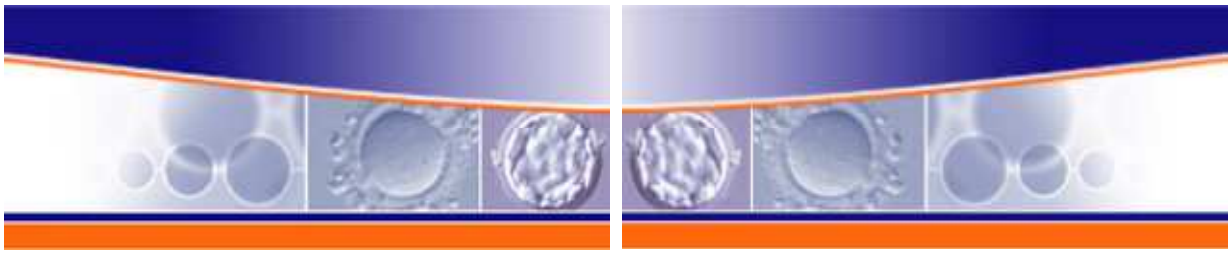
Western Australian Reproductive Technology Council

Annual Report

1 July 2008 - 30 June 2009



Annual Report of the Western Australian Reproductive Technology Council

1 July 2008- 30 June 2009

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) 9489 2818

Compiled by:

The Western Australian Reproductive Technology Council

September 2009
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
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 2008-2009. 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 2008-2009 financial year are as follows:

In an advisory role, Council provided feedback concerning the *Surrogacy Bill 2007*, which was passed by Parliament on 10 December 2008. Council collaborated with Legal and Legislative Services in the development of subsidiary legislation for this Bill. The progress of the Bill through the Parliament had been interrupted by the 2008 State Government election, but the goodwill of Members of Parliament exercising a 'free vote' ensured the successful passage of this legislation. The commencement date of the *Surrogacy Act 2008* (Surrogacy Act) was 1 March 2009, subsequent to which Council has been required to consider the protocols and patient information submitted by the three WA fertility clinics who will offer this additional service. There has been considerable interest in this legislation by couples who have been waiting for a number of years to pursue surrogacy as a means by which to create their family.

Council assessed and recommended the approval to reissue Practice and Storage Licences for six of the seven fertility clinics offering assisted reproductive technology (ART) services in Western Australia. A new clinic was issued a provisional licence in November 2008, being the seventh licensee to offer ART services in WA. This process required significant work on behalf of the Council as the Fertility Society of Australia's accreditation process, a condition of obtaining a licence, was changed significantly in 2008. In order to meet the requirements of the HRT Act without unnecessary duplication of the audit process, an analysis of the gap and overlap with the new system required development and implementation.

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 on behalf of the Council has been sought from the State Solicitor's Office regarding a number of contentious matters. The first of the advices related to 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. A second matter centred on

interpretation of legislative parameters for the posthumous collection, export and use of gametes, in addition to being subject to considerable ethical debate by Council.

Legislative amendments addressing these two important matters and other issues identified by the *Select Committee on the Human Reproductive Technology Act 1991* have been identified and Council is hopeful that these may be addressed in the coming financial year with the consent of the Parliament.

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 an ongoing focus, and the policy is soon to be finalised and disseminated to clinics. 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.

In addition to other matters that require Council approval under the HRT Act, 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*.

It is not possible for Council to operate effectively without the significant support of a number of people who provide their expertise and time to attend to matters requiring Council consideration. I especially wish to acknowledge and thank Council and Committee members for their dedicated and ongoing commitment over the past 12 months. The important contribution of Dr Sandra Webb and Dr Stephen Junk who retired from the PGD Committee during this year, and who have had a long association with the Council over many years, also warrants recognition.

I would also like to acknowledge and thank Ms Deborah Andrews for her continuing legal support and guidance regarding the HRT Act, and Ms Linda Taylor, A/Senior Policy Officer, for her assistance with the *Surrogacy Act 2008*. Finally, on behalf of Council I wish to acknowledge the ongoing financial contribution by the Department of Health, and the administrative support provided by the Executive and Deputy Executive Officers to Council. The financial and practical support from the Department of Health is essential to enable the Council to carry out its statutory duties.

Yours sincerely

CA Michael AO
CHAIR
Reproductive Technology Council

9 September 2009

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 Directorate (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 Act	Surrogacy Act 2008
2008-2009 year	Refers to the period 1 July 2008 until 30 June 2009

EXECUTIVE SUMMARY

This Annual Report has been prepared by the Reproductive Technology Council (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 for Health, in order 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 Council for the year ending 30 June 2009.

As outlined in the HRT Act, the Council has an important role as an advisory body to the Minister for Health 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.

As at 30 June 2009, there were seven establishments in WA licensed to provide ART services. Six of the seven fertility clinics sought the reissuance of Practice and Storage Licences in 2008-2009, and these clinics were also required to undergo accreditation review by the Reproductive Technology Accreditation Committee (RTAC) of the Fertility Society of Australia; a condition of licence in WA. The way in which fertility clinics are audited for accreditation by RTAC underwent a significant change during 2008-2009. Western Australian clinics were among the first in Australia to undergo accreditation under the new system, which involves annual audit by an external certifying body. Under the HRT Act, Council has responsibility for advising the CEO regarding the issuance of Practice and Storage Licences in WA, and this has been a significant focus for Council and in particular executive officers during the year.

Figures collected from annual reporting data submitted by Western Australian licensees show that WA fertility clinics undertook more than 4500 cycles of in vitro fertilsation (IVF) or frozen embryo transfer (FET) in the 2008-2009 year, treating over 2000 women and couples. The number of IVF cycles decreased slightly this year compared to last, but this was offset by the marginal increase seen in the number of frozen embryo transfers undertaken in WA.

Executive support to the Council was disrupted in 2007-2008 with the departure of long-standing Department of Health executive support staff. However, Council activity in policy making and other regulatory matters has resumed in 2008-2009. Council membership has been stable during this year, with the exception of the resignation of deputy Council member Dr Shirley Bode. The departure of Dr Sandra Webb from the Pre-implantation Genetic Diagnosis (PGD) Advisory Committee has brought to an end Dr Webb's long association with the Council. Dr Webb was instrumental in the development of the HRT Act and the establishment of the Council itself, and her valuable understanding of ART regulation in WA will be missed. Dr Stephen Junk, whose scientific knowledge as a practising embryologist greatly assisted the development of PGD policy in WA, also resigned from the PGD Advisory Committee in 2008.

The 2008-2009 budget allocation to Council was $41430, with expenditure totalling $28249 for the year. The Financial Statement outlining the distribution of expenses is provided in this Annual Report. As reflected in the Financial Statement, the residual effect of the loss of executive support staff during the 2007-2008 year has impacted on budget expenditure for this financial year. The most significant discrepancy being that a portion of members' sitting

fees have not been drawn from the Council cost centre for the 2008-2009 year. Council has a long record of remaining within the allocated budget, and predicts expenditure for the forthcoming financial year will reflect a similar pattern of expenditure as seen in previous years.

Council consideration of ART regulatory matters required response to more than 55 general queries and concerns from WA fertility clinics and ART professionals. In addition, deliberation by Council members was required on more than 50 specific applications requiring Council approval under the HRT Act. These applications included embryo storage extensions, PGD applications, import applications and export of donated human reproductive material plus research and innovative procedures undertaken by fertility clinics.

Other matters that have dominated Council discussion during 2008-2009 include State surrogacy legislation and the posthumous collection, storage and use of gametes. The *Surrogacy Act 2008* was proclaimed in December 2008, and Council and executive support staff have been involved in providing advice on subsidiary legislation as well as the provision of advice to fertility clinics and members of the public seeking information on the legislation. The posthumous use of gametes has also been a significant focus for Council during this year. A number of cases where sperm have been collected posthumously under order from the Supreme Court have renewed public and political interest in this matter. Support for the use of gametes by the Minister for Health has engendered consideration of policy and possible change to legislation around this issue, and Council has agreed in principle with amendment to legislation allowing the conditional posthumous collection and use of gametes.

Other legislative amendments are also recommended for consideration in the forthcoming year: the defeat of the HRT Amendment Bill in May 2008 has rendered WA legislation on embryo research inconsistent with the Commonwealth and other Australian jurisdictions, and led to uncertainty about the regulation of embryo research in this State. Other outstanding recommendations arising from the 1999 'Report from the Select Committee on The Human Reproductive Technology Act 1991 require consideration, and Council has made a number of recommendations of areas where legislative change is warranted, including amendments to allow the creation of 'saviour siblings'. Technological advances and evolving ethical thinking on ART issues requires ongoing review of ART regulation in the State.

The effective operation of Council requires the significant and dedicated support of Council and Committee members, and the ongoing financial and administrative support provided by the Department of Health. This support is essential to enable the Council to meet all of the responsibilities set out in the HRT Act and the recently enacted surrogacy legislation and to ensure the effective regulation of ART services in Western Australia under these Acts.

INTRODUCTION

The Western Australian Reproductive Technology Council (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). Membership of the Council is determined by the Minister for Health, who has responsibility to ensure that the Council is comprised of individuals with special knowledge and experience in matters dealt with under the Act. Expertise in assisted reproductive technology (ART) underpins the Council's membership. However, Council must also be representative of the general community. Membership therefore also includes consumer representation, representatives for children born from ART and members with experience in public health matters and ethical and legal expertise.

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 internationally.

The Council is responsible for providing advice to the CEO regarding the issuance of Practice and Storage Licences to clinics providing ART services. Exemptions allowing medical practitioners to carry out artificial fertilisation procedures in Western Australia may also be issued by the CEO. Licences and exemptions 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 Licences, licensees must have accreditation through the Reproductive Technology Accreditation Committee (RTAC) of the Fertility Society of Australia (FSA), or another prescribed body. The process by which RTAC accredits licensees has changed in the past twelve months, and WA licensees were among the first clinics in Australia to undergo the new accreditation process. This new accreditation process is described further on page 14.

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 National Health and Medical Research Council (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, with the defeat of the Human Reproductive Technology Amendment Bill 2007 (HRTA Bill) in the Legislative Council in May 2008, the mechanism whereby the NHMRC is able to licence and monitor research on excess ART embryos in WA is under question. This remains a matter for future consideration and legislative change.

MEMBERSHIP OF THE COUNCIL 30 June 2009

Member	Nominee of:
Professor Con Michael **Chair**	The Australian Medical Association
Ms Leah Bonson	Department of Child Protection
Dr Simon Clarke	Royal Australian and New Zealand College of Obstetricians and Gynaecologists
A/Professor Jim Cummins	The Minister for Health
Mr Peter Fox	The Health Consumers' Council
Professor Roger Hart	The Department of Obstetrics and Gynaecology, University of Western Australia
Dr Brenda McGivern	The Law Society of Western Australia
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

Membership of Council cont...

Deputy Member	Nominee of:
Dr Shirley Bode	Health Consumers' Council (until February 2009)
A/Professor Neville Bruce	The Minister for Health
Dr Peter Burton	University of Western Australia (from June 2009)
Reverend Brian Carey	The Minister for Health
Dr Angela Cooney	The Australian Medical Association
Ms Leonie Forrest	The Law Society of Western Australia
Dr Janet Hornbuckle	Royal Australian and New Zealand College of Obstetricians and Gynaecologists
Ms Anne- Marie Loney	Department of Child Protection (from June 2009)
Ms Sue Midford	The Health Consumers' Council
Dr Nyaree Jacobsen	Deputy Executive Officer *ex officio* Senior Policy Officer, DoH
Ms Jenny Parker	Deputy Executive Officer *ex officio* Senior Policy Officer, DoH

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 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), Ms Iolanda Rodino, Ms Patrice Wringe, Ms Jenny O'Callaghan (*ex officio*), Ms Jen Parker *(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), Professor Roger Hart, Dr Brenda McGivern, Ms Sue Midford, Dr Joe Parkinson, Ms Patrice Wringe, Ms Jenny O'Callaghan *(ex officio*) and Dr Nyaree Jacobsen (*ex officio*).

PGD Advisory Committee

The PGD Advisory Committee was previously named the PGD (Implementation) Technical Advisory Committee. However, changes to the Committee's name and terms of reference were endorsed in February 2009, following the effective implementation of the legislative amendments concerning genetic diagnosis of embryos. Membership of the Committee was also amended to reflect this progress.

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 factors that it should consider when deciding whether to approve PGD, both generally and for specific cases.

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

3. To advise the Council as to how the ongoing process of approval of PGD should be managed effectively by the Council.

4. To monitor the outcomes of diagnostic procedures involving embryos.

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, but not limited to, counselling in relation to PGD with the Counselling Committee and legal issues in relation to PGD with a Department of Health lawyer.

Membership:

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

- two members of the Council, chosen to maximise relevant experience and expertise on the Committee.
- one clinical geneticist (or in the event none is available a suitably qualified clinician or genetic counsellor)
- one laboratory geneticist
- one human embryologist (to be recommended by RTAC or holding office in RTAC or Scientists in Reproductive Technology (SIRT)
- one consumer representative
- committee executive officer (DoH RT Unit staff)

Membership:

Dr Beverly Petterson (Chair), Dr Peter Burton (from November 2008), Ms Karen Hajigabriel (from November 2008), Dr Stephen Junk (until August 2008), Dr Ashleigh Murch, Dr Sharron Townshend, Dr Sandra Webb (until February 2009), 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), Professor Roger Hart, Dr Joseph Parkinson, Dr Beverly Petterson, Ms Jenny O'Callaghan *(ex officio)* 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.

Dr Nyaree Jacobsen
Senior Policy Officer and Deputy Executive Officer of the Council (0.6 FTE)

Ms Jenny Parker
Senior Policy Officer and Deputy Executive Officer of the Council (0.4 FTE)

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

REPRODUCTIVE TECHNOLOGY COUNCIL
FINANCIAL STATEMENT 1 July 2008 - 30 June 2009

The Department of Health funds the administration of the HRT Act, including the operations of the Council. The 2008-2009 budget allocation was $41,430, with expenditure totalling $28,249 for the financial year. This amount represents an under-expenditure of the allocated budget that can be attributed to sessional fees being paid from another cost centre. Sessional fees and external consulting fees typically represent around 75% of the allocated budget. The Training/Registration/Course Fees expenditure is higher in this budget than most years as Council has funded registration fees for interested members to attend the 2009 FSA Conference from this budget. The FSA Conference is to be held in Perth (October 2009). This represents a valuable opportunity for members to gain understanding about a wide range of issues relevant to Council activities, and it is anticipated that there will be a reduction in conference registration and associated accommodation and travel expenses in next year's budget.

Council has a long record of remaining within the allocated budget, and anticipates that with resumption of full executive support being provided to Council, and sessional fees being paid from the Council budget, that expenditure will reflect a similar budget to past years.

REPRODUCTIVE TECHNOLOGY COUNCIL Expenses by Category	Expenditure ($)	Income ($)
Staff or Council:		
Training/Registration/Course Fees Travel Interstate Accommodation	**$12452** **$ 1735** **$ 258**	
Food supplies/catering	**$ 1929**	
Administration and clerical	**$ 0**	
Purchase of external services:		
Sessional fees: (External Consulting Fees) Reproductive Technology Council	**$ 8803**	
Other expenses:		
Books/ magazines/ subscriptions	**$ 0**	
Freight/ cartage/ postal	**$ 12**	
Printing including Annual Report	**$ 990**	
Stationery	**$ 1545**	
Audio-visual	**$ 433**	
Maintenance equipment	**$ 92**	
TOTAL	**$28,249**	
Budget Allocation		**$41,430**

OPERATIONS OF THE COUNCIL 2008-2009

Meetings

The Council met on eleven occasions during the 1 July 2008 to 30 June 2009 period, with attendances reaching quorum at all meetings. One extraordinary meeting was held to discuss matters concerning posthumous collection and use of gametes, with legal guidance provided at this meeting by Department of Health and State Solicitor's Office legal representatives. The Counselling Committee met on seven occasions; the PGD Advisory Committee met on four occasions, with several applications for PGD assessed out of session by this committee before being considered at the following Council meeting. The Embryo Storage Committee met on four occasions during the year. The Licensing and Administrative Committee met on one occasion to discuss the issuance of Storage and Practice Licences to six of the seven clinics providing ART services in WA. While the Scientific Advisory Committee did not meet during the 2008-2009 period, issues relating to innovative procedures or proposed research projects were dealt with during Council meetings with input from Scientific Advisory Committee members.

Membership

Outgoing members in 2008-2009

Council membership has remained stable during the 2008-2009 year, with the exception of the resignation of deputy Council member Dr Shirley Bode, representative of the Health Consumers' Council. Other valued members of Council's committees who stepped down from their positions during 2008-2009 include Dr Stephen Junk and Dr Sandra Webb.

Dr Stephen Junk resigned from the PGD Advisory Committee in August 2008. As a practising embryologist and scientist, Dr Junk's knowledge and understanding in the area of ART was of tremendous value both to Council and to the PGD Advisory Committee. His contribution in the development of PGD policy in WA warrants particular recognition.

Dr Sandra Webb resigned from the PGD Advisory Committee in February 2009. While Dr Webb's valuable contribution as a member of the PGD Advisory Committee since its inception deserves recognition, it must also be viewed in the context of Dr Webb's involvement with ART in WA. Dr Webb was principal policy adviser to the DoH and the Minister for Health on ART for the period between 1985 and 2005, and her input into the development of the HRT Act plus her role as executive officer to the Council from 1992 to May 2003 has directly influenced the understanding and regulation of ART in WA. Council would like to acknowledge Dr Webb's significant contribution to ART in WA during her time with the Department of Health.

Council also welcomed three new members. Dr Peter Burton, an experienced embryologist, joined the PGD Advisory Committee along with Ms Karen Hajigabriel (as a consumer representative) in November 2009, Dr Burton also being appointed to the Council as a deputy member in June 2009. Ms Anne-Marie Loney also was appointed as a deputy member of Council in June 2009, as a representative for the Department for Child Protection.

Department of Health Staff assisting the work of the Council

After some disruption in the provision of DoH executive support for the Council during 2006 - 2007, the continued appointment of DoH Executive and Deputy Executive Officers allowed the resumption of core Council activities during 2008-2009.

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

Dr Nyaree Jacobsen (0.6FTE) 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 Advisory Committee, and the Embryo Storage Committee.

Ms Jenny Parker (0.4FTE) Ms Parker was appointed to provide additional administrative and policy development support to the RTU and Council, and shares Deputy Executive Officer duties with Dr Jacobsen. Ms Parker's responsibilities have included management of the Voluntary Register and Council session fees, plus overseeing the organisation of the Surrogacy Education Forum with Ms Powell in early 2009. Ms Parker has taken maternity leave at the end of the 2008-2009 year, and Council wishes her well in this change of role.

Ms Melissa Chantry holds the position of Research Officer in the Health Information and Reporting Directorate of DoH, and has been an invited guest at Council meetings since May 2006. 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 Frances Powell- Ms Powell was placed for a four month period with the RTU as a Graduate Officer through the Graduate Development Program 2009. Ms Powell assisted with the organisation of the Surrogacy Education Forum 'Implications for Practitioners of the Surrogacy Act 2008' following the enactment of surrogacy legislation in early 2009. Her administrative skills greatly assisted the activities of the RTU, and staff and Council would like to thank Ms Powell for her valuable contribution during her time with the unit.

Acknowledgements

The Council gratefully acknowledges:

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

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

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

LICENSING ISSUES

Establishments licensed under the *Human Reproductive Technology Act 1991* at 30 June 2009

Practice and Storage Licences:

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

Fertility Specialists South Pty Ltd
1st Floor 764 Canning Hwy
Applecross 6153

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

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

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

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

Practice (AI only) and Storage Licences:

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

New practice and storage licensee

In 2008-2009, Practice and Storage Licences were issued to a new business entity, Fertility Specialists South Pty Ltd. Fertility Specialists South is affiliated with Fertility Specialists of Western Australia, and was established to provide ART services previously unavailable south of the Swan River. On recommendation from the Council, the CEO of Health issued Fertility Specialists South with interim licences until 31 August 2009. The clinic will undertake relicensing and RTAC accreditation early in the 2009-2010 financial year.

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. However, the Human Reproductive Technology Amendment Bill 2007 (HRTA Bill), which aimed to provide consistency between WA legislation on embryo research and the Commonwealth legislation, was defeated in the Legislative Council in May 2008. This defeat and consequent inconsistency between State and Commonwealth legislation has led to uncertainty regarding the authority for the NHMRC to license and monitor excess ART embryo research in WA, and the scope of research permitted in WA. To resolve the legal uncertainty for legislators, researchers and licensees, the State Solicitor's Office has recommended amendment to the HRT Act. The possible means of acheiving this are currently under legal consideration. There are no establishments currently undertaking research in Western Australia under NHMRC Licence.

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 practise artificial insemination procedures in Western Australia. The Council did not receive any new applications for an exemption to practise an artificial insemination procedure during 2008-2009. A list of practitioners currently issued with exemptions is provided in Appendix 1.

Fertility Society of Australia accreditation

Accreditation by the Fertility Society of Australia (FSA) is a condition of licence for fertility clinics granted a Practice or Storage Licence under the HRT Act. The FSA has established the Reproductive Technology Accreditation Committee (RTAC) to oversee accreditation of fertility clinics.

Previously, RTAC had responsibility for undertaking site visits and providing assessment of fertility clinics across all Australian jurisdictions. The RTAC Code of Practice for Assisted Reproductive Technology Units provided guidance and set out standards for fertility clinics required for accreditation. However, in 2008-2009, the FSA and RTAC changed this process, following review of the RTAC Code of Practice in May 2008. A major change in the revised accreditation process has been the requirement for licensees to appoint their own certification body to undertake the accreditation of the licensee. To ensure a consistent standard of accreditation, certification bodies themselves must have Joint Accreditation System of Australia and New Zealand (JAS-ANZ) accreditation. Inspectors with expertise in the fertility industry also take part in the accreditation process.

Previously, accreditation was granted for 3 years. With the new system, critical criteria and a selection (one third) of good practice criteria will be audited on an annual basis, with a complete audit at least once every three years during which all critical and good practice criteria are assessed.

During early 2009, five of the seven Western Australian fertility clinics underwent accreditation under the new system. As above, accreditation is required for the issuance of Practice and Storage Licences to fertility clinics in Western Australia. Feedback from Western Australian fertility clinics that have gone through the accreditation process has been positive, with general findings that the process was beneficial and thorough.

The new licensee, Fertility Specialists South, had been accredited under the old system, undergoing inspection by RTAC committee members in September 2008. A one year accreditation was granted, as is usual following the establishment of a new assisted reproductive unit, and a complete audit under the new system is due in September 2009.

Information circulated to licensees

In the 2008-2009 year, Council considered and provided written responses to more than 55 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:

- Blastocyst culture as a routine procedure
- Embryo storage policy
- Vitrification of embryos as a routine procedure
- Waiting lists for donor sperm

This correspondence is set out in Appendix 5.

Complaints

The Council did not receive any formal complaints regarding the operations of licensees during the year. One issue concerning the provision of donor sperm for the creation of families was investigated to the satisfaction of the Council. Council received one letter of complaint regarding the decision of Council not to extend an embryo storage period, due to lack of eligibility of the couple to undertake IVF.

LICENSEE APPLICATIONS TO COUNCIL 2008-2009

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 2008-2009 year. A list of applications received by Council from licensees in 2008-2009 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 granted. Approval for an extension may be granted under s24 (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.

Applications for embryo storage extensions must be made on a Form 8 by eligible participants (that is, by those for whom the embryos were created, or by recipients if they have been donated). Under the HRT Act, Council is unable to grant an extension once the embryo storage period expires. Applications to extend the storage period of embryos donated for research purposes are submitted on a Form 9, and can be made by the eligible participants, or by the licensee. In cases where participants are applying to extend the storage of embryos for their 'own use', supporting documentation, for example confirmation that the participants are still eligible to undertake IVF, may be requested.

To guide decision-making in these matters, and inform to participants and clinics with embryos in storage, the Embryo Storage Committee is continuing to develop 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 2008-2009, the Embryo Storage Policy is nearing completion and will be distributed to licensees for feedback prior to final ratification by Council.

For the 2008-2009 year, fifteen Form 8 applications to extend an authorised embryo storage period were approved by Council on the recommendation of the Embryo Storage Committee. Of these applications, five were granted a 12 month extension. Six were granted a 24 month extension and three were granted six month extensions. One application was granted a six week extension in order to provide documentation that supported their application. One Form 9 application (for use in research) was approved.

Research Project applications

Research projects undertaken by licensees (other than research on excess ART embryos requiring an NHMRC licence) must receive Council approval. While *general* Council approval has been granted for some types of research, including surveys of participants or research involving additional testing of samples collected at time of a procedure, *specific* approval is required for all other research projects. Summary information indicating the current status and related matters of any Council approved research project must be submitted with the licensee's annual report. One application to undertake research was approved by Council in 2008-2009. A list of approved research projects active in 2008-2009 is provided in Appendix 3.

Innovative Procedure 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, but requires that these procedures are monitored through the approval process and annual reporting requirements. As technology advances and new techniques are more widely adopted, it may be appropriate to consider certain procedures as 'routine' rather than as an innovative. However, while international acceptance of the efficacy and safety of a procedure may deem that it is no longer 'innovative', a licensee will still be required to demonstrate that they have sufficient expertise with the procedure for this to be approved as routine for their clinic.

To provide further clarification of the criteria of procedures that may be considered 'innovative', Council endorsed the definition from the 2007 NHMRC Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research that an innovative procedure is:

> A therapeutic, diagnostic or laboratory procedure that is aimed at improving reproductive outcomes beyond existing methods but has not been fully assessed for safety and/or efficacy.

As an example, vitrification is a form of cryopreservation in which oocytes or embryos undergo ultra-rapid freezing. The advantage of vitrification over traditional 'slow cooling' methods is the relative simplicity of the method, and that ultra-rapid freezing reduces the likelihood of ice crystal formation and subsequent damage to cell membranes. However, one risk associated with this procedure has been that cells are exposed to higher volumes of potentially toxic cryoprotectants than volumes used in the slow cooling method.

With refinement of the methodology including the use of less toxic cryoprotectants, international and local experience has shown significant improvements in pregnancy rates following the use of embryos preserved through vitrification, with no increased associated adverse outcomes when compared to traditional cryopreservation of embryos. However, pregnancy outcomes following oocyte vitrification are still less successful than embryo cryopreservation, and the long-term safety of the procedure, in particular with regard to outcomes of children born following vitrification of oocytes, still warrants monitoring. For this reason, oocyte vitrification remains, in most cases, an innovative procedure in WA.

Innovative Procedures approved during 2008-2009

Council approved two applications from licensees to undertake the vitrification of oocytes as an innovative procedure during the 2008-2009 year.

Innovative to Routine approvals during 2008-2009

Following clinical experience of the vitrification method of cryopreservation, four clinics have applied for and been granted approval by Council to undertake the vitrification of embryos as a routine procedure.

Other procedures that have been reclassified from innovative to routine procedures include:

Blastocyst Culture

This involves the in-vitro maturation of embryos beyond two to three days of development (when embryos had previously been transferred) to day 5. While delaying embryo transfer until day 5 of development is not recommended for all IVF patients, where it is appropriate this method has been associated with improved implantation rates. Clinics were notified that *in general*, Council now considers that blastocyst culture may be practised as a routine procedure. As noted above, clinics must still be able to demonstrate knowledge and expertise in the methodology before this will be deemed routine for a particular clinic.

Assisted hatching

This procedure involves creating a small hole in the zona pellucida, or outer shell of the embryo, to assist the embryo to hatch. Hatching must occur to allow implantation in the uterus. This procedure has been approved by Council as a routine procedure for two licensees. However, criteria restricting the use of assisted hatching to certain types of patients remain in place. International studies examining outcomes of assisted hatching suggest that for some patients (for example younger patients), improved pregnancy rates are inconclusive, and as the method has been linked with an increase in twinning rates (associated with poorer health outcomes for babies compared with singleton births) Council determined that these criteria continue to be applied when this procedure is considered for patients.

Innovative procedures approved under Direction 9.4 for 2008-2009 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.

Council approval of each individual PGD application is supported by advice from the PGD Advisory Committee. Each application 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.

PGD/PGS services offered in Western Australia

There are currently four licensees offering embryo diagnostic services to patients in Western Australia. One licensee received 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.

In January 2009, a second clinic was approved to undertake PGS on site in WA. The PGD Advisory Committee assessed compliance with the requirements of the HRT Act and the 'Policy on Approval of Diagnostic Procedures involving Embryos', before making a recommendation to Council. These requirements include achieving (or working towards) NATA accreditation of the laboratory, and requirements for supervision and staff training in biopsy and diagnostic techniques are also set out in the Policy. Approval was granted in

January 2009. This clinic also anticipates offering PGD services at its laboratory in WA in the near future. Embryo biopsies taken for PGS by the remaining licensee, and all biopsies currently taken for PGD in WA, are couriered to a laboratory in Victoria or New South Wales for analysis.

In Western Australia, since the HRT Act was amended to allow diagnostic testing on embryos in 2004, Council has approved more than 60 applications to undertake PGD.

The use of PGD and PGS in Western Australia is discussed more comprehensively on page 30. PGD applications received by Council in 2008-2009 are tabled in Appendix 3.

Practices under the Human Reproductive Technology Act 1991 requiring Council approval.

Directions to the HRT Act set out additional practices for which licensees must seek Council approval. For the 2008-2009 year, licensees sought Council approval under Directions 6.2 and 6.6 and 8.8.

Direction 5.8 Psycho-social preparation required where recipient is known to the donor: 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 6.2 Import of donated reproductive material:
Except as approved under direction 6.3, a person to whom the licence applies must not, without the approval of the Council, accept from outside the State for use in an artificial fertilisation procedure, gametes, embryos or eggs undergoing fertilisation where donation of human reproductive material has been involved, if the information that would be required under the Act for the registers, had the donated human reproductive material been collected in this State, is not available to him/her.

Direction 6.3 Council may approve import without information for registers:
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 Council may approve export of donated gametes, embryos or eggs undergoing fertilisation for use in an artificial fertilisation procedure: 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 IVF treatments to avoid likely transmission of an infectious disease:
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 Restriction on use of fresh donated eggs:
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 Council may approve collection of eggs despite direction 8.7 in exceptional circumstances: 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.

Approvals granted in 2008-2009 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. Through the licensing process undertaken in 2008- 2009, all clinic licensee consent forms and patient information sheets were examined by the Executive and Deputy Executive Officer for Council to assess compliance with the HRT Act, and to provide feedback on the 'readibility' of these documents for patients.

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. A primary function of Council, also set out in the HRT Act is to advise the CEO and Minister for Health on matters relating to ART.

In this capacity, Council activity as an advisory body has been directed in particular at the legislation permitting surrogacy in Western Australia. After an arguably lengthy period of time before Parliament, the *Surrogacy Act 2008* was passed and commenced on 1 March 2009. Council was asked to provide input into the final drafting of subsidiary legislation on surrogacy, and Council members also participated in the Surrogacy Education Forum organised by Ms Jenny O'Callaghan, Ms Jen Parker and Ms Frances Powell in their capacity as DoH officers. This legislation is outlined further on page 26.

Another matter generating significant public interest has been the posthumous collection and use of gametes. At the request of the Minister for Health, Council has deliberated on this matter, and has committed to considering amendment of the HRT Act to allow the conditional use of gametes posthumously. This is discussed further on page 29.

The Counselling Committee resumed activity in 2008-2009 to convene two professional development sessions for Approved Counsellors: In December 2008, Dr Jon Rampono presented "Support and Management of Clients with Mental Health Issues Seeking Fertility Treatment". Dr Joe Parkinson also facilitated a workshop for approved counsellors on "Ethical Decision-making in Practice". Both sessions were well attended.

Future activity

Ongoing consideration of posthumous use of gametes is identified as a future Council focus. Other areas identified as warranting future Council attention include:

- A 'Time to tell campaign' encouraging 'openness' in the area of donor conception.
- Sperm donor shortages
- Embryo storage matters arising from the Embryo Storage Policy
- Ongoing support and information for professionals and information regarding surrogacy legislation in WA.
- Infertility associated with delay in starting a family.

Council participation at relevant meetings and conferences

FSA Conference 2008

Council provided funding or part-funding for three members of Council to attend the 2008 Fertility Society of Australia (FSA) Conference held on 20-22 October 2008 in Brisbane. Council members Mr Peter Fox, A/Professor Jim Cummins and Dr Nyaree Jacobsen attended the conference, with Ms Jenny O'Callaghan also attending under DoH funding. The exposure to a wide range of ART-related issues from a scientific, medical and psychosocial perspective was of particular value to Department of Health staff providing executive support to Council.

Ms O'Callaghan also attended the Australian and New Zealand Infertility Counsellors Association (ANZICA) meeting on Saturday 18 October, with A/Professor Dr Cummins and Dr Jacobsen attending the Serono Symposium 'Beyond the Light Microscope' held on 19 October 2008 in Brisbane prior to the FSA Conference.

The FSA Conference also provided the opportunity to display the DVD developed by the RTC Counselling Committee "Becoming a Family', which was accepted as an E-poster at the conference.

Other

Ms Jenny O'Callaghan, Dr Nyaree Jacobsen and Ms Jen Parker attended the public seminar coordinated by A/Professor Jim Cummins on "Genetic Screening and Counselling' held on 15 May 2009.

Council policy development

Policy development during the 2008-2009 year included:

- Licensing requirements- the change in the FSA accreditation process led Council to reconsider how licensing requirements set out in the HRT Act would complement but not duplicate these accreditation requirements. A gap analysis was undertaken to identify those requirements of the HRT Act that may *not* be examined through the RTAC accreditation process. Licensees were asked to submit documentation selected through this process as part of their licence applications submitted in March 2009.

- Surrogacy- in particular Council consideration of subsidiary legislation.

- Embryo Storage Policy, this remains as a draft document, but following the receipt of further guidance from the DoH Legal and Legislative Services regarding compliance with the HRT Act, this is ready to be distributed to licensees for feedback.

- Development of Voluntary Register Policy. While the Voluntary Register is managed by the Department of Health, Counselling Committee members provided input into the policy, in particular regarding psycho-social factors for registrants accessing information about, and potential contact with, other matched parties.

- Consideration of Council's position, and possible recommendations for legislative amendments on posthumous collection and use of gametes, which remains under development.

OPERATIONS OF THE COUNSELLING COMMITTEE 2008 - 2009

Key Focus Areas

The Counselling Committee met on seven occasions during the 2008-2009 year. During the course of the year the Counselling Committee has convened to:

- Provide guidance to Council and Department of Health staff responsible for drafting legislation for the *Surrogacy Act 2008*. The Counselling Committee in particular focussed on the requirements for implications counselling, and the psychological assessment for surrogacy arrangements. These matters are set out in detail in the Surrogacy Regulations 2009. The Counselling Committee also assisted with recommendations for the Surrogacy Education forum.

- Undertake a survey of fertility clinics and patients regarding clinic counselling practices and patient access to counselling services. Recommendations resulting from the survey included developing a brochure for patients, increasing access to telephone counselling and consideration of group counselling sessions for patients. The committee recommended the survey be repeated every two years to monitor availability and uptake of counselling services in fertility clinics.

- Undertake a review of the Voluntary Register (VR) Policy. Discussion in particular focussed on the apparent interest of parents of donor offspring. While the primary intent of the VR was to facilitate information between donors and donor offspring, many registrations have been received from parents seeking information about other children who share common genetic parentage with their child (half-siblings). Confidentiality issues and management of sharing identifying information when two parties are registrants of the VR were discussed for the purpose of advising Department of Health staff developing the VR Policy.

- Oversee production of the 'Becoming a Family' DVD. This explores issues faced by same-sex female couples seeking ART services. Ms Antonia Clissa was asked to oversee completion of the DVD, which was accepted as an E-Poster at the 2008 FSA Conference. Copies have since been distributed to clinics and counsellors, and to interested members of the public on request.

- Provide Council with advice on psychosocial matters in ART, including implications of the five-family limit for donor reproductive material, and the posthumous use of gametes.

- Conduct two training sessions for Approved Counsellors. Eminent psychiatrist Dr Jon Rampono presented to counsellors on "Support and Management of Clients with Mental Health Issues Seeking Fertility Treatment", and Dr Joe Parkinson facilitated a workshop on "Ethical Decision-making in Practice". Both sessions were very well attended.

Approved Counsellor's Applications

Council received one application in 2008-2009 for a counsellor to be approved to provide fertility counselling as an Approved Counsellor under the HRT Act. This was approved by Council with a set period of supervision prior to the applicant being recognised as an Approved Counsellor. As of June 2009 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 practices, 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 (though it should be noted that licensees must also indefinitely retain the original records). 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, concern arose regarding the legality of researchers external to the DoH accessing data on the RT Register. Give the recognised public health benefit that may be gained through epidemiological evaluation of this data, this matter has been flagged by Council and legislative amendments have been recommended to facilitate researcher access to non identifying information from the RT Register linked to other data sets.

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

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 was made in recognition of the need to know their genetic parentage often experienced by children conceived from donor material.

The Voluntary Register provides a service for parties involved in donor conception in the State who wish to access their donor and/or recipient information. This includes children born from donor material donated *before* 2004: for these children, there is no legislated

authority to access information about their donor. Donors who are seeking information about any child born as a result of their donations and parents of donor offspring seeking information about any other children that have been born from the same donated reproductive material (who are biological half-siblings to their children) may also register. Relevant non-identifying information can be passed on to an applicant, and identifying donor information can 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.

For donations given after 1993, Voluntary Register information will be derived from the Department of Health 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. The Voluntary Register does not provide an 'outreach service', so donor parties that have not registered are not contacted on behalf of registrants.

Joining the Register is voluntary, and interested parties contacting the RT Registrar 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 2008-2009

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

2 donor offspring-requests for application forms
2 completed applications received from donor offspring

9 donor-requests for application forms
6 completed applications received from donors

The Voluntary Register has recorded 126 registrations since the inception of the data-base in November 2002. To date the registrants include 69 parents of donor-conceived offspring, 47 donors and 10 donor-conceived adults.

Development of the Department of Health Voluntary Register Policy has been a focus for RTU staff during this year, with input and feedback on the policy provided by the Counselling Committee. The Voluntary Register Policy has now been completed, and this will provide the basis for training of Approved Counsellors on counselling parties who have been matched through the Voluntary Register. While non-identifying information has been provided to many registrants on the Voluntary Register, to date there has been only one match where two parties who received reproductive material from the same donor have indicated the desire to receive identifying information about the other party. However, at this point in time neither party has undertaken the required counselling that will precede the exchange of identifying information. Counselling is considered highly desirable so that all parties have a common understanding of what the exchange of information will entail. A public awareness campaign has been proposed to increase awareness of the service offered by the Voluntary Register.

SIGNIFICANT DEVELOPMENTS IN REPRODUCTIVE TECHNOLOGY DURING 2008-2009

Surrogacy Act 2008

In 1999, following a review of the legislation regulating ART in WA, the Report of the Select Committee on the *Human Reproductive Technology Act 1991* made the recommendation that legislation on surrogacy be developed. This overturned a previous recommendation that IVF surrogacy should not be permitted in Western Australia, and reflected evolving public and political acceptance for surrogacy as a means to allow people, who would otherwise be unable to have a child, to become parents. Also of influence was the awareness that private surrogacy arrangements were in fact taking place, and as exemplified by the Re Evelyn case, unregulated arrangements exposed parties arguably more to the risk of dispute. The regulation of surrogacy arrangements was perceived as a means to minimise the risk of such negative outcomes, and to protect all parties as much as possible, in particular children born from these arrangements. Commercial surrogacy, where a birth mother receives benefits beyond what are considered 'reasonable expenses', would still be prohibited. The resultant proposed legislation, the Surrogacy Bill 2007, was introduced to the Western Australian Parliament on 1 March 2007. The Surrogacy Bill 2007 aimed at the regulation of IVF surrogacy, not previously permissible under the HRT Act, and to provide a mechanism for parentage orders to be made for any child resulting from a surrogacy arrangement.

After passing through the Lower House with several amendments, the Bill was referred to the Standing Committee on Legislation, a Committee of the legislative Council, for further review. The resulting report "The Standing Committee on Legislation in relation to the Surrogacy Bill 2007", 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 has the responsibility for the assessment of surrogacy applications; the draft Directions to the Surrogacy Bill had previously required a committee/panel be set up by the IVF clinic providing surrogacy services.

These recommendations were accepted, and after almost two years before Parliament, the *Surrogacy Act 2008* (Surrogacy Act) was assented to in December 2008. Subsidiary legislation, including the Surrogacy Regulations 2009, Surrogacy Directions 2009, and Family Court (Surrogacy) Rules 2009, were gazetted in February 2009. With the exception of Australian Capital Territory legislation allowing parentage orders to be made under certain circumstances, Western Australia was the first Australian State to enact specific legislation permitting surrogacy. Surrogacy legislation in other jurisdictions is under consideration; Victoria has recently enacted new legislation regulating ART including provision for surrogacy arrangements, and the adoption of consistent surrogacy legislation across the remaining states and territories is currently also under consideration. In terms of the provision of IVF surrogacy services, as no legislation disallowed surrogacy arrangements in ACT and NSW, arrangements have been coordinated by fertility clinics in these jurisdictions, with policy underpinned by NHMRC guidelines and clinic protocols.

The Surrogacy Act sets out eligibility requirements for parties seeking a surrogacy arrangement, and prescribes the preparation and assessment process for all parties to an arrangement. For a couple to be eligible to commission a surrogacy arrangement, the couple or the woman must be eligible for IVF under the HRT Act. Hence, women who are infertile or unable to carry a child for medical reasons, but not infertile due to age, may seek to undertake a surrogacy arrangement. Medical and psychological assessments are required for all parties including the arranging parents, the birth parents and any donors involved in the arrangement. Legal advice must be sought, and implications counselling must also be

undertaken by all parties for an arrangement to be approved. Both traditional and gestational surrogacy is permitted under this legislation, although the provision for parentage orders made following the birth of a child through a surrogacy arrangement may vary depending on the genetic input from the birth mother and arranged (surrogate) parents. An arrangement must not be a commercial arrangement between the parties.

The Surrogacy Regulations outline the requirements to meet before an application seeking Council approval of an arrangement is submitted. The strict requirement for both birth and arranged parents to seek counselling and legal advice, plus the medical and psychological assessment process set out by the legislation, aims to protect all parties involved with a surrogacy arrangement, and in particular to safeguard the rights and best interests of any child created.

R 5. Application for approval of surrogacy arrangement

(1) An application to the Council for the approval of a surrogacy arrangement is to be in a form approved by the Council.

(2) The application is to be accompanied by-

(a) evidence of the age and obstetric history of the birth mother; and

(b) evidence of the age of each arranged parent; and

(c) a copy of the signed surrogacy arrangement; and

(d) a copy of the certificate referred to in regulation 4(3); and

(e) a copy of a clinical psychologist's report referred to in section 17(c)(ii) of the Act for each of the parties stating the name of the clinical psychologist who undertook the assessment and the day on which the assessment was completed; and

(f) a written note from each legal practitioner who has provided legal advice about the effect of the surrogacy arrangement to a party stating –

(i) the name of the practitioner providing the advice; and

(ii) the name of the person to whom the advice was provided; and

(iii) the day on which the advice was provided; and

(iv) whether the advice was independent legal advice within the meaning given in section 14 of the Act;

and

(g) a copy of a medical practitioner's report referred to in section 17(d) of the Act for each of the parties stating-

(i) the name of the medical practitioner who undertook the assessment; and

(ii) the day on which the assessment was completed; and

(iii) details of any concerns the medical practitioner has about the effect that involvement of the person in the surrogacy arrangement may have on any known condition of the person; and

(iv) details of any medical condition of the person that may pose a risk to a child born as a result of the surrogacy arrangement; and

(v) in the case of the arranged parents, whether the eligibility criteria set out in section (19)(1)(b) of the Act have been met.

Council approval of a surrogacy arrangement is necessary before a fertility clinic can provide an artificial fertilisation procedure to a couple, and is also a prerequisite for the Family Court to make a parentage order for any child born from an arrangement. An exception to this is where a child has been born from a surrogacy arrangement *prior* to the proclamation of the Surrogacy Act. In this circumstance, arranged parents can apply for a parentage order within 12 months of the proclamation date, though preparatory counselling and legal advice must still be undertaken by all parties, and all parents must consent to the parentage order.

Implementation of surrogacy services in WA

In order to inform practitioners about the legislation and to facilitate the timely implementation of surrogacy services in WA, the Department of Health held a Surrogacy Education forum 'Implications for Practitioners of the Surrogacy Act 2008'. Speakers with experience in surrogacy assessments and arrangements from NSW, ACT and WA presented to a range of professionals with an interest in ART including clinicians, psychologists, fertility nurses and managers and Approved Counsellors.

In addition to this, family law practitioners received information on the legislation from DoH legal and policy officers on the Surrogacy Act at a Family Law Practitioners seminar in May 2009.

At this point in time, three WA fertility clinics have indicated they will provide surrogacy services. The coordination of surrogacy services can only be undertaken by a fertility clinic following the approval by Council of relevant documentation, including patient information sheets and consent forms. While it will arguably take some time to fine-tune clinic protocols and documents and to identify professionals willing to provide advice and assessments for surrogacy, for the small number of couples in Western Australia affected by this legislation, the opportunity to undertake a surrogacy arrangement and to achieve legal parentage of a child through surrogacy will be very welcome.

Posthumous collection, storage and use of gametes

Advances in medical knowledge and technology enable the potential for interventions that challenge existing medical and ethical principles. The creation of children using gametes after the death of the gamete provider similarly poses such a challenge and has generated ethical and legal debate internationally as well as within Australia.

In Western Australia, the HRT Act currently prohibits the posthumous use of gametes:

> **Direction 8.9** of the Act sets out that any person to whom the licence applies must not knowingly use or authorise the use of gametes in an artificial fertilisation procedure after the death of the gamete provider.

Victorian legislation has recently been enacted that allows the conditional use of gametes posthumously, when such use is approved by a Patient Review Panel. The NHMRC guideline 6.15 *Posthumous Use of Gametes* also sets out the prescribed conditions that may allow the posthumous use of gametes to be considered, though the guidelines acknowledge that state legislation may prohibit the use of gametes after a person has died.

Over recent years, there have been a number of cases in Western Australia where sperm has been collected posthumously under an order from the Supreme Court of Western Australia. The Minister for Health, Dr Kim Hames has indicated his support for the possible posthumous use of gametes, and has sought Council consideration of amendment to the HRT Act to permit this usage in WA. Council has agreed in principle to the Minister's suggestion, and aims to provide recommendations regarding the conditions under which this practice could be permitted in WA.

Matters of informed and effective consent, the welfare of any child born as a result of posthumous gamete use and ownership issues of posthumously collected or stored gametes will be important factors considered by Council in developing recommendations around this issue.

The authority for the Court orders allowing the posthumous collection sperm in WA was provided under the *Human Tissue and Transplant Act 1982*. Some uncertainty existed as to whether collection under this Act ought to result in the gametes being considered 'donated'. This matter required determination, as Council approval is required where the export of donated human reproductive material including gametes is sought. At the extraordinary meeting held on 10 June 2009 and following the advices of the Senior Legal Adviser in the Department of Health and from State Solicitor's Office, Council agreed that gametes collected posthumously under the HTT Act 1982 would be considered donated. It was therefore decided that Council does have the authority to consider applications to export such stored gametes from the state. In reaching this determination, Council noted that the *Human Tissue and Transplant Act 1982* pre-dated the technology enabling the creation of embryos from posthumously collected gametes. It was unlikely therefore that this legislation sought to address such a scenario.

This point notwithstanding, Council will consider applications for export of posthumously collected gametes on a case by case basis. In addition, Council has committed to consider the conditions under which artificial fertilisation using posthumous gametes in Western Australia ought to be allowed, and to provide advice to the Minister for Health on this issue. This will be a Council priority for the 2009-2010 year.

Preimplantation genetic diagnosis and screening in Western Australia

Some people are at high risk of having a child born with a serious genetic condition. Many genetic conditions can now be detected before a child is born, for example through tests during a pregnancy (prenatal testing) via chorionic villus sampling (CVS) or amniocentesis. Alternatively, following an IVF procedure, an embryo may be tested before it is transferred to a woman's uterus for implantation. This diagnostic testing on embryos includes preimplantation genetic diagnosis (PGD) and preimplantation genetic screening (PGS).

While prenatal testing and preimplantation testing will both provide similar genetic information about a fetus or embryo, undertaking this testing process *before* pregnancy occurs may offer some benefit to a couple. In particular, the selection of an embryo free from a particular genetic condition can decrease the risk of a couple having to undergo a termination following an adverse result picked up through amniocentesis or CVS. Couples who have suffered multiple miscarriages may also be advised to consider IVF and embryo testing in order to establish if genetic anomalies have been a causal factor in these miscarriages, and to minimise the chance of further miscarriage of subsequent pregnancies. The expense of IVF (partially funded by Medicare) and PGD/PGS (not covered by Medicare) may preclude some couples seeking this technology; postnatal medical and diagnostic services are covered more comprehensively by Medicare.

PGD

PGD is the analysis of single gene defects and translocations, where part of one chromosome has been transferred to another chromosome. These will be conditions known to be carried by one or both of the partners in a couple, and potentially inherited by any children born to the couple. These include conditions such as Huntington disease, thalassaemia, sickle cell anaemia and cystic fibrosis. PGD applications must be approved by Council on a case-by-case basis, and will be initially assessed by the PGD Advisory Committee which then makes a recommendation to Council. Approval will usually be subject to a preliminary feasibility study supporting that the genetic condition is able to be tested through PGD. Each application must be accompanied by a report from a clinical geneticist outlining the matters that have been discussed with each couple. Factors that influence the approval process include the severity of the condition, and the risk of a child inheriting the condition.

PGS

PGS is performed to screen embryos for chromosomal abnormalities, where one or more chromosomes may be extra or missing in an embryo. Such chromosomal anomalies are known as aneuploidy. An aneuploidy will not necessarily be carried by either of the genetic parents, but through certain risk factors such as age of the parent may be more likely to occur in embryos created from the couple's gametes. Embryos can be screened to determine whether they have the correct number and arrangement of specific chromosomes. Currently, testing involves looking at between 7 and 9 specific chromosomes (out of the possible 23 pairs) for more commonly seen aneuploidy conditions. Advances in technology may allow all chromosomes to be tested in the future, for example, through micro-arrays. Women of advanced maternal age, those who have had recurrent miscarriages or a number of failed IVF attempts may be recommended aneuploidy testing of their embryos. Down Syndrome is an example of an aneuploidy condition that may be detected through PGS.

Approved licensees may undertake PGS where eligible IVF patients are considered to be at risk of producing an embryo with chromosomal abnormalities. Council policy, developed by the PGD Advisory Committee and ratified by Council in November 2007 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, and PGS for these patients can be undertaken without specific Council approval.

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.

In many cases, the biopsy is carried out on day 3 embryo, where one (sometimes two) cells are removed for analysis. In other cases biopsy may be performed on a 5 day old embryo (known as a blastocyst), which, due to further maturation and time for cell division, allows more than one cell to be removed. At day 5 a small sample of embryonic cells that go on to develop into the placenta (known as trophoblasts) are removed for testing.

Accuracy of PGD

PGD and PGS utilise different methodologies for analysis. PGD has an accuracy of between 97-99%, so the chance of a false result is very low. However, as the test is only looking for a specific condition, the risk of other abnormal conditions still exists. For this reason, prenatal testing such as amniocentesis may still be recommended if a pregnancy is achieved. For aneuploidy, accuracy of the result is between 90-95%.

A summary of results collected from Australian and New Zealand infertility clinics showed that in 2006, the live birth rate per IVF/ PGD cycle was approximately 18%. As with IVF alone, a number of IVF/PGD cycles may be needed to achieve the birth of a child.

Uncertainty of benefit from PGS

While PGS initially was regarded as a useful tool assisting the prediction of embryo viability, the benefit in terms of pregnancy and live birth outcomes for patients undergoing IVF for PGS for aneuploidy has been questioned in recent years. Studies have shown variable outcomes in terms of implantation, pregnancy rates, and rates of spontaneous abortions following PGS. Harper, Sermon et al (2008) reiterate that the difficulties in determining the benefits, if any, of PGS derive from the lack of well-designed randomised controlled trials examining live birth outcomes and miscarriage rates. “The debate on the benefit of PGS is ongoing. The disadvantages of PGS are that it is labour intensive, invasive to the embryo and expensive. Mosaicism is common in cleavage stage embryos and analysis of only one cell means that some embryos, that may have developed normally, would not be considered for transfer if the single cell tested gives an abnormal result. The advantages of PGS are that aneuploid embryos which have little or no viablility are not transferred or frozen. In this way, high risk patients potentially avoid miscarriage and viable abnormal pregnancy”. With regard to the concern about mosaicism, where different cells in the same embryo exhibit a different genetic makeup, a recent randomized controlled study examined the chromosomal constitution of 166 embryos tested and found to be abnormal through PGS analysis. These embryos were reanalysed to test the results of the initial diagnosis, and how well the chromosomal constitution of one biopsied cell reflected the status of the entire embryo. Interestingly, though the same diagnosis as that in the initial analysis was only reproduced in slightly more than one third of cases, the second analysis still revealed an abnormal result in the other cells. The results of this study by Hanson, Hardarson et al (2009) identified a false positive and a false negative rate of around 4.1%, concluding that “PGS seems to be a good method for selecting against chromosomally abnormal embryos but not for determining an embryo's exact chromosomal constitution”.

Harper, Sermon et al conclude that multicentred randomised controlled trials would “help to clarify whether PGS has any value for IVF patients, and if so, to specify those subsets of patients for whom PGS is efficacious”. The use of day 5 blastocysts for biopsy and application of micro-array technology also warrants exploration to determine the effectiveness and reliability of PGS as an embryo screening and selection tool.

Another current ethical matter involving the use of embryo diagnostic technology is the use of PGD and HLA testing for the creation of saviour siblings. From the 2007-2008 Annual Report:

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.

Amendment of the HRT Act to allow all parents to access PGD and HLA testing has been one of the recommendations made to the Minister for Health by the Reproductive Technology Council in 2008-2009. In other states of Australia, PGD for the creation of a saviour sibling has been approved for a number of families, for example more than 15 saviour sibling babies have been born following use of this technology in New South Wales. Council is hopeful that this matter will be progressed in the forthcoming year.

Hanson C., Hardarson T., Lundin K., Bergh C., Hillensjö T., Stevic J., Westin C., Selleskog U., Rogberg L. and Wikland M. "Re-analysis of 166 embryos not transferred after PGS with advanced reproductive maternal age as indication", *Human Reproduction,* 2009, Advance Access published online on July 22, 2009

Harper J., Sermon K., Geraedts J., Vesela K., Harton G., Thornhill A., Pehlivan T., Fiorentino F., SenGupta S., de Die-Smulders C., Magli C., Moutou C., and Wilton L. *Human Reproduction,* 2008 *Vol 23*, No 3, pp478-480.

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*, 2005 Vol 20, No 4, pp845-847.

PRESENTATIONS AND PUBLICATIONS BY COUNCIL MEMBERS AND STAFF 2008-2009

Associate Professor Jim Cummins

Presentations

Public symposium: "Genetic screening and genetic testing" May 15 2009, Murdoch University.

Publications

Cummins, J. M., Sperm motility and energetics. In: T. R. Birkhead, et al., Eds.), Sperm Biology: An Evolutionary Perspective. Elsevier, San Diego, 2009.

Okabe, M., Cummins, J. M., 2007. Mechanisms of sperm-egg interactions emerging from gene-manipulated animals. Cell Mol Life Sci. 64, 1945-58.

Wakayama, S., et al., 2008. Nuclear reprogramming to produce cloned mice and embryonic stem cells from somatic cells. Reprod Biomed Online. 16, 545-52.

Professor Roger Hart

Presentations

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

"The Early Life Influences on Reproduction"
Fertility Society of Australia & New Zealand Annual Meeting, Brisbane 2008

"The effect of Obesity on Reproduction", "The Influence of Fibroids on Fertility"
And "Hysteroscopic resection of Fibroids"
Endoscopic Surgery in Infertility, Perth 2008

Publications

1. Hart R, Hickey M, Maouris P, Buckett W. Excisional surgery versus ablative surgery for ovarian endometriomata. *Cochrane Database of Systematic Reviews* 2008, Issue 2. Art. No.: CD004992. DOI: 10.1002/14651858.CD004992.pub3.
2. Glujovsky D, Pesce R, Fiszbajn G, Sueldo C, Hart R, Ciapponi A Endometrial Preparation For Women Undergoing Embryo Transfer With Frozen Embryos Or Embryos Derived From Donor Oocytes. Review In: *Cochrane Database of Systematic Reviews* 2008 ***(10% contribution)***
3. Hart R. Fertility options for adults and children with a cancer diagnosis. British Medical Journal 2008 ;337:a2045. ***(100% contribution)***
4. Hart R. Infertility and PCOS. Panminerva Medica. 2008; Dec 50 (4):305-14. ***(100% contribution)***.
5. Showell M, Brown J, Hart RJ, Yazdani A, Stankiewicz M. Cochrane Review Antioxidants

for male subfertility 2008 *Cochrane Database of Systematic Reviews* 2008, Issue 4. Art. No.: CD007411. DOI: 10.1002/14651858.CD007411. ***(20% contribution)***

6. Burke C, Nathan E, Karthigasu K Garry R. Hart R. Laparoscopic entry—the experience of a range of gynaecological surgeons. Gynecological Surgery 2009; 6:125-33.
7. Garry R, Hart R, Kathigasu KA, Burke C. A re-appraisal of the morphological changes within the endometrium during menstruation: a hysteroscopic, histological and scanning electron microscopic study Hum. Reprod. Advance Access pub February 27, 2009
8. Clarke J, Showell MG, Hart R, Agarwal A, Gupta S. Antioxidants for female subfertility. The Cochrane Collaboration. Protocol Published by John Wiley & Sons, Ltd. 2009. DOI: 10.1002/14651858.CD007807.

Ms Sue Midford

Presentations

Experiences in surrogacy
'Implications for Practitioners of Surrogacy Act 2008' March 2009

Dr Beverly Petterson

Publications

Hansen M, Colvin L, Petterson B, Kurinczuk JJ, de Klerk N, Bower C. (2009*). Human Reprod May 20th Epub ahead of print*. Twins born following assisted reproductive technology: perinatal outcome and admission to hospital.

Hansen M, Colvin L, Petterson B, Kurinczuk JJ, de Klerk N, Bower C. (2008*). Human Reprod **23(6)** 1297-305, Epub 2008 Mar 28*. Admission to hospital of singleton children born following assisted reproductive technology (ART)

Dr Joe Parkinson

Presentations

'Understanding Assisted Reproductive Technology' and 'ART: Some Ethical Issues' presented to the Catholic Education Commission of WA, 6-7 October 2008 and 28-29 May 2009.

'Ethical Issues in ART and Stem Cell Research' presented to secondary students, 5 August 2008.

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 practise 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 2009-2010.

Exemption No	Practitioner Name	Suburb	Post Code
E034	Dr RT Chapman*	Perth	WA 6000
E027	Dr DP Day	Kelmscott	WA 6111
E050	Dr R Kirk	Northam	WA 6401
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 2009

Name	Professional Address	Telephone / Fax No
Ms Antonia Clissa	Concept Fertility Centre PO Box 966 SUBIACO WA 6008	Ph 0412 653 854
Ms Deborah Foster-Gaitskell*	1) 62 Churchill Ave, SUBIACO WA 6008 2) 193 South Terrace, SOUTH FREMANTLE WA 6162	Ph (08) 9271 3582 Fax (08) 9388 3740
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 Cailin Jordan	Hollywood Fertility Centre Monash Ave, NEDLANDS WA 6009	Ph (08) 9389 4200
Ms Rosemary Keenan*	6 The Lakes Mews Karrinyup Lakes Lifestyle Village, GWELUP WA 6018	Ph (08) 9447 8365
Ms Mandi MacShane	Bassendean Chiropractic and Wellness Centre 103 Old Perth Road, BASSENDEAN WA 6054	Ph (08) 9379 3838 Ph 0408 479 453
Ms Suzanne Midford*	1) Perth Psychology Services Suite 6/401 Oxford St Mt HAWTHORN WA 6016 2) 2/36 Ormsby Terrace 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) Concept Fertility Centre PO Box 966 SUBIACO WA 6008 2) Keogh Institute for Medical Research QE Medical Centre NEDLANDS WA 6009 3) Private Practice North/South	Ph (08) 9382 2388 Ph (08) 9346 2008 Fax (08) 9380 6387 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	Ph (08) 9443 3655 Fax (08) 9443 8665 Ph (08) 9422 5400
Dr Elizabeth Webb	1) Fertility North, Suite 213, Joondalup Health Campus, JOONDALUP 6027 2) Suite 201, Specialist Medical Centre Joondalup Health Campus JOONDALUP WA 6027	Ph (08) 9301 1075 Ph (08) 9400 9871

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

APPENDIX 3

OPERATIONS OF LICENSEES FOR THE FINANCIAL YEAR 2008-2009

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

Background

Under the *Human Reproductive Technology Act 1991* (HRT Act) fertility clinics licensed under the Act are required to submit annual reporting data at the end of each financial year. This summary was put together from information submitted from these licensees. Six clinics in Western Australia have been issued Storage Licences and Practice Licences authorising artificial fertilisation procedures including in vitro fertilisation (IVF), one of which was established in November 2008. The remaining (seventh) licensee has a Storage Licence and a Practice Licence limited to providing artificial insemination. Information required from this 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 the Concept Fertility Centre (Concept) has been provided by Concept.

All information was submitted in a collated form and referred to the financial year, ending at 30 June 2009. 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 2008-2009 financial year, semen donations from 97 men were stored with WA storage licensees. Of these, 24 were new donors. There has been a decrease in sperm donor numbers since 2004 when amendment to the legislation required that all new donors consent to release of their identifying information to any offspring conceived from their donation. The issue of low donor numbers has been identified by Council as a matter for further consideration.

The age distribution of donors demonstrates a continuing trend of an increase in the average age of the donor at the time of donation (Table 1, Figure 2). The majority of donors (87.6%) with donations in storage in 2008-2009 were over 30 years of age, and 46.4% were over 40. This trend may be due to the social issues and potential implications associated with the 2004 amendments; younger men who do not yet have families of their own may be more hesitant to donate, knowing that their identifying details will be available to donor offspring at 16 years of age.

Where the marital status of the donor was known, 64.1% of donors were single, 29.5% were married or in a de facto relationship, and 6.4% donors were divorced. The marital status of 19.6% of donors was unknown. These proportions have remained relatively consistent when compared with previous years.

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 13 exempt practitioners

at the end of the 2008-2009 financial year with two exempt practitioners requesting revocation of their exemption for the 2009-2010 financial year.

TABLE 1: 2008-2009 AGE OF SPERM DONOR AT TIME OF DONATION

Age of Donor (years)	Number (%)
18-25	3 (3.1)
26-30	9 (9.3)
31-35	16 (16.5)
36-40	24 (24.7)
41-49	36 (37.1)
50 +	9 (9.3)
Total	97 (100)

FIGURE 1: SPERM DONORS IN WA

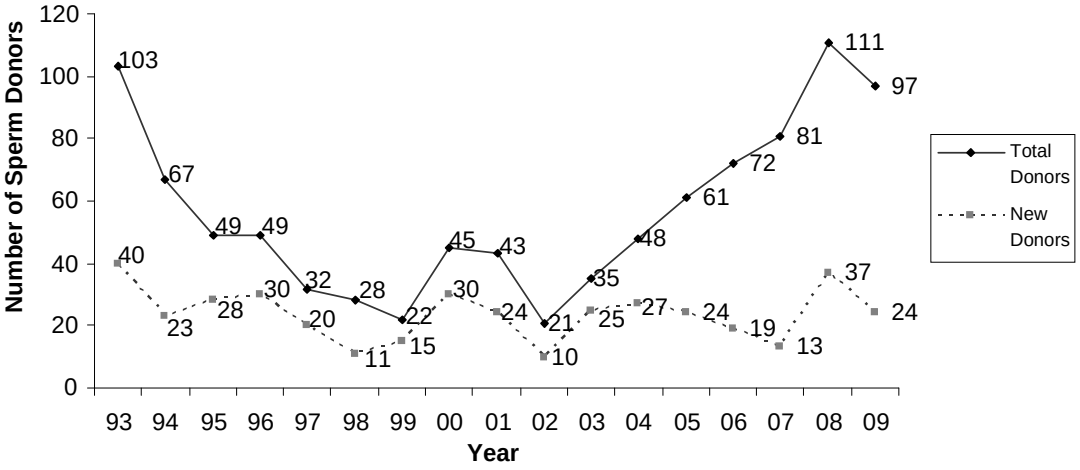
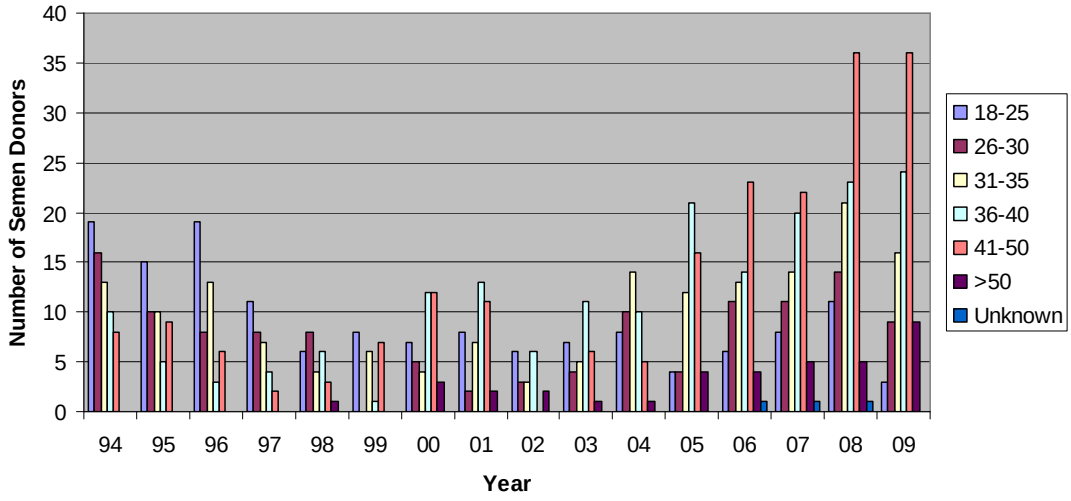


FIGURE 2: NUMBER OF SEMEN DONORS BY AGE



Embryo storage

Table 2 shows that 17 334 embryos were in storage at the end of the 2008-2009 financial year. The total number of embryos in storage has continued to increase since 1993 (as illustrated in Figure 3). This trend may be partially explained by the increased usage of FET over fresh IVF and embryo transfer. However, the largest factor contributing to this year's increase is the significantly lower number of embryos that were allowed to succumb in 2008-2009: during this year 547 embryos were allowed to succumb (similar to the 2006-2007 figure of 544 embryos) compared to 1448 in 2007-2008. The number of embryos frozen after oocyte pickup marginally increased (by 60) from the previous financial year. It is expected that these embryos will either be used in IVF or for research. A total of 5566 embryos were stored following treatment and 3228 stored embryos were used in treatments during the year.

TABLE 2: DISPERSAL OF STORED EMBRYOS 2008-2009

	NUMBER OF EMBRYOS
Embryos in storage 30/06/08	15828
Embryos created from IVF	5566
Transferred into WA clinics from interstate	134
Transferred between clinics in WA	185
Transferred to clinics outside WA (interstate/overseas)	100
Used in frozen embryo transfer treatments	3228
Allowed to succumb with consent of couples	547
Embryos in storage 30/06/09	**17334**

FIGURE 3: TRENDS IN EMBRYO STORAGE

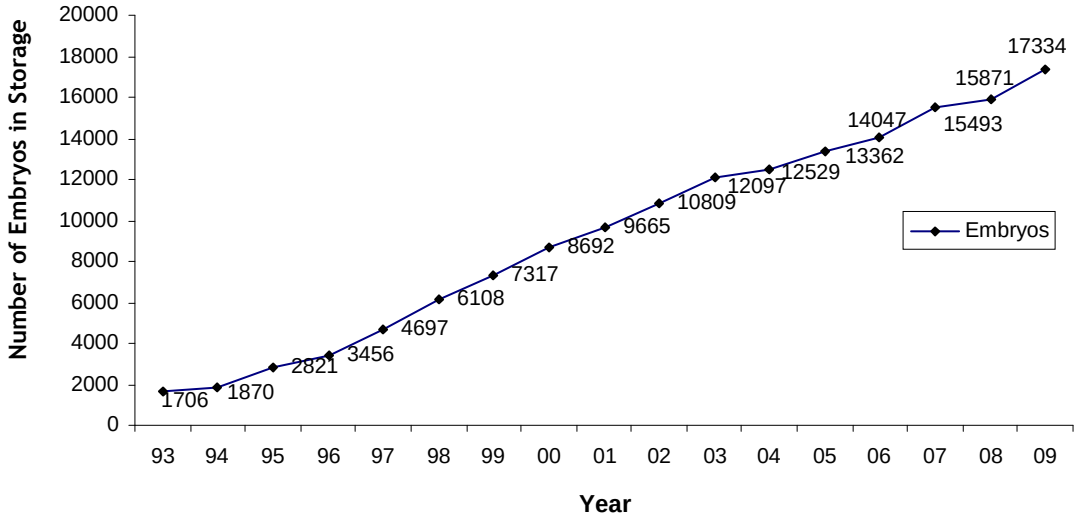
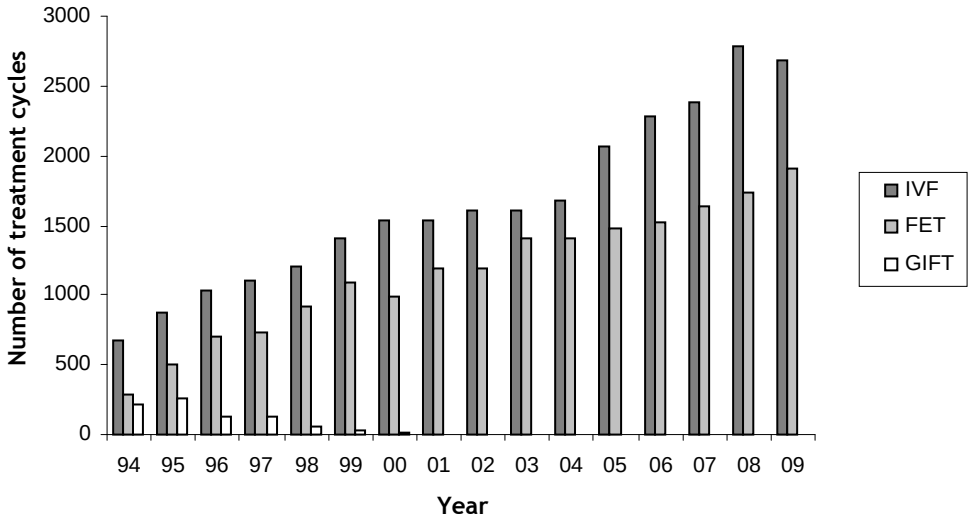


TABLE 3: 2008-2009 IVF AND GIFT TREATMENTS

	IVF (fresh)	FET (frozen)	GIFT	TOTAL
Women treated	1815	964	0	N/A
Cycles begun	2684	1911	0	4595
Cycles with egg retrieval	2398	-	0	2398
Cycles with gamete or embryo transfer	1942	1705	0	3647
Cycles with embryos storage	1265	-	0	1265
Number of cycles using donor:				
Semen	120	93	0	213
Eggs	29	67	0	96
Embryos	12	23	0	35
Total	161	183	0	344
Number of cycles from which eggs or embryos were donated:				
Eggs donated	43	-	0	43
Embryos donated	0	-	-	0
Breakdown of treatment cycle details				
Cycles with IVF/GIFT same cycle	0	-	0	0
Cycles with surgical sperm aspiration	225	-	0	225
Cycles with ICSI*	1709	-	-	1709
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



In Vitro Fertilisation, Frozen Embryo Transfer and Gamete Intra Fallopian Transfer treatments

Table 3 shows that during the 2008-2009 financial year, 1815 women began oocyte retrieval cycles for IVF and 964 began FET. While there were 190 fewer women commencing oocyte retrieval this year than in 2007-2008, the number of cycles for IVF and FET were relatively consistent (4595 compared to 4523 in 2007-2008). As with many health services, ART behaves in some ways as a 'luxury' item, and it is possible that the levelling out of cycle numbers has resulted from a more constrained economic environment. As illustrated in Table 3, of all cycles begun, 2684 (58.4%) were for IVF and 1911 (41.6%) were for frozen embryo transfer. Figures 4 and 5 illustrate the increase in the proportion of FET cycles, with a decrease in IVF cycles performed compared to the last financial year.

No licensee reported the use of GIFT for 2008-2009; this procedure has not been used by any clinics in Western Australia since the 2005-2006, when only one cycle of GIFT was performed.

Of the 2684 cycles begun for fresh IVF with ovarian stimulation, 89.3% were successful in proceeding to oocyte retrieval and 72.4% proceeded to transfer of fresh embryos (Figure 5). These figures show an increase in the rate of oocyte retrieval by only 1% from last financial year, and a sizeable decrease of 12.1% in the transfer rate from 2007-2008. Of the 1911 frozen embryo transfer cycles begun, 1705 (89.2%) proceeded to transfer.

Overall, donated human reproductive material was involved in 6.7% of all IVF cycles with oocyte retrieval during the year, showing a 1% increase from last year. Donor semen was used in 5% of cycles (120 cycles); donor eggs were used in 1.2% of cycles (29 cycles) and there were 12 IVF cycles with fresh embryos donated. A higher proportion of frozen embryo transfer cycles (10.7%) involved the use of donated gametes or embryos. Donor embryos were used in 1.3% of all FET cycles with transfer (23 cycles); donor eggs in 3.9% (67 cycles) and donor semen in 5.5% (93 cycles).

FIGURE 5: IVF (FRESH) TREATMENTS

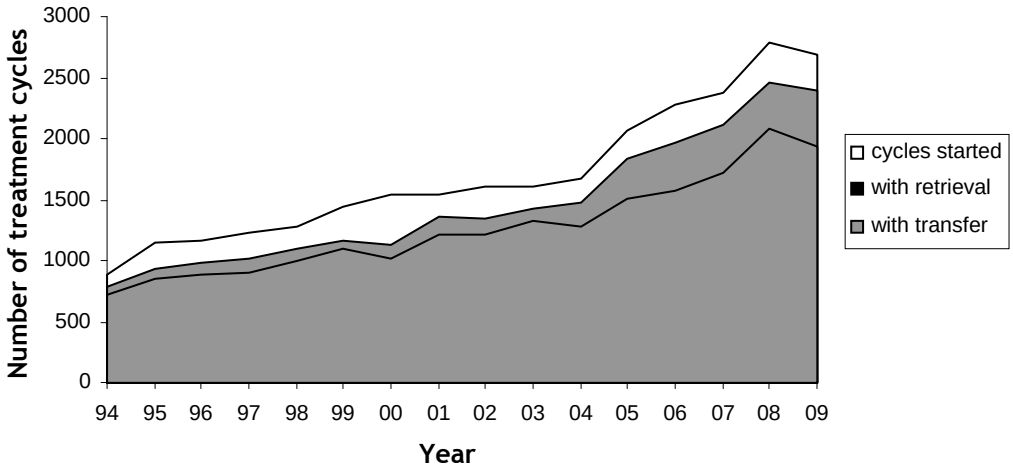
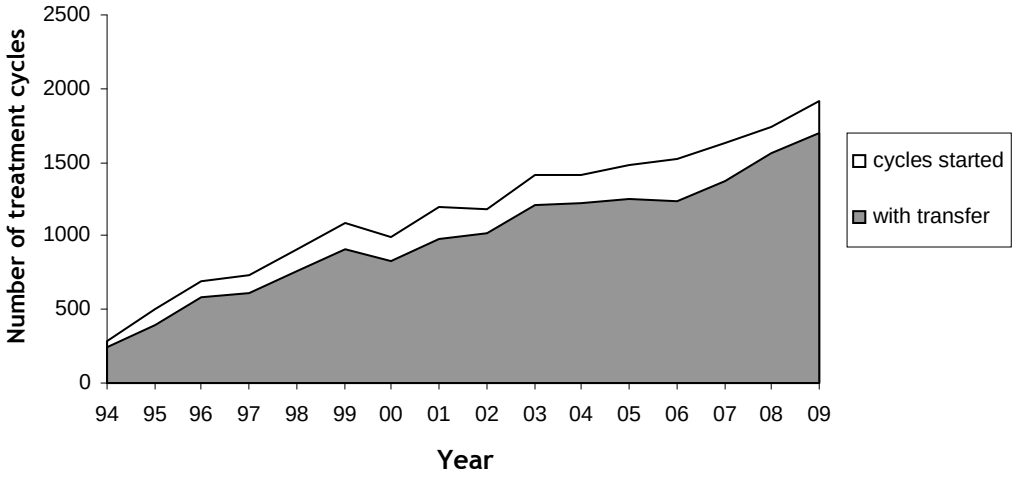
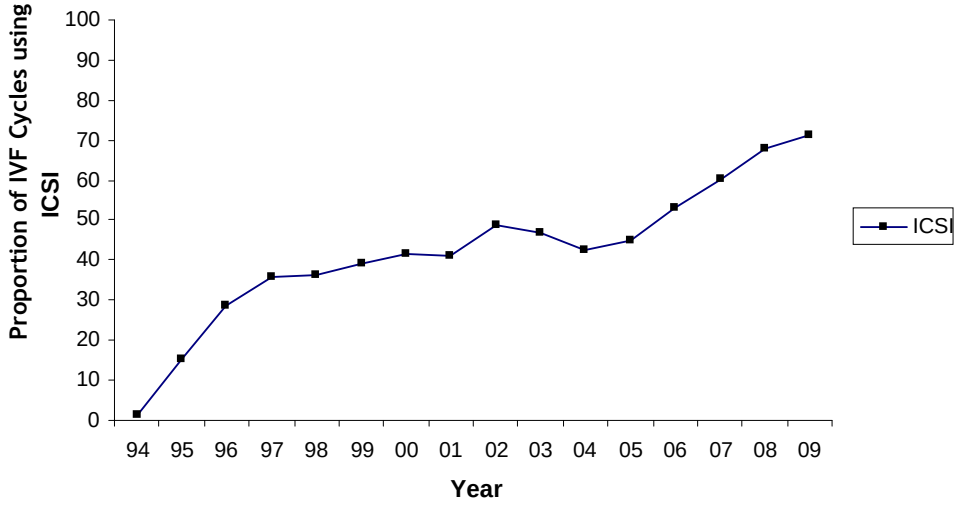


FIGURE 6: FET TREATMENTS



Of all 2398 IVF treatment cycles with successful oocyte retrieval, 1709 (71.3%) involved intra-cytoplasmic sperm injection (ICSI). As illustrated in Figure 6, the use of ICSI has increased since the last financial year, and this has been the general trend since this technique was taken up by WA clinics in 1994. ICSI, which involves injection of one sperm directly into the egg, has become a routine practice in cases of male fertility problems and poor fertilisation. Sperm retrieved from the epididymis or testis was used in 215 of the ICSI treatment cycles.

FIGURE 7: IVF CYCLES USING ICSI



Treatment of patients referred from the Public Fertility Clinic

During the year 87 patients from the King Edward Memorial Hospital (KEMH) Infertility Clinic were referred to Concept Fertility Centre for fertility treatment. As can be seen from Table 4, 59 women were treated with fresh IVF transfer and 28 with frozen transfer. The results for this year indicate a decline in the number of public patients treated since 2007-

2008. During the year 100 fresh IVF and 74 FET treatment cycles were commenced for these patients, with more FET cycles and fewer IVF cycles performed than the previous year. This year 53 of the IVF cycles involved micro-manipulation (ICSI). Of the 174 cycles started for public patients, only 2 cycles reported using donated gametes (one cycle using donor semen and one using donor oocytes), and no cycles used donor embryos. In addition, there were 19 IVF cycles and 2 FET cycles reported as using assisted hatching. Blastocyst culture was used in 32 IVF cycles and 38 FET cycles.

There were 66 artificial insemination procedures performed for public patients between 1 July 2008 and 30 June 2009. Of these, 9 treatments used donor sperm and the remaining 57 treatments used the woman's partner's sperm. This is an increase from the 48 artificial insemination procedures performed in the previous year, all of which involved use of the partner's sperm.

TABLE 4: IVF AND RELATED TREATMENT OF PUBLIC PATIENTS

	No. of Patients					No. of Treatment Cycles				
	04/05	05/06	06/07	07/08	08/09	04/05	05/06	06/07	07/08	08/09
IVF	77	81	82	75	59	111	130	143	134	100
GIFT	0	0	0	0	0	0	0	0	0	0
FET	30	24	25	25	28	115	97	91	67	74
TOTAL	107	105	107	100	87	226	227	234	201	174

Intra-uterine insemination (IUI)

Both licensees and exempt practitioners are authorised to carry out IUI procedures. A total of 1722 IUI cycles were reported by seven licensees, a similar figure to the 1713 performed in 2007-2008. The overall ongoing clinical pregnancy rate per treatment cycle carried out was 7% (120 ongoing pregnancies). Of these pregnancies, 115 were singleton (95.8%), 5 were twin (4.2%), with no triplet or quadruplet births. These figures show that a greater proportion of IUI procedures resulted in singleton pregnancies than in previous years; the proportion of singleton births has increased steadily over the past 15 years.

The information provided showed that 80.4% of the IUI procedures performed involved use of the partner's sperm and 19.6% used donor sperm. The majority (44.5%) were natural cycles (no ovulation induction). 43.3% of cycles involved the use of gonadotrophin, and clomid was used in 12.3% of the cycles. These figures show a significant decline in the use of clomid, and an increase in the proportion of natural cycles as compared to last year. Gonadotrophin (follicle-stimulating hormone) is used in assisted reproduction as this use is associated with an increased live birth rate when compared to 'no treatment' for women experiencing infertility problems.

Four of the reported five sets of twins followed gonadotrophin stimulation, three conceived from the woman's partner's sperm and one set conceived from donor sperm. The remaining set of twins followed clomid stimulation and were conceived from the partner's sperm.

One exempt practitioner carried out IUI in 2008-2009.

Serious morbidity and mortality in women undergoing treatment

Overall the six clinics licensed to provide IVF reported a total of 20 cases of severe ovarian hyper-stimulation relating to 2684 IVF stimulation cycles (0.7% of stimulation cycles, with a clinic range of 0–1.6%). Women presenting with severe OHSS symptoms were diagnosed on ultrasound, showing on average 17.5 follicles measuring over 12mm.

Patients also presented with a number of other conditions, including severe pelvic infection, severe abdominal pain, ovarian bleed, and ovarian hematoma; three patients were hospitalised. There were no reports of mortality in association with fertility treatment during the year.

Counselling (2008-2009)

Licensees reported providing 2316 counselling sessions during 2008-2009, compared to 1884 sessions in the previous year. While this figure represents a 23% increase for this financial year, this is a decline on the rate of increase compared to the 39% increase in counselling sessions seen over the previous two financial years. This may be attributable to the reduction in IVF cycles performed this financial year as compared to 2007-2008. However, there is a slight trend towards greater acceptance of counselling overall which was indentified in the audit of counselling sessions undertaken in this financial year (see page 24)

Most (83%) participants received a single session of counselling. The majority (78%) involved information counselling, while the remaining participants (21.5%) accessed support counselling. Therapeutic counselling only made up 0.5% of sessions provided to patients.

From the remaining 17% of participants who accessed more than one session of counselling, over 55% were support counselling sessions, with just over 20% being counselling sessions for information. This shows a significant difference to last year's figures where most counselling sessions were for information and just over twenty percent were for support. Only 4.5% of counselling sessions were in relation to a matter associated with infertility, which shows a substantial decline when compared to the 2007-2008 figure of 26%. The proportion of participants attending counselling for personal matters not related to infertility was just over 1%, and only 0.5% of sessions were cited as being for a personal crisis.

Counselling concerning issues of donation for donors or recipients made up more than 30% of all counselling. This represents a 7% decrease on counselling sessions recorded in the previous year, despite an increase in the number of cycles involving donation seen for 2008-2009. Counselling must be accessed prior to donation, so these current cycles may relate to human reproductive material donated (and cryopreserved) in previous years. Counselling prior to known donation is mandatory under the HRT Act, and donor and recipient counselling is a requirement for RTAC accreditation. 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. Completed. Council awaiting study results
PIVET Medical Centre
Approved 08/08/00

R024 Research into optimal method of oocyte cryopreservation
PIVET Medical Centre
Approved (Out of session) October 2006

R025 Research into optimal method of oocyte cryopreservation
PIVET Medical Centre
Approved 17/06/09

Innovative clinical/laboratory practices at 1 July 2009

Innovative practice number	Procedure approved	Licensee and date approved
I 009	Assisted hatching	Concept Fertility Centre Approved 06/02/2001
I 016	In vitro maturation	Concept Fertility Centre Approved 13/12/2005
I 017	Oocyte cryopreservation	Concept Fertility Centre 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 025	Vitrification of oocytes	Hollywood Fertility Centre Approved 09/12/08
I 026	Vitrification of oocytes	Fertility North Approved 20/05/09

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 2008-2009 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 001/2008-02	Chromosomal translocation	Concept Fertility Centre Approved 04/08/08
PGD 027/2008-01	Robertsonian translocation	Fertility Specialists of WA Approved 9/09/08
PGD 001/2008-03	BRCA1 gene	Concept Fertility Centre Approved 27/10/08
PGD 027/2008-02	Chromosomal translocation	Fertility Specialists of WA Approved 27/10/08
PGD 001/2008-04	Cystic fibrosis	Concept Fertility Centre Approved 18/11/08
PGD 027/2008-03	Spinal muscular atrophy	Fertility Specialists of WA Approved 18/11/08
PGD 001/2009-01	Chromosomal translocation	Concept Fertility Centre Approved 10/02/09
PGD 001/2009-02	Marfan Syndrome	Concept Fertility Centre Approved 22/04/09
PGD 027/2009-01	Robertsonian translocation	Fertility Specialists of WA Approved 22/04/09
PGD 025/2009- 01	Cystic Fibrosis	Hollywood Fertility Centre Approved 29/04/09
PGD 025/2009- 02	Robertsonian translocation	Hollywood Fertility Centre Approved 29/04/09
PGD 025/2009- 03	Charcot-Marie-Tooth type 1B	Hollywood Fertility Centre Approved 17/06/09
PGD 025/2009- 04	Cystic fibrosis	Hollywood Fertility Centre Approved 17/06/09

Applications under Directions in 2008-2009

Direction 6.2

To import donated reproductive material for use in an artificial fertilisation procedure.	PIVET Medical Centre - Approved 8/07/08 Fertility North – Approved 8/07/08 PIVET Medical Centre – Approved 17/06/09

Direction 6.3

To import without information for Registers on compassionate grounds.	Hollywood Fertility Centre - Approved 12/08/09 PIVET Medical Centre - Approved 9/12/08

Direction 6.6

To export donor gametes, embryos or eggs undergoing fertilisation for use in an artificial fertilisation procedure.	PIVET Medical Centre - Approved 17/06/09

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 08/07/08 Concept Fertility Centre - Approved 12/08/08 Fertility Specialists of WA - Approved 18/11/08 Concept Fertility Centre - Approved 9/12/08 Fertility Specialists of WA - Approved 17/03/09

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. During the 2008-2009 year, Information Management and Reporting (IMR) directorate 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

Reproductive Technology Council

RE: BLASTOCYST CULTURE AS A ROUTINE PROCEDURE

Dear Licensee

The Reproductive Technology Council (Council) Meeting on 12 August 2008 included the consideration of the status of blastocyst culture as a routine vs innovative procedure under Part 2, Schedule 5 of the Directions to the *Human Reproductive Technology Act 1991* (HRT Act).

In recognition that blastocyst culture is now an established procedure both in Australia and internationally, and the increasing evidence supporting the safety and efficacy of the procedure, Council agreed that *in-principle*, blastocyst culture may be considered a routine procedure in fertility clinics in Western Australia.

However, under Part 2, Schedule 5, Council must consider the status of routine procedures in the context of the expertise and requirement for the procedure **within each clinic**. Specifically:

> **Schedule 5, Directions under the HRT Act**
> **PART 2.CRITERIA FOR DECIDING IF A PROCEDURE IS ROUTINE**
>
> For a procedure to be considered routine documentation should be able to be provided to the Council (on request) showing that the procedure adopted-.
> - is expected to be, or is currently, successful in the local clinic (eg details of results or relevant staff training undertaken); and
> - is considered a necessary element of the routine practice in the clinic.

Council would, therefore, notify you that, in the event that (you) wish to change the status of blastocyst culture from an innovative to a routine procedure, the provision of a statement supporting the above requirements, in addition to any modified patient consent form or patient information sheets are required by Council for consideration.

Please note that the approval of blastocyst culture as a routine procedure is subject to the requirement that reporting on all blastocyst culture procedures performed at (your clinic) will be included in the treatment data set submitted to the Department of Health Reproductive Technology Register data collection.

Yours sincerely

CA Michael AO

Chair Reproductive Technology Council 10 September 2008

Reproductive Technology Council

RE: EMBRYO STORAGE POLICY

Dear Licensee

As you may be aware, the Embryo Storage Committee of the Reproductive Technology Council (Council) has undertaken the development of a policy around embryo storage issues. This policy aims to provide guidance to Council, licensees and participants on issues involving the extension of authorised embryo storage periods, and the basis on which Council may consider approval of an extension.

Under S.24 (1a) of the *Human Reproductive Technology Act 1991* (HRT Act), Council may approve a storage period longer than 10 years when it considers "there are special reasons for doing so in a particular case". The HRT Act also sets out that the primary purpose 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 a National Health and Medical Research Council License.

You may be aware that, as an interim policy, Council has in general granted 12 month extensions for applications to extend storage beyond 10 years. This has been in place pending development of a comprehensive policy on the matter. However, it is important to note that many extensions granted by Council under the interim policy did not meet the criteria likely to be set out in the final Embryo Storage Policy.

For example, documentation will be required at the time of application such as signed consent forms for embryos intended for donation, or documentation that supports that participants are still eligible for IVF under the HRT Act. The reason for which an extension is sought will also need to be more comprehensively explained by the applicants.

To ensure that participants are informed regarding the impending changes to embryo storage extension approvals, any participants receiving approval for an extension, from this time on, will be advised of the policy change when receiving notification of the approval from Council. Furthermore, upon ratification of the Embryo Storage Policy by Council, it is intended that all applicants who have been granted extensions over the last 2 years will also be notified about the policy.

Western Australian legislation sets out that licensees have a responsibility to take reasonable steps to notify participants regarding expiry of their embryo storage period *3 months prior* to the expiry date and to provide assistance with regard to their application. This is a reasonable period of time for licensees and applicants to ensure that a valid request for an extension is adequately prepared once the Embryo Storage Policy is implemented.

The Embryo Storage Committee intends to consult with licensees regarding the policy before it is sent to Council for ratification. It is anticipated that this will be towards the end of 2008, with the Policy implementation aimed for early 2009. Supplementary information for participants is also in development, and licensee feedback will also be sought on this prior to publication. For any further enquiries regarding this matter, please contact Ms Jenny O'Callaghan on 9222 4490 or Dr Nyaree Jacobsen on 9222 4471 (Mon-Wed).

Yours sincerely

CA Michael AO

Chair
Reproductive Technology Council **20 September 2008**

Reproductive Technology Council

RE: VITRIFICATION OF EMBRYOS AS A ROUTINE PROCEDURE

Dear Licensee

The Reproductive Technology Council (Council) Meeting on 29 April 2009 included the consideration of vitrification of embryos as a routine vs. innovative procedure under Part 2, Schedule 5 of the Directions to the *Human Reproductive Technology Act 1991* (HRT Act).

In recognition that vitrification of embryos has become accepted as an arguably superior cryopreservation procedure both in Australia and internationally, and the increasing evidence supporting the safety and efficacy of the procedure, Council agreed that *in-principle*, vitrification of embryos may be considered a routine procedure in fertility clinics in Western Australia.

I note that at (your clinic) the vitrification of embryos has already been deemed a routine procedure.

As such, you are not required to notify the Council with an annual progress report on this procedure. However, please be aware that the Department of Heath directorate, Information Management and Reporting (IMAR), will be seeking additional information on vitrification for the treatment data set submitted quarterly by (you) for the Reproductive Technology Register, as per Schedule 2 in the Directions under the HRT Act.

Where both slow freezing and vitrification are used for the cryopreservation of embryos and oocytes, it is considered beneficial to identify which method has been used in a treatment cycle.

Yours sincerely

CA Michael AO

Chair Reproductive Technology Council

13 May 2009

Reproductive Technology Council

RE: WAITING LISTS FOR DONOR SPERM

Dear Licensee,

I have been asked to request information from all of the clinics regarding the length of time that clients seeking to use donor sperm are required to wait before sperm becomes available for their use. I understand because donation can be directed in Western Australia, that some men may choose not to allow sperm they are donating to be used by people in certain groups, thus it is important that this information about waiting times be broken down in the following categories:

- Heterosexual couples
- Lesbian couples
- Single women

Of course some recipients may also not avail themselves of the sperm that is offered to them and may choose to wait. For these clients please include the average time taken before they accept sperm offered.

This information will assist the Council understand the pressure on clinics that lead to requests for the importation of donor sperm from other states or countries where there are different requirements in terms of number of donor families that may be created, and information available for inclusion on the Reproductive Technology Register held by the Department of Health.

Kind regards

Jenny O'Callaghan

Executive Officer Reproductive Technology Council

28 July 2009

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.]