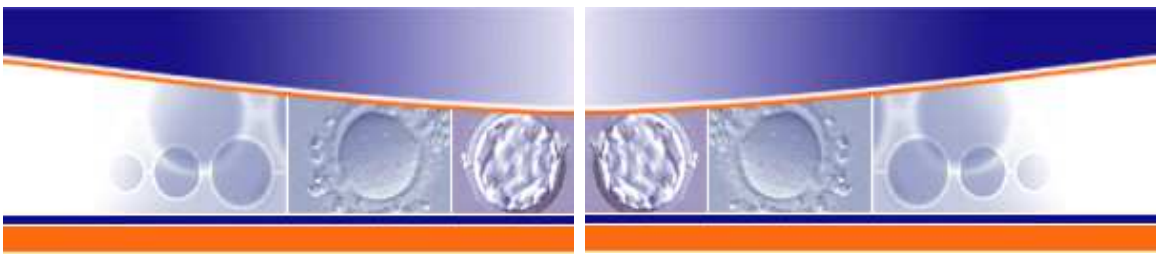
Western Australian Reproductive Technology Council

Annual Report

1 July 2007 – 30 June 2008



Annual Report of the Western Australian Reproductive Technology Council

1 July 2007- 30 June 2008

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

The Western Australian Reproductive Technology Council

189 Royal Street, East Perth WA 6004

For further information please contact-
The Council's web site at

http://www.rtc.org.au

or
Executive Officer
Ms Jenny O'Callaghan (08) 9222 4490

Compiled by:

The Western Australian Reproductive Technology Council

September 2008
Perth, Australia

Council would like to thank Alpha: Scientists in Reproductive Medicine for the permission to use the images included in this report. http://www.alphascientists.org

Reproductive Technology Council

Dr Peter Flett
Acting Chief Executive Officer
Department of Health
189 Royal Street
Perth WA 6004

Dear Dr Flett

It is with pleasure that I submit to you the Annual Report of the Reproductive Technology Council (Council) for the financial year 2007-2008. This report sets out details of reproductive technology practices in this State and activities of the Council during the year, as required by the *Human Reproductive Technology Act 1991* (HRT Act). It is in a form suitable for submission by you to the Minister for Health and also, as is required, to be laid by the Minister before each House of Parliament.

A summary of the main issues and concerns dealt with by the Reproductive Technology Council in the 2007-2008 financial year are as follows:

Council assessed and recommended the approval of practice and storage licences for one fertility clinic that had previously held provisional licenses, bringing to six the number of licensees offering assisted reproductive technology (ART) services in Western Australia.

In an advisory role, Council provided feedback concerning the Surrogacy Bill 2007, which was before Parliament. Council has collaborated with Legal and Legislative Services in the development of subsidiary legislation for this Bill and provided information to the Legislative Council's Standing Committee on Legislation for a review on the legislation in February 2008.

The Council has continued to liaise with Legal and Legislative Services within the Department of Health to clarify practice issues and interpretation of the HRT Act where required. Legal advice has been sought on two main matters: firstly, regarding the role of research and access of authorised parties to information held in the Reproductive Technology Register and secondly, regarding the implications of the defeat of the Human Reproductive Technology Amendment Bill 2007 regulating research involving excess ART embryos, which has implications for the licensing of embryo research under the HRT Act. Legal advice has been sought on a number of other matters during the year.

Applications for extensions to the storage period for embryos have required consideration and the approval of Council. The development of a Council Embryo Storage Policy has been a focus for the 2007-2008 year and this policy is soon to be finalised. The policy is important in providing Council members with guidance for the assessment of embryo storage applications, to outline options for ART participants regarding their stored embryos as well as providing direction for ART clinics regarding end of embryo storage issues.

Council has continued to receive applications for the diagnostic testing of embryos. Guidelines on the approvals process for the genetic testing of embryos have been set

out in the *Policy on Approval of Diagnostic Procedures Involving Embryos*. These guidelines have been reviewed over the past two years, a process involving consultation with clinicians and legal services, addressing eligibility issues for genetic testing of embryos and clarifying aspects of the requirements under the HRT Act.

The functions of the Council were interrupted in the early part of the financial year due to extended sick leave taken by the Executive Officer, Ms Antonia Clissa. Ms Clissa had provided excellent support to the Council over the previous four years, and her departure was experienced as a significant loss to Council. The appointment of the Executive and Deputy Executive Officers has allowed the work of the Council to resume.

It is not possible for Council to operate effectively without the significant and dedicated support of a number of people who volunteer their expertise and time to attend to matters brought to the attention of Council. I especially wish to acknowledge and thank Council and Committee members for their ongoing commitment over the past 12 months. I would also like to recognise and thank Ms Deborah Andrews for her continuing legal support and guidance. Finally, on behalf of Council I wish to acknowledge the ongoing financial and administrative support provided by the Department of Health. This support is essential to enable the Council to carry out its statutory duties.

Yours sincerely

CA Michael AO
CHAIR
Reproductive Technology Council

02 September 2008

CONTENTS

GLOSSARY

AI	Artificial insemination
ART	Assisted reproductive technology
CEO	Chief Executive Officer, Department of Health
DI	Donor insemination
DoH	Department of Health WA
FET	Frozen embryo transfer
FSA	Fertility Society of Australia
GIFT	Gamete intra fallopian transfer
HLA	Human Leukocyte Antigen
HRT Act	Human Reproductive Technology Act 1991
HRTA Bill	Human Reproductive Technology Amendment Bill 2007
ICSI	Intra cytoplasmic sperm injection
IMR	Information Management and Reporting (DoH)
IUI	Intra uterine insemination
IVF	In vitro fertilisation
NHMRC	National Health and Medical Research Council
PGD	Pre-implantation genetic diagnosis
PGS	Pre-implantation genetic screening (for aneuploidy)
RTAC	Reproductive Technology Accreditation Committee (Committee of the Fertility Society of Australia)
RTC	Western Australian Reproductive Technology Council (Council)
RTCCC	RTC Counselling Committee
SCNT	Somatic cell nuclear transfer
Surrogacy Bill	Surrogacy Bill 2007
2007-2008 year	Refers to the period 1 July 2007 until 30 June 2008

EXECUTIVE SUMMARY

This Annual Report has been prepared by the Reproductive Technology Council for the Chief Executive Officer (CEO), Department of Health, to comply with the requirements of Section 5(6) of the *Human Reproductive Technology Act 1991* (HRT Act). As set out in the HRT Act, the CEO is required to submit an annual report to the Minister, so that copies are laid before each House of Parliament. The Annual Report outlines the use of assisted reproductive technology in the State, and the operations of the Reproductive Technology Council (Council) for the year ending 30 June 2008.

As outlined in the HRT Act, the Council has an important role as an advisory body to the Minister and to the CEO on matters in reproductive technology, the administration of the HRT Act and providing advice on licensing matters for artificially assisted human reproduction in Western Australia. The Council is also charged with the responsibility of setting and monitoring the standards of practice for those licensed to carry out assisted reproductive technology (ART) practice, and to promote informed public debate and consultation on issues relating to infertility and reproductive technology.

The Council's 2007-2008 year began in a climate of some uncertainty, following the Council's executive officer taking extended sick leave, and the resignation of the deputy executive officer towards the end of the 2006-2007 year. Both officers had provided an excellent level of executive support to Council, and had developed an extensive understanding of the issues pertaining to the provision of ART services in Western Australia. The departure of these *ex officio* members of Council, therefore, was a significant loss to the Council.

During this period, Council continued to oversee the consideration of ART regulatory matters that required Council approval under the HRT Act. These included the consideration of pre-implantation diagnosis (PGD) of embryos, embryo storage extensions, and licensee applications for Council to waive Directions under the Act. However, additional activities such as policy development and the promotion of public debate on ART issues in WA were, by necessity, suspended at this time. With the appointment of new officers to these executive positions midway through the 2007-2008 year, such functions of the Council are gradually resuming.

One issue that has required particular Council focus in the 2007-2008 year has been the progression of proposed surrogacy legislation through Parliament. While the Surrogacy Bill 2007 has since been erased from Parliament due to the impending State Government election (announced for September 2008), for much of the 2007-2008 year Council has been involved in consideration of surrogacy policy, particularly with regard to subsidiary legislation. Related Council activity includes providing a submission to the Standing Committee on Legislation (a committee of the Legislative Council) which undertook a review of the proposed legislation, and subsequent attendance at the public hearings for this Standing Committee review. The Reproductive Technology Council Counselling Committee (RTCCC) has also been involved in providing advice on matters concerning the legislation, on issues such as the assessment of parties in proposed surrogacy arrangements. In the event that the Bill is re-introduced to Parliament and passed following the 2008 State election, the provision of professional and public education and policy development around surrogacy will be a substantial Council focus in the 2008-2009 year.

Another legislative development with particular relevance to ART research in WA has arisen following the defeat of the Human Reproductive Technology Amendment Bill 2007 (HRTA Bill). The HRTA Bill was introduced to Parliament in WA with the aim of achieving national consistency in research conducted on embryos. The defeat of this Bill will impact on the

capacity for research on embryos under a National Health and Medical Research Council (NHMRC) licence in this state. Under the current HRT Act, research involving excess ART embryos must be conducted under an NHMRC licence. With the defeat of the Bill, the authority for the NHMRC Embryo Research Licensing Committee (NHMRC Licensing Committee) to oversee such research is unclear, and legal advice has been sought on this issue. To date, no NHMRC licences have been granted for the authorisation of research on excess ART embryos for research in Western Australia.

A PGD (Implementation) Technical Advisory Committee (PGD Committee) review of the Council's "Policy on approval of Diagnostic Procedures involving Embryos", was completed in 2007-2008, with an updated version of the policy now available. The review identified an anomaly in the HRT Act that allows some, but not all, parents of children suffering from conditions that may be treated by transplantation of donor tissue (such as bone marrow) to seek approval for embryo diagnosis and human leukocyte antigen (HLA) testing to create a saviour sibling. Following advice by the PGD Committee, Council agreed that this anomaly warranted attention, and has sought legal advice on how this inequity in the legislation may be amended.

The 2007-2008 budget allocation to the Council was $38,080. The Financial Statement outlining the distribution of expenses is provided in this Annual Report. As reflected in the Financial Statement, the loss of permanent executive support staff appointed to the Council for much of the 2007-2008 year lead to a temporary suspension in many Council activities, and the payment of sitting fees for Council and Committee members and other expenses during this time was also affected. Consequently, the Financial Statement shows a significant surplus for this year, while the forthcoming 2008-2009 budget may need to accommodate the payment of outstanding sitting fees from the 2007-2008 year.

As at 30 June 2008, there were six establishments in Western Australia providing ART services under both a Practice Licence and a Storage Licence. One recently established licensee, operating under a provisional licence issued in 2006-2007, was re-licensed following accreditation from the Reproductive Technology Accreditation Committee (RTAC) of the Fertility Society of Australia (FSA). Under the HRT Act, the issuance of licenses is dependant on fertility clinics being accredited by RTAC or a similar prescribed organisation. Accredited fertility clinics may be granted a licence by the CEO, following the receipt of advice from the Council.

Executive support concerns notwithstanding, Council has played an active role in the regulation of ART practice in Western Australia in 2007-2008. For the next year, preparation for the forthcoming accreditation and licensing of fertility clinics in WA in 2008-2009 will require considerable Council attention. In the event that the legislation is enacted, Council also anticipates ongoing involvement in the development and implementation of surrogacy policy, to facilitate surrogacy as a means of creating a family for eligible couples.

INTRODUCTION

The Western Australian Reproductive Technology Council (the Council) was established to undertake functions relating to the practice of and research in reproductive technology in Western Australia, as set out by the *Human Reproductive Technology Act 1991* (the HRT Act).

Functions of the Reproductive Technology Council

Section 14 of the HRT Act outlines the functions of the Council. These include;

providing advice to the Minister on issues relating to reproductive technology, and the administration and enforcement of the HRT Act;

providing advice to the Chief Executive Officer (CEO) of Health on matters relating to licensing, administration and enforcement of the HRT Act;

to formulate and review a Code of Practice and guidelines to govern assisted reproductive technology practices and storage procedures undertaken by licensees, and thereby to regulate the proper conduct, including counselling provision, of any reproductive technology practice;

to encourage and facilitate research, in accordance with the HRT Act, into the causes and prevention of all types of human infertility and the social and public health implications of reproductive technology and

to promote informed public debate on issues arising from reproductive technology, and to communicate and collaborate with other similar bodies in Australia and wider.

The Council is responsible for providing advice to the CEO regarding the issuance of practice and storage licences (or if appropriate, exemptions) in Western Australia. These licences regulate the use of reproductive technology for the purpose of assisting people who are unable to conceive children naturally or without risk to a naturally-conceived child. As a condition of the storage and practice licenses, licensees must have accreditation through the Reproductive Technology Accreditation Committee (RTAC) of the Fertility Society of Australia (FSA), or another prescribed body.

In addition to the above licensing requirements of the HRT Act, amendments to the HRT Act in 2004 also set out that research on excess ART embryos must be carried out under a NHRMC licence. Excess ART embryos are embryos created for the purpose of reproduction, but determined to be excess to the needs of the participant couple, and may be donated for the purpose of research. The NHMRC Licensing Committee is charged with the responsibility for undertaking this licensing process in Western Australia. However, the defeat of the HRTA Bill in the Legislative Council in May 2008 is likely to impact on the mechanism whereby the NHMRC licence and monitor ART research in WA. The implications for the defeat of the Bill are discussed further on page 26.

MEMBERSHIP OF THE COUNCIL 30 June 2008

Member	Nominee of:
Professor Con Michael **Chair**	The Australian Medical Association (Prior nominee of Royal Australian and New Zealand College of Obstetricians and Gynaecologists).
Ms Leah Bonson	Department of Child Protection (from May 2008)
Dr Simon Clarke	Royal Australian and New Zealand College of Obstetricians and Gynaecologists (from May 2008)
A/Professor Jim Cummins	The Minister for Health
Ms Leonie Forrest	The Law Society of Western Australia (until May 2008)
Mr Peter Fox	The Health Consumers' Council (from May 2008)
A/Professor Roger Hart	The Department of Obstetrics and Gynaecology, University of Western Australia
Dr Brenda McGivern	The Law Society of Western Australia (from May 2008)
Dr Joe Parkinson	The Minister for Health
Dr Beverly Petterson	The Minister for Health
Ms Patrice Wringe	The Health Consumers' Council
Ms Jenny O'Callaghan	Executive Officer *ex officio* Senior Policy Officer, DoH (from Jan 2008)

Membership of Council cont...

Deputy Member	Nominee of:
Dr Shirley Bode	Health Consumers' Council (from May 2008)
A/Professor Neville Bruce	The Minister for Health
Reverend Brian Carey	The Minister for Health
Dr Angela Cooney	The Australian Medical Association
Ms Leonie Forrest	The Law Society of Western Australia (from May 2008)
Dr Janet Hornbuckle	Royal Australian and New Zealand College of Obstetricians and Gynaecologists (from May 2008)
Ms Sonja Lundie-Jenkins	The Health Consumers' Council (until September 2007)
Dr Brenda McGivern	The Law Society of Western Australia (until May 2008)
Ms Sue Midford	The Health Consumers' Council
Mr Hans-willem van Hall	The Minister for Community Development (until Sept 2007)
Dr Nyaree Jacobsen	Deputy Executive Officer *ex officio* Senior Policy Officer, DoH (from November 2007)

COMMITTEES OF THE COUNCIL

Counselling Committee

Terms of Reference:

In relation to counselling-

1. 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 CEO 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), Mr Peter Fox (consumer representative), Mr Hans-willem van Hall (until September 2007), Ms Iolanda Rodino, Ms Patrice Wringe, Ms Jenny O'Callaghan (*ex officio*).

Embryo Storage Committee

Terms of Reference:

With the agreement of the Minister for Health as required under s(10)(4) of the HRT Act, the Council, by resolution under s11(1) of the HRT Act, may delegate this Committee to:

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

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

Membership:

Rev Brian Carey (Chair), Dr Brenda McGivern, Ms Sue Midford, Ms Patrice Wringe, Ms Jenny O'Callaghan (*ex officio),* Dr Nyaree Jacobsen (*ex officio*) and Ms Melissa Chantry (Information Management and Reporting, DoH, invited guest).

Licensing and Administration Advisory Committee

Terms of Reference:

1. Advise the Council on matters relating to licensing under the HRT Act, including the suitability of any applicant and the conditions that should be imposed on any licence.

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

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

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

Membership

Professor Con Michael (Chair), Ms Leonie Forrest, Dr Roger Hart, Ms Jenny O'Callaghan *(ex officio*) and Dr Nyaree Jacobsen (*ex officio*).

PGD (Implementation) Technical Advisory Committee

For the purposes of these Terms of Reference the term pre-implantation genetic diagnosis (PGD) is taken to include all diagnostic procedures that may be carried out in vitro upon or with a human embryo or egg undergoing fertilisation prior to implantation.

Terms of Reference:

1. To advise the Council on a suitable framework for the approval of PGD under the HRT Act, both generally and for specific cases.

2. To advise the Council on factors that it should consider when deciding whether to approve PGD.

3. To advise the Council on standards for facilities, staffing and technical procedures.

4. To advise the Council as to how the ongoing process of approval of PGD should be managed effectively by the Council, once the implementation phase is over.

5. To advise the Council on other relevant matters as requested by the Council.

The Committee may consult with relevant experts in the preparation of this advice for the Council including, counselling in relation to PGD, with the Counselling Committee.

Membership:

(Chair to be member of the Council, appointed by the Council from membership of the Committee).

- 2 members of the Council, chosen to maximise relevant experience and expertise on the Committee.
- 1 Clinical geneticist (or in the event none is available a suitably qualified clinician or genetic counsellor)
- 1 Laboratory geneticist
- 1 Human embryologist (to be recommended by RTAC or holding office in RTAC or Scientists in Reproductive Technology (SIRT)
- 1 DoH lawyer with an understanding of requirements of the Act
- Committee Executive Officer (DoH RT Unit staff)

Dr Beverly Petterson (Chair), Dr Sandra Webb, Ms Daphne Andersen (until October 2007), Dr Steve Junk, Ms Sonja Lundie-Jenkins (until September 2007), Dr Ashleigh Murch, Dr Sharron Townshend, Ms Jenny O'Callaghan (*ex officio)* and Dr Nyaree Jacobsen (*ex officio)*.

Scientific Advisory Committee

Terms of Reference:

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

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

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

Membership:

A/Professor Jim Cummins (Chair), Dr Roger Hart, Dr Phillip Matson, Dr Joseph Parkinson, Dr Beverly Petterson and Dr Nyaree Jacobsen *(ex officio)*.

Staff of the Reproductive Technology Unit Department of Health

Ms Jenny O'Callaghan
Senior Policy Officer and Executive Officer of the Council. Appointed in January 2008.

Dr Nyaree Jacobsen
Senior Policy Officer and Deputy Executive Officer of the Council. Appointed in November 2007 (0.7 FTE)

Ms Jenny Parker
Senior Policy Officer and Deputy Executive Officer of the Council. Appointed in June 2008. (0.4 FTE)

Ms Melissa Chantry
Research Officer, Health Information Division, Information Management and Reporting.

REPRODUCTIVE TECHNOLOGY COUNCIL
FINANCIAL STATEMENT 1 July 2007 - 30 June 2008

The Department of Health funds the administration of the HRT Act, including the operations of the Council. The 2007-2008 budget allocation was $38,080.00, with expenditure totalling $6,812.31 for the financial year. This amount represents a significant under-expenditure of the allocated budget. As previously noted, certain aspects of Council activity were suspended during the 2007-2008 year due to a changeover in staff providing executive support to the Council. In addition, due to changes in the payment method for members' sessional (sitting) fees, these fees for 2007-2008 were not derived from this budget. Sessional fees and external consulting fees typically represent around 75% of the allocated budget. Council has a long record of remaining within the allocated budget, and anticipates that with resumption of executive support, expenditure will reflect a similar budget to previous years, with adjustment for the 2008-2009 year.

REPRODUCTIVE TECHNOLOGY COUNCIL Expenses by Category	Expenditure ($)	Income ($)
Staff or Council:		
Training/Travel	$0	
TOTAL	**$0**	
Food supplies/catering	$375	
Administration and clerical	$2372.31	
TOTAL	**$2447.31**	
Purchase of external services:		
Sessional fees: (External Consulting Fees) Reproductive Technology Council	$0	
External consulting fees and advertising	$4000	
TOTAL	**$4000**	
Other expenses:		
Books/magazines/subscriptions	$0	
Freight/ cartage/postal	$0	
Printing and stationery incl. Annual Report Website Domain expenses	$65	
TOTAL	**$65**	
TOTAL	**$ 6,812.31**	
Budget Allocation		**$38,080.00**

OPERATIONS OF THE COUNCIL 2007-2008

Meetings

The Council met on nine during the 1 July 2007 to 30 June 2008 period, with attendances reaching quorum at all meetings. Two extraordinary meetings were held to discuss Council's submission on Surrogacy to the Standing Committee on Legislation (Legislative Council) and licensing of Fertility Specialists of WA. The Counselling Committee met on four occasions; the PGD (Implementation) Technical Advisory Committee (PGD Committee) met on one occasion, although several applications for PGD were assessed out of session before being approved at the following Council meeting. The Embryo Storage Committee met on two occasions during the year. Council considered several urgent applications for the extension of storage of embryos out of session. The Licensing and Administrative Committee and the Scientific Advisory Committee did not meet during the 2007-2008 period.

Membership

Outgoing members in 2007-2008

Several valued members of the Council and committees to the Council resigned from Council positions during the year.

Ms Antonia Clissa- Executive Officer to the Council. As Executive Officer, Ms Clissa was an integral member of Council for a period of more than four years. During this time, drawing on a substantial knowledge of the area of assisted reproductive technology and in particular her background in infertility counselling, Ms Clissa provided Council with an exceptional level of executive support. Ms Clissa took extended leave from the Department of Health from June 2007. Her contribution to the Council has been significant, and Council extends its thanks and appreciation for this.

Ms Sonja Lundie-Jenkins retired from Council and the PGD Committee on expiry of her nominated period of membership in September 2007. Ms Lundie-Jenkins had been a deputy member of Council, as a Health Consumers' Council representative, since October 2003. Council appreciated Ms Lundie-Jenkins valuable contribution to the operations of both the Council and the PGD Committee during her tenure.

Mr Hans-willem Van Hall retired from Council in September 2007 following the expiry of his nominated term on Council. As Department of Child Protection representative, Mr Van Hall offered a professional understanding of relevant issues, particularly concerning the impact on children conceived through ART.

Ms Daphne Andersen resigned from the PGD Committee in November 2007. Ms Andersen, previously a DoH legal officer, was a member of the PGD Committee since its inception in 2004. Her substantial legal knowledge of the HRT Act and issues in ART proved very valuable to the PGD Committee, in particular as WA licensees were first permitted to seek PGD of embryos in 2004. Ms Andersen continues to work with Council and the Reproductive Technology Unit (RTU) in the development of surrogacy legislation.

Department of Health Staff assisting the work of the Council

The 2007-2008 year saw a significant upheaval in the provision of DoH executive support for the Council, with the resignation of the Deputy Executive Officer, Ms Amalia Burmas, at the end of 2006-2007 financial year, and the Executive Officer, Ms Antonia Clissa taking extended leave at this time. The effective loss of the executive support to Council saw the suspension of many Council activities, in particular the convening of Council committees, policy development and public education. Ms Melissa Chantry and Ms Doris Lombardi, assumed many of the essential executive duties of the Council during the interim period prior to the appointment of Dr Nyaree Jacobsen as Deputy Executive Officer in November 2007, and Ms Jenny O'Callaghan as Executive Officer in January 2008. Council wishes to thank Ms Chantry and Ms Lombardi for their assistance during this time. The resumption of executive duties has been steady during the 2007-2008 year, although the limited opportunity for a handover of duties has impacted on the continuity of some ongoing Council activities.

Ms Jenny O'Callaghan was appointed in January 2008 as Senior Policy Officer, DoH, and under the HRT Act as Executive Officer to Council. As Senior Policy Officer, Ms O'Callaghan also has responsibility for the management of the Reproductive Technology Unit, including administration of the Voluntary Register, and provides secretariat support for the RTC Counselling Committee and other Council committees as required.

Dr Nyaree Jacobsen (0.7FTE) was appointed in November 2007 as Senior Policy Officer for the DoH, and Deputy Executive Officer to Council under the HRT Act. Responsibilities of this position have included the provision of secretariat support for the PGD Committee, and the Embryo Storage Committee.

Ms Melissa Chantry was appointed as Research Officer in the Health Information and Reporting Directorate of DoH, and has been an invited guest at Council meetings since May 2006. In addition to undertaking many duties that assisted the Council to continue to function in the interim period between the appointments of the executive positions to the Council, Ms Chantry has responsibility for the collation of licensee reporting information, and the maintenance of the Reproductive Technology (RT) Register. Ms Chantry is an authorised officer under the HRT Act, and manages the applications for embryo storage extensions that come before Council.

Ms Jenny Parker (0.4FTE) Ms Parker recently joined the DoH to provide additional administrative and policy development support to the RTU and Council, and share Deputy Executive Officer duties.

Acknowledgements

The Council gratefully acknowledges:

The continuing legal support and expertise in the area of ART provided by Ms Deborah Andrews, DoH Legal and Legislative Services.

Data management and support from Mr Tony Satti, Mr Max Le and Ms Melissa Chantry from Information Management and Reporting (IMR).

Administrative and accounting support from Ms Doris Lombardi, Ms Annette Davey, Mr Lex Cassidy and Mr Louie Miovski.

LICENSING ISSUES

Establishments licensed under the *Human Reproductive Technology Act 1991* at 30 June 2008

Practice and Storage Licenses:

In Vitro Laboratory Pty Ltd trading as Concept Fertility Centre
King Edward Memorial Hospital
Bagot Road
Subiaco WA 6008

Fertility North Pty Ltd
Suite 213 Specialist Medical Centre
Joondalup Health Campus
Shenton Avenue
Joondalup WA 6027

Western IVF Pty Ltd trading as Fertility Specialists of Western Australia
Bethesda Hospital
25 Queenslea Drive
Claremont WA 6010

Sydney IVF Perth Pty Ltd trading as Hollywood Fertility Centre
Hollywood Private Hospital
Monash Avenue
Nedlands WA 6009

JL Yovich Pty Ltd trading as PIVET Medical Centre
166-168 Cambridge Street
Leederville WA 6007

Practice (AI only) and Storage Licenses:

The Keogh Institute for Medical Research (Inc.)
Sir Charles Gairdner Hospital
2 Verdun Street
Nedlands WA 6009

Establishments licensed in Western Australia by the National Health and Medical Research Council

The NHMRC (through the Embryo Research Licensing Committee) is authorised to license research projects involving excess ART embryos under Part 4B of the HRT Act.

There are no establishments currently undertaking research in Western Australia under NHMRC licence. It is likely that the defeat of the HRTA Bill the Legislative Council in May of this year (2008) will impact on the future issuance of NHMRC licences. As at 1 July 2008, DoH

is awaiting legal advice regarding this matter. The implications for research in WA are discussed further on page 26.

Exemptions under the Human Reproductive Technology Act 1991

Medical practitioners that meet the requirements of the HRT Act may apply for an exemption from a licence to practice artificial insemination procedures in Western Australia. The Council did not receive any new applications for an exemption to practice an artificial insemination procedure during 2007-2008. A list of practitioners currently issued with exemptions is provided in Appendix 1.

Reproductive Technology Accreditation Committee site visits

Accreditation by the Fertility Society of Australia (FSA) is a condition of licence for establishments granted a practice or storage licence under the HRT Act. The FSA has established the Reproductive Technology Accreditation Committee (RTAC) to undertake site visits as part of the accreditation process.

Following an interim one year accreditation, an RTAC review panel undertook an inspection of Western IVF Pty Ltd, trading as Fertility Specialists of WA on 9 November 2007. RTAC accreditation was granted to Fertility Specialists of WA until November 2010.

The remaining five Western Australian clinics licensed under the HRT Act are due for an RTAC accreditation review in January 2009. However, this is likely to be under a new accreditation system, following an FSA announcement in 2008 that the current triennial inspection process was to be replaced with an annual inspection and clinic assessment to be conducted by an external accreditation organisation. The details of this new process have yet to be finalised. However, it is anticipated that these details will be available towards the end of 2008, following the release of a new FSA code of practice for ART clinics.

Information circulated to licensees

In the 2007-2008 year, Council considered and provided written responses to more than 35 licensee concerns and enquiries. This was in addition to licensee applications to Council outlined in the following chapter. In addition to this individual licensee correspondence, all licensees received information from Council regarding the following matters:

Human Leukocyte Antigen (HLA) testing for the creation of saviour siblings

Under the current HRT Act, an anomaly exists whereby access to PGD and HLA testing for the creation of saviour siblings is limited to individuals or couples who are eligible, through medical infertility, to access IVF under S23 of the Act. On consideration of this anomaly (outlined more broadly on page 27 of this report), Council agreed to examine how the inequity of access to HLA technology may be addressed, and has sought legal advice on this issue.

Request to increase number of recipient families per gamete donor

A request by a licensee to consider increasing the number of families potentially created from donor reproductive material from five families to ten families, was received by Council, and referred on to the RTCCC for consideration. The issue

underpinning this request was licensee concern about sperm donor shortage in Western Australia. The RTCCC considered this matter, in particular with regard to the potential psychological impact on a donor conceived child if more than four other families were biologically related to him/her, and the psychological implications for the donor of having offspring in many families. The risk of accidental consanguinity (for example, where biologically related people may unknowingly marry or commence a sexual relationship) was also a consideration, especially in a population the size of Perth. Based on these concerns, the RTCCC and Council did not support the request to increase the number of recipient families that may be created from a gamete donor from five to ten families. Future empirical research documenting the impact, or otherwise, of these factors may warrant Council reconsideration of the issue in the future.

This correspondence is set out in Appendix 5.

Complaints

The Council received four formal complaints regarding the operations of licensees during the year. Two complaints concerned patient record keeping matters, and one matter concerned the propriety of licensee advertising. These issues were investigated to the satisfaction of the Council. One complaint highlighted the issue of the restricted availability of donor sperm for single women. The issue of sperm donor shortage has been flagged as an issue warranting further attention by Council in the 2008-2009 year.

LICENSEE APPLICATIONS TO COUNCIL 2007-2008

Under the HRT Act, specific approval from Council is required for clinics to carry out certain practices, including the storage of embryos beyond ten years, research projects, innovative procedures and diagnostic testing of embryos. Outlined below are practices that were granted approval during the 2007-2008 year. A list of applications made by licensees in 2007-2008 is provided in Appendix 3.

Embryo Storage applications

Amendments to the HRT Act in 2004 increased the initial authorised storage period for embryos created for ART from three years to a ten year authorised period. To permit embryos to remain in storage beyond this ten year period, Council approval must be sought. Approval for an extension may be granted under S 24 (1a) of the HRT Act if Council considers there are "special reasons for doing so", and applications are assessed by Council on a case-by-case basis to determine the merits of each application for extension.

To guide decision-making in these matters, and inform participants and clinics with embryos in storage, the Embryo Storage Committee is developing a Council Embryo Storage Policy. Council recognises that the majority of ART participants store embryos with the intention to use or to donate these embryos for the creation of children. However, a small proportion of embryos are stored by participants who, after completing their ART treatments, remain uncertain as to the intended future purpose of their stored embryos. Assisting and preparing participants to make a decision regarding their embryos, prior to reaching the end of the authorised ten year period, will be a primary focus of the Embryo Storage Policy. The policy is likely to emphasise licensee communication with participants, and require a series of reminders over the authorised ten year storage period as a means of facilitating this decision-making. Supporting literature, including a pamphlet outlining options at the end of the storage period, such as participants holding a ceremony for their embryos, is also in the process of development. At the end of 2007-2008, the Embryo Storage Policy remains in draft format. However, it is anticipated that this will be finalised by the end of 2008, following a consultation period with licensees. As an interim measure, prior to the completion of the policy, embryos storage applications have in most instances been granted a 12 month extension.

For the 2007-2008 year, 29 applications to extend Embryo Storage periods were approved by Council on the recommendation of the advice of the Embryo Storage Committee. Of these applications, 26 were granted a 12 month extension. One extension was granted for 24 months and one for 36 months. One applicant was granted one month to outline more comprehensively the basis for their application. This applicant was subsequently granted a 12 month extension.

Research Project applications

Part 4B of the HRT Act states that research conducted using excess ART embryos must be carried out under an NHMRC Licence. Research projects *not* requiring an NHMRC licence must receive Council approval. Summary information indicating the current status and related matters of any research project must be submitted with the Licensee Annual Reporting. No new applications to undertake research projects were approved by Council in 2007-2008. A list of approved research projects active in 2007-2008 is provided in Appendix 3.

Innovative Practice applications

Approval to use an innovative procedure must be sought from Council under Direction 9.4. The HRT Act permits clinics to introduce new and innovative ART procedures, whilst allowing a closer degree of monitoring of these procedures through the approval process and annual reporting requirements. As technology advances and new techniques are more widely adopted, it may be appropriate to consider procedures as routine rather than as an innovative. The criteria for deciding if a procedure is routine are set out in Part 2 of Schedule 5 of the Act. Council may consider approving a procedure as a routine procedure when peer reported literature, evidence of international practices and documentation of licensee expertise in performing the procedure support the licensee's application.

Council approved one application to undertake vitrification of embryos as an innovative procedure in 2007-2008. Vitrification is a form of cryopreservation in which oocytes or embryos undergo ultra-rapid freezing. This may involve direct or indirect contact with liquid nitrogen to induce the ultra-rapidly cooled state. Traditionally, cryopreservation has been a complex procedure involving a number of steps to slowly cool embryos (and less successfully, oocytes) using cryoprotectants to decrease the risk of ice-crystal formation. Ice crystals form from cellular fluid, and can expand to cause damage to cell membranes of the embryo or oocyte. The advantage of vitrification is the relative simplicity of the method, and that ultra-rapid freezing reduces the likelihood of ice crystal formation. However, one risk associated with this procedure is that embryos are exposed to higher volumes of potentially toxic cryoprotectants than volumes used in the slow cooling method. Research conducted on refining the methodology, including the use of less toxic cryoprotectants, has led to the worldwide acceptance of vitrification of both embryos and oocytes as a means of cryopreservation, with higher pregnancy rates associated with the use of vitrified embryos when compared to traditional cryopreservation of embryos. However, the long-term safety of the procedure, with regard to outcomes of children born following vitrification of oocytes or embryos, still requires monitoring.

Innovative procedures approved under Direction 9.4 for 2007-2008 are listed in Appendix 3.

Applications to allow diagnostic testing of embryos

Amendments to the HRT Act in 2004 noted above in Embryo Storage Applications, also allowed approved licensees to undertake pre-implantation genetic diagnosis (PGD) and pre-implantation genetic screening (PGS) of embryos. These procedures allow the testing of embryos at significant risk of a serious genetic abnormality or disease, with an aim to allow an embryo free of the adverse condition to be selected for implantation. Sex selection of embryos is only considered for approval when there is a risk of embryos carrying or developing a serious sex-linked genetic disease.

PGD looks at single gene defects and translocations. PGD applications must be approved by Council on a case-by-case basis, as Council must be satisfied that the condition will pose a serious risk to the embryo (as a potential child). Approval may be subject to a preliminary feasibility study supporting that the proposed PGD is able to be tested.

PGS is performed to screen embryos for chromosomal abnormalities, where one or more chromosomes may be extra or missing in an embryo. This is known as aneuploidy, and is a serious genetic abnormality. Approved licensees may undertake PGS without specific case-by-case Council approval in cases where eligible IVF patients are considered to be at risk of producing an embryo with chromosomal abnormalities.

The Policy on Approval of Diagnostic Procedures involving Embryos outlines that:

- women over 35 years of age
- women who have had more than two miscarriages

- women with more than two failed IVF attempts where embryos have been transferred
- women referred by a clinical geneticist with a family history of aneuploidy not caused by translocations or other chromosomal rearrangements

may be considered suitable for PGS.

Council approval of each individual PGD application is supported by advice from the PGD Committee. Each letter must be accompanied by a letter from a clinical geneticist. Factors that influence the approval process include the severity of the condition, and the risk of a child inheriting the condition.

There are currently four licensees offering this service to patients in Western Australia. One licensee has approval to perform PGS on embryo biopsies at its laboratory facility in Western Australia, and has approval to undertake PGS analysis on behalf of a second WA licensee at this facility. For embryo biopsies taken for PGS by the remaining licensees, and for all biopsies taken for PGD in WA (which relies on a different method of analysis than PGS), embryo biopsies are couriered to a laboratory in Victoria for analysis.

PGD applications received by Council in 2007-2008 are tabled in Appendix 3.

Applications to waive Directions under the Human Reproductive Technology Act 1991

Directions to the HRT Act set out additional practices for which licensees must seek Council approval. For the 2007-2008 year, licensees sought Council approval under Directions 6.6 and 8.8, and sought approval to waive Direction 8.4/5.8

> **Direction 5.8:** Prior to any artificial fertilisation procedure involving donated reproductive material where a potential donor is known to the recipients, the licensee must ensure that the donor and recipient involved, and the spouse or de facto partner of the donor and recipient (if any), have undertaken psycho-social counselling as set out in Part 2 of Schedule 4 or such other psycho-social preparation as has been approved by the Council.
>
> **Direction 6.3:** The Council may, on compassionate grounds, approve the import of donated gametes, embryos or eggs undergoing fertilisation where the required donor identifying information is not available.
>
> **Direction 6.6**: The Council may approve the export for use in an artificial fertilisation procedure of donated gametes, embryos or eggs undergoing fertilisation to an approved person who has given a written undertaking using Form 10 in Schedule 1, to provide the licensee with information that would be required for the registers, had the donated material been used within this State.
>
> **Direction 7.7:** the licensee must ensure that an IVF procedure directed at reducing the risk of transmission of an infectious disease, such as AIDS or hepatitis, is not undertaken without the prior approval of the Council.
>
> **Direction 8.4:** The licensee must ensure that fresh donated eggs are not to be used in an artificial fertilisation procedure, including the creation of an embryo for fresh transfer, where the recipient is known to the donor, unless
> (a) the recipient(s) has been given information about the fallibility of an HIV test under such circumstances; and

(b) a period of at least six months has elapsed between the donor and recipient completing psychosocial preparation as required in accordance with Direction 5.8.

Direction 8.8: In exceptional circumstances, Council may approve the collection of eggs from a participant who has three or more embryos or eggs undergoing fertilisation in storage.

In 2007-2008, Council approved two applications to export donated gametes, embryos or eggs under Direction 6.6, and three applications under Direction 8.8 were approved. In addition, Council considered one application to waive Direction 8.4b and to reduce the cooling off-period and psycho-social preparation for known sperm donation. This was approved on compassionate grounds.

These approvals are set out in Appendix 3.

Protocols, Patient Information and Consent Forms.

Part 4: "Information" in the Directions under the HRT Act outlines the necessary information that licensees and exempt practitioners must provide patients, in order that their consent to undertake ART procedures is considered "effective" under the HRT Act. The requirement under Direction 2.20 for licensees to notify Council of any changes to these forms acts as an additional means of monitoring the quality and consistency of patient information and consent forms.

Since April 2007, new and amended documents submitted by ART clinics have been assessed by Council, rather than out of session by the Chair of the Licensing and Administrative Advisory Committee, as had previously occurred.

The Council recognises the importance of providing clear and accurate information to patients seeking ART services.

During the 2007-2008 year, Council looked at changes to consent forms and to patient information sheets relating to changes in clinic procedures including:

- Oocyte freezing
- Known donor only policy
- General ART procedures
- Recipient access to potential genetic information from donor material.

THE COUNCIL'S ROLE AS AN ADVISORY BODY

The Council has a prescribed role to promote public debate on issues pertaining to reproductive technology, and to communicate and collaborate with similar organisations or groups.

The discontinuity of executive staff supporting the Council has arguably impacted on Council's function as an advisory body for the 2007-2008 year. As a result, Council has not been as active in the promotion of public debate as in previous years. While several issues have been earmarked for future activity, one area in which Council involvement continued during the 2007-2008 year was surrogacy legislation. This issue is discussed more comprehensively in the following section "Significant Developments in Reproductive Technology During 2007-2008". A summary of Council's activity in this area in 2007-2008 is provided below. This builds on work initiated in 1999 following the Report of the Select Committee on the *Human Reproductive Technology Act 1991* recommendation to develop legislation for the regulation of surrogacy.

- Feb 2008: After discussing relevant issues at an extraordinary meeting, Council provided a written submission to the Standing Committee on Legislation on matters of interpretation of the WA Surrogacy Bill 2007.
- 20 Feb 2008: Council representation was provided by Dr Brenda McGivern at the public hearings for the Standing Committee on Legislation. Other Council members also provided witness statements at the public hearings, although these were independent to their role on Council and reflected their professional viewpoints.
- May 2008-ongoing: The RTCCC provided guidance to legislative officers for the development of Directions to the Surrogacy Bill.
- May 2008: Council provided guidance to DoH officers for the purpose of developing a nationally consistent surrogacy model across Australian jurisdictions.

Council also acted to promote awareness of the data-linkage issue, highlighting to DoH the potential impact that cessation of data-linkage to the RT Register would pose to current and future ART research in Western Australia.

Future activity

Areas identified as warranting future Council action as an advisory body include:

- sperm donor shortage
- embryo storage matters arising from the Embryo Storage Policy
- infertility associated with delay in starting a family.

Information sessions on surrogacy issues will also need to be delivered to a range of groups including licensees, potential participants, Approved Counsellors and family law professionals in the event that the Surrogacy Bill is passed.

Council participation at relevant meetings and conferences

Council members (Dr Bev Petterson, Executive Officer Ms Jenny O'Callaghan and Deputy Executive Officer Dr Nyaree Jacobsen) attended the public seminar coordinated by A/Professor Jim Cummins on "The changing nature of the family in 2008".

As noted above, the lack of executive support during the 2007-2008 year impacted on Council members participating on behalf of Council at relevant meetings and conferences. With the exception of the above-mentioned participation, much of the usual Council activity, including attendance at the FSA Annual Scientific Meeting 2007 (FSA Conference), was suspended for 2007-2008.

Council policy development

Policy development during the 2007-2008 year included:

- RTCCC provision of advice on policy guiding registrant access to information from the voluntary register in the Voluntary Register Policy.
- Embryo Storage Policy, currently under development by the Embryo Storage Committee.
- The PGD Committee undertook a review of the "Policy on approval of diagnostic procedures involving embryos". The new version received Council ratification on 20 November 2008. The policy is included in Appendix 7.

OPERATIONS OF THE COUNSELLING COMMITTEE 2007 - 2008

Meetings

The Counselling Committee met on four occasions during the 2007-2008 year.

Key Focus Areas

During the course of the year the Counselling Committee has convened to:

- provide guidance to Council regarding the Surrogacy Bill. Counselling and participant assessment requirements for surrogacy arrangements were considered by this committee. The RTCCC has an ongoing role in providing advice to officers developing the legislation, and to inform Council on such matters in the event that surrogacy legislation is passed.
- discuss a proposed amendment to Direction 8.1 regarding an extension to the current number of families that are able to be created using the gametes from one donor, from five to ten families. RTCCC recommended that the five family limit continue until such time as there is evidence based research that would allow Council to consider increasing the number of families. This recommendation was accepted by Council and clinics were advised of this decision.
- recommend Council support the completion of the video about same sex (female) couples using donor sperm to create a family. Ms Antonia Clissa, former Executive Officer of the Council was contracted to facilitate this and develop additional promotional material for use by ART participants and industry members.
- liaise with the Embryo Storage Committee on the development of an Embryo Storage Brochure
- survey counsellors and set priorities for training over the next 12 months, with the main consideration being given to the implications for Approved Counsellors posed by surrogacy legislation.
- review the Voluntary Register Policy
- explore how counselling services might be expanded for ART participants.

Approved Counsellor's Applications

Council received one application in 2007-2008 for a counsellor to be approved to provide fertility counselling as an Approved Counsellor under the HRT Act. Following an assessment of qualifications and experience of the applicant, the RTCCC recommended the application be accepted. Council agreed with this recommendation. Clinics have identified that the low number of practicing Approved Counsellors is an issue of concern. Accordingly, increasing the number of practicing counsellors with approval status is one of the RTCCC aims for the 2008-2009 year.

As of June 2008 there were 11 Approved Counsellors able to provide specialist counselling services to participants in infertility treatment. Five counsellors have additional training enabling them to undertake work with children regarding "telling issues" about their biological heritage. A list of Approved Counsellors is included in Appendix 2.

REPRODUCTIVE TECHNOLOGY REGISTERS

The Reproductive Technology Register

The Reproductive Technology Register (RT Register) was established in 1993 to record a wide range of data relating to the practice of ART in Western Australia. Licensees and exempt practitioners are required to provide information concerning the treatment of ART patients. The information required is set out in Schedule 2 Part 2 of the Directions under the HRT Act (included in Appendix 4).

The RT Register allows ongoing monitoring of ART practice, provides a significant data resource for epidemiological research in ART in Western Australia and also ensures that information relating to the identity and outcomes of ART treatment cycles are recorded in a central and secure location. This is of particular importance when ART treatments have involved the use of donated reproductive material, as the RT Register provides a record of identifying information relating to donation and birth outcomes that have resulted from those donations*. In 2004, amendments to the HRT Act set out that all donated reproductive material, including gametes and embryos, must only be accepted when the donor consents to allow identifying information about the donor to be given to any child (reaching 16 years of age) conceived from the donation.

The RT Register is managed through the DoH Information Management and Reporting Directorate. In 2007-2008, concern arose regarding the legality of researchers external to the DoH accessing data on the RT Register. This matter is outlined in the section on "Significant Developments in Reproductive Technology during 2007-2008".

*It should be noted that licensees must also indefinitely retain the original records.

Current Research Projects accessing RT Register data

"Significant adverse health outcomes in children born from assisted conception treatment". Council approval received on 14 November 2001.

"Hospital morbidity outcomes in women following treatment through Assisted Reproductive Technology (ART) in Western Australia". Recommenced in 2008.

Voluntary Register

The Voluntary Register provides a service for Western Australian parties involved in donor conception who wish to access their donor and/or recipient information. This includes children conceived in WA using donor gametes or embryos ("donor offspring") who wish to find out about their biological origins, as well as donors who are seeking information about any child born as a result of their donations. Parents of donor offspring may also seek information about any other children that have been born from the same donated reproductive material, who are biological half-siblings to their children. Relevant non-identifying information can be passed on to an applicant, and identifying donor information will be passed on to a donor conceived child, conceived before the 2004 HRT Act amendments, who has reached over 18 years of age, when written consent from the donor is provided.

Since 2004, amendments to the HRT Act specify that donor material cannot be accepted by a clinic unless a donor consents to identifying information being provided to any child conceived from that donation (when that child reaches 16 years of age). This amendment is in recognition of the need, often experienced by children conceived from donor material, to know their genetic parentage.

For children born from donor material donated *before* 2004, there is no legislated authority to access information about their donor. The Voluntary Register, therefore, provides a means for donor offspring to find out non-identifying information about their donor, and with donor consent, identifying information. For donations given after 1993, this information will be derived from the DoH RT Register. Donations provided before the establishment of the RT Register in 1993 are derived from clinic and practitioner records. In some cases, record keeping has been inaccurate or non-existent, so it is not possible to guarantee the availability of information for Voluntary Register registrants with regard to pre-1993 donor procedures.

Joining the Register is voluntary, and interested parties contacting the RT Registrar, currently Ms Jenny O'Callaghan, will be forwarded a registration form for completion and return to the DoH for inclusion on the Voluntary Register. A website, http://www.voluntaryregister.health.wa.gov.au has been developed to provide information regarding this process.

Voluntary Register applications for 2007-2008:

10 parent-requests for application forms.
9 completed applications returned from parents

4 donor offspring-requests for application forms
1 completed application received from donor offspring

11 donor-requests for application forms
11 completed applications received from donors

The Voluntary Register has recorded 108 registrations since the inception of the data-base in November 2002. To date the registrants include 59 parents of donor-conceived offspring, 41 donors and 8 donor-conceived adults *.

The development of Voluntary Register Policy, including counselling requirements prior to any proposed contact between parties, has been identified as a matter requiring consideration. Subsequently, the Voluntary Register Policy has been a focus for the RTU, and in particular for the RTCCC, who have provided consultation on this policy during the year. The Voluntary Register Policy is in final draft form as at the end of the 2008 financial year.

* NB- these are corrected figures from previous figures reported.

SIGNIFICANT DEVELOPMENTS IN REPRODUCTIVE TECHNOLOGY DURING 2007-2008

Surrogacy Bill 2007

The Surrogacy Bill was introduced to the Western Australian Parliament on 1 March 2007, to provide State legislation that deals directly with surrogacy issues. Under current legislation, IVF surrogacy (where a woman or couple who are unable to conceive a child for medical reasons access IVF technology to allow a surrogate to carry a child on their behalf) is not permitted in Western Australia. No capacity exists to allow arranged parents to obtain legal parentage for a child born from a surrogacy arrangement. The Surrogacy Bill 2007 was aimed at the regulation of IVF surrogacy, and to provide a mechanism for parentage orders to be made. The Bill prohibits any arrangement for reward or profit. The strict requirement for both surrogate and arranged parents to seek counselling and legal advice, plus the medical and psychological assessment process set out by the proposed surrogacy legislation, aims to regulate surrogacy in a manner that optimises the protection of all parties involved with a surrogacy arrangement, and in particular to safeguard the rights and best interests of any child created.

The Surrogacy Bill passed through the Legislative Assembly with a number of amendments, including the provision to allow a court to dispense with the consent of the birth mother and make a parentage order in favour of the arranged parents, in the event that the birth mother was not a genetic parent to the child, and where one of the arranged parents was genetically related to the child. The court would have to consider that such a transfer of legal parentage was in the best interests of the child. In November 2007, following the passage of the amended Surrogacy Bill through the lower house and the second reading in the upper house, the Surrogacy Bill was referred to the Standing Committee on Legislation for a review into matters of interpretation of the proposed legislation. This Committee sought submissions from relevant organisations and individuals on the legislation. Council provided a written submission, and was also represented at the public hearings into surrogacy conducted by the Committee in February 2008.

“The Standing Committee on Legislation in relation to the Surrogacy Bill 2007” report, tabled in Parliament in May 2008, made 12 recommendations with regard to the Surrogacy Bill. Of particular relevance to Council was the recommendation that Council establish a committee/panel to assess surrogacy applications; the draft Directions to the Surrogacy Bill had previously required a committee/panel be set up by the IVF clinic involved in an arrangement. The 12 recommendations have since been incorporated into the Surrogacy Bill, and drafting of subsidiary legislation to the Surrogacy Bill is also underway. The RTCCC has provided advice with regard to counselling and assessment provisions set out in the draft Directions.

Members of Parliament were able to make a conscience vote on the Surrogacy Bill. Having passed previously by both the lower house and the upper house (albeit with amendments), it was considered likely that the Bill would be passed. However, the decision to call a State Government election for early September 2008 makes the final passage of the Bill less certain at the time of writing.

Human Reproductive Technology Amendment Bill 2007

The Human Reproductive Technology Amendment Bill 2007 (HRTA Bill) was introduced to WA Parliament in March 2007. This followed an undertaking by WA and other states to aim to achieve consistency across Australia in legislation relating to the use of human embryos in research.

The HRTA Bill passed through the WA Legislative Assembly. However, on 6 May 2008 the Bill was defeated in the Legislative Council. In addition to limiting the scope for research in WA, this defeat poses some concerns for the way in which ART research, currently allowed under the HRT Act, is licensed and monitored in WA.

Legislative changes set out in the HRTA Bill mirrored the Commonwealth *Prohibition of Human Cloning for Reproduction Act 2002* and the *Research Involving Human Embryos Act 2002* (RIHE Act). These Commonwealth Acts were introduced following recommendations from the 2005 Legislation Review Committee Report, the Lockhart Report, which was commissioned to consider the broad implications of research using reproductive technologies.

The Commonwealth Acts (and subsequent HRTA Bill) allow a person to apply to an NHMRC licensing committee for a licence to use or create embryos for certain research practices. These practices expand on those allowed on excess ART embryos in WA under the current HRT Act. Excess ART embryos are those created for reproduction, but are excess to the reproductive needs of a person or couple.

Research practices that may be approved by the NHMRC licensing committee under the Commonwealth Acts include:

- The creation of human embryos other than by fertilisation of a human egg by a human sperm, and use of such embryos;
- The creation of human embryos (other than by fertilisation of a human egg by a human sperm) and containing genetic material provided by more than 2 persons, and use of such embryos;
- The creation of human embryos using precursor cells from a human embryo or a human fetus, and use of such embryos;
- Research and training involving the fertilisation of a human egg, up to the first mitotic division, outside the body of a woman for the purposes of research or training;
- The creation of hybrid embryos by the fertilisation of an animal egg by human sperm, and use of such embryos up to the first mitotic division, if i) the creation or use is for the purposes of testing sperm quality, and ii) the creation or use will occur in an accredited ART centre.

(Explanatory Memorandum, HRTA Bill (now defunct).

While this legislation permits the *creation* of embryos, the Commonwealth Acts prohibit embryos created or used under such a licence being allowed to mature beyond 14 days development (suspension periods notwithstanding), and also prohibits the use of an embryo created by a means other than by fertilisation to be used for reproduction.

The creation of a human embryo for research purposes is a significant position shift to that of the HRT Act. The current HRT Act does not allow the creation of a human embryo in vitro for a purpose other than to assist persons who are unable to achieve pregnancy by natural means, or whose children are otherwise likely to be affected by a genetic abnormality or disease.

The HRTA Bill, therefore, potentially opened up research in WA, significantly widening the scope for research in the area of embryonic stem cells and other ART research.

Part 4B of the HRT Act had been declared as a corresponding state law for the purposes of the RIHE Act (having corresponded to previous Commonwealth RIHE legislation). This allowed the NHMRC to license and monitor research on excess ART embryos in WA. With the defeat of the HRTA Bill and the revocation of the declaration that the HRT Act was a corresponding State law for the purposes of the RIHE Act, the capacity of the HRT Act to confer powers to the NHMRC has been called into question.

Legal advice has been sought by the DoH to look at the implications that the defeat of the HRTA Bill, and subsequent withdrawal of corresponding State law status, pose to research under NHMRC licence in WA. Preliminary advice suggests that there may be some scope for organisations that operate under Commonwealth authority, such as corporations, to apply for a licence from the NHMRC, if the research complies with the HRT Act. This advice has yet to be clarified.

In the short term, as there is no research being conducted under an NHMRC licence in WA, the impact of the defeat of the HRTA Bill has been arguably limited. However, longer-term, it is likely that future research in this field in WA will be stymied from the narrower scope for research and the legal uncertainty for researchers requiring NHMRC approval.

Saviour Siblings

The term "saviour sibling" has been used to describe a child born with genetic characteristics specifically selected to assist in the treatment of an illness of an existing brother or sister.

Typically, the ill sibling has a condition that may respond to a tissue transplant of haematopoietic stem cells. These include congenital diseases such as the blood disorders B thalassaemia and sickle cell anaemia, or neoplastic diseases such as leukaemia. The transplantation of compatible donor tissue, such as cells from cord blood or bone marrow may potentially cure such conditions. In cases where a suitable matched donor is not readily available for the child, biological parents could undertake to create embryos from which, through PGD for human leukocyte antigen (HLA) typing, a tissue-matched embryo is selected. Subsequent implantation and gestation of the HLA-matched embryo may successfully lead to the birth of a child who can provide compatible haematopoietic stem cells or tissue for their ill sibling.

The ethical arguments underpinning the process of saviour siblings are varied and complex, and derive primarily from the issue of creating a child to be used, in effect, as a treatment for another, in addition to the physical and psychological impact of harvesting tissue (which may be an ongoing process) from the child, for no direct health benefit to that child. There is also a significant risk of the undertaking being unsuccessful and how this may impact on the savior sibling and their family.

While many lobby groups, such as the UK based "Comment on Reproductive Ethics" (CORE), remain opposed to the creation of saviour siblings on ethical grounds, in general, ethicists consider that the overall benefits to the ill and to the saviour sibling outweigh the potential harm to the saviour sibling (Shenfield et al 2005). Underpinning this position is the premise that parents will love a created child independent of their "role" as a saviour sibling, and that procedures such as solid organ transplants would not be considered (at least not until a child is old enough to effectively provide consent to such an invasive procedure).

Accordingly, a growing acceptance worldwide for the use of PGD and tissue typing for the creation of saviour siblings has been seen. This includes in the UK, where, after a lengthy

legal challenge, a House of Lords decision has allowed the Human Fertilisation and Embryology Authority (HFEA) to decide on matters involving PGD and HLA tissue typing (Sheldon 2005). A New Zealand independent governmental advisory group, the Advisory Committee on Assisted Reproductive Technology (ACART) also has recently proposed extending the use of saviour sibling-created matched tissue to non-sibling family members (Jones 2008).

In Australia, the NHMRC Ethical Guidelines on the use of Assisted Reproductive Technology in Clinical Practice does allow for the provisional selection of tissue-matched embryos, stating:

> **12.3 Seek advice before using PGD to select an embryo with compatible tissue for a sibling**.
>
> Except in the case of siblings, PGD must not be used to select a child to be born with compatible tissue for use by another person. When requested to select an embryo with tissues compatible with a sibling of a child to be born, clinics must seek advice from a clinical ethics committee (or relevant state or territory regulatory agency).
>
> **12.3.1** The ethics committee or relevant agency should ascertain that:
>
> the use of PGD will not adversely affect the welfare and interests of the child who may be born; the medical condition of the sibling to be treated is life-threatening; other means to manage the medical condition are not available; and the wish of the parents to have another child as an addition to their family and not merely as a source of tissue.

In Western Australia, the HRT Act sets out the conditions under which PGD of embryos may be approved. The use of HLA or tissue testing for the purpose of creating saviour siblings is not specifically addressed in this legislation. However, legal advice sought during the development of the RTC Policy on Approval of Diagnostic Procedures involving Embryos 2008, identified that a discrepancy exists in the HRT Act that could potentially allow some, but not all, parents to apply for PGD in order to create a saviour sibling for an ill child.

Specifically, a parent or couple who is eligible for IVF due to *medical reasons* under the HRT Act *may* be able to pursue this option, but an ineligible parent (for example, through not being deemed "infertile"), or one who is only eligible for IVF to avoid conceiving a child likely to be affected by a genetic abnormality or a disease, would *not* be able to pursue this option.

Council, on advice from the PGD Committee, and following consideration of the ethical arguments and the inequity of the current legislation, agreed to seek legal advice with regard to removing this discrepancy in the HRT Act.

To date, Council has not received any specific requests to approve PGD for HLA testing to create a saviour sibling. However, Council considers that it is important to have both policy and a legal framework in place in the event that such a case arises. Legal advice regarding this matter has, therefore, been sought, and Council action on the issue will be determined following this.

Jones, B 2008, "New Zealand committee proposes legalisation of prohibited fertility practices". *BioNews.org.UK*, 28 July 2008 http://www.BioNews.org.uk/new.lasso?storyid=3926

Sheldon, S 2005, "Commentary- Saviour Siblings and the Discretionary Power of the HFEA", *Medical Law Review, 13*, Autumn 2005, pp.403-411.

Shenfield F., Pennings G., Cohen J., Devroey P. and Tarlatzis B. (ESHRE taskforce of Ethics and Law) "Taskforce 9: the application of preimplantation genetic diagnosis for human leukocyte antigen typing of embryos", *Human Reproduction, Vol 20*, No 4, pp845-847.

Sperm Donor Shortage

Donor sperm in ART is utilised in a range of cases, including couples who cannot conceive due to male infertility, single women or female same-sex couples seeking to have a child, or where a male partner is carrying a significant genetic condition that may pose a risk to a child conceived with his genetic material. Sperm donation, as with egg/oocyte and embryo donation, may be by a person known to the recipient, as a *known donor,* or be through an anonymous or *unknown donor,* and sourced from an IVF clinic with a storage licence.

A shortage of sperm donors in Australia, particularly for unknown donors, has been a recognised concern in ART practice for a number of years. Further media attention was given to the issue in 2007-2008, reflecting the growing recognition in Australia that a shortage of sperm donation is impacting on the provision of ART services.

Media coverage of one consequence of the shortage included a "60 Minutes" report (*D.I.Y. Mums*, 30 March 2008) on women importing sperm from overseas for self-insemination. The ABC also covered this trend on "The 7.30 Report", "*Sperm Shortage in Aussie fertility clinics",* July 2008.

In Western Australia, requirements for gamete-donation that have reportedly impacted on the availability of unknown donor sperm include the prohibition of payment for sperm donation (reimbursement for out-of-pocket expenses is allowed), and the requirement that children conceived from donor gametes shall have access to the identity of the donor when they reach the age of 16 years. Consent from the donor to permit access to their identity must be provided before sperm is accepted by licensees or exempt practitioners.

The receipt of payment for sperm donation is prohibited under both in Commonwealth and WA legislation. The RTAC guidelines and the NHMRC code of ethics also set out that this payment for gamete donation is not permitted.

Access to information regarding the identity of the donor also has been attributed with impacting on the number of willing donors in Western Australia. The principle underpinning this requirement derives from the growing recognition that children conceived from donor gametes have a right to know their genetic background. The lack of knowledge about genetic or biological heritage (often referred to by children conceived from donor gametes) has been described by the term "genealogical bewilderment". Access to donor identity, in addition to the non-identifying descriptive information about a donor, aims to minimise the risk of such a negative emotional outcome for children born from gamete donation.

In Western Australia, the issue of sperm donor shortage has been brought to Council's attention through a number of matters during the 2007-2008 year. These include:

- A licensee request to raise the five family limit to ten recipient families. This request refers to Direction 8.1 under the HRT Act, which sets out that for each donor of gametes, there are no more than five recipient families known to the licensee, including families that may be outside of Western Australia, unless the Council has given approval.

This request was not approved by Council, on advice from the RTCCC, on the premise that knowledge of the existence of a large number of biologically-related families (and half-siblings) may pose a harmful psychological impact on donor children. The risk of consanguinity (blood relationship because of common ancestry) may also be a factor in Western Australia due to the relatively small population in the State (see Appendix 5).

- Another matter presented to Council concerned a complaint from an ART patient outlining that, as a single woman seeking donor sperm for AI, she had not been able

to secure an unknown donor despite application at several clinics. She had subsequently conceived a child through a known donor, but had been quite distressed by her experiences when initially seeking an unknown donor.

In this case, another factor that may have influenced the patient's access to a donor is the capacity for donors to direct their donations. In Western Australia, a donor may specify, for example, if they have a preference for a donation to be given to a couple, rather than a single woman. This may have made it even more difficult for this patient to access a donor.

- Further attention to the issue was noted with the tabling of a letter from the Chair of the NHMRC Embryo research Licensing Committee (7 May 2008) circulated through the RTAC Chair, regarding ART units (in WA, these are the licensees) importing donor sperm for which donors have received payment or valuable consideration. As noted above, this is not allowed in Australia.

While licensees are able to seek Council approval to import sperm from an overseas source, it is not always feasible that the donor source will meet all the requirements set out in the legislation. For example, the sperm bank cited in the 60 Minutes report as a growing supplier of donor sperm in Australia has a 35 family unit limit policy. Other requirements that may not be met when donor sperm are sourced from overseas include the right for children reaching 16 years of age to access donor identifying information, and that donors must not be paid for the donation.

Council may approve the importation of sperm (with the exception of paid donations) when there are exceptional circumstances, or on compassionate grounds. Approval may be considered, for example, when a couple already has a child created from donor sperm sourced overseas, and wish to conceive another child who will be a full sibling to their existing child.

Figures from the 2006-2007 Annual Report reveal that while there were only 13 "new" sperm donors recorded in WA in 2007, the two *lowest* new donor figures recorded since 1993 were reported in 1998 and 2002. New donor numbers for these years were 11 and 10 new donors respectively. Total sperm donors had steadily risen to 81 in 2007, up from the lowest total sperm donor figures in 1999 and 2002, which had 22 and 21 sperm donors in total. Furthermore, 2007-2008 figures show that 37 new sperm donors were accepted by clinics in this year. The proportion of unknown to known donors in this figure is not identified, as this is not recorded in clinic annual reporting data. Thus, the fluctuation in sperm donor numbers seem to illustrate that sperm donation in Western Australia is influenced by a number of factors, not simply the policy of identifying donors when a donor conceived child reaches 16 years of age.

Nevertheless, unknown sperm donor shortage has been recognised by Council as a genuine concern to licensees utilising unknown sperm donors in their treatment of infertility and provision of ART to single women or same sex couples. However, Council considers that the relaxation of existing guidelines and legislation to allow an expansion of sperm donation usage (such as allowing 10 families to be created rather than 5) will arguably be to the detriment of children conceived from gamete donations.

In order to identify other means of addressing the issue (such as encouraging the acceptance of known donations as demonstrated by donor ART policy in New Zealand), Council has flagged this matter for further consideration, including further discussion with relevant stakeholders, in the 2008-2009 year.

Data Linkage

The RT Register was established in 1993 to record details of treatment cycles and outcomes from ART practices in WA. This register is just one of a number of registers managed by the WA DoH. The authority for the collection and use of data from the RT Register is set out in the HRT Act.

In addition to recording the data of individuals accessing health services in Western Australia, health data collections provide a significant population health and epidemiology research resource. In particular, the potential to *link* the data collections may allow the collation and examination of large volumes of information about population health outcomes, associated with a wide range of health and lifestyle factors. The linking of information from different data sets is known as *data-linkage*. Linking of other data sets to the RT Register, may allow health outcomes, such as hospital morbidity and birth outcomes associated with participation in ART, to be determined.

The HRT Act and legislation regarding the RT Register were initially developed with the intention that ART practices, including innovative and technological advances, would be monitored. However, in 2007 a query regarding access to data under the HRT Act highlighted a concern that this legislation, in protecting the confidentiality and privacy of participants accessing ART services, appeared to limit the capacity for researchers to access data. Several research and licensee projects, where information regarding birth outcomes had previously been linked for monitoring purposes, were suspended in order that legal advice could be sought.

The ensuing legal advice was to the effect that such linkage *was* permissible under the HRT Act if it was for the purposes of research to which the Act applied, and that linked information provided to such researchers be truly de-identified at the point of supply. Subsequently, approval for two suspended research projects to continue was granted by Council in May 2008.

The long-term safety of both established and innovative ART procedures will primarily be determined through public health and epidemiological research. The responsibility of authorised officers, DoH data management and Council is to ensure that any such research is undertaken within a strictly regulated process that safeguards the privacy rights of individuals with information held on the Register.

PRESENTATIONS AND PUBLICATIONS BY COUNCIL MEMBERS AND STAFF 2007-2008

Reverend Brian Carey

Presentations

"Is it ethical to be perfect?" Presentation to Medical and Allied Health Professionals in the Bunbury region, 27 June 2008.

Associate Professor Jim Cummins

Presentations

"The changing nature of the family in 2008"; Public Seminar (Murdoch University) 16 May, 2008.

"ART in 2008", Public Lecture (Mandurah chapter of U3A) 22 July, 2008.

Associate Professor Roger Hart, Reproductive Medicine

Presentations

1. "Ovulation induction in Women with PCOS"
Joint Thai Fertility Society and ASPIRE Meeting Bangkok, November 2007

2. "Prenatal Programming of PCOS"
5th International Congress on The Developmental Origins of Adult Disease, Perth, November 2007.

3. "IVF Implications for the Offspring"
5th International Congress on The Developmental Origins of Adult Disease, Perth, November 2007.

4. "Fertility Issues for women with breast cancer"
Breast Cancer Care Nurses of Australia and New Zealand, Fremantle 2008.

Publications

1. Hart R, Karthigasu K, "The benefits of virtual reality simulator training for laparoscopic surgery", *Women's Health: Current Opinion in Obstetrics and Gynaecology* 2007 Aug;19(4):297-302

2. Hart R, "Polycystic Ovarian Syndrome – Prognosis and Treatment Outcomes", *Women's Health: Current Opinion in Obstetrics and Gynaecology* (Eds) Aquilina J, Ayida G:" Lippincott, Williams & Wilkins, London 2007 Dec, 19(6):529-35.

3. Hart R, Sloboda D, Doherty D, Norman R, Franks S, Newnham J, Dickinson J, Hickey M, "The effect of intrauterine exposure to maternal androgens on the incidence of Polycystic Ovarian Syndrome in a cohort of Australian adolescents – the Raine cohort". *Early Human Development* 2007; 83: suppl S54.

4. Hart R, Hickey M, Maouris P, Buckett W, "Excisional surgery versus ablative surgery for ovarian endometriomata", *Cochrane Review 2008*

5. Menninger I, Hart R. "Hysteroscopic sterilisation", *Fallopian Tubes* (Eds) Djahanbakhch, Saridogan and Allahbadia Anshan Publishing House, Tunbridge Wells, UK. 2008. ISBN 9781905740741

6. Sloboda D, Hart R, Hickey M. "The developmental origins of reproductive health", DoHaD 2008 (in Press).

APPENDIX 1

EXEMPTIONS ISSUED BY COUNCIL UNDER THE HUMAN REPRODUCTIVE TECHNOLOGY ACT 1991

Section 28 of the HRT Act outlines that medical practitioners may apply for an exemption to practice artificial insemination procedures without a licence. Current practitioners issued with such an exemption are identified below. Exempt Practitioners marked with an asterix * have requested the revocation of their exemption from 2008/2009.

Exemption No	Practitioner Name	Suburb	Post Code
E023	Dr PK Bairstow *	Bunbury	WA 6230
E034	Dr RT Chapman	Perth	WA 6000
E027	Dr DP Day	Kelmscott	WA 6111
E001	Dr ZN Dorkham *	Bunbury	WA 6230
E050	Dr R Kirk	Northam	WA 6401
E046	Dr TP Knight *	Mandurah	WA 6210
E024	Dr DN Lawrance	Kelmscott	WA 6991
E025	Dr HH Leslie	Albany	WA 6330
E016	Dr KA McCallum	Kalgoorlie	WA 6430
E003	Dr KT Meadows	Murdoch	WA 6150
E051	Dr WD Patton	Rockingham	WA 6168
E017	Dr C Russell-Smith	Kwinana	WA 6167
E022	Dr BGA Stuckey	Nedlands	WA 6009
E029	Dr JM Vujcich	West Perth	WA 6005
E028	Dr RJ Watt	Mandurah	WA 6210
E049	Dr M Zafir	Albany	WA 6330

APPENDIX 2

LIST OF APPROVED COUNSELLORS AT 30 JUNE 2008

Name	Professional Address	Telephone / Fax No
Ms Deborah Foster-Gaitskell*	62 Churchill Ave SUBIACO WA 6008	Ph (08) 9271 3582 Fax (08) 9388 3740
Ms Lisa Hasard	Pivet Medical Centre 166-168 Cambridge St LEEDERVILLE WA 6007	Ph (08) 9382 1677 Fax (08) 9382 4576
Ms Jane Irvine	Roe Street Centre for Human Relationships-FPWA 70 Roe St NORTHBRIDGE WA 6003	Ph (08) 9228 3693 Fax (08) 9227 6871
Ms Rosemary Keenan*	6 The Lakes Mews Karrinyup Lakes Lifestyle Village GWELUP WA 6018	Ph (08) 94478365
Ms Suzanne Midford*	1) Perth Psychology Services 7/401 Oxford St Mt HAWTHORN WA 6050 2) 2/36 Ormsby Tce MANDURAH WA 6210	Ph (08) 9387 6468 Fax (08) 9387 6468
Ms Helen Mountain	Genetic Services of WA King Edward Memorial Hospital Centre for Women's Health Bagot Road SUBIACO WA 6008	Ph (08) 9340 1525 Fax (08) 9340 1678
Ms Iolanda Rodino*	1) Keogh Institute for Medical Research QE Medical Centre NEDLANDS WA 6009 2) Fertility Specialists of WA Bethesda Hospital 25 Queenslea Dr CLAREMONT WA 6010 3. Private Practice North/South Ph:	Ph (08) 9346 2008 Fax (08) 9380 6387 Ph (08) 9340 6419 Ph (08) 9389 7212
Ms Margaret Van Keppel*	1) 267 Walcott Street NORTH PERTH WA 6006 2) Pivet Medical Centre 166-168 Cambridge St LEEDERVILLE WA 6007 3) Hollywood Fertility Centre Monash Ave NEDLANDS WA 6009	Ph (08) 9443 3655 Fax (08) 9443 8665 Ph (08) 9389 4200
Ms Elizabeth Webb	Fertility North Suite 213 Specialist Medical Centre Joondalup Health Campus Shenton Ave JOONDALUP WA 6027	Ph (08) 9400 9965
Ms Antonia Clissa	Concept Fertility Centre PO Box 966 SUBIACO WA 6008	Ph 0412 653 854
Ms Cailin Jordan	Hollywood Fertility Centre Monash Ave NEDLANDS WA 6009	Ph 0415 924 779 Ph (08) 9389 4200

* Counsellors able to undertake "telling issues" counselling of children.

APPENDIX 3

OPERATIONS OF LICENSEES FOR THE FINANCIAL YEAR 2007-2008

The aggregated data, tabulation, graphical representation, analysis and interpretation of the data in this Appendix were kindly provided by Information Management and Reporting, Department of Health.

Background

This summary was put together from information submitted in relation to six Storage Licences and five Practice Licences authorising artificial fertilisation procedures, including in vitro fertilisation (IVF), as required by the *Human Reproductive Technology Act 1991* (HRT Act). In addition, one practice licensee is licensed only to carry out artificial insemination. Information required from this practice licensee on the provision of intra-uterine insemination has been included in this summary. Information about patients referred from the public fertility clinic at King Edward Memorial Hospital to licensee Concept Fertility Centre has been provided by Concept.

All information was submitted in a collated form, and refers to the period 1 July 2007 to 30 June 2008 (2007-2008). While it is not possible to provide any data on outcomes of treatments undertaken during the financial year just ended due to the necessary lag time required for reporting, this summary shows the scale and type of activities carried out under licence.

Semen storage and donation

During the 2007-2008 financial year, semen donations from 111 men were stored with WA storage licensees. Of these, 37 were new donors. This is a notable increase of 24 from the number of new donors in 2006-2007. The number of new donors for 2007-2008 is at its highest since 1993, when there were 40 new donors (illustrated in Figure 1). There has been a decrease in sperm donor numbers since 2004 when amendments to the legislation required that all new donors consent to release of their identifying information to any offspring conceived from their donation. This spike in new donors for 2007-2008, therefore, was not predicted from previous reports, and is possibly attributable to a change in policy in some clinics where patients are encouraged to actively seek known donors, which may circumvent the long waiting time for anonymous donors. There has also been increased media coverage on the shortage of sperm donors in Western Australia- both newspaper and television media have reported on this issue throughout 2007-2008.

The age distribution of donors (Table 1) indicates that the majority (77.5%) were over 30 years of age, 37.8% of which are over 40. There appears to be a general trend towards semen donation from older donors (Figure 2). Where the marital status of the donor was known, over 77% of donors were single, 22% were married or in a de facto relationship and only 1 out of the 111 donors was divorced.

Reporting by storage licensees indicated that during the year, donor semen was supplied to one WA exempt practitioner. As detailed in Appendix 1, there were 16 exempt practitioners at the end of 2007-2008 with 3 exempt practitioners requesting revocation of their exemptions for 2008-2009.

TABLE 1: 2007-2008 SEMEN DONOR AGES

Age of Donor (years)	Number (%)
18-25	11 (9.9)
26-30	14 (12.6)
31-35	21 (18.9)
36-40	23 (20.7)
41-49	36 (32.4)
50 +	6 (5.4)
Total	**111 (100)**

FIGURE 1: SEMEN DONORS IN WA

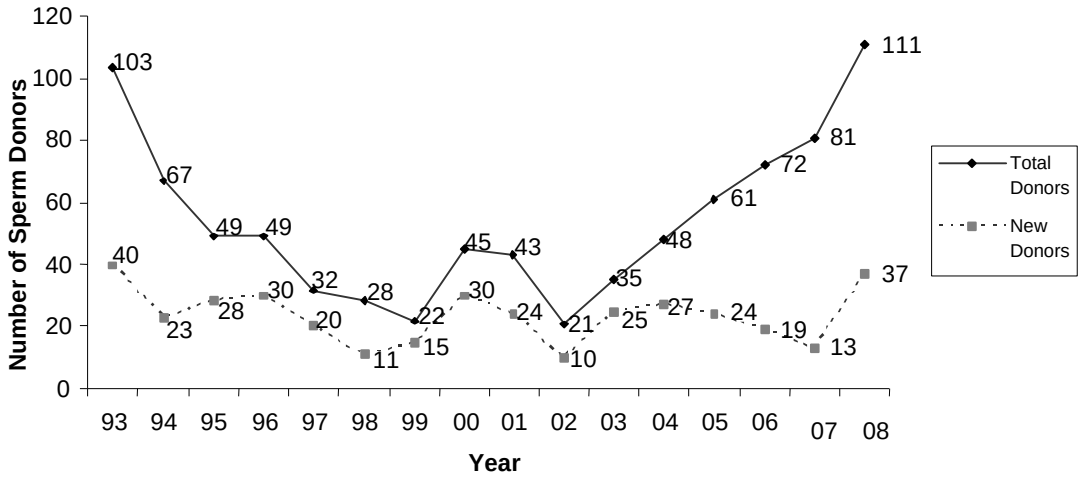
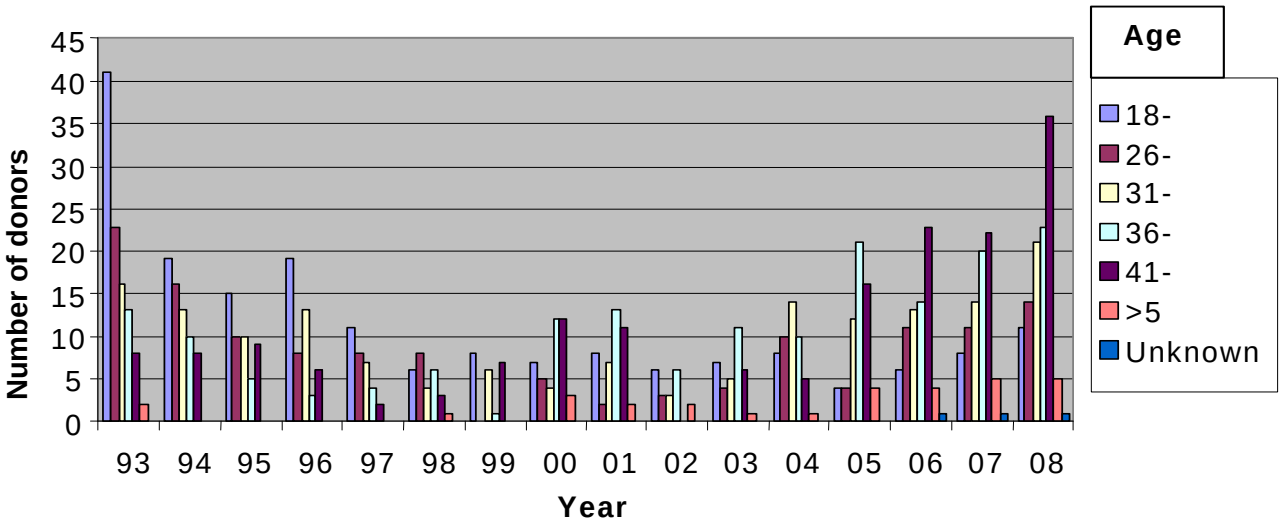


FIGURE 2: NUMBER OF SEMEN DONORS BY AGE



Embryo storage

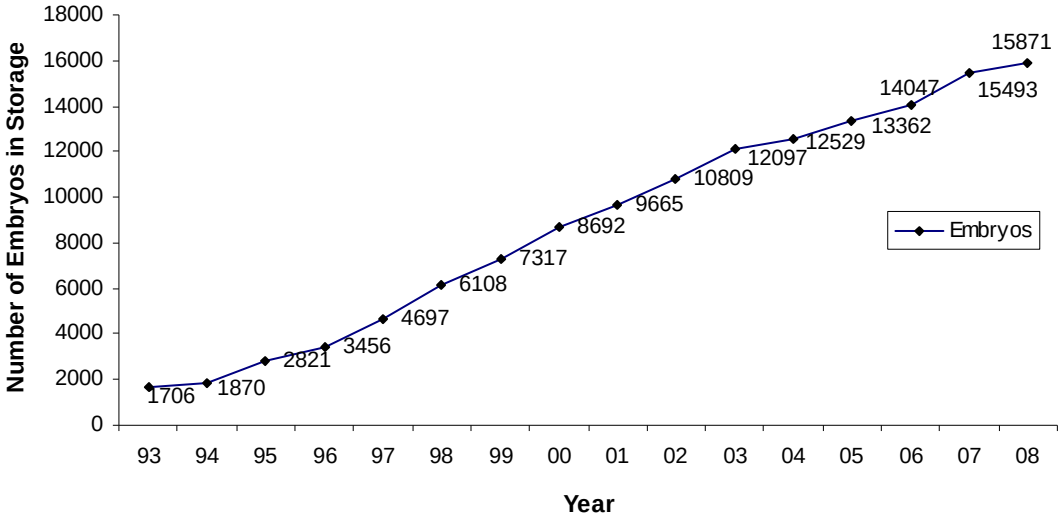
Table 2 shows the total number of embryos in storage at the end of 2007-2008 as 15,871. The total number of embryos in storage has continued to increase since 1993 (as illustrated in Figure 3). Although there was a sharp increase between 2005-2006 and 2006-2007 (10.3%), the figure from this financial year shows this rate has somewhat slowed. A net export of embryos transferred interstate (compared to 2006-2007, when a net import of embryos occurred), may explain some slowing in the rate illustrated by Figure 3. This is despite the notable increase in the number of people undertaking IVF as demonstrated by the rise in the number of commenced oocyte retrieval cycles, which this year increased by 16.8% over 2006-2007 figures. Frozen embryo transfer (FET) cycles increased by 14.2% this year, therefore a greater number of embryos were removed from storage for embryo transfer in these cycles than in 2006-2007, somewhat countering the increase in embryos stored as a result of creation through IVF undertaken in 2007-2008: A total of 5506 embryos were stored following treatment, while 3607 stored embryos were used in treatments during the 2007-2008 year.

A significant increase in the number of embryos allowed to succumb was recorded for 2007-2008, the figure this year being 1448 compared to 544 in 2006-2007. This possibly reflects the proportion of stored embryos approaching their ten year storage expiry date. Patients who have completed their treatment within this period will often allow their remaining embryos to succumb. Under the HRT Act, embryos are not permitted to be stored for longer than ten years unless Council approval to extend the authorised storage period has been granted.

TABLE 2: DISPERSAL OF STORED EMBRYOS 2007- 2008

	No of embryos
Embryos in storage 30/06/07	**15 493**
Embryos created from IVF	5506
Transferred into WA clinics from interstate	45
Transferred between clinics in WA	180
Transferred to clinics outside WA (Patients moving interstate/overseas)	130
Used in frozen embryo transfer treatments	3607
Allowed to succumb with consent of couples	1448
Embryos in storage 30/06/08	**15 871**

Figure 3: Trends in Embryo Storage



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

Table 3 shows that during 2007-2008, 2005 women began oocyte retrieval cycles for IVF and 954 began FET. No licensees reported use of GIFT for 2007-2008. Use of GIFT in ART has been negligible since 2000. A total of 4532 cycles were started for IVF and FET, an increase on the previous year (4012 cycles). As shown in Table 3, of the 4532 treatment cycles initiated in 2007-2008, 2779 (61.4%) were for IVF and 1744 (38.6%) were for FET.

Of the 2779 cycles begun for IVF (for fresh embryo transfer), 88.3% proceeded to oocyte retrieval and 84.5% proceeded to transfer fresh embryos or gametes. This is a considerable increase from the transfer rates in 2006-2007 of 72.1%.

For 2007-2008, 1744 FET cycles were started, with 1561 (89.5%) proceeding to transfer.

Overall, donated human reproductive material was involved in 5.7% of all IVF cycles with oocyte retrieval during the year. In 3.6% (89) of cycles, donor semen was used; donor eggs were used in 1.9% of cycles (47 cycles) and there were 5 IVF cycles with fresh embryos donated. A higher proportion of frozen embryo transfer cycles (7.0%) involved use of donated gametes or embryos. Donor embryos were used in 1.3% of all FET cycles with transfer (21 cycles); donor eggs in 2.8% (44 cycles) and donor semen in 2.9% (45 cycles).

Of all 2455 IVF treatment cycles with successful oocyte retrieval, 1670 (68%) involved intra-cytoplasmic sperm injection (ICSI). As illustrated in Figure 6, use of ICSI has increased since the last financial year. Since its introduction in WA in 1994, the early increase in use of ICSI may be explained by ICSI becoming a mainstream practice in cases of male fertility problems and poor fertilisation. The use of ICSI has continued to increase in recent years, at a higher rate than in earlier years, particularly from 2005 onward. Sperm retrieved from the epididymis or testis was used in 216 of the ICSI treatment cycles.

TABLE 3: 2007-2008 IVF and GIFT TREATMENTS

	IVF (fresh)	FET (frozen)	GIFT	TOTAL
Women treated	2005	954	0	N/A
Cycles begun	2779	1744	0	4532
Cycles with egg retrieval	2455	-	0	2455
Cycles with gamete or embryo transfer	2075	1561	0	3636
Cycles with embryos storage	1359	-	0	1359
Number of cycles using donor:				
Semen	89	45	0	134
Eggs	47	44	0	225
Embryos	5	21	0	26
Total	141	110	0	251
Number of cycles from which human reproductive material was donated:				
Eggs donated	51	-	0	51
Embryos donated	0	-	-	0
Breakdown of treatment cycle details				
Cycles with IVF/GIFT same cycle	0	-	0	0
Cycles with surgical sperm aspiration	216	-	0	216
Cycles with ICSI*	1670	-	-	1670
Cycle with Fallopian embryo/egg transfer	0	0	0	0

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

FIGURE 4: ART TREATMENT TRENDS

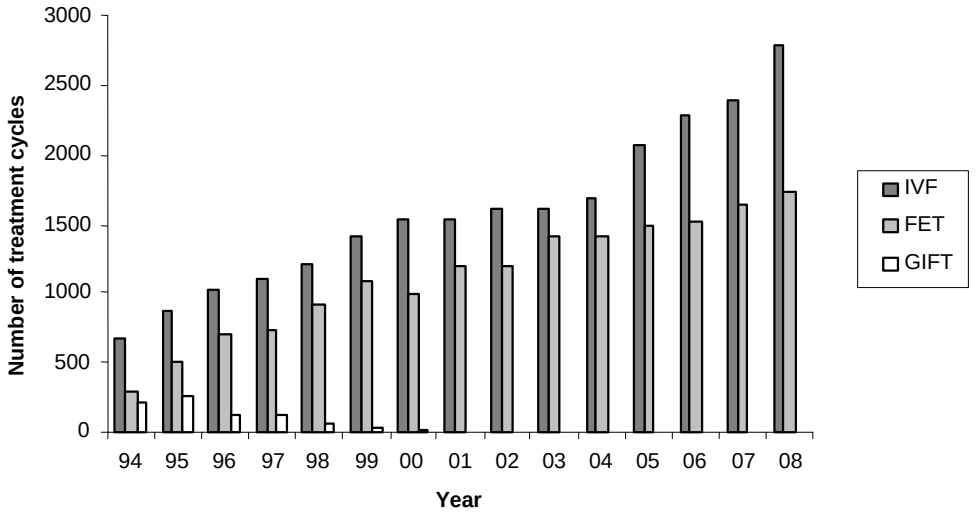


FIGURE 5: IVF (FRESH) AND GIFT TREATMENTS*

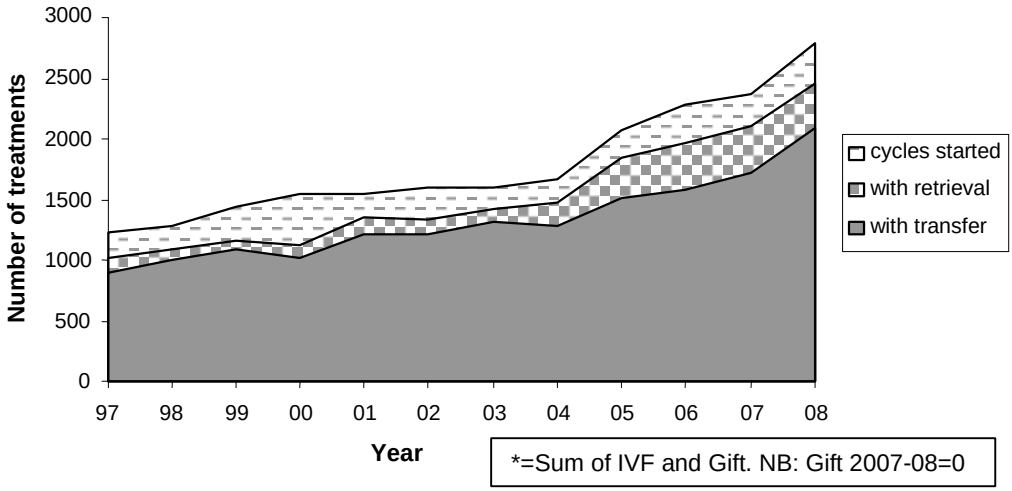


FIGURE 6: IVF CYCLES USING ICSI

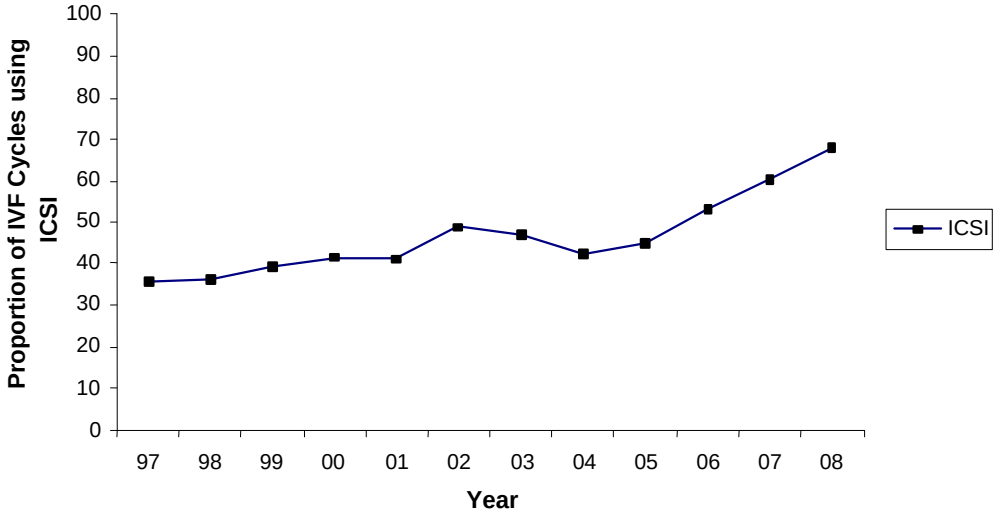
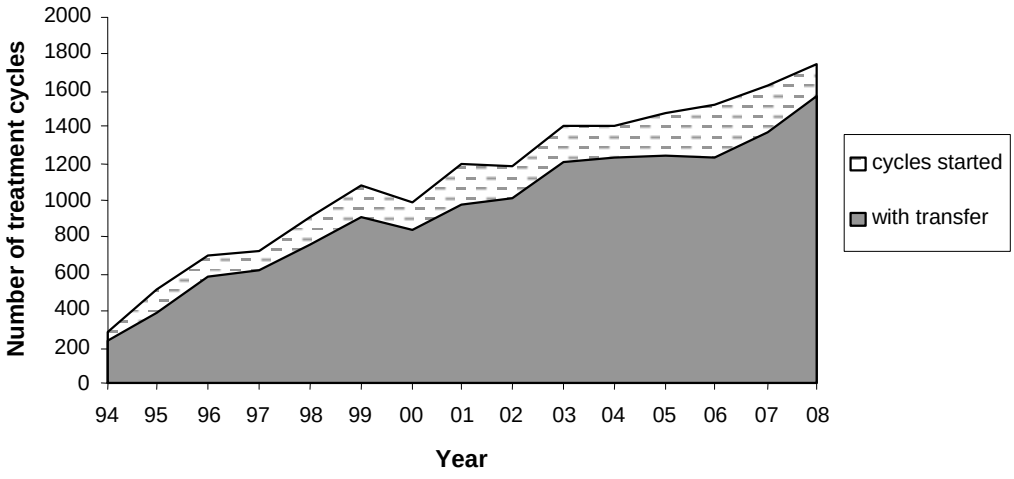


FIGURE 7: FET TREATMENTS



Treatment of patients referred from the Public Fertility Clinic

During 2007-2008, 148 patients from the King Edward Memorial Hospital (KEMH) Infertility Clinic were referred for treatment at Concept Fertility Centre. As can be seen from Table 4, 100 women underwent treatment for IVF and/or FET; 75 women were treated with fresh IVF transfer and 25 with frozen embryo transfer. The number of public patients treated is similar to the number treated last year.

During 2007-2008, 134 fresh IVF and 67 FET treatment cycles were commenced for public patients. This year 69 of the IVF cycles involved micro-manipulation (ICSI). Of all the 201 cycles for public patients only 2 cycles reported using donated gametes or embryos. In these cases donor semen was used. In addition, there were 23 IVF cycles and 13 FET cycles reported where assisted hatching was used. Sixty three IVF cycles and 25 FET cycles used extended culture. No cycles were undertaken where embryos had undergone diagnostic testing.

There were 48 artificial insemination treatments (all using husband's sperm) between 1 July 2007 and 30 June 2008, for public patients. This is a decrease from the 66 artificial insemination treatments performed in the previous year.

TABLE 4: IVF AND RELATED TREATMENT OF PUBLIC PATIENTS

	No. of Patients					No. of Treatment Cycles				
	03/04	04/05	05/06	06/07	07/08	03/04	04/05	05/06	06/07	07/08
IVF	65	77	81	82	75	82	111	130	143	134
GIFT	0	0	0	0	0	0	0	0	0	0
FET	27	30	24	25	25	104	115	97	91	67
TOTAL	**92**	**107**	**105**	**107**	**100**	**186**	**226**	**227**	**234**	**201**

Intra-uterine insemination (IUI)

The Council is continuing to monitor IUI carried out by licensees and exempt practitioners. In 2007-2008, a total of 1713 IUI cycles were reported by six practice licensees- reflecting very closely last year's figure of 1718 IUI cycles. The overall ongoing clinical pregnancy rate per treatment cycle carried out was 8.8% (151 ongoing pregnancies), and of the pregnancies where plurality was known, 131 were singleton (92.3%), 8 were twin (5.6%), two were triplets (1.4%) and one quadruplet pregnancy resulted. These figures show a greater proportion of IUI procedures resulted in singleton pregnancies than compared to outcomes reported in 2006-2007.

The information provided showed that 88.1% of the IUI cycles involved use of the partner's sperm, with 11.9% using donor sperm. The majority (46.1%) involved the use of gonadotrophins. 36.3% of cycles did not involve the use of ovulation induction, and Clomid was used in 16.8% of the cycles. These figures show a reversal in the number of cycles using gonadotrophins and the number of natural cycles as compared to last year's figures (35.3% and 46.7% respectively in 2006-2007). Gonadotrophins (follicle-stimulating hormone) are used in assisted reproduction as they are associated with increased live birth rates when compared with "no treatment" for women experiencing infertility problems.

As noted above, IUI resulted in two sets of triplets. Both sets of triplets followed gonadotrophin stimulation, one set using husbands/partner sperm (AIH) and one set using donor sperm (AID). Of the eight sets of twins reported, two followed natural cycles, one

followed a clomid cycle and the other five sets resulted from ovulation induction by gonadotrophins. Two sets of twins resulted from AID and six resulted from AIH.

Two exempt practitioners carried out AIH and or AID in 2007-2008, undertaking 66 cycles in total.

Serious morbidity and mortality in women undergoing treatment

The six licensees reported a total of 23 cases of severe ovarian hyper-stimulation (OHSS) resulting from the 2779 IVF cycles initiated in 2007-2008 (0.8% of total cycles, with a clinic range of 0–2.4%). The severe OHSS cases presented (on ultrasound) with an average of 17.5 follicles measuring over 12mm. There was one case of severe pelvic infection, and 11 cases of other serious morbidity. There were no reports of mortality in association with fertility treatment during the year.

Counselling

Licensees reported providing 1884 counselling sessions during 2007-2008, compared to 1353 sessions in the previous year. This represents a 39.2% increase for this financial year.

Most (82%) participants received a single session of counselling. The majority (85%) involved information counselling, while the remaining participants (14.5%) accessed support or therapeutic counselling.

From the remaining 18% of participants who accessed more than one session of counselling (19.7%), over 35% were information counselling sessions, just over 20% were counselling sessions for support, 26.4% were counselling sessions in relation to a matter associated with infertility and just over 1% of these sessions were regarding counselling for other personal matters not related to infertility. Almost 3 % of sessions were for a personal crisis and 12.7% of sessions were for other reasons.

Counselling concerning issues of donation for donors or recipients made up 37.4% of all counselling. This represents an 8.5% increase on that recorded in the previous year. The increase is likely to be attributable to the increase in the number of treatments this year involving donated reproductive material compared to 2006-2007. Counselling prior to known donation is mandatory under the HRT Act. For one IVF clinic, over half (53.5%) of all counselling offered for the year was related to issues of donation. All clinics reported that the majority of the counselling took place on site at the clinic.

Active research projects with Council approval

R019 Phase III, Multicentre open label randomised trial to assess the efficacy and convenience of orgalutron
PIVET Medical Centre Approved 08/08/00
Council awaiting study results.

R023 Research into optimal method of oocyte cryopreservation
PIVET Medical Centre
Approved (Out of session) October 2006

Innovative clinical/laboratory practices

Innovative practice number	Procedure approved	Licensee and date approved
I 015	Blastocyst culture and transfer	Fertility North Approved 29/10/2004
I 017	Oocyte cryopreservation	Concept Fertility Centre Approved 17/10/2006
I 018	Blastocyst culture	Fertility Specialists WA Approved 17/10/2006
I 019	Assisted hatching	Fertility Specialists WA Approved 23/01/07
I 020	In vitro maturation	Fertility Specialists WA Approved 23/01/07
I 021	Oocyte cryopreservation	Fertility Specialists WA Approved 23/01/07
I 022	Oocyte cryopreservation (incl oocyte vitrification)	PIVET Medical Centre Approved 20/02/07
I 023	Vitrification of embryos	PIVET Medical Centre Approved 20/02/07
I 024	Vitrification of cleavage and blastocyst embryos	Hollywood Fertility Centre Approved 21/08/07

Diagnostic testing of Embryos

Under Direction 9.9, licensees must seek approval from Council to undertake Pre-implantation Genetic Diagnosis (PGD) of embryos. Applications approved for PGD during the 2007-2008 financial year are listed below. In many cases, approval is subject to a positive feasibility study of the proposed PGD procedure.

PGD Number	Condition tested	Licensee and approval date
PGD 003/2007-01	Unbalanced translocation	PIVET Medical Centre Approved 17/07/07
PGD 001/2007-06	Cystic Fibrosis	Concept Fertility Centre Approved 17/07/07
PGD 001/2007-07	Unbalanced translocation	Concept Fertility Centre Approved 17/07/07
PGD 001/2007-08	ABCD1 gene adrenoleukodystrophy mutation	Concept Fertility Centre Approved 21/08/07
PGD 001/2007-09	Charcot-Marie-Tooth (CMT) disease Type 1B	Concept Fertility Centre Approved 21/08/07
PGD 003/2007-02	Haemophilia Type A, Factor VIII	PIVET Medical Centre Approved 21/08/07
PGD 001/2007-10	Huntington Disease	Concept Fertility Centre Approved 09/10/07
PGD 001/2007-11	Spinal Muscular Atrophy	Concept Fertility Centre Approved 09/10/07
PGD 027/2007-01	Unbalanced translocation	Fertility Specialists of WA Approved 9/10/07

PGD approvals cont…

PGD 001/2007- 12	Unbalanced Robertsonian translocation	Concept Fertility Centre Approved 20/11/07
PGD 001/2007-13	Muscular Dystrophy (selection of female embryos)	Concept Fertility Centre Approved 11/12/07
PGD 001/2008-01	B-thalassaemia	Concept Fertility Centre Approved 08/04/08

Applications under Directions 6.3, 7.7 and 8.8

Direction 6.6

To export embryos from WA licensee to for donation to couple in Melbourne, Victoria.	PIVET Medical Centre Approved 20/11/07
To export embryos and donor sperm to Albury, New South Wales.	PIVET Medical Centre Approved 11/12/2007

Direction 8.4b and 5.8

Waive cooling off period and concurrent quarantine period for donor sperm.	Client Request/ Hollywood fertility Centre Approved 05/02/2008

Direction 8.8

Waive 8.7 to allow further oocyte collection where more than 3 or more embryos are in storage under 8.8.	Fertility Specialists of WA Approved 21/08/2007
Waive 8.7 to allow further oocyte collection where more than 3 or more embryos are in storage under 8.8.	Fertility North Approved 21/08/2007
Waive 8.7 to allow further oocyte collection where more than 3 or more embryos are in storage under 8.8.	Fertility Specialists of WA Approved 11/12/2007

APPENDIX 4

REPORT FROM THE REPRODUCTIVE TECHNOLOGY REGISTER

Registers of assisted reproductive technology treatments were established under the HRT Act. These registers include information on each cycle of *in vitro* fertilisation (IVF), gamete intra-fallopian transfer (GIFT) and donor insemination (DI). This information is collected from all practice licences and exempt practitioners licensed under the HRT Act.

Data from the registers have been collected since 8 April 1993. Recently, Information Management and Reporting (IMR) directorate has collaborated with the Reproductive Technology Unit to provide IT support to update the Register and improve the security and efficiency of the data reporting, importing and management process. Areas for improvement have been identified and include reviewing the relevance of the data fields requested from clinics. Assisted reproduction treatments and technology have progressed and changed significantly over the past ten years, and policy changes must also be taken into account (such as the possibility of treatment cycles associated with surrogacy arrangements) when determining the data fields of relevance today.

Reproductive technology register data structure

Information is collected on all assisted reproductive technology procedures defined as:

- All **Oocyte Pick Ups (OPU)**
- All **Cancelled cycles where follicle stimulating hormones have been administered**
- All Cycles where **frozen embryos are thawed** regardless of the intention or outcome of the thawing process
- All cycles where artificial insemination is performed using donated sperm (ie **donor insemination**)
- Each occasion where embryos are either **donated or moved** into or out of an IVF Unit from a different unit

The following fields of information are to be collected by each licensed assisted reproductive technology clinic in Western Australia and reported to the RT Register as required by the HRT Act.

No	Name	Notes	Type & Length
1	Unit	This is the unit number supplied by the NPSU used to identify the clinic.	Num-3
2	Site	This is the clinic site where the most significant part of the treatment was carried out	Num-2
3	Pat_ID	This is the female participants ID code. This is a unique ID for the patient. This can take whatever form the Unit wishes.	Char-8
76	Partner ID	This is the identification code of the partner of the female participant.. This should also be completed for lesbian couples.	Char-8
4	Mdob	Participant date of birth.	Date-10
5	Pdob	That is the husband/ partners date of birth. Can be left blank if single or oocyte/embryo donor.	Date-10
6	Don_age	Age of the egg or embryo donor. Completed in years at time of donation.	Num-2

7	N_13200	The number of billed Australian Medicare item 13200.	Num-2
8	Ci_tube	Answer "yes" if in the opinion of the treating clinician or clinic there is significant tubal disease present. Otherwise answer "no".	Char-1
9	Ci_endo	Answer "yes" if in the opinion of the treating clinician or clinic there is significant endometriosis contributing to this couple's subfertility. Otherwise answer no.	Char-1
10	Ci_male	Answer "yes" if in the opinion of the treating clinician or clinic there is a significant male problem. Otherwise answer "no".	Char-1
11	Ci_oth	Answer "yes" if in the opinion of the treating clinician or clinic there is subfertility due to any other factors **apart from** female age, tubal disease, male factor, endometriosis or sterilization. Possible examples could include fibroids, ovulation disorders or premature ovarian failure. If there is no clinical subfertility (eg egg donor, preimplantation genetic diagnosis or other non-fertility reason for ART), answer "No".	Char-1
77	Ci_oth specify	This is a description of "Ci_oth", ie the reason for infertility.	Char-50
12	Ci_unex	Answer "yes" if in the opinion of the treating clinician or clinic there is clinical subfertility without any apparent explanation. If there is no clinical subfertility (eg egg donor, preimplantation genetic diagnosis or other non-fertility reason for ART), answer "No".	Char-1
78	Ci_FSter	Answer "yes" if in the opinion of the treating clinician or clinic there is subfertility due to tubal ligation or medical sterilisation of the female participant. Otherwise answer "no".	Char-1
79	Ci_Mster	Answer "yes" if in the opinion of the treating clinician or clinic there is subfertility due to vasectomy or medical sterilisation of the male partner. Otherwise answer "no".	Char-1
13	N_prless	This is the number of all known pregnancies less than 20 weeks in the female partner regardless of whether by ART or by a different partner.	Num-2
14	N_prmore	This is the number of all known pregnancies reaching 20 weeks or more in the female partner regardless of whether by ART or by a different partner.	Num-2
15	Cycle_id	This is a number allocated to the cycle, which is unique to the cycle not just the patient.	Char-10
16	Cycle date	This field must be completed for all cycles. For treatment cycles this is according to the Medicare definition and is the date of LMP for unstimulated cycles or, where FSH is used, the first date of FSH administration. For cycles where the only process is movement or disposal of embryos, this is the date of embryo movement.	Date-10
80	Procedure type	That is the type of procedure. Including: • Donor Insemination (DI) • Gamete Intra-Fallopian Tube Transfer (GIFT) • OPU with or without fresh transfer or egg fertilisation (IVF) • Frozen embryo transfer (FET) • OPU with fresh and frozen embryo transfer (IVF+FET) • GIFT with simultaneous FET (GIFT+FET) • Cancelled OPU (Can OPU) • Cancelled FET (Can FET) • Embryo Move ie embryo disposal or export • Embryo Move for Research	
17	Surr	Is this procedure part of a surrogacy arrangement	Char-1
18	Ov_Stim	Was injectable follicle stimulating hormone (FSH) administered. Does not include clomiphene or hCG alone unless FSH was also administered.	Char-1
19	Di_insem	Where the cycle is for donor insemination this is the date of first donor insemination in this cycle.	Date-10
81	Drug 1	Drug administered one, that is the name of the first drug administered. This should include only drugs which are used to regulate a cycle/ pregnancy.	Char-30
82	Drug 1 Dose	This is the total dose of Drug 1. The dose is that administered over the entire cycle/pregnancy.	Num-10
83	Drug 1 Days	This is the total number of days Drug 1 was administered for over the entire cycle/pregnancy.	Num-3

84	Drug 2	Drug administered two, that is the name of the second drug administered.	Char-30
85	Drug 2 Dose	This is the total dose of Drug 2. The dose is that administered over the entire cycle/pregnancy.	Num-10
86	Drug 2 Days	This is the total number of days Drug 2 was administered for over the entire cycle/pregnancy.	Num-3
87	Drug 3	Drug administered three, that is the name of the third drug administered.	Char-30
88	Drug 3 Dose	This is the total dose of Drug 3. The dose is that administered over the entire cycle/pregnancy.	Num-10
89	Drug 3 Days	This is the total number of days Drug 3 was administered for over the entire cycle/pregnancy.	Num-3
90	Drug 4	Drug administered four, that is the name of the forth drug administered.	Char-30
91	Drug 4 Dose	This is the total dose of Drug 4. The dose is that administered over the entire cycle/pregnancy.	Num-10
92	Drug 4 Days	This is the total number of days Drug 4 was administered for over the entire cycle/pregnancy.	Num-3
93	Drug 5	Drug administered five, that is the name of the fifth drug administered.	Char-30
94	Drug 5 Dose	This is the total dose of Drug 5. The dose is that administered over the entire cycle/pregnancy.	Num-10
95	Drug 5 Days	This is the total number of days Drug 5 was administered for over the entire cycle/pregnancy.	Num-3
96	Drug 6	Drug administered six, that is the name of the sixth drug administered.	Char-30
97	Drug 6 Dose	This is the total dose of Drug 6. The dose is that administered over the entire cycle/pregnancy.	Num-10
98	Drug 6 Days	This is the total number of days Drug 6 was administered for over the entire cycle/pregnancy.	Num-3
99	Retrieval General Anaesthetic	Whether General Anaesthetic was administered for OPU.	Char-1
100	Retrieval Antibiotics	Whether Antibiotics were administered OPU.	Char-1
101	Retrieval Other Medication	Whether any other medication was used OPU. This should include sedatives.	Char-10
102	Transfer General Anaesthetic	Whether General Anaesthetic was administered for embryo transfer.	Char-1
103	Transfer Antibiotics	Whether Antibiotics were administered for embryo transfer.	Char-1
104	Transfer Other Medication	Whether any other medication was used for embryo transfer. This should include sedatives.	Char-10
105	OHSS	Whether there was any ovarian hyper stimulation, and if so the severity.	
106	Retrieval Method	Method of OPU. Cancelled cycles are those where the cycle is stopped prior to any attempt to retrieve oocytes, if oocyte retrieval is attempted and no eggs are retrieved the cycle is not considered cancelled. In this case the method of attempted retrieval should be entered.	Char-20
20	Opu_date	The date that oocyte retrieval was performed. Leave blank if no OPU was performed.	Date-10
21	N_eggs	Number of oocytes which are retrieved at OPU. Include any immature oocytes that are identified.	Num-2
107	N_eggsexp	Number of oocytes which were donated for research or quality assurance.	Num-2
108	N_eggsdisc	Number of oocytes which were discarded as they were abnormal or immature.	Num-2
109	N_eggsfroz	Number of oocytes which were frozen.	Num-2
22	N_donated	Number of oocytes donated to someone else.	Num-2
23	N_recvd	Number of eggs received from someone else.	Num-2
24	N_gift	Number of eggs replaced in a gift procedure	Num-2
110	FertCode	If fertilisation through IVF or ICSI was attempted a code should be attributed to the fertilisation procedure. If there was no fertilisation attempted this field may be left blank. The	Char-8

		fertilisation code must be unique to the fertilisation not just the patient. Required when a fertilisation is attempted or for transfer of embryos (eg FET or embryo move), otherwise leave blank.	
25	N_insem	Number of eggs treated with IVF, do not include ICSI oocytes	Num-2
26	N_ICSI	Number of eggs treated with ICSI	Num-2
111	EggsNotFert	Number of oocytes not fertilised	Num-2
112	EmbryoFresh	Number of embryos fresh transferred	Num-2
39	N_clfroz	Number of zygotes or cleavage stage embryos (i.e. <4 days since fertilisation) frozen.	Num-2
40	N_blfroz	Number of blastocyst embryos (i.e. >4 days since fertilisation) frozen.	Num-2
41	emdonexp	This field serves two purposes: (1) Records the number of embryos that are to be donated to someone else (donor cycle); (2) Records the number of embryos to be exported from the current unit to another unit	Num-2
113	EmbExpLic	If embryos are exported to another unit, please specify receiving units "Unit" code or Licensee number or the Licence number of a NHMRC embryos research approval.	
114	EmbryoAbnorm	Number of embryos that were considered abnormal and allowed to succumb	Num-2
115	EmbryoSurplus	Number of embryos that were normal however excess to patient needs therefore allowed to succumb	Num-2
27	Sp_site	Site of sperm extraction. That is ejaculated, epididymal, testicular or bladder.	Char-1
28	Sp_persn	Person whose sperm was used in insemination. To be filled out for donor insemination or use of sperm in IVF.	Char-1
116	SpDonorLic	If a sperm donor was used the "Unit" code storage licensee from whom that sperm came from is required.	Char-3
117	SpDonorID	If a sperm donor was used the sperm donors id is required.	Char-8
118	SpPrepWashing	If washing was used in sperm preparation.	Char-1
119	SpPrepGradient	If gradient method was used in sperm preparation.	Char-1
120	SpPrepSwimup	If swim up was used for sperm preparation	Char-1
121	SpPrepOther	Any other preparations methods that were used. Include Isolate here. The "Other" method should be specified	Char-20
122	ChemStim	If chemical stimulation was used the name of the chemical stimulant is specified.	Char-20
123	Manipulation	If a micro manipulation technique was used to assist in fertilisation eg. PZD, SUZI please specify the technique used here. Not necessary to include ICSI here.	Char-20
29	N_fert	Number of eggs fertilised normally. The critical issue is the opinion of the treating embryologist. Thus even if two pronuclei are not seen but cleavage occurs, provided the embryologist considers this to be a normal fertilisation then it should be included.	Num-2
30	PGD	Answer yes where PGD in any form has been performed on any of the embryos. Otherwise answer no.	Char-1
132	NumPGD	Number of embryos biopsied for genetic testing.	Num-2
133	N_Aneup_Test	Number of embryos tested for aneuploidy.	Num-2
134	N_SGD_Tested	Number of embryos tested for specific gene disorder.	Num-2
135	SGD_Specify	Please specify the name of the specific gene disorder tested (eg cystic fibrosis).	Char-20
136	N_PGD_Normal	Number of embryos considered normal after testing.	Num-2
137	N_Aneup	Number of embryos with aneuploidy.	Num-2
138	N_SGD	Number of embryos with the specific gene disorder tested for.	Num-2
31	Ass_hatc	Answer yes where assisted hatching in any form has been performed on any of the embryos.	Char-1
32	Emrecimp	This field serves two purposes: (1) Records the number of embryos that are to be received from donation (recipient cycle); (2) Records the number of embryos to be imported into the current unit from another unit.	Num-2
33	N_clthaw	Number of zygotes or cleavage stage embryos thawed with the intention of performing an embryo transfer if they survive.	Num-2
34	N_blthaw	Number of blastocysts (ie greater than 4 days culture from fertilisation) thawed with intention of performing an embryo transfer if they survive.	Num-2

35	Et_date	This is the date of embryos transfer. To be left blank if there was no embryo transfer.	Date-10
124	FertLicensee1	That is the "Unit" code of the clinic where the fertilisation took place. This field is only required where there is embryo transfer, disposal or export, otherwise it may be left blank.	Num-3
125	FertCode1	This is the code attributed to the fertilisation procedure. This field is only required where there is embryo transfer, disposal or export, otherwise it may be left blank.	Char-8
126	FertLicensee2	That is the "Unit" code of the clinic where the fertilisation took place. This field is only required where a second set of embryos was used in the same cycle of embryo transfer, disposal or export.	Num-3
127	FertCode2	This is the code attributed to the fertilisation procedure. This field is only required where a second set of embryos was used in the same cycle of embryo transfer, disposal or export.	Char-8
128	DonorOwnEmbryos	Whether donor embryos or a couples own embryos were used in embryo transfer.	Char-1
129	N_clunsuitable	Number of zygotes or cleavage stage embryos thawed that are unsuitable for transfer.	Num-2
130	N_blunsuitable	Number of blastocysts (ie greater than 4 days culture from fertilisation) thawed that are unsuitable for transfer.	Num-2
36	N_emb_et	Number of zygotes of cleavage stage embryos (i.e. <4 days since fertilisation) transferred.	Num-1
37	N_bl_et	Number of blastocyst embryos (i.e. >4 days since fertilisation) transferred.	Num-1
38	Emb_icsi	Were any of the transferred embryos fertilised by ICSI?	Char-1
131	Transfer Site	This is the site of embryo transfer, ie either uterine or fallopian tube	Char-1
42	Emb_disp	The number of frozen embryos disposed of in accordance with patient or Government request.	Num-2
43	Pr_clin	Whether there was a clinical pregnancy. A clinical pregnancy must fulfil one of the following criteria: 1. Known to be ongoing at 20 weeks; 2. Evidence by ultrasound of an intrauterine sac (with or without fetal heart); 3. Examination of products of conception reveal chorionic villi; or 4. A definite ectopic pregnancy that has been diagnosed laparoscopically or by ultrasound.	Char-1
44	Pr_end_dt	Date the pregnancy ended. This is the date on which delivery, miscarriage or termination takes place. This date must eventually be completed if the answer to pr_clin is "yes". If the exact date is unknown, enter an approximate guess. Where multiple birth occur over more than one date, enter the date of the first baby born.	Date-10
45	N_fh	Number of fetal hearts seen on first ultrasound (intrautreine only)	Num-2
46	Pr_ectop	If this pregnancy is an ectopic pregnancy or a combined ectopic and uterine (heterotopic) pregnancy, enter "yes".	Char-1
47	Pr_top	Elective termination of pregnancy. Do not include pregnancies where a planned fetal reduction of a multiple pregnancy results in subsequent unintended miscarriage, or a pregnancy where there has been an IUFD requiring induced delivery. Give reasons for TOP in Abn_less (field 49).	Char-1
48	Pr_reduc	Where selective reduction was performed due to fetal abnormality. Give details in Abn_less (field 49).	Char-1
49	Abn_less	This field applies to elective terminations of pregnancy and fetal reductions due to fetal abnormality. Specify as much detail as possible.	Text-250
50	Mat_comp	Maternal complications of pregnancy. Insert as much detail as possible.	Text-250
51	N_deliv	Number of babies delivered after 20 weeks. Include all live born and stillborn babies.	Num-1
52	CS	Caesarean delivery. Doesn't matter whether CS was planned or emergency. If any of a multiple birth are a caesarean section delivery, answer yes.	Char-1
53	Bab1_out	Outcome of first baby born. Either stillbirth, live birth or neonatal death.	Char-1
54	Bab1_sex	Gender of first baby born	Char-1
55	Bab1_wt	Birth weight in grams of first baby born	Num-4

56	Bab1_abn	Abnormality in the first baby born, if applicable. Put as much details as known about congenital malformation.	Text-250
57	Bab1_nnd	Date of Neonatal death of first baby born. Leave blank if no neonatal death.	Date-10
58	Bab2_out	Outcome of second baby born.	Char-1
59	Bab2_sex	Gender of second baby born	Char-1
60	Bab2_wt	Birth weight in grams of second baby born	Num-4
61	Bab2_abn	Abnormality in the second baby born, if applicable. Put as much details as known about congenital malformation.	Text-250
62	Bab2_nnd	Date of Neonatal death of second baby born, if applicable.	Date-10
63	Bab3_out	Outcome of third baby born.	Char-1
64	Bab3_sex	Gender of third baby born	Char-1
65	Bab3_wt	Birth weight in grams of third baby born	Num-4
66	Bab3_abn	Abnormality in the third baby born, if applicable. Put as much details as known about congenital malformation.	Text-250
67	Bab3_nnd	Date of Neonatal death of third baby born, if applicable.	Date-10
68	Bab4_out	Outcome of fourth baby born.	Char-1
69	Bab4_sex	Gender of fourth baby born	Char-1
70	Bab4_wt	Birth weight in grams of fourth baby born	Num-4
71	Bab4_abn	Abnormality in the fourth baby born, if applicable. Put as much details as known about congenital malformation.	Text-250
72	Bab4_nnd	Date of Neonatal death of fourth baby born, if applicable.	Date-10
73	Morb_adm	Answer yes if the female partner is admitted to hospital with any condition (excluding any pregnancy-related issues, such as an ectopic pregnancy) that could be in any way related to fertility treatment, eg. OHSS, infection or bleeding after eg. pick up.	Char-1
74	Mrb_ohss	If the cause of the morbidity is OHSS answer yes.	Char-1
75	Morb_inf	Provide details of the morbidity. Put in as much detail as known about the cause of morbidity.	Text-250

APPENDIX 5

INFORMATION CIRCULATED BY COUNCIL TO LICENSEES

RE: Council position on HLA testing for the creation of saviour siblings

Dear Licensee

You may be aware from recent media coverage that the Reproductive Technology Council (Council) has undertaken to consider the position in Western Australia regarding the issue of "saviour siblings", where matched embryos that could potentially provide donor material for an ill sibling may be selected through the use of Pre-implantation Genetic Diagnosis (PGD) and Human Leukocyte Antigen (HLA) testing.

Under the current *Human Reproductive Technology Act 1991* (HRT Act), an anomaly exists whereby persons [S23 (a) (i) and (ia)] who are unable to conceive a child due to medical reasons, and therefore likely to benefit from IVF, may be able to undertake PGD and HLA testing of embryos to "match" siblings. However, the Act does not permit HLA testing where the eligibility for IVF is based on the risk of a child being affected by a genetic abnormality or a disease [S23(a) (ii)], and it does not permit those who are not eligible for IVF to undertake HLA testing or tissue typing of an embryo.

While the ethical and medial issues surrounding this matter are complex and significant, Council has agreed to examine how the inequity of access to HLA technology may be addressed, and is currently seeking legal advice on this issue.

Preliminary advice is that an amendment to the HRT Act will be necessary to remove the discrepancy. This promises to be a lengthy process, with the possibility that any required amendments may ultimately be rejected.

Until such time as the HRT Act is amended, current WA legislation only allows persons eligible for IVF due to medical reasons to seek approval to access this technology.

Please note that Council will advise you of any further changes in this matter.

Yours sincerely

CA Michael AO
Chair
Reproductive Technology Council

28 May 2008

RE: consideration of increasing limit of 5 families per gamete donor

Dear Licensee

The concern raised by a number of clinics, that there is a shortage of sperm donors currently in WA, is acknowledged as legitimate. The Counseling Committee of the RTC proposed organising a seminar in 2008 with interested parties invited (including clinics, future clients wishing to access sperm donation, etc.) to discuss ways this concern could be addressed.

Following consideration by Council about the possibility of increasing the number of recipient families that could access the donation of sperm from one donor, Council has accepted the recommendation made by the Counseling Committee that at this time in Western Australia it would not be in the interests of the community to allow this to occur.

The reasons Council rejected the suggestion to increase the number of recipient families per donor included:

- The psychological impact on donor children if more than four other families were biologically related to him/her.
- The risk of accidental consanguinity given the relatively small population of Western Australia.
- Comparison with the limits set on the number of other children conceived by the one donor ('number of children' was more usual than number of 'recipient families') in other parts of Australia and worldwide with larger populations.
- The potential implications for donors now, who may be contacted by donor offspring when they reach adulthood should the limit on the number of these children/families be increased.
- Alternative options and the impact of these options, to increase the number of known donors have not been fully explored in Western Australia at this time.

We look forward to input from the clinics regarding this matter in the future, and will advise you of the date of the planned seminar.

Yours sincerely

CA Michael AO
Chair
Reproductive Technology Council

30 April 2008

APPENDIX 6

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

The general functions of the Reproductive Technology Council are covered in section 14 of *the Human Reproductive Technology Act 1991*, which in effect set its Terms of Reference.

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;

(c) after consultation with bodies representing persons having relevant expertise 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 licence supervisor 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 human egg collected in the course of an in vitro fertilisation procedure;
  (ii) human gametes intended for subsequent use in an artificial fertilisation procedure;

(iii) any human egg undergoing fertilisation;
(iv) any human 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) Subsection (1)(e)(iv) does not apply in relation to an excess ART embryo except in relation to the use of such an embryo that is an exempt use as defined in section 53W(2).

(2a) The Council must not grant approval to any research being conducted upon or with a human embryo unless —
(a) the embryo is intended for use in the reproductive technology treatment of a woman and the Council is satisfied, on the basis of existing scientific and medical knowledge, that the research is unlikely to leave the embryo unfit to be implanted in the body of a woman; or
(b) the research consists of a use referred to in section 53W(2)(b) or (f).

(2b) The Council must not grant approval to any diagnostic procedure to be carried out upon or with a human embryo unless —
(a) the embryo is intended for use in the reproductive technology treatment of a woman and the Council is satisfied, on the basis of existing scientific and medical knowledge, that —
(i) the diagnostic procedure is unlikely to leave the embryo unfit to be implanted in the body of a woman; and
(ii) where the diagnostic procedure is for the genetic testing of the embryo, there is a significant risk of a serious genetic abnormality or disease being present in the embryo; or
(b) the diagnostic procedure consists of a use referred to in section 53W(2)(d) or (f).

(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 NHMRC, as for the time being prescribed;
(ii) criteria established by a body referred to in section 29(5)(a)(i) or (ii), as for the time being prescribed; or
(iii) a provision of, or any principle set out in, or requirement under, this Act, as from time to time amended,

the Council shall endeavour to ensure that effect is given to that provision, requirement or direction.

[Section 14 amended by No. 17 of 2004 s. 11; No. 55 of 2004 s. 523.]

Functions of the Council in relation to permitted embryo storage

24. (1) In relation to the storage of any human gametes, human egg undergoing fertilisation or human embryo —

(a) the primary purpose stated in any consent to the storage of a human embryo must relate to the probable future implantation of that embryo or its probable future use under an NHMRC licence; and

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

(i) human gametes;

(ii) a human egg undergoing fertilisation; or

(iii) a human embryo, but no human egg undergoing fertilisation or human embryo shall be stored for a period in excess of 10 years except with the approval of the Council under subsection (1a).

(1a) The Council may, on an application by an eligible person, approve in writing a longer storage period for a human egg undergoing fertilisation or a human 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 10 years, or if a longer storage period has previously been approved under subsection (1a), before the end of that period.

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

(2) In subsection (1a) —

"eligible person", in relation to a human egg undergoing fertilisation or a human embryo, means —

(a) a person who is or is to be a participant in an artificial fertilisation procedure in which the egg or embryo is to be used;

(b) a person for whom the egg or embryo was developed; or

(c) in the case of an excess ART embryo, except in relation to the use of such an embryo referred to in section 10(2)(e) of the Commonwealth Human Embryo Act, the licensee.

(3) Three months before the end of a period of storage permitted under this section the licensee must take reasonable steps to notify each person for whom the human egg undergoing fertilisation or human embryo is being stored.

(4) If a period of storage permitted under this section comes to an end and no application has been made for the extension of the storage period, the licensee may, if the licensee has complied with subsection (3), allow the human egg undergoing fertilisation or the human embryo to succumb and will not be liable to anyone for so doing.

[Section 24 amended by No. 1 of 1996 s. 5 and 6; No. 3 of 2002 s. 75; No. 17 of 2004 s. 18.]

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:

S. 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 in the HRT Act -

11. Annual report on reproductive technology

(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.*

[Schedule amended by No. 78 of 1995 s. 147.]

APPENDIX 7

POLICY ON APPROVAL OF DIAGNOSTIC PROCEDURES INVOLVING EMBRYOS