</b>	7	28.0 (0-30.0)	28.0 (0-30.0)		7	36.8
<b>No:</b>	18	72.0	72.0		12	63.2
<b>Blighted ovum:</b>	1	4.0	4.0			
<b>Missed abortion:</b>	0	0.0	0.0			
<b>Spontaneous abortion:</b>	0	0.0	0.0			
<b>Ectopic:</b>	1	4.0	4.0			
<b>Therapeutic abortion:</b>	0	0.0	0.0			
<b>Ongoing clinical pregnancy at 20 weeks: (range<sup>1</sup>)</b>	5	20.0 (0-20.0)	20.0 (0-20.0)		5	26.3
<b>Late pregnancy loss:</b>	0	0.0	0.0		0	0.0
<b>Pregnancies with live births: (range<sup>1</sup>)</b>	5	20.0	20.0	100.0	5	26.3
<b>Plurality:</b>						
<b>1 (range<sup>1</sup>)</b>	5	20.0 (0.0-20.0)	20.0 (0.0-20.0)	100.0		
<b>2 (range<sup>1</sup>)</b>	0	0.0	0.0	0.0		
<b>Live Births:</b>	5	20.0	20.0			
<b>Still Births:</b>	0	0.0	0.0		0	0.0
<b>Neonatal deaths (within 28 days of birth):</b>	0	0.0	0.0			

*Footnotes:*

1) (range<sup>1</sup>) gives the range of results from the three IVF clinics.

**TABLE 8: Frozen Embryo Transfers between 1 January and 31 December 1999**

	Treatment Cycles				No. of Embryos		Women	
	N	%	%	%	N	%	N	%
<b>Treatment cycles begun for FET: (range<sup>1</sup>)</b>	930 (80-512)	100.0					636	100.0
<b>Cancelled:</b>	8	0.9					8	1.3
<b>Number embryos thawed:</b>					2781	100.0		
<b>Number embryos flawed:</b>					986	35.5		
<b>Totally failed thaw:</b>	12	1.3					12	1.9
<b>Embryos transferred -</b>	910	97.8	100.0		1795	64.5	623	98.0
<b>Own:</b>	828		91.0		1619			
<b>Donor -</b>								
<b>Egg:</b>	29		3.2		62			
<b>Sperm:</b>	19		2.1		39			
<b>Egg + Sperm:</b>	1		0.1		2			
<b>Embryo:</b>	33		3.6		73			
<b>Number embryos per transfer -</b>								
<b>Mean: (range<sup>1</sup>)</b>					2 (1.8-2.7)			
<b>Median: (range<sup>1</sup>)</b>					2 (2-3)			
<b>Clinical pregnancy -</b>								
<b>Yes: (range<sup>1</sup>)</b>	189	20.3 (17.5-25.4)	20.8 (20.0-26.2)				187	29.4
<b>No:</b>	721	77.5	79.2				436	68.6
<b>Blighted ovum:</b>	7	0.8	0.8					
<b>Missed abortion:</b>	19	2.0	2.1					
<b>Spontaneous abortion:</b>	3	0.3	0.3					
<b>Ectopic:</b>	4	0.4	0.4					
<b>Therapeutic abortion:</b>	1	0.1	0.1					
<b>Ongoing clinical pregnancy at 20 weeks: (range<sup>1</sup>)</b>	155	16.7 (11.3-21.6)	17.0 (12.9-22.3)				155	24.4
<b>Late pregnancy loss:</b>	0	0.0	0.0				0	0.0
<b>Pregnancies with live births: (range<sup>1</sup>)</b>	149 <sup>2</sup>	16.0 (10.0-21.0)	16.4 (11.4-21.6)	100.0			149 <sup>2</sup>	23.4
<b>Plurality:</b>								
<b>1 (range<sup>1</sup>)</b>	126	13.5 (7.5-17.8)	13.8 (8.6-18.3)	84.6 (75.0-85.7)				
<b>2 (range<sup>1</sup>)</b>	23	2.5 (2.0-3.3)	2.5 (2.0-3.4)	15.4 (14.3-25.0)				
<b>Live Births:</b>	171	18.4	18.8					
<b>Still Births:</b>	4 <sup>3</sup>	0.4	0.4				4	0.6
<b>Neonatal deaths (within 28 days of birth):</b>	1 <sup>4</sup>	0.1	0.1					

*Footnotes:*

- 1) (range<sup>1</sup>) gives the range of results from the three IVF clinics.
- 2) Three women were lost to follow up and their birth details were unavailable therefore they are excluded from confinement data.
- 3) Three singletons and one baby from a twin pregnancy
- 4) One baby from a twin pregnancy

Note: One woman moved to NSW prior to giving birth. The treating clinic reported a birth outcome (one singleton), and this has been included in the confinement data.

**TABLE 9: Donor Insemination treatments and outcomes carried out between 1 January and 31 December 1999**

	Treatment Cycles			Women	
	N	%	%	N	%
<b>DI carried out:</b> <b>(range<sup>1</sup>)</b>	384 (30-237)	100.0		137	100.0
<b>No. DIs per woman treated -</b>					
<b>Mean:</b> <b>(range<sup>1</sup>)</b>				2.8 (1.7-3.4)	
<b>Median:</b> <b>(range<sup>1</sup>)</b>				2 (1-3)	
<b>Clinical pregnancy -</b>					
<b>Yes:</b> <b>(range<sup>1</sup>)</b>	36 (1-22)	9.4 (3.3-14.9)		35	25.5
<b>No:</b>	348	90.6		102	74.5
<b>Blighted ovum:</b>	1	0.3			
<b>Missed abortion:</b>	5	1.3			
<b>Spontaneous abortion:</b>	0	0.0			
<b>Ectopic:</b>	0	0.0			
<b>Therapeutic abortion:</b>	0	0.0			
<b>Ongoing clinical pregnancy at 8 weeks:</b> <b>(range<sup>1</sup>)</b>	30	7.8 (3.3-14.9)		30	21.9
<b>Late abortion (post 8 weeks):</b>	1	0.3		1	0.7
<b>Pregnancies with live births:</b> <b>(range<sup>1</sup>)</b>	27 <sup>2</sup>	7.0 (3.3-10.6)	100.0	27	19.7
<b>Plurality:</b>					
<b>1</b> <b>(range<sup>1</sup>)</b>	25	6.5 (3.3-8.5)	92.6 (80.0-100)		
<b>2</b> <b>(range<sup>1</sup>)</b>	2	0.5 (0.0-2.1)	7.4 (0.0-20.0)		
<b>Live Births:</b>	29	7.6			
<b>Still Births:</b>	0	0.0		0	0.0
<b>Neonatal deaths (within 28 days of birth):</b>	1 <sup>3</sup>	0.3			

*Footnotes:*

1) (range<sup>1</sup>) gives the range of results from 4 holders of Practice Licenses and pooled results from 7 Exemptees who performed 1 or more DI's during the period.

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

3) 1 singleton

Note: Two women moved interstate prior to giving birth. In each case the treating clinic reported a birth outcome (two singletons), and these are included in the confinement data.

**TABLE 10: Donation of Human Reproductive Material between  
1 January and 31 December 1999**

	IVF-ET	GIFT	FET	DI	TOTAL
<b>Number of Treatment Cycles -</b>					
<b>Donor Egg:</b>	9	0	29	-	38
<b>Donor Sperm:</b>	24	1	19	384	428
<b>Donor Egg+Sperm:</b>	0	0	1	-	1
<b>Donor Embryo:</b>	0	-	33	-	33
<b>Number of Babies Born -</b>					
<b>Donor Egg:</b>	6 <sup>3</sup>	0	6	-	12 <sup>3</sup>
<b>Donor Sperm:</b>	7	0	4	29	40
<b>Donor Egg+Sperm:</b>	0	0	0	-	0
<b>Donor Embryo:</b>	0	-	9	-	9
<b>Number of Donors Used -</b>					
<b>Donor Egg:</b>	9	0	20	-	28 <sup>1</sup>
<b>Donor Sperm:</b>	18	1	14	76	88 <sup>1</sup>
<b>Donor Embryo<sup>2</sup>:</b>	0	-	19	-	19

*Footnotes:*

- 1) There were 88 individual sperm donors and 28 individual egg donors whose sperm and eggs were used in 1999. 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 two stillbirths

## **APPENDIX 5**

### **INFORMATION CIRCULATED TO LICENSEES**

**TO** : ALL PERSONS TO WHOM THE LICENCE APPLIES UNDER THE  
*HUMAN REPRODUCTIVE TECHNOLOGY ACT 1991* TO CARRY  
OUT IN-VITRO FERTILISATION (IVF) PROCEDURES

**FROM** : PROFESSOR CON MICHAEL, CHAIR, REPRODUCTIVE  
TECHNOLOGY COUNCIL (COUNCIL)

**RE** : POSITION REGARDING IVF PROCEDURES UNDER THE HRT ACT  
IN CONNECTION WITH SURROGACY ARRANGEMENTS

**DATE** : 14 AUGUST 2000

### **Background**

You will be aware that in November 1999 the Government responded to the Report of the Select Committee on the *Human Reproductive Technology Act 1991* (HRT Act) by supporting a number of recommendations relating to surrogacy.

Currently, policy is being developed in relation to surrogacy arrangements prior to approval to draft surrogacy legislation being sought.

In March 2000 the Council wrote to remind you that section 23 of the HRT Act places stringent responsibilities on licensees carrying out any IVF procedure. In particular, the Council expressed concern about the uncertainties that may arise should a child be born in connection with a surrogacy arrangement, in the absence of legislation specifically permitting surrogacy arrangements in this state.

The following information is provided as further guidance in this matter.

### **Current Position**

The HRT Act makes no express reference to surrogacy arrangements.

However, section 23 of the HRT Act sets out the requirements which must be satisfied in order for persons to access IVF procedures and prohibits such procedures where those requirements are not met.

#### ***Section 23***

An *in vitro* fertilisation procedure may be carried out where –

- (a) it would be likely to benefit –
  - (i) persons who, as a couple, are infertile; or
  - (ii) a couple whose child would otherwise be likely to be affected by a genetic abnormality or disease;
- (b) each of the participants required to do so has given an effective consent;

- (c) the persons seeking to be treated as members of a couple are –
  - (i) married to each other; or
  - (ii) are co-habiting in a heterosexual relationship as husband and wife and have done so for periods aggregating at least 5 years, during the immediately preceding 6 years;
- (d) the reason for infertility is not age or some other cause prescribed for the purpose of this paragraph; and
- (e) consideration has been given to the welfare and interests of –
  - (i) the participants; and
  - (ii) any child likely to be born as a result of the procedure,and in the opinion of the licensee that consideration does not show any cause why the procedure should not be carried out,

but not otherwise.

The words “persons seeking to be **treated as members of a couple**” in s.23(c) of the HRT Act can be taken to mean the treatment being sought by the couple is an IVF procedure to be carried out upon the female member of the couple.

As such, the implantation of an egg or embryo into a surrogate would not fall within the requirements of s.23 of the HRT Act because the person being treated, ie the surrogate, is not a member of the couple.

Accordingly it appears that under s.23 of the HRT Act as it presently stands, IVF procedures are not permitted to be carried out upon surrogates for the purposes of surrogacy arrangements.

On this basis, it follows that licensees are not to permit or facilitate the export of an embryo from Western Australia use in an IVF procedure for the purpose of a surrogacy arrangement. (Direction 6.4)

### **Recommendation**

It is recommended that any licensee contemplating carrying out an IVF procedure upon a surrogate or permitting/facilitating the export of embryos from this State for such purpose, seek legal advice on the lawfulness of these actions under the HRT Act.

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Con Michael, Chair, Reproductive Technology Council

**TO:** ALL PERSONS TO WHOM THE LICENCE APPLIES UNDER THE *HUMAN REPRODUCTIVE TECHNOLOGY ACT 1991* TO CARRY OUT ARTIFICIAL FERTILISATION PROCEDURES, AND ALL MEDICAL PRACTITIONERS EXEMPT FROM THE REQUIREMENT TO BE LICENSED TO PERFORM ARTIFICIAL INSEMINATION PROCEDURES

**FROM:** PROFESSOR CON MICHAEL, CHAIR, REPRODUCTIVE TECHNOLOGY COUNCIL (COUNCIL)

**RE:** POSITION REGARDING PARENTAL RIGHTS AND RESPONSIBILITIES OF DONORS OF HUMAN REPRODUCTIVE MATERIAL FOR CHILDREN BORN AS A RESULT OF ARTIFICIAL FERTILISATION PROCEDURES UNDER CERTAIN CIRCUMSTANCES PURSUANT TO THE *ARTIFICIAL CONCEPTION ACT 1985*

**DATE:** 14 AUGUST 2000

### **Background**

The Government Response to the Report of the Select Committee on the *Human Reproductive Technology Act 1991* (HRT Act) tabled on 24 November 1999 supported the recommendation that, if found to be conflicting with the HRT Act, the Artificial Conception Act 1985 (AC Act) should be amended to ensure that gamete donors would have no legal responsibilities for offspring.

The Ministry of Justice is addressing amendment of the AC Act.

### **Current Position**

Currently it appears that the AC Act may not shield donors of gametes or embryos from parental rights and responsibilities (including maintenance) in circumstances where a child is born, as a result of an artificial fertilisation procedure using donor material, to a:

- single woman,
- married woman (de jure or de facto) whose husband/partner has not consented to the artificial fertilisation procedure, or
- woman who has undergone a gamete intra fallopian transfer (GIFT) procedure.

“Artificial fertilisation procedure” under the HRT Act includes artificial insemination, *in vitro* fertilisation (IVF) and GIFT procedures.

“Fertilization procedure” under the AC Act includes artificial insemination and IVF procedures, but it is unclear whether GIFT procedures are included in this reference.

## Requirements under the HRT Act

Accordingly, you are reminded of the following requirements under the HRT Act:

### Duty to Inform

- Prior to giving consent to donate or use donated reproductive material, all prospective donors and recipients must have their attention drawn (ie. given oral explanation supported by written information) to the uncertainty in the application of –
  - i) the AC Act and in particular the likely exceptions to the protection otherwise provided in that Act to donors of reproductive material in terms of parental rights and responsibilities, as set out in the 3 instances described above,
  - ii) the Family Law Act 1975 (CW).

(Direction 4.2)

- Given the requirement for spouses/de facto partners, if any, of prospective donors to give effective consent to the donation or use of donated reproductive material, it would be prudent for those persons to also be informed of these matters prior to giving consent to the donation or use.  
(Direction 3.4, 3.5, 3.6, and 3.9)
- Before a licensee/exempt practitioner gives effect to a consent to an artificial fertilisation procedure, each participant (including donors) must be provided with a suitable opportunity to receive proper counselling about the implications of the proposed procedure and such other relevant and suitable information as is proper or required by the Directions.  
(Section 22(7) of the HRT Act, Direction 4.2)

### Written Consent

- Prior to the donation or use of donor reproductive material for an artificial fertilisation procedure effective consent is required from all participants and their respective spouses/de facto partners, if any. To be effective, consent to the donation or use of gametes, eggs in the process of fertilisation or embryo must be in writing. Such written consent is required of all donors; recipients of donated reproductive material and their respective spouses/de facto partners, if any.

For example, where an artificial fertilisation procedure using (or directing for use) donated reproductive material is contemplated for a married woman (de jure or de facto) the written and effective consent of her husband/de facto partner to the procedure must be obtained.

(Section 22(8) of the HRT Act, Direction 3.4, 3.5 and 3.6)

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Con Michael, Chair, Reproductive Technology Council

**GENERAL APPROVAL  
UNDER THE *HUMAN REPRODUCTIVE TECHNOLOGY ACT 1991*  
OF  
SOME REPRODUCTIVE TECHNOLOGY RESEARCH  
INVOLVING PARTICIPANTS.**

The Reproductive Technology Council (Council) has by resolution granted general approval under s20(2)(b) of the *Human Reproductive Technology Act 1991* (**Act**) for licensees to carry out, authorize, facilitate or become involved in the following categories of reproductive technology research involving adult participants:

- Non invasive research relating to reproductive technology, such as surveys of participants during a current treatment cycle, subject to these being carried out with effective consent of participants and approval for the particular research project having been sought and gained from the relevant Institutional Ethics Committee (IEC).
- Research based on records (described in s44(1) of the Act and relating to artificial fertilisation (AF) procedures held by licensees), subject to compliance with confidentiality requirements of the Act (in particular s49 (2)(a); s46(4)(b)) and approval for the particular research project having been sought and gained from the relevant IEC, which should determine whether participant consent is required.
- Research involving additional testing of samples collected at time of the AF procedure, subject to the effective consent of participants for each purpose for which testing will occur and approval for the particular research project having been sought and gained from the relevant IEC. This research may involve some additional testing of samples or extra volumes (such as blood).

At no time shall research needs dictate clinical decision making.

Approval for any changes or additions to approved clinical or laboratory procedures remain subject to the current Directions, under which the person responsible must obtain the specific approval of the Council for any proposed research, or any clinical or laboratory procedure that may be considered innovative (Directions 9.3, 9.4). Any proposed change or addition to approved routine clinical or laboratory procedures is to be notified by the person responsible to the Council prior to the introduction of the change in accordance with Direction 9.2.

**Agreed by resolution at a meeting of the Reproductive Technology Council, 6 February 2001.**

**ASSISTED HATCHING: Standards and conditions for approval as an innovative practice under the *Human Reproductive Technology Act 1991* (Act)**

**WA Reproductive Technology Council, July 2000**

**Background**

At its meeting of 27 June 2000 the Reproductive Technology Council (Council) agreed to recommendations of its Scientific Advisory Committee that, based on available information in the peer reviewed literature, assisted hatching (AH) may now be approvable under the Act as an innovative practice. The Council also agreed to certain criteria or conditions to be placed on any approvals granted and on what would be required of applications.

A recent review article by A. de Vos and A. Van Steirteghem (Cells, Tissues, Organs 2000; 166:220-227) (attached) reported five randomised controlled studies which suggested that AH was of no benefit to the overall patient population, but might be of value in increasing embryo implantation rates in selected cases. There was no evidence of benefit for patients simply of advanced maternal age and findings in relation to the use of AH for cases with thicker zonae were contradictory. There was no theoretical cause for concern in relation to increased birth defects, but multiple pregnancy was of major concern.

### **Standards and conditions for current approval of assisted hatching under the Act**

The Council considers that, in its considered opinion, information in the peer reviewed literature suggests AH may now be approvable under the Act as an innovative practice under the following conditions-

- The technique used should be limited to partial zona dissection and zona drilling with acid Tyrode's solution, unless adequate justification can be given for the use of other methods
  - AH should only be offered to women aged 38 or older with elevated basal FSH ( $>12$  iu/l) and poor prognosis embryos (ie thick zonae, low developmental rate and/or excessive fragmentation), or women with 3 or more failures of implantation following IVF, unless adequate justification can be given for extension of these criteria
  - Clinics should carefully consider the risk of multiple births in decisions about the numbers of AH embryos to be implanted, and to include information about these risks in their patient information
  - Patient information should also include specific information from the literature about the likely safety and effectiveness of the procedure and what is known about birth outcomes
  - Clinics using AH should monitor outcomes of treatments and report on these in the short term (up to birth). At the time of annual reporting (and any other time as requested by the Council) any clinic using AH should notify the Council how many women and treatment cycles it was used for, and what the indications for use were. Clinics should also provide information about any birth outcomes (including monzygosity or otherwise of twins) in these reports
  - The Council should ensure that standard reporting requires clinics using AH to provide these short term outcomes for the use of AH, but also allows the Council to monitor and report on the longer term outcomes of treatments using AH
- Any clinic proposing to carry out AH must provide evidence that their staff have suitable experience and expertise to perform AH effectively, which may include experience with animal embryos.

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

January 2001

### **Background**

Given the widely acknowledged need for the ongoing evaluation of short and long term outcomes of treatment by intra-cytoplasmic sperm injection (ICSI), the Reproductive Technology Council still considers this to be an 'innovative practice'.

These draft Minimum Standards have been developed by the Reproductive Technology Council (Council) based on the experience of members, the peer-reviewed literature and consultation with the clinics. Following their implementation they will set the standards for the use of ICSI in Western Australia. They may be amended from time to time to reflect the current state of knowledge about the procedure and its outcomes.

Preliminary discussion by the Council's Scientific Advisory Committee was based on a discussion paper prepared for the Council by Ms Michele Hansen. This paper laid out the questions to be considered in deciding whether any screening and/or follow-up requirements should be imposed on WA clinics offering ICSI treatment, with attachments describing the history of ICSI approval in WA clinics; the results of follow-up research on ICSI infants in WA; information about variations to the traditional ICSI technique and their safety implications; and options for follow-up of ICSI infants.

The following paper includes a summary of current concerns about ICSI (section 2); currently acceptable minimum standards for ICSI (section 3); minimum standards for required screening prior to ICSI (section 4); follow-up of ICSI offspring (section 5); and a position paper on the current state of knowledge about treatment outcomes (section 7).

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

January 2001

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 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 including-
    - 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 fertilisation rate <10% 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.

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

January 2001

## **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 of ICSI offspring**

- 3.1 Factors that should be addressed by follow-up studies -
- Birth defects
  - Gonadal dysgenesis and genital malformations
  - Sex chromosome anomalies
  - Cancer
  - Intellectual handicap and psychiatric disorder
  - Morbidity
  - Cerebral palsy
  - Cystic fibrosis
  - Infertility in ICSI adult offspring

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

January 2001

## **3.2 Follow-up by the Council**

- The Council should request that the Reproductive Technology Unit (RT Unit) routinely monitor birth outcomes through data linkage, at the time of annual reporting.
- The Council should 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.

## **3.3 Follow-up by licensees**

- The clinics should be required to provide an annual report of short-term outcomes of ICSI, where possible including birth outcomes. They should also continue to be required to report any matters of concern arising from their own experience or from the literature.
- Clinics should also be encouraged to design and carry out their own additional follow-up studies.

## **3.4 Options for follow-up by other researchers.**

- The Council should write to all clinics and research bodies such as the Institute for Child Health Research, Edith Cowan University (Professor Alan Bittles) and UWA Department of Anatomy and Human Biology pointing out the importance of this research and offering endorsement from the Council for carrying it out.
- The Council should also consider supporting the pursuit of collaborative research.

## Summary of current concerns about ICSI

- To date most studies show that clinical outcomes are similar with IVF and ICSI, with no increase in multiple births or major birth defects when ICSI is compared to IVF. However, a recent study using WA data found that both these groups have a two-fold excess risk of major birth defects compared to naturally conceived infants.
- There is well documented increased genetic risk in couples attempting ICSI, including documentation from a cohort of couples assessed in WA which showed that among 168 males with 'unexplained' low sperm counts, 22% were found to have a genetic disorder as the probable cause.
- Data from Belgium also suggests that there may be a four-fold increased risk of sex chromosome anomalies in ICSI offspring compared to the general population (0.83% compared to 0.19-0.23%). An increased prevalence of autosomal chromosome aberrations has also been suggested.
- The available literature also suggests reason for particular caution in the use of immature testicular cells, in part because of the difficulties in identification of immature cells, but also because of the risk of transmission of chromosomal aberrations, of de-novo chromosomal aberrations, of genetic transmission of Y chromosome deletions and of genomic imprinting anomalies which could only be detected later in development.
- There is evidence that a reduction in the prevalence of multiple births following assisted conception (including ICSI) would markedly reduce the numbers of infants progressing to advanced retinopathy of prematurity and cerebral palsy.
- Available information suggests no cause for concern about childhood cancers following ICSI although the length of follow-up is still quite short (the median in one study was only 3 years and 9 months). Two studies, both criticised for study design, showed conflicting findings about mental development in ICSI offspring.
- Concerns have been expressed in the literature about the potential for polyspermia and increased risk for cytogenetic abnormalities where ICSI is used in the re-fertilisation of oocytes that have failed to fertilise in conventional IVF ('rescue ICSI').
- The decision to use ICSI should be a clinical decision made in advance and not on the day of egg retrieval when informed consent and reflection is impossible, yet that is often not the case.

**Position Paper on the current state of current state of knowledge about treatment outcomes associated with use of the ICSI technique.**

(Reproductive Technology Council July 2000).

When the ICSI technique was developed a number of possible reasons why birth defects may occur more commonly in ICSI babies were identified by scientists<sup>1-3</sup>.

These potential risks include:

- (i) the risks associated with using sperm which potentially carry genetic abnormalities, some of which may be related to the cause of the infertility, e.g. the specific mutations associated with infertility seen in some cases of cystic fibrosis;
- (ii) the possibility of using sperm with structural defects, which again may or may not be related to the cause of the male infertility, e.g. using spermatozoa with impaired centrosome activity;
- (iii) the potential for mechanical and biochemical damage associated with the actual injection process, and the possible introduction of foreign material into the oocyte during the injection process;
- (iv) and finally, there is the issue of the selection, by the ICSI technician, of a single sperm for injection into a single oocyte which bypasses all natural selection processes.

These theoretical concerns will become real concerns if they lead to abnormalities in the babies born following ICSI.

To date most studies<sup>4-11</sup> show that clinical outcomes are similar with IVF and ICSI, with no increase in multiple births or major birth defects. However, many of these studies have suffered from methodological limitations including small sample size and inappropriate comparison groups. Researchers have consistently compared the prevalence of birth defects in ICSI infants to that in infants from the general population classified according to different definitions of what constitutes a birth defect, and which are major and minor. (see Endnote)

A large number of children born following ICSI will need to be examined in well designed studies before we can be certain whether or not these babies are at an increased risk of having major birth defects.

The number of potential concerns increase when sperm are obtained from testicular biopsy or epididymal aspiration, in part because of the difficulties in identification of immature cells, but also because of the risk of transmission of chromosomal aberrations, of de-novo chromosomal aberrations, of genetic transmission of Y chromosome deletions and of genomic imprinting anomalies which could only be detected later in development.<sup>12,13,14,15</sup> As yet the number of children born following ICSI using sperm from testicular biopsy or epididymal aspiration is far too small to allow us to reach any conclusions about their risk of major birth defects. We simply do not have enough information about this particular group at present to reach a conclusion either way.

At present, because of the risk of undetected polyspermia and an increased risk of cytogenetic abnormalities there are concerns about the use of ICSI to re-fertilise eggs that have failed to fertilise by conventional IVF.<sup>16,17</sup>

Infants conceived by ICSI appear to be at greater risk of sex chromosome anomalies than the general neonatal population.<sup>4, 5, 12, 18</sup> Reports from the large Belgian ICSI cohort<sup>5</sup> suggest that ICSI infants have a four-fold excess risk of sex chromosome anomalies (0.83% (95% CI 0.3 to 1.6%)) compared to the range of estimates reported in the literature for the general neonatal population (0.19-0.23%). An increased prevalence of autosomal chromosome aberrations has also been suggested.

To date there have only been two studies that have looked at mental development in ICSI children, each with differing results. One study<sup>19</sup>, conducted in Sydney, found ICSI children had lower scores on the Bayley Mental Development Index (MDI) than IVF and naturally conceived children while a Belgian study<sup>20</sup> found that both ICSI and IVF children had a very high MDI assessed with the same scale. Both studies have been criticised in the literature<sup>21</sup> because of small sample size and the potential for biased sample selection in terms of parental socio-economic background. In addition, the Bayley MDI may not be an appropriate scale for use in predicting later mental development so the results from these studies may only have a low to moderate correlation with later intellectual functioning.

A number of studies suggest that a reduction in the prevalence of multiple births following assisted conception (including ICSI) would markedly reduce the numbers of infants progressing to advanced retinopathy of prematurity and cerebral palsy.<sup>22,23,24</sup>

Finally, according to three studies in the literature,<sup>25,26,27</sup> the incidence of cancer in children conceived by assisted conception is not significantly increased above the incidence for the general population. These studies have only included a limited number of infants conceived by ICSI and the length of follow-up is still relatively short (the median length in the most recent study<sup>25</sup> was only 3 years and 9 months).

***Endnote:***

One study<sup>28</sup> in particular has highlighted the problem of inappropriate comparison data. This study reclassified the birth defects reported from a large Belgian ICSI<sup>29</sup> cohort according to the classification system used by the Western Australian Birth Defects Registry. The study found that Belgian ICSI infants had a two-fold excess risk of major birth defects compared to infants born in Western Australia over the same time period. The Belgian group's response to this reclassification was to argue that the ICSI children had been more closely scrutinised for the presence of birth defects as part of an intensive follow-up study and that the majority of the heart defects found were detected by ultrasound examination after birth.<sup>30</sup> Naturally conceived infants would not normally be subject to this level of scrutiny. They explained that many of the heart defects were transient, closing spontaneously before 1 year of age and should not have been reclassified as major birth defects by the Western Australian group. Excluding these defects gave a prevalence of major malformations of 5.23% compared to the 3.78% observed in Western Australia (odds ratio 1.41 (95% confidence interval 0.91 to 2.16)), which was not statistically significant.

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

**FROM: DR MARK McKENNA  
DEPUTY CHAIR  
REPRODUCTIVE TECHNOLOGY COUNCIL**

**DATE: 10 JULY 2001**

**RE: IMPORT OF DONATED HUMAN REPRODUCTIVE  
MATERIAL**

### **Background**

There are occasions when a WA clinic may wish to import donated human reproductive material (usually semen) from outside the state. This may either be from interstate or from overseas.

A number of requirements of the *Human Reproductive Technology Act 1991* (Act) and Directions are applicable to these situations. Approval by Council for importation in each case is not required. Rather compliance with requirements under the Act is left to the licensee. Council is able to monitor compliance with these requirements in accordance with Direction 6.1.

Put simply, exceptions aside, Direction 6.1 prohibits the importation of donated gametes, unless the licensee ensures that all the information required under the Act for the Register is available, including donor identification. Monitoring of information available from the Reproductive Technology Register indicates that up to December 31 1998 there has been compliance with Direction 6.1, although 16 sperm donors resided outside the State (including 11 from overseas).

However in relation to the issue of importation of donated human reproductive material into Western Australia, there are two other important aspects requiring licensee compliance with the Directions, namely:

- The requirements relating to effective consent of the donors;
- The five family limit for each donor.

### ***Consent of Donors***

Prior to the importation of human reproductive material, licensees need to ensure they have complied with all of the relevant requirements of the Act and Directions, such as those relating to consent (Ss.22 (1), (3), (6-9); Directions 3.1, 3.5, 3.9, 4.2, 7.1 ).

The licensee remains responsible under the Act to ensure the requirements of the Act and Directions are complied with.

### **The Five Family Limit**

Direction 8.1 provides for limits to the number of offspring a donor may have.

“Direction 8.1 The licensee 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.”

It should be noted that this limit is explicit and may be stricter than that set in most other jurisdictions, including Denmark.

### **Recommendations**

Licensees are advised to consult with their legal advisers concerning compliance with the provisions relating to consent in circumstances where importation of human reproductive material is being contemplated.

Licensees are reminded not to import semen from any source unless the licensee can ensure for each donor of gametes there are no more than five known donee families.

### **Future changes**

The Council is currently reviewing the position concerning importation of donated material. Where, following its review the Council considers it appropriate, it may make some recommendations to the Commissioner regarding changes to the Directions.

It should be noted however that, in the event the Act is amended to provide a right of access by offspring to identifying information about the donor (as recommended by the Select Committee), sperm may not be imported from sources that are unable to release details of donor identity to participants.

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Mark McKenna, Deputy Chair Reproductive Technology Council

**APPENDIX 6**

**AUDIT OF COUNSELLING:**  
**Phase one.**

## **AUDIT OF COUNSELLING: Phase One**

### *Introduction*

A Parliamentary Select Committee that reviewed the Human Reproductive Technology Act 1991 (Act), during 1997-1999, considered the importance of information and counselling for people accessing assisted reproductive technology treatment. The Select Committee recognised that these matters have been the subject of discussion since reproductive technology services became available for infertile people.

From the information it received, the Select Committee was concerned about whether obligations with regard to counselling were being met and whether counselling was seen as an integral part of assisted reproductive technology treatment. Whilst most people receive information from approved counsellors before signing consents to treatment, few seemed to receive support and therapeutic counselling through the fertility clinics from approved counsellors during their treatment cycles.

To determine ways that the uptake of counselling services by approved counsellors could be improved, the Select Committee recommended an audit of these services.

The valuable role of support groups for people accessing assisted reproductive technology treatment was also recognised and it was recommended that the audit include the role of support groups.

The Government Response to the recommendations of the Select Committee, tabled in November 1999, endorsed the recommendations in relation to the audit of counselling and support groups. In May 2000, the Minister for Health referred this recommendation to the Reproductive Technology Council (Council) for action. The Reproductive Technology Council Counselling Committee conducted the audit.

### *Background information*

#### *National and State guidelines*

The importance of informed decision making and counselling, for people accessing assisted reproductive technology treatment, has been confirmed and promoted at national as well as State level.

The National Health, Medical and Research Council (NHMRC) and the Reproductive Technology Accreditation Committee (RTAC) both provide guidelines on informed decision making and counselling. Guidelines have been prepared for RTAC Accreditation of Counselling Services.

The Human Reproductive Technology Act makes a number of provisions to ensure that people have access to information before they consent to treatment, and also that people have access to counselling. The Directions provide amplification on the ways that these provisions must be met.

Section 5 of the Directions deals with Assistance with Decision-making and Counselling. It states that a licensee of a clinic must ensure that all couples

undergoing IVF procedures have access to an approved counsellor<sup>1</sup>. The licensee must ensure that the cost of at least one hour with an approved counsellor for each IVF cycle begun, as well as an extra hour when the decision is being made to withdraw from further IVF treatment, is included in the overall cost of treatment.

Gamete and embryo donors and recipients are also *strongly encouraged* to undertake counselling, and at least one hour of counselling is *compulsory* for persons using known donations. (This latter requirement has recently been under scrutiny by the Council. It has been decided that an approved counsellor must provide a minimum of three hours counselling when a donor is known to a recipient, and that recipients and donors be seen separately and then together, in three individual sessions. The current Directions are to be modified accordingly).

### *Description of counselling*

There is a substantial body of literature that defines counselling and describes its main areas. These can be broken into three broad areas, namely, informed decision-making; support; and therapy. The Select Committee provided a similar breakdown, taken from the Human Fertilisation and Embryology Authority (HFEA) (UK).

HFEA divides counselling into three areas, namely:

1. implications counselling - involves information gathering, increasing understanding of the issues per se and the implications for patients, their families and for any children born as a result of the treatment;
2. support counselling - gives emotional support at times of particular stress; and
3. therapeutic counselling - helps people to identify and deal with the implications and consequences of infertility and treatment, to adjust their expectations and accept their situations.

Numbers one and two can, to some extent, be provided by a number of people, including a variety of clinic staff, for example, doctors, nurses, genetic experts, administrative staff, and scientists. Support counselling is often provided within a person's family and social networks.

Generally professional counsellors, those who are trained to assist people in dealing with complex emotional and social issues, provide therapeutic counselling. Professional counsellors also can, and often do, provide information and support. There are no defined lines between the three types of counselling, with the provision of information and support often being interspersed with therapeutic services.

There can be a blurring between the role of professional counselling and the role of other professional staff who provide information and support.

### *Infertility counselling issues*

Given the complexity of fertility treatment from medical, ethical, and psychosocial perspectives it is likely that many people accessing treatment may need counselling in

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<sup>1</sup> Approved Counsellors must be recognised as such by the Reproductive Technology Council and be eligible for full ANZICA membership. They must have appropriate training and qualifications in counselling theory and technique; substantial and satisfactory supervised, post-training counselling experience; and reasonable knowledge of life-span issues associated with infertility and psycho-social issues in infertility treatment.

all or some of the three counselling areas to some degree, at some time during the course of treatment.

At the beginning of the process, recognising the impact of infertility and making decisions about future lifestyle can be a major issue for resolution. Obtaining information on the pathways for creating a family and weighing up the pros and cons of each option is another important early consideration. Then the treatment options with the advantages and disadvantages of each need to be examined. During the course of treatment people have to adjust to the physical and emotional effects of treatment. The success or lack of success also has to be adjusted to. Depending on people's philosophical, moral or religious beliefs, they may have to come to terms with moral dilemmas.

It can be concluded, therefore, that people accessing assisted reproductive technology treatment need information for informed decision-making and support during the process of treatment, but some of this may be provided outside the confines of professional counselling. For example, comprehensive information may be available in written form. Support services are often available within people's family and support structure. However, some people may need professional therapeutic counselling at some stage(s) of the process.

Some people may be annoyed that they have to attend counselling sessions in order to access medical treatment. This is not a requirement for other types of medical treatment. Neither do parents who conceive naturally have to be 'counselled' before they get pregnant. Therefore they may refuse to participate. Others may feel that receiving counselling implies that they have 'problems'. Others may have access to adequate counselling outside the parameters of the fertility clinics.

A particular function of this audit was to find out the reasons for the perceived poor uptake of support and therapeutic counselling, as provided through fertility clinics.

#### *Extent of audit*

The Reproductive Technology Council Counselling Committee considered the intent of the Select Committee's recommendations. The Select Committee agreed that information and counselling are important components of receiving fertility treatment. It was concerned that many people participating in treatment are not receiving support and therapeutic counselling through the clinics from professional counsellors (approved counsellors under the Act). It also wished to find out the extent of the role of support groups in relation to the provision of support and information.

Based on the Select Committee's findings and recommendations, it was decided that the following areas required auditing:

- the awareness of people about the counselling services by approved counsellors available through the fertility clinics;
- people's perceptions of the components of counselling;
- reasons for participating or not participating in counselling provided by approved counsellors through the clinics;
- the perceived benefits of counselling;
- the perceived limitations/drawbacks of counselling;

- obtaining views on specific issues, eg confidentiality of counselling, the preparation of assessment reports, whether counselling should ever be mandatory, and group counselling;
- changes to the current system that could improve access to counselling services by approved counsellors;
- in relation to support groups – people’s awareness and use of them, and their views as to their effectiveness.

Obtaining the views, opinions and experiences of groups with possibly different perspectives was considered important. Three such groups were identified, namely:

1. Consumers;
2. approved counsellors; and
3. clinic staff.

### *Objectives of the audit*

The objectives of the audit were as follows:

- to discover whether consumers were being made aware of their entitlements in relation to counselling by approved counsellors through fertility clinics;
- to determine the number of consumers of assisted reproductive technology treatment who reported that they had received, or were receiving, counselling from approved counsellors through the fertility clinics and the perceived benefits of such counselling;
- to ascertain the reasons why consumers used, or did not use, counselling services from approved counsellors through the fertility clinics;
- to obtain the views of consumers, clinic staff and approved counsellors on specific issues, eg the need for mandatory counselling, confidentiality in counselling, counsellors preparing assessment reports, issues in relation to donors and recipients of donated gametes and embryos;
- to find out the perceptions of consumers, clinic staff and approved counsellors on the role and benefits of counselling;
- to get advice on possible changes to the current clinic arrangements that could increase the take up rate of counselling services from approved counsellors; and
- to find out whether people using fertility services were aware of, and use support groups and their perceptions of their role and effectiveness.

### *Methodology*

#### *Two phases*

It was decided to conduct the audit of counselling in two phases. In the first phase the views of consumers, approved counsellors who provide regular services for fertility clinics, and clinic staff were canvassed. These views relate mainly to counselling by approved counsellors rather than other ‘informal’ counselling provided by other clinic staff.

In the second phase, the views of a wider 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 individual and families.

### *First phase*

Written questionnaires were distributed to 'clinic' counsellors, clinic staff and consumers. The questions were prepared to meet the objectives as set out above, and were adapted for each of the three study groups. A pilot group of consumers provided input into the final questionnaire used.

### *Sample*

The survey sample was obtained in the following way:

- Consumers: clinics were asked to hand out a questionnaire to all patients using IVF treatment for a nominated one-month period. In addition, all donors making donations in the same nominated month were to be asked to complete a questionnaire. That one-month period was extended to allow a greater response rate from consumers.
- Clinic staff: staff of all clinics were asked to complete a questionnaire.
- Approved Counsellors: the counsellors who provide a regular service to a clinic were sent a questionnaire.

### *Second phase*

A questionnaire was sent to the remainder of approved counsellors and to a range of other counsellors working in family related agencies. This questionnaire was less specific and canvassed views on the broader issues of infertility. This phase commenced in August 2001.

**APPENDIX 7**  
**CLONING: Multiplying questions**

## **CLONING: Multiplying questions**

**About cloning: considering the procedures, their medical and ethical implications and potential policy responses.**

**‘Cloning’ is taken to mean the production of a cell or organism with the same nuclear genome as another cell or organism<sup>1</sup>.**

Since Dolly the Sheep bounded on to our horizons in early 1997 the press and the scientific literature have been obsessed with cloning, but as the years have gone on the questions and answers seem to keep multiplying and community interest in them has not waned.

In August 2001 President Bush announced the lifting the total ban in the US on the use of Federal funding for human embryo research. Federal funds may now be used for the funding of some research using embryonic stem cells, but although limited to the 64 existing human embryonic stem cell lines already in existence around the world, there may now be exploration of the potential of these cell lines. No Federal funds are to be used for the derivation or use of stem cells from newly destroyed embryos or for the creation of embryos for research purposes. This position reflects the President’s fundamental commitment to preserving human life, but also his desire to promote vital medical research.

Italian doctor Antinori has shocked and outraged the world with his plans to produce the first cloned human by the end of 2002. The Australian Government has embarked on a fast moving process towards the development of a national ban on human cloning and consistent regulation of assisted reproductive technology and related procedures (such as those that would enable the production of embryonic stem cell lines), with the goal of having this regulation in place by the middle of 2002.

**There are two distinct types of cloning, which overlap in some ways but are also quite distinct.**

**‘Human cloning’** (or sometimes, to make it quite clear, ‘human reproductive cloning’), refers to the use of cloning technology (such as somatic cell nuclear transfer) with the deliberate intention of producing a person who is a genetic copy of another person.

The other type of cloning, which may be called **‘therapeutic cloning’**, refers to medical and scientific applications of cloning technology which do not result in the production of genetically identical fetuses or babies<sup>1</sup>. Therapeutic cloning may give rise to tissues that have the potential for a myriad of therapeutic applications in the treatment of diseased tissues or organs, for delivery of healthy genes to organs with missing or defective proteins and for basic research into human development.

Issues and concerns for each of the types of cloning will now be considered in more detail.

### **Human cloning (reproductive cloning).**

Dolly the sheep was produced by ‘somatic cell nuclear transfer’ (SCNT), after the transfer of the nucleus of an adult breast cell to an enucleated donor egg. The revolutionary aspect of this procedure was that a fully differentiated adult cell had been ‘re-programmed’ through the procedure, to develop into a new animal. Prior to this cloning had been achieved in frogs and cattle, but only by the transfer of undifferentiated embryonic cells.

However, SCNT is not always a cloning procedure and has been used in a controversial IVF programme to transfer the nucleus of a fertilised egg to an enucleated donor egg in order to avoid transmission of a mitochondrial disease<sup>2</sup>. To complicate the issues further, reproductive

cloning may also be achieved through splitting of an embryo ('artificial twinning'), as has been carried out successfully in cattle and mice for many years and occurs naturally during the development of identical twins.

Reproductive cloning is currently thought by most scientists to be dangerous<sup>3</sup>. Enough evidence has accumulated since Dolly, through reports of the birth of 'successful' clones of mice, cattle, goats, and pigs, to confirm that the procedures are extremely inefficient and result in multiple gestational and neonatal failures. At best only a few percent of embryos developed survive to birth and many die in the perinatal stage. The 'large offspring syndrome' is common and placental malfunction is thought to lead to the embryonic death frequently observed. Newborn clones often display respiratory distress and circulatory problems and even apparently healthy survivors may suffer immune dysfunction or kidney or brain malformation. These problems appear to be explained by failures in genomic reprogramming. For defects of this type there are no methods of detection (such as through prenatal diagnosis) available now, or in the foreseeable future.

It is vital to consider separately concerns that relate to known and unknown risks of the procedure, and concerns inherent to cloning itself.

Important aspects for consideration include<sup>4</sup>-

- The intention or objective behind the procedure.

For example, the cloning of an existing child may be desired to provide a compatible tissue donor, or so a couple can have a second child in cases of secondary infertility. The cloning of an adult would allow an infertile couple to have a child who is the genetic offspring of one of them, without having to resort to use of an unknown gamete provider, or it would enable a person in a homosexual relationship or a single woman to reproduce alone. It would also enable someone to have a child of known (and desired) phenotype.

- The circumstances of the procedure.

How the procedure is carried out, how safe and effective it is, the significance of the destruction of many embryo in the process, the 'opportunity cost' of resources needed and whether the cells came from an embryo or an adult are all relevant.

- The consequences of the procedure.

For example, attention needs to be paid to the interests of the child (Is it in the child's interest to be born with an expected and desired phenotype and to know their genetic heritage eg susceptibility to certain illnesses?), to the potential impact on society at large, to issues relating to discrimination towards those who can afford the treatments.

Human cloning is already banned under legislation in WA, SA and Victoria and in June 2001, when the Commonwealth Gene Technology Act 2000 came into operation, its s.192B brought in a ban on human cloning, applicable to corporations. Human cloning is prohibited under the National Health and Medical Research Council's 'Ethical guidelines for assisted reproductive technology'. The Australian Academy of Science suggests it is unethical and unsound and should be prohibited, as do UNESCO, the World Medical Association and the Council of Europe. Laws in Japan, Denmark, Germany, Norway, Spain, Sweden and Switzerland ban it and, although the UK Parliament has just voted to allow the development of embryos for research, it will still make human cloning illegal.

The ban in the Gene Technology Act is thought to be an interim measure and the Council of Australian Governments in July 2001 agreed to the development of legislation around the Nation that bans human cloning in a consistent manner. These laws should be in place in each State by June 2002. It will be important that this legislation is based on the principle that attempts to clone a whole human are to be prohibited, rather than the prohibition being based on any particular procedure and care should be taken with the wording to avoid any inadvertent impact on the lawfulness of therapeutic cloning.

### **‘Therapeutic cloning’ and stem cells**

As noted earlier, ‘therapeutic cloning’ refers to the medical and scientific applications of cloning technology which do not result in the production of genetically identical fetuses or babies. Therapeutic cloning usually involves the use of ‘stem cells’.

Stem cells may be derived from embryos, or from other sources, including a number of adult tissues. How the stem cells are derived, what they may be used for, and how safe and effective their clinical uses may be is generally poorly understood by society as a whole. This is not surprising as in the scientific and clinical worlds understanding and refinement of the questions is growing at an amazing rate on many fronts.

There can be no single response to the many different aspects of therapeutic cloning and stem cells research and the clinical applications, but probably the most difficult questions to be answered about cloning now relate to the development and use of stem cells from embryos (ES cells) to derive clinically useful cells or tissues for transplantation in the treatment of many devastating diseases.

**A ‘stem cell’ is an undifferentiated cell which is a precursor to a number of differentiated (specialised) cell types.**

Stem cells may be **totipotent** (with the capacity to develop into a complete embryo and its placenta); **pluripotent** (capable of producing more than one type of cell or tissue); or **multipotent** (differentiated cells capable of giving rise to a limited number of multiple tissue types)<sup>1</sup>. Stem cells must be self-renewing.

During differentiation certain genes in the undifferentiated cell become activated or inactivated, and differentiated cells develop with specific structures and functions.

Stem cells may come from-

the inner cell mass of the human embryo (embryonic stem cells or **ES cells**).

These embryos may have been developed by the use of cloning techniques specifically for this purpose (therapeutic cloning), or donated by couples who have completed their infertility treatment and have ‘spare’ embryos;

primordial germ cells in the gonadal ridge of the embryo/fetus (**EG cells**) (that is usually originating from aborted fetuses);

a number of sites in the adult body (**Adult stem cells**); and

placental and umbilical cord tissue.

- **Embryonic stem cells (ES cells).**

ES cells, which come from the inner cell mass of a 5-6 day old human embryo, have the potential to develop into all or nearly all of the tissues in the body, from each of the three

germ layers that make all the organs of the body (pluripotentiality). ES cells appear to have the great potential in therapeutic cloning as they are flexible and relatively easily cultured.

Techniques have now been developed to permit the prolonged in vitro culture and proliferation of human ES lines. Research is now showing that the ES cells will differentiate into a range of cell types either spontaneously or in response to specific culture conditions. These factors are slowly becoming better understood. If the cells are to be manipulated and grown in sufficient quantities and of the required type for transplantation, it is vital that the genetic and molecular requirements to achieve this are well understood. Although ES cells have been maintained through hundreds of divisions it is not yet known whether they can be maintained indefinitely.

ES cells were derived from mice nearly 20 years ago, but from humans only in 1998. There are now 64 human ES cell lines in laboratories around the world.

- **Embryonic germ cells (EG cells)** are derived from fetal tissues, in particular from the primordial germ cells of the gonadal ridge of the 5-10 week fetus.

These cell lines are pluripotent and easily replicated in the laboratory, but have important differences to ES cells. For example, although pluripotent they appear to be less flexible than ES cells and have only been cultured through 70-80 replications, while ES cells have been maintained through hundreds of replications. In addition, when EG cells are injected into immuno-compromised mice, they do not develop in the same way, for example they do not develop the benign tumours that develop when ES cells are similarly injected.

- **Adult stem cells.**

Adult stem cells share some of the characteristics of ES cells. They can renew themselves, and can develop into specialised cell types. Typically they can yield all of the cell types of the tissue from which they originate, that is they are 'multipotent'.

Adult stem cells are scattered and occur in some, but not all, adult tissues. They have been found in bone marrow, blood, the cornea and retina of the eye, brain, skeletal muscle, dental pulp, liver skin, the lining of the GI tract and pancreas. They are undifferentiated cells found in a differentiated (specialised) tissue in the adult.

Adult stem cells are relatively rare and are more difficult to isolate and purify. There are insufficient numbers for direct transplantation and they do not replicate easily in culture. These cells appear unable to proliferate in an unspecialised state for long periods of time. The failure of these cells to proliferate in culture may limit the amount of tissue available for transplantation.

Partial de-differentiation and re-programming of adult cells would provide alternative approaches to the development of cell lines and tissues for transplantation that would bypass many of the most difficult ethical issues associated with ES cells. Re-programming of adult cells was shown to be possible in the development of 'Dolly', where an adult breast cell had been fused by SCNT with an enucleated unfertilised egg. Previously differentiation of adult cells was thought to be irreversible. To date this process (SCNT) is the only way the adult cell can be re-programmed.

**Plasticity** is a new concept and refers to the ability of an adult stem cell from one tissue to generate the specialised cell types of another tissue<sup>4</sup>. Recently reported examples are that under specific conditions adult stem cells from bone marrow of rats generated cells that resemble neurons and other cell types found in the brain, and that new heart muscle cells were generated in mice also from adult stem cells in bone marrow. Recent research has shown that

a mixture of cells from fat tissue or umbilical cord blood are capable of developing into blood cells, bone cells and perhaps others, but these results might be due to multiple types of precursor cells rather than a single cell. Cord blood appears similar to other haemopoietic tissue.

In an exciting recent breakthrough Australian scientists have now separated, purified and identified stem cells from the mouse brain which are pluripotent, that is have the capacity to develop into cells of another tissue<sup>5</sup>. It remains vital to show that one adult cell type can reproducibly become another and subsequently self replicate. It is also important to further identify the essential growth factors and regulators of stem cell self-renewal and differentiation. The ability to stimulate this development and growth of stem cells to repair damaged tissue within the body would be the ultimate goal.

### **The potential of embryonic stem cell therapies.**

Many scientists believe that stem cell research may eventually lead to therapies that could be used to treat diseases that afflict millions of people around the world. However, although this research is advancing rapidly, it is still at a very early stage. Treatments may include replacing destroyed dopamine-secreting neurons in a Parkinson's patient's brain; transplanting insulin-producing pancreatic beta cells in diabetic patients; and infusing cardiac muscle cells in a heart damaged by myocardial infarction. A major focus will probably be on the treatment of neurological diseases such as spinal cord injury, MS, Parkinson's and Alzheimers'.

Research using both ES cells and adult stem cells is providing different and vital answers to questions about human development and the differentiation of cells and tissues. At present at least, the demand for the use of ES cells will continue, as ES cells appear more flexible, easier to cultivate in the numbers needed for transplantation, and therefore of greater therapeutic potential than adult stem cells.

One human organ (skin) is readily cultured to provide replacement tissue for burns victims, developed from their own skin and therefore self-compatible. Self compatible or patient specific tissues may be developed, in theory, through the use of SCNT with a cell taken from the patient and the development of an embryo from which an ES line is derived. This would circumvent the serious problems of immune rejection of the transplantation.

However, it is thought more likely that commercial interest will focus rather on the development of **generic** cell lines and tissues that could be used to treat many patients. A 'blood bank' of ES cells may allow a compromise between the need for patient specific cell lines and generic cell lines, through the possibility of there being a bank of cell lines of the most common antigen types.

For use of these generic cell lines or tissues to be useful, more work is required to combat the risk of **immune rejection**. This would require high doses of drugs to combat rejection, or the cells would have to be stripped of their surface antigens to prevent rejection. The use of these generic cells or tissues for certain types of tissue repair where rejection is of lower risk (such as for cornea transplantation or in the brain which is a relatively immunologically privileged site) would be more successful.

There appears to be no particular advantage with regard to immune rejection for ES cells over adult stem cells.

## **Research challenges include-**

- Learning how to stimulate specific and predictable differentiation in ES cells into specialised cell populations, and understanding the growth factors and nutrients that function during embryonic development
- Purifying and stimulating appropriate and sufficient development in adult stem cells in culture and within the body.
- Overcoming immune rejection through modification of the cells, the patient's immune system or both. With the exception of the current practice in haemopoietic stem cell transplantation much basic research lies ahead. To date most work on transplantation and tissue regeneration has been carried out in mice, and a great deal of work is required to transfer these applications to humans. The response of the transplant in the body is still often unpredictable, and ES cells often result in the formation of benign tumours.
- Developing targeted therapeutic delivery systems such as for cancer research and testing candidate drugs.

## **Ethical challenges and the Australian response**

Society at large (and the Australian Government in particular) seems to have made up its mind about reproductive cloning (cloning humans), and the answer is to be a clear 'NO'!

The use of stem cells derived from adult or fetal tissues will proceed, under the guidelines and careful oversight of human research ethics committees and other bodies that are already in place to oversee other human research and clinical practice.

However, controversial questions remain to be resolved about the development and use of ES cells in therapeutic cloning as, in spite of recent breakthroughs with adult stem cell research, it is unlikely that all demand for research and use of ES cells will be superseded. The most fundamental issues to be addressed revolve around the status that should be applied to the human embryo from which the ES cells are derived. This impacts on decisions about what uses the embryo may be put to and whether it is appropriate to develop an embryo with no intention to implant it. Is there a moral difference between developing an embryo specifically for transplantation and the use of 'spare embryos' for this purpose?

Along with the proposed ban on human cloning, the Australian Government has also undertaken to have consistent national regulation of ART (which will cover ES cell research) in place by June 2002. Although the process for developing these standards is now well under way, the position to be taken on the use of ES cells is not yet finalised. What will the approach adopted for Australia be?

As has just been decided in the UK, will the development of early human embryos for therapeutic cloning be permitted, thus opening the way for the development of patient specific cells and tissues for transplantation?

Or as set out in the NHMRC guidelines (and the WA Act), will the prohibition on the development of a human embryo other than for the treatment of infertile couples continue in place? This limits the potential source of ES cells to those from embryos donated by couples who have completed their IVF treatment and have 'spare' embryos? This would mean that the cells and tissues available for transplantation will come from generic cell lines, and the use of immuno-suppressive drugs will be necessary.

Or like the US, will the decision about ES cell research be to not allow the destruction of any more embryos for research, thus limiting research to the 64 ES cell lines already in existence around the world?

Or might all ES cell, research and use be banned?

## REFERENCES

1. Human Stem Cell Research, April 2001. Australian Academy of Science, Canberra, ACT.
2. Barritt JA, Brenner CA, Malter HE and Cohen J, 2001. Mitochondria in human offspring derived from ooplasmic transplantation. *Human Reproduction*, 16 (3), 513-516.
3. Jaenisch, R and Wilmut, I, 2001. Don't clone humans. *Science*: 291; p. 2552
4. Scientific, ethical and regulatory considerations relevant to cloning human beings, 1998. NHMRC, Australian Health Ethics Committee.
5. Rietz, RL, Valcanis, H, Brooker, GF, Thomas, T, Voss, AK and Bartlett, PF, August 2001. Purification of a pluripotent neural stem cell from the adult mouse brain: *Nature* 412, 736 – 739.
6. Stem Cells: Scientific progress and future research directions, 2001. US Department of Health and Human Services, National Institutes of Health. Bethesda Maryland.

## **APPENDIX 8**

### **PUBLICATIONS: REPRODUCTIVE TECHNOLOGY COUNCIL**

<b>PUBLICATIONS: REPRODUCTIVE TECHNOLOGY COUNCIL</b>
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1. A Summary of the Human Reproductive Technology Act (Booklet);
2. Questions and Answers on the Donation of Human Reproductive Material: (Booklet ) revised 1998;
3. Donor Insemination: The facts (leaflet);
4. Semen Donation: The facts (leaflet);
5. What the Human Reproductive Technology Act Means for You (leaflet);
6. Infertility Counselling and the list of Approved Counsellors: (Flier) revised May 2000;
7. 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.
8. Discussion paper on Human Embryo Experimentation (Booklet) (1990).
9. Infertility Information: General information and support for infertility, and patient rights and dealing with concerns about services you have received. (Leaflet): revised 2000.
10. 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.
11. 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.
12. Surrogacy: from different perspectives (1998).  
Proceedings of a seminar convened by the Reproductive Technology Council in 1997. Reproductive Technology Council, Perth.  
ISBN 0 7307 0090 9.
13. 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.

**APPENDIX 9**

**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*.”