ANNUAL REPORT

1 JULY 2005 – 30 JUNE 2006

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

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

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Dr Neale Fong
Chief Executive Officer
Department of Health
1 Alvan Street
SUBIACO WA 6008

Dear Dr Fong

It is with pleasure that I submit to you this Annual Report of the Reproductive Technology Council (Council). This Report is for the financial year 2005-2006. It sets out details of reproductive technology practices in this State and activities of the Council during the year, as required by the *Human Reproductive Technology Act 1991* (HRT Act). It is in a form suitable for submission by you to the Minister for Health and also, as is required, to be laid by the Minister before each House of Parliament.

The work of the Council this year has been dominated by applications for diagnostic testing of embryos and applications for extensions to the storage period for embryos. These are both the outcomes of the amendments to the HRT Act, which came into operation on 1 December 2004. Council held focus groups to assist in the development of an embryo storage policy and carried out a media campaign informing IVF participants with embryos in storage about the extension of the storage period from 3 to 10 years and for extensions beyond 10 years applications must be made to the Council by the participants themselves.

Throughout the year Council has been busy refining the policy and processes for the approval of genetic testing of embryos and working with clinics and legal services to clarify the understanding of the requirements of the HRT Act, addressing eligibility for genetic testing of embryos. Council also participated in site visits of licensed assisted reproductive technology (ART) clinics as part of the Reproductive Technology Accreditation Committee (RTAC) accreditation, now a legal requirement as a condition of licence. Council was also involved in the recommendation of licensing of all ART clinics in WA whose licences expired in March 2006. Council also participated in consultations with the Lockhart Review Committee and provided a submission to the Committee.

Other significant amendments implemented on the advice of Council have included the reduction in the cooling off period for psycho-social preparation for known egg and embryo donation and the approval for licensed ART clinics to collect and store eggs for later use for those eligible under the HRT Act.

In 2006 there were significant changes in the membership of the Council, in particular the resignation of Professor Mark McKenna who has served on Council since its

inception in 1992. Professor McKenna brought a great deal of corporate knowledge and knowledge of the state of play of ART across Australia. He will be greatly missed.

The work of the Council is not possible without the ongoing support of a significant number of people. Among these I would like to pay special tribute to the commitment of Dr Sandy Webb who served Council from the establishment of the Interim Committee in 1988. Dr Webb has provided Council with ongoing expert guidance over the pioneering days of ART in this State. Council was pleased that her contribution was acknowledged in the Queen's Birthday Honours list in October 2005. Council is also pleased that Dr Webb has agreed to continue providing her expertise on two of its Committees. Council would also like to thank Ms Deborah Andrews for her continuing legal support and guidance and to acknowledge the ongoing financial and administrative support provided by the Department of Health. This support is essential to enable the Council to carry out its statutory duties.

Yours sincerely

CA Michael AO
CHAIR
Reproductive Technology Council

26 September 2006

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EXECUTIVE SUMMARY

This Annual Report has been prepared by the Reproductive Technology Council (Council) for the Commissioner of Health, to comply fully with all the requirements of the WA *Human Reproductive Technology Act 1991* (HRT Act). The information in the Report enables the Commissioner to submit his own report to the Minister for Health, on the activities of the Council and the use of reproductive technology in the State during the financial year 2005/2006, and is in a form suitable for the Minister to lay before both Houses of Parliament as required by the HRT Act.

The Report details the activities of the Council in the financial year 2005/2006. Information reported by clinics licensed under the HRT Act, gives summary information about their activities during the financial year 2005/2006. The report also includes information from a variety of sources about various matters of significance to the public interest in reproductive technology.

The area of assisted reproductive technology (ART) this year has been dominated by applications for diagnostic testing of embryos and applications for extensions to the storage period for embryos. These are both the outcomes of the amendments to the HRT Act, which came into operation on 1 December 2004. Council held focus groups to assist in the development of an embryo storage policy and carried out a media campaign informing IVF participants with embryos in storage about the extension of the storage period from 3 to 10 years and for extensions beyond 10 years applications must be made to the Council by the participants themselves.

Throughout the year Council has been busy refining the policy and processes for the approval of genetic testing of embryos and working with clinics and legal services to clarify the understanding of the requirements of the HRT Act, addressing eligibility for genetic testing of embryos. In August 2005 Council also participated in site visits of licensed ART clinics as part of the Reproductive Technology Accreditation Committee (RTAC) accreditation now a legal requirement as a condition of licence. Overall RTAC was satisfied that there was substantial compliance by ART clinics with RTAC's 2004 Code of Practice. Council was also involved in the recommendation of licensing of all ART clinics in WA whose licences expired in March 2006. Council also participated in consultations with the Lockhart Review Committee and provided a submission to the Committee.

Other significant amendments implemented on the advice of Council have included the reduction in the cooling off period for psycho-social preparation for known egg and embryo donation, the approval for licensed ART clinics to collect and store eggs for later use for those eligible under the HRT Act.

In 2006 there were significant changes in the membership of the Council, in particular the resignation of Dr Mark McKenna who has served on Council since its inception in 1992. Dr McKenna brought a great deal of corporate knowledge and knowledge of the state of play of ART across Australia. He will be greatly missed.

In its public education role the Council with assistance from the approved counsellors held an evening of focus groups for those with embryos in storage. In collaboration with the clinics, KEMH Genetic Services WA, KEMH Cytogenetics Unit, the

Department of Health and Genesis Support Group Council held a Diagnostic Testing of Embryos PGD/PGS (Implementation) Seminar in August 2005 following the amendments to the HRT Act. This seminar was primarily aimed at clinic staff and approved counsellors under the HRT Act.

The 2005/06 budget allocation for the Reproductive Technology Unit, which includes funding for all operations of the Council, was $38,880. The Annual Report includes the financial statement for the year. The major expense for the year is payment of sitting fees for members of the Council and its 5 Committees.

MEMBERSHIP OF THE COUNCIL
30 June 2006

MEMBERS

Professor Con Michael, Chair (Nominee of the Royal Australian and New Zealand College of Obstetrics and Gynaecology);
Professor Mark McKenna, Deputy Chair (Nominee of the Australian Medical Association) until 1 May 2006;
A/Professor Jim Cummins, (Nominee of the Minister for Health);
Ms Leonie Forrest, (Nominee of the WA Law Society);
Ms Sue Hudd, (Nominee of the Minister for Community Development) until 1 May 2006;
Ms Yvonne Patterson, (Nominee of the Minister for Community Development) appointed 23 May 2006;
Dr Roger Hart, (Nominee of the Department of Obstetrics and Gynaecology, University of WA);
Ms Stephanie Knox, (Nominee of the Health Consumers' Council);
Fr Joe Parkinson, (Nominee of the Minister for Health);
Dr Beverly Petterson, (Nominee of the Minister for Health);
Ms Patrice Wringe, (Nominee of the Health Consumers' Council – Women's Interest);
Ms Antonia Clissa, (Executive Officer, Senior Policy Officer Reproductive Technology, Department of Health, *ex officio*)

DEPUTY MEMBERS

Dr Angela Cooney, (Nominee of the Australian Medical Association);
Ms Linda Savage Davis, (Nominee of the WA Law Society) until 26 August 2005;
Dr Brenda McGivern, (Nominee of WA Law Society) appointed 18 October 2005;
Professor Alan Harvey, (Nominee of the Minister for Health) until 1 May 2006;
A/Professor Neville Bruce, (Nominee of the Minister for Health) appointed 23 May 2006
Dr Stephen Junk, (Nominee of the Department of Obstetrics and Gynaecology, University of WA);
Ms Sonja Lundie-Jenkins, (Nominee of the Health Consumers' Council);
Mr Philip Matthews, (Nominee of the Minister for Health) until 1 May 2006;
Reverend Brian Carey, (Nominee of the Minister for Health) appointed 23 May 2006;
Ms Sue Midford, (Nominee of the Women's Policy Development Branch); and
Mr Hans-willem van Hall, (Nominee of the Minister for Community Development);
Ms Amalia Burmas, (Research Officer, Reproductive Technology, Department of Health, *ex officio*)

COMMITTEES OF THE COUNCIL
TERMS OF REFERENCE AND MEMBERSHIP
30 June 2006

Counselling Committee

Terms of Reference:

In relation to counselling-

1a) establishing standards for approval of counsellors as "approved counsellors", as required by the Code of Practice or directions of *Human Reproductive Technology Act 1991* for counselling within licensed clinics, and for counselling services available in the community;

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

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

d) convening training programs for counsellors if required;

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

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

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

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

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

Membership:

Ms Sue Midford (Chair); Ms Stephanie Knox (consumer representative); Mr Peter Fox (consumer representative); Ms Colleen Brown (consumer representative); Mr Robert Sterry (consumer representative); Mr Hans-willem van Hall; Ms Iolanda Rodino; Ms Patrice Wringe; Ms Amalia Burmas (*ex officio) and* Ms Antonia Clissa (*ex officio).*

Scientific Advisory Council

Terms of Reference:

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

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

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

Membership:

Professor Alan Harvey (Chair) until 1 May 2006; A/Professor Jim Cummins; Dr Roger Hart; Fr Joseph Parkinson; Dr Beverly Petterson; Dr Sandra Webb and Ms Amalia Burmas *(ex officio)*

Embryo Storage Committee

Terms of Reference:

With the agreement of the Minister for Health as required under s(10)(4) of the *Human Reproductive Technology Act 1991* (HRT Act), the Reproductive Technology Council (Council), by resolution under s11(1) of the HRT Act, may delegate this Committee to-

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

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

Membership:

Ms Sue Hudd (Chair) until 1 May 2006; Ms Sue Midford; Ms Leonie Forrest; and Dr Sandra Webb *(ex officio)* until December 2005; Ms Antonia Clissa (*ex officio*); Ms Amalia Burmas (*ex officio)*

Licensing and Administration Advisory Committee

Terms of Reference:

1. Advise the Reproductive Technology Council (Council) on matters relating to licensing under the *Human Reproductive Technology Act 1991* (HRT Act), including the suitability of any applicant and the conditions that should be imposed on any licence.

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

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

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

Membership:

Dr Mark McKenna (Chair) until 1 May 2006; Professor Con Michael; Dr Roger Hart; Ms Leonie Forrest; Ms Stephanie Knox and Dr Sandra Webb *(ex officio)* until December 2005; Ms Antonia Clissa; (*ex officio*) and Ms Amalia Burmas, *(ex officio)*

PGD (Implementation) Technical Advisory Committee

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

Terms of Reference:

1. To advise the Reproductive Technology Council (Council) on a suitable framework for the approval of PGD under the *Human Reproductive Technology Act 1991* (HRT Act), both generally and for specific cases.

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

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

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

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

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

Membership:

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

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

Dr Beverly Petterson (Chair); Dr Ashleigh Murch; Sharron Townshend; Dr Steve Junk; Ms Sonja Lundie-Jenkins; Ms Daphne Andersen; and Dr Sandra Webb *(ex officio*) until December 2005; Ms Antonia Clissa (ex officio)

STAFF OF THE REPRODUCTIVE TECHNOLOGY UNIT

Dr Sandra Webb; Senior Policy Officer (Reproductive Technology) retired on the 9 December 2005

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

Ms Amalia Burmas; Research Officer (Reproductive Technology) until June 2006 and appointed as Senior Project Officer (Reproductive Technology) and Deputy Executive Officer of the Council; the Research Officer position is currently vacant and

Ms Joy Foyle; Administrative Officer (0.25FTE)

REPRODUCTIVE TECHNOLOGY COUNCIL 2005/2006
FINANCIAL STATEMENT

The Department of Health funds the administration of the HRT Act, including the operations of Council, which incorporates Infrastructure and Workforce Development. The 2005/06 budget allocation was $38,880 with expenditure of $36,213.00 for the financial year.

During this financial year $4600 was generated from application fees for the re-licensing of ART clinics. This income does not directly generate income for the Council, as fees are payable to the Commissioner for Health.

	Expenditure ($)	**Income ($)**
Staff or Council:		
Training/Registration/Course Fees	443.00	
Travel interstate Airfares Accommodation	628.03 194.40	
Motor vehicle/Taxis	102.72	
TOTAL	**1,368.15**	
Food supplies/catering	1,466.30	
Administration and clerical	960.00	
TOTAL	**2,426.30**	
Purchase of external services:		
Sessional fees: (External Consulting Fees) Reproductive Technology Council Council Committees: Counselling Scientific Advisory Embryo Storage Licensing and Administration Approved counsellors	21,287.00	
External consulting fees and Advertising	950.00 9,380.92	
TOTAL	**31,617.92**	
Other expenses:		
Books/magazines/subscriptions	202.50	
Freight/ cartage/postal		
Printing and stationery incl. Annual Report Website Domain expenses	510.00 88.00	
Total	**800.50**	
TOTAL	**36,212.87**	
Budget Allocation		**38,880.00**

OPERATIONS OF THE COUNCIL
1 JULY 2005 TO 30 JUNE 2006

MEETINGS, MEMBERSHIP AND STAFFING

Meetings

The Reproductive Technology Council met on ten occasions during the year, with an average attendance of 86 per cent. The Counselling Committee met on three occasions; the PGD (Implementation) Technical Advisory Committee met on six occasions; the Scientific Advisory Committee and the Embryo Storage Committee on eight occasions while the Licensing and Administrative Committee met on one occasion.

Membership

In October 2005, Dr Brenda McGivern was appointed as the deputy member nominee for the WA Law Society following the resignation of Ms Linda Savage Davis who had served on Council since May 2003. Ms Savage Davis chaired the Council's 2004 seminar on IVF eligibility issues under the HRT Act at the last minute when the previous Chair was unable to attend due to illness. There were also several significant changes to Council's longstanding memberships as result of terms expiring in May 2006. Ms Yvonne Patterson was appointed as the nominee of the Minister of Community Development in place of Ms Sue Hudd who had served on Council since May 1999. Ms Hudd as Chair of the Embryo Storage Committee often made herself available for urgent Committee meetings to consider embryo storage applications. Her expertise on child and family welfare issues provided Council with much valuable guidance. Reverend Brian Carey was appointed deputy member in place of Dr Phillip Matthews who served on Council since October 1999 as nominee of the Minister for Health with experience in ethics. Dr Matthews had often assisted the Council in its deliberations over complex issues and had been a speaker on ethical issues in ART at Council sponsored seminars. A/Professor Neville Bruce was appointed deputy member in place of Professor Alan Harvey. Professor Harvey who had served on Council as a nominee of the Minister for Health since October 1995 was also the recent Chair of the Scientific Advisory Committee. His scientific and research knowledge was valuable in Council's considerations of new scientific developments and ensured Council's focus on setting high standards for patient safety. Professor Mark McKenna resigned in May 2006 having served on Council since 1992. Professor McKenna had been an inaugural member of the Council initially as the nominee of the Fertility Society of Australia and then as the Australian Medical Association nominee. Professor McKenna was also the Chair of the Licensing and Administrative Committee and had also been a member of Scientific Advisory Committee. Professor McKenna's historical and corporate knowledge of Council operations and his understanding of ART and the system in Australia was a great asset to Council and will be greatly missed.

Staff assisting the work of the Council

There was a significant change to the staff assisting the work of the Council with the resignation from the Department of Health of Dr Sandra Webb the inaugural Executive Officer of the Council. Dr Webb retired in December 2005 after 20 years of service in the Department of Health. The Council is fortunate that Dr Webb

willingly agreed to continue to provide her expert scientific advice by being appointed to serve on the Council's Scientific Advisory and PGD (Implementation) Technical Advisory Committees. In June 2006, Ms Amalia Burmas was appointed as Senior Project Officer (Reproductive Technology) to provide scientific advice to both the Council and the Department of Health thereby creating a vacancy in the Research Officer position which oversees the Reproductive Technology (RT) Register and liaises with the clinics. Ms Burmas will continue in her role as the Deputy Executive Officer and will provide training and handover to the new incumbent once the position is filled. As Senior Policy Officer, Ms Antonia Clissa has been responsible for the management of the RT Unit and continued to offer policy advice to the Commissioner of Health and Minister for Health. Ms Clissa has continued with the management of the Voluntary Register for Information about Donation in Assisted Reproduction. As Executive Officer, Ms Clissa has performed executive functions for Council and continued to liaise with licensed clinics, approved counsellors and the Department of Health's legal and legislative services.

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

THE COUNCIL GRATEFULLY ACKNOWLEDGES-

Management support from Ms Merran Smith and Mr Tony Satti, administrative and secretarial support from Mrs Susan Marsh, Ms Denise Jesnoewski and Mrs Philomena Valladares;
Accounting and administrative support from Ms Pam Addison and Mr Lex Cassidy;
Data linkage by Ms Di Rosman and the staff in the Data Linkage Group;
The provision of data concerning birth outcomes by Mrs Vivien Gee and the staff who manage the Midwives' Notification System; and
the continuing legal support of Ms Deborah Andrews and Ms Daphne Andersen of Legal and Legislative Services.

LICENSING MATTERS

The five Storage Licences and four Practice Licences expired on 1 March 2006 therefore Council was required to assess all applications for renewal this financial year. All existing licensees reapplied for practice and storage licences. Council had requested information on the processes the clinics had developed to address the extension of the initial embryos storage period from 3 years to 10 years; the requirement for Approved Counsellors to be an integral member of the clinic team employed on a permanent basis; disclosure of identifying information in cases of donation of human reproductive material; timely reporting of information to the Council for annual reporting and to the Reproductive Technology Register; and dissemination of information to clinic staff across all disciplines. The Council recommended to the Commissioner of Health that as all had shown substantial compliance with the requirements of the HRT Act that they all be issued with respective licences.

There was a change of ownership at Hollywood Fertility Centre with Sydney IVF becoming a major shareholder. There was also an application for licences received for a new ART clinic, which is currently being considered by the Council.

Three medical practitioners requested revocation of their Exemptions from the requirement to be licensed to carry out artificial insemination (Dr BD Roberman, Dr PD Green and Dr MJ Cohen). During the year there were no new applications for Exemptions.

RTAC Site Visits

The Fertility Society of Australia's Reproductive Technology Accreditation Committee (RTAC) carried out site visits in Western Australian (WA) ART units for RTAC accreditation in August 2005. With the December 2004 amendments to the Directions under HRT Act it is a condition of each license that the licensee is accredited to carry out reproductive technology by RTAC and that this accreditation is maintained. Four (4) RTAC representatives visited the WA units with 2 representatives from the Council. Other Council members also had the opportunity to meet with RTAC representatives at a meeting held in August 2005. Overall RTAC was satisfied that there was substantial compliance by ART clinics with RTAC's 2004 Code of Practice which endorses the Quality Management System (QMS) model of risk assessment with the emphasis on ART units to determine how best to assess and manage risks. All ART clinics were required to provide evidence of impending introduction of QMS and by the end of 2006 all units are required to fully comply.

Information circulated to Licensees

Licensees received information concerning: the reduction in the cooling off period for psycho-social preparation for known egg donors and known embryo donors; the Updated Minimum Standards for ICSI Use, Screening, Patient Information and Follow-Up in WA Fertility Clinics; the Application under Direction 7.7- IVF treatment to avoid the transmission of an infectious disease and the Information on Oocyte Cryopreservation.

Protocols, Patient Information and Consent Forms

Licensees were requested to submit all protocols, patient information and consent forms with their licence applications including any documentation revised during the year. Direction 9.1 requires licensees to keep and maintain a protocol manual that complies with the Requirements for Clinic Protocol Manuals. Under Direction 9.2 licensees must ensure that the protocol manual is approved by the Council. The Council's role is to approve documentation in consultation with its appropriate Committees while the responsibility for updating and amending protocol manual documents remains the responsibility of the clinics. In terms of consent forms the Council will continue to monitor them to ensure that they are clear and understandable and meet the requirements of the HRT Act. Furthermore with the new requirements of the RTAC Code of Practice regarding quality assurance systems, it is more appropriate that clinics remain responsible for the development of consent forms.

Complaints

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

EMBRYO STORAGE APPLICATIONS

During the year the Council received the first applications for extension to the permitted storage period of embryos since the 2004 amendments to the HRT Act. These amendments extended the initial storage period from 3 years to 10 years. Council considered a total of 12 applications. Of these 11 were made by the participants with responsibility for the embryos and 1 was made by a licensee. Extensions were granted to the embryo storage period for all 12 applications received.

The amendments to the HRT Act clarified that only participants with responsibility for a set of embryos, that is persons for whom an embryo was developed or is to be used in an artificial fertilisation procedure, could apply for extensions to the permitted storage period. Additionally, where embryos had been declared excess, that is the persons with responsibility for the embryos had consented to their use in an approved embryo research project, the licensees could apply for an extension to the storage period. Therefore, the one application made by the licensee was for a set of embryos that had been declared as excess ART embryos.

The reasons that were provided by participants seeking extensions to the permitted storage period of their embryos have been classified into a number of categories. The majority of participants were intending to use the embryos in the future for their own treatment (54.5%). A significant proportion of participants (27.3%) indicated they were seeking an extension as they wanted more time to decide on the future of their embryos. One application was made as the participants were in the process of donating the embryos to another eligible participant and one application was made as the couple were currently unable to use the embryos due to medical reasons.

Council has been monitoring storage of embryos in Western Australia (see Appendix 3 for the most recent figures). It is recognised that the majority of embryos currently in storage are in the process of being used in treatment or being donated. However, it was acknowledged that there were a small proportion of embryos being kept in storage by participants who had completed their IVF treatment and were having difficulties deciding what to do with these embryos. Council recognised it needed to address this group to be able to achieve equilibrium between the number of embryo stored and the number of embryos removed from storage each year. Therefore, with the 2004 amendments to the HRT Act clarifying conditions regarding embryos in storage, Council considered it opportune to develop a policy on embryo storage, including considerations that Council should take into account when granting extensions.

Council is still in the process of developing this policy, however has to date undertaken a consultation through focus groups of participants with embryos in storage and run an advertising campaign informing the public of changes in legislation to embryo storage. Until the policy is finalised Council has been granting extensions of one year to the storage period of embryo storage applications that have been approved.

Eight meetings of the Embryo Storage Committee were convened during the year. Four were urgent meetings for embryo sets whose storage was due to expire prior to the next Council meeting. Four meetings were held to discuss development of the embryo storage policy.

SPECIFIC APPROVALS FOR RESEARCH, INNOVATIVE PRACTICES AND DIAGNOSTIC TESTING OF EMBRYOS

Specific Approval of Innovative Procedures

During the year the Council considered two applications for specific approval of innovative procedures. One of these was approved and one was approved conditional upon amendments being made to the patient information and consent forms. Once these amendments are made the Council will grant full approval to this practice.

I016 In Vitro Maturation of Immature Human Oocytes
Concept Fertility Centre
Approved 11/04/2006

I017 Cryopreservation of Oocytes
Concept Fertility Centre
Conditional Approval 16/05/2006

Specific Approval of Research Procedures

In 2005/2006 there were no applications received by Council for specific approval of research projects. One clinic sought extension to their protocols for one of their research projects, however, Council was not able to consider the request until further information was received (which was not received prior to the end of the financial year).

Specific Approval for Diagnostic Testing of Embryos

In this financial year there were applications from 2 licensed ART clinics to undertake Preimplantation Genetic Screening (PGS) for aneuploidy, which were approved by the Council. There are now three licensed ART clinics undertaking PGS for aneuploidy in WA. There were 19 applications received for Preimplantation Genetic Diagnosis (PGD) for specific conditions in this financial year of which Council approved 18 applications. One application was withdrawn

Summary information on all currently approved research and innovative practices and diagnostic testing of embryos submitted by licensees with their annual reports is included in Appendix 3.

Approval to Waive Directions under the Human Reproductive Technology Act 1991

The Directions to the HRT Act require Council to approve certain practices. This year Council received applications to waive Direction 7.7 and Direction 8.8.

Direction 7.7 indicates that an IVF procedure directed at reducing the risk of an infectious disease is not undertaken without the prior approval of the Council. Two applications were received in this financial year relating to Direction 7.7, of which one was for a male participant with Hepatitis C and the other for a female participant with Hepatitis B. Both of these applications were approved (one in the 2006/07 financial year).

Under the Directions to the HRT Act a licensee must not allow collection of oocytes for the treatment of a participant who has 3 or more embryos of the same biological parentage already in storage. Direction 8.8 allows Council to waive this requirement where it considers the circumstances are exceptional. One application was received under direction 8.8 and approved.

RELEVANT PRESENTATIONS AND PUBLICATIONS BY COUNCIL MEMBERS AND STAFF

Council members

Associate Professor Jim Cummins

From September to December 2005 Dr Cummins was visiting professor at Osaka University's Genome Information Research Centre (GIRC) in Osaka, Japan sponsored by the Japanese government. The GIRC group, comprising around 25 academics, postgraduate students and technical and ancillary staff, is interested in mammalian fertilization and reproductive biology.

A/Professor Cummins held weekly 2 hour laboratory meetings on reproductive molecular biology and included topics of general social and political interest such as the law regarding reproductive technology and ethical issues concerning topics such as cloning and stem cell technology.

He also presented seminars to the following groups at the forefront of reproductive and biomedical research in Japan;
RIKEN Kobe Institute, Laboratory for Genomic Reprogramming (Dr Teruhiko Wakayama);
RIKEN Tsukuba Institute, Bioresource Engineering Division (Dr Atsuo Ogura);
Keio University Department of Biosciences and Informatics, Yokohama (Professor Motonori Hoshi) and
Yamanashi University Hospital Department of Obstetrics and Gynecology, Kofu (Professor Kazunori Hoshi).

Dr Roger Hart

Prizes

ESHRE 2006 Prague, Czech Republic*. Overall Poster Prize Presentation*
"Age at menarche is related to birthweight and postnatal body mass index in a cohort of Australian adolescents" by Roger Hart, Deborah M Sloboda, Dorota Doherty, Craig Pennell, Martha Hickey.

Presentations

'Fertility Current Concerns and Future Solutions' Nurses Study Day, Perth 2005.

Publications

Hart R, Hickey M, Maouris P, Buckett W, Garry R. Excisional surgery versus ablation surgery for the management of ovarian endometriomata. *Human Reproduction* 2005; 20 (11):3000-7.

Hart R, Norman R. Polycystic Ovarian Syndrome - prognosis and outcomes. *Best Practice & Research in Clinical Obstetrics and Gynaecology* 2006; 20(5)

Hart R, Doherty D, Karthigasu K, Garry R. The Value of Virtual-Reality Simulator Training in The Development of Laparoscopic Surgical Skill. *Journal of Minimally Invasive Therapy* 2006; 13(2):126-33

Karthigasu K, Garry R, Hart R. Case Report of Failed Tubal Occlusion Using Essure™ pbc (Permanent Birth Control) Hysteroscopic Sterilisation Procedure. *Australian and New Zealand Journal of Obstetrics and Gynaecology* 2006; 46(4):365-7.

Hassan SN, Alfozan H, Qadri H, Hart R. Ovarian cyst aspiration prior to IVF. 2006 Cochrane Protocol In: *The Cochrane Library*. Issue 3

Hart R. The Hysteroscopic Management of Fibroids. In: *Uterine Leiomyomata: Pathogenesis and Mangement*. Ed Brosens I. Taylor and Francis Medical Books Ltd, Abingdon, UK. 2005.

Garry R, Hart R. Outcome measures. In *Sutton. Modern Management of Endometriosis.* Chapter 5. 2005 Taylor & Francis, Oxford England.

Hart R. Definitions, Prevalence and Symptoms of Polycystic Ovaries and The Polycystic Ovary Syndrome. In Agrawal and Allahbadia (Eds). *Polycystic Ovary Syndrome.* Chapter 2 2006. Anshan Publishing House, Tunbridge Wells, UK.

Rev Dr Joseph Parkinson STL PhD

Lectures

'Ethical Issues in Stem Cell Research', Adult education lecture,19 October 2005

'Moral Issues in Human Reproductive Technology and Stem Cell Research' two-day professional in-services of secondary teachers, 28-29 November 2005 and 16-17 February 2006

Presentations

'Reproductive Technology and Stem Cell Research' Three secondary school presentations, 27-28 July 2005

Ms Patrice Wringe

Presentations

'Reproduction and the Law' – UWA Law School – Panel – 5 October 2005

Staff

Dr Sandra Webb

Presentations

Intergenerational Donor Issues under the HRT Act 1991 - Human Research Ethics Committee – Joondalup Health Campus — 28 July 2005

Ms Amalia Burmas

Presentations

'Reproduction and the Law' – UWA Law School – Panel – 5 October 2005

Ms Antonia Clissa

Presentations

Intergenerational Donor Issues under the HRT Act 1991 - Human Research Ethics Committee – Joondalup Health Campus — 28 July 2005

Voluntary Register and changes to the HRT Act 1991 – Genesis Consumer Support Group 20 March 2006

Attendance at relevant meetings by Council members with Council support

The Council sponsored the attendance of the Executive Officer to the Embryo Donation Seminar conducted by ANZICA held on 12 May 2006 in Adelaide. Issues covered included embryo donation and RTAC compliance. Dr Sheryl de Lacey presented findings from her research on people's decisions around embryo donation. This was timely given Council's work on the development of embryo storage policy.

Members with Chairing responsibilities were supported by Council to gain training in chairing meetings due to the increasingly ethically complex issues confronting committees. Council funded Dr Bev Petterson's training on How to Run Meetings, which she attended on 21 July 2006.

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

Seminars

Embryo Storage Focus Groups

Following changes to the legislation in 2004 permitting the storage of embryos from 3 years to 10 years, Council had been receiving applications from participants for extensions beyond 10 years as provided for in the legislation. Council in consultation with the Embryo Storage Committee had turned its mind to developing an embryo storage policy to consider applications for extensions beyond the permitted 10 years. The Committee recommended that this policy be developed following consultation with consumers who would assist the Council to understand the needs and thoughts of people with embryos in storage. Council agreed that the focus group was an appropriate strategy to include participants in the development of policy as well as for the development of relevant patient resources. Only people with embryos in storage (or those who previously had embryos in storage) for a period of more than 5 years were invited to attend. ART clinics were approached to send out invitations to their patients with embryos in storage and an advertisement was included in the Genesis (patient support group) newsletter.

The focus groups would be used to gather information on the issues surrounding embryos storage and the support required by participants to assist them to make decisions regarding their embryos. In total 1100 consumers were invited to participate. The focus groups were held on Monday 1 May 2006 from 6- 9pm. Approximately 50 consumers attended with each group of 8-10 participants being facilitated by an approved counsellor and the assistance of a scribe. Several main themes emerged from the focus groups including that there is a wide range of feelings associated with decision making for those with embryos in storage. People, including those within a couple, attributed different levels of status to the embryo. Some people discussed the need to ritualise the process of letting the embryos succumb (for example by blessing them or burying them) to assist them to move on with their lives. For others, making a decision about their embryos in storage was more about making a decision about their own treatment and reproduction. This tended to be associated with accepting that they had completed their families or that they would remain childless. There was also a group of participants who are unable to consider the options and therefore would find it extremely difficult to make a decision about the fate of their embryos. For this group storing their embryos indefinitely or until the participants themselves died was the only acceptable option. For some couples this option was acceptable to only one party. Council agreed that it would need to find an approach that would help these people to undertake the decision making process. Other consumers indicated the importance of taking their embryos home where they would allow them to succumb.

Information

Many participants indicated they wanted more information about the options available regarding embryo storage. For instance they wanted to be able to access information at the right time from various sources such as a written document, from the website and from seminars. The focus groups supported the need for Council to produce an

information resource for participants which would be available through clinics and via the website. Additionally, as many participants had not been aware of the changes to the legislation prior to attending the focus groups the Council carried out a newspaper advertisement campaign throughout June and July 2006 in *The West Australian* newspaper, and other community newspapers informing those with embryos in storage of the changes to the legislation and in particular of their responsibilities of keeping their contact details current with the clinics.

RTC Website

The Council website has been updated throughout the year to include the updated notices and policies issued by Council. The website has been a useful resource for ART participants, ART clinics and students as well as for those from other jurisdictions. Throughout the year there have been over 40 email inquiries generated through the website on matters relating to legislation and its amendments, access and eligibility for IVF, importation and exportation of human reproductive material, saviour sibling, surrogacy, access to ART for single women and lesbians. There have also been requests from other national and international jurisdictions such as Victoria, South Australia, Hong Kong and the US. From January to June 2006 (the only figures available due to change in system in the Department of Health) there have been 3,554 unique visitors to the website. Throughout the period recorded, the highest activity months were March, followed by May, April, February and June 2006 with a total of 4,231 visits from January to June 2006. The most popular documents identified on the site were the publications, "Questions and Answers about the donation of human reproductive material", infertility information followed by frequently asked questions (FAQ's) page and information on the licensed clinics.

Media Contacts

Throughout the financial year the Council provided information and clarification on the following matters of public concern to the media, which included print, radio and television.

- 8 August 2005 - Male Infertility. Peta Rule for *The West Australian*
- 24 October 2005 – 'Secret of the Fathers', Janine Cohen, ABC Four Corners programme
- October 2005 - Clarification on PIVET Medical Centre's advertisement in *The West Australian* on Tuesday 25 October 2005 seeking the Western Australian public to write to the Minister for Health asking for the repeal of the HRT Act.
- 2 November 2005, Press Release to *The West Australian* concerning the HRT Act and regulation of ART in WA.
- 20 January 2006 - 'Access to IVF treatment for older women diagnosed as obese and of advanced maternal age' –- Cecile O'Connor, Channel 9
- 20 March 2006 – 'Access to IVF treatment for older women diagnosed as obese and of advanced maternal age' - Mara Pritchard, Channel 7
- 3 May 2006 – Radio Interview with Radio 6PR on Surrogacy
- 10 May 2006 – Screening of IVF embryos, Peta Rule, *The West Australian*
- 15 May 2006 - ART research in WA and Research Involving Human Embryos, Peta Rule, *The West Australian*
- 29 May 2006 - Donor Conception programme SBS TV, Caroline Ayoub
- 16 June 2006 - Egg Freezing, Peta Rule, *The West Australian*

Legislative Review Committee of Australia's *Prohibition of Human Cloning Act 2002* and the *Research Involving Human Embryos Act 2002*

On 17 June 2005, the Australian Government Minister for Ageing, the Hon Julie Bishop MP, appointed the Legislation Review Committee to conduct an independent review of the *Prohibition of Human Cloning Act 2002* and the *Research Involving Human Embryos Act 2002*. These Acts establish a strict regulatory framework to prohibit certain unacceptable practices including human cloning, and to regulate, through the NHMRC, research involving excess human embryos created through assisted reproductive technology. The Review Committee was required to report to the Council of Australian Governments (COAG) and table reports in the Australian Parliament by 19 December 2005. The Committee was required to consult with the Australian, State and Territory governments and a broad range of people with expertise or experience in relevant disciplines. The Committee sought written submissions as part of the consultation process due by 9 September 2005. The statutory functions of the Council (s.14 of the HRT Act) allowed it to comment very broadly on the terms of reference of the Committee.

The Council limited its submission to areas where it had practical experience of relevance. The Council was also asked to be part of the face-to-face consultation sessions that the Legislative Review Committee was undertaking in considering the scope and operation of both the *Prohibition of Human Cloning Act 2002* and the *Research Involving Human Embryos Act 2002*. These face-to-face meetings occurred on Friday 21 October 2005 and Professor Mark McKenna and Ms Antonia Clissa represented Council. At the consultation, Professor McKenna and Ms Clissa presented and further elaborated on points from the Council's written submission to the Review Committee. Particular areas of focus were the timing of consent and the process of consent for use of excess embryos in NHMRC approved research projects. In relation to the process of consent for use of excess embryos in NHMRC approved research project, Council raised the need for further consideration of this process, especially the two tiered consent, which required participants to provide a second consent for the specific research project they would donate their embryos to. Professor McKenna pointed out that many patients go through a grieving process when making decisions to pass on their embryos and that many patients would not want to be contacted again. The Review Committee was encouraged to further consult with consumer groups to identify the best process of consent. The Review Committee was particularly interested in identifying the public's view on permitting therapeutic cloning. The Council informed the Review Committee that based on the debate at the time of the 2004 amendments to the HRT Act, there did not appear to be public support for therapeutic cloning. Three other Council members, Professor Alan Harvey, Steve Junk and Dr Father Joe Parkinson partook in the face-to-face consultations representing their interests outside Council.

OPERATIONS OF THE COUNSELLING COMMITTEE
1 JULY 2005 TO 30 JUNE 2006

Meetings and membership

The Counselling Committee met on three occasions during the year. A subgroup of the Committee also held 4 meetings with consumers for the development of the video resource for same sex parents using donor to create their families.

Key Focus Areas

The focus for the Committee has been in the planning of the Embryo Storage Focus Groups in consultation with Approved Counsellors, which was held in May 2006.

The Committee has continued to:

- Develop the video as a resource for same sex women using donor semen to create their families.
- Provide guidance to Council on the cooling off period for psycho-social preparation/counselling in cases of known egg and embryo donation.
- Monitor the development of consumer resources in relation to embryos in storage.
- Provide guidance on the development of strategies for informing participants with embryos in storage.
- Monitor ART Clinics' Compliance with Counselling Requirements under the HRT Act.
- Monitor the process for disclosure of identifying information through the Voluntary Register.

Approved Counsellor Applications

There were no new applications to the Committee during the year although there were several inquiries concerning the requirements to be recognised as an approved counsellor. Ms Elise Frankel decided not to pursue extending her term as an approved counsellor due to the few numbers of ART patients that were presenting to her clinical practice. Currently there are 15 approved counsellors under the HRT Act with 12 available to provide clinical consultations.

Diagnostic Testing of Human Embryos PGD/PGS Implementation Seminar

As diagnostic testing of embryos is now permitted in Western Australia following changes to the HRT Act in December 2004, the Council held a seminar on 10 August 2005 for clinic staff and approved counsellors in particular. The aim of the seminar was to increase staff knowledge in the area of embryo diagnostic testing in order to be of greater assistance to potential participants. The seminar covered scientific, embryology, legal, consumer and psychosocial/counselling aspects. Some of the feedback suggested that the approved counsellors and in particular clinic counsellors, may require further input in the form of a case study workshop to follow up on some of the issues raised at the seminar.

REPRODUCTIVE TECHNOLOGY REGISTERS

Requests for Information from the Reproductive Technology (RT) Register

A number of requests for data from the Reproductive Technology (RT) Register were made through the year. Two requests were made by the media for figures on the number of assisted reproductive technology treatments and births from 1993 to 2002 and the number of IVF treatments in the 2004/05 financial year. This information was sought for articles about the general increase in use of IVF and the trend towards older participants accessing this treatment.

Information was sought from the RT Register relating to the 2004 amendments to the HRT Act extending the initial storage period of embryos from 3 to 10 years. The Council was provided with data on the number of embryo sets in storage approaching the ten year storage period so they could anticipate the number of applications. There was also a request from a lecturer at Murdoch University for the number of embryos in storage in WA.

Another request came from a researcher regarding a comparison on the number of birth from IVF treatments using fertilisation by Intra Cytoplasmic Sperm Injection versus standard fertilisation for each year.

Research Involving RT Register

During the year data was extracted for Dr Liz Milne, from the Institute of Child Health Research, for a research study being conducted on risk factors for childhood cancers. Some studies have identified that there is an increase incidence of genetic imprinting errors occurring in embryos exposed to culture media. Some of these imprinting errors have been associated with some conditions that are associated with childhood cancer, such as retinoblastoma and Beckwith-Wiedemann syndrome. However, as the incidence of these conditions in the population is very low researchers agree that further studies are required to confirm such findings. Dr Milne was intending to investigate whether children born through ART in WA were at increased risk of developing childhood cancer.

Voluntary Register of Information about Donation in Assisted Reproduction

There have been a total of 119 requests for applications to join the register since the Voluntary Register (VR) was launched in November 2002 to the end of June 2006. The VR has 67 registrants and 52 application forms not returned. In the last financial year 13 parents, 11 donors and 2 donor conceived adults requested application forms and while 6 parents, 7 donors and 2 donor conceived adults returned completed applications forms. To date the registrants include 35 parents of donor-conceived offspring, 26 donors and 5 donor-conceived adults. Since November 2002, 32 parents of donor-conceived offspring, 19 donors and 1 donor-conceived adult have requested application forms to join the register, which have not been returned.

SIGNIFICANT DEVELOPMENTS IN ASSISTED REPRODUCTIVE TECHNOLOGY DURING THE YEAR

Changes to the Cooling Off Period for Psycho-Social Preparation for Known Egg Donation

A change of great importance to some participants was the reduction of the cooling off period in cases of known egg donation from 6 months to 3 months. It came to the attention of Council that perhaps women were being disadvantaged especially as women are delaying starting their families. The initial intention under the Directions of the *Human Reproductive Technology Act 1991* was that the 6 months cooling off period should take place concurrently with the RTAC requirement of 180 days quarantine period. This is possible in the case of sperm donation but in cases of known egg donation, these cannot take place concurrently and it effectively means that recipients of egg donation must wait at least 12 months unless it is permitted for them to proceed with fresh embryo transfer. Consultation with clinic counsellors indicated unanimous support that there be a reduction in the cooling off period from 6 months to a minimum of 3 months for known egg donors. This means that effectively if a known donor and recipient choose to undergo fresh embryo transfer the treatment could begin after 3 months cooling off period or if they undergo the 180 days quarantine, then treatment can begin after 9 months instead of the current 12 months after the cooling off period. The situation would not change for known sperm donation, as RTAC does not permit use of fresh sperm.

Changes to the Cooling Off Period for Psycho-Social Preparation for Known Embryo Donation

Council recognised that in embryo donation people may be more attached the to embryos (than in gamete donation), especially if they have had children from the same set of embryos. It was also acknowledged that in decision making about the future of stored embryos people often give careful consideration to their options and the consequences before deciding to donate. Therefore Council agreed to changes to the cooling off period for psycho-social preparation for known embryo donation should also be reduced to a minimum of three months.

Oocyte Cryopreservation Or Egg Freezing For Women Wanting To Freeze Eggs For Later Use

In May 2006 Council informed the ART clinics that they are permitted to collect and store oocytes (eggs) for women who may be eligible to use them later. Legal advice indicates that the collection and storage of mature oocytes through oocyte cryopreservation, is considered a storage procedure under the HRT Act. Therefore, it is subject to the general provisions under the HRT Act and Directions, such as consents and information giving as well as the specific requirements of gamete storage in Part 6 of the Directions. The eligibility criteria under Section 23 of the HRT Act are not applicable to storage procedures. As oocyte cryopreservation meets the criteria as an innovative procedure Council approval is required. Given the associated technology is relatively new, patients would need to be appropriately informed of the risks and benefits and of the eligibility criteria for later use. Those women who wish to access this procedure are generally those under 35 who want to store their oocytes at an age when they are of a good quality for future use "just in case" they experience difficulties getting pregnant at an older age.

REPRODUCTIVE TECHNOLOGY IN THE PRESS

The material presented in the following section, *Reproductive Technology in the Press*, has been derived from articles reported during the past year in the media. The Reproductive Technology Council (Council) has included this material to provide a snapshot of issues surrounding Assisted Reproductive Technology (ART) that have gained media attention. The Council does not necessarily agree with what has been reported and gives no assurance regarding the accuracy of any information reported by the media. The Council encourages readers to make their own assessments on the issues reported herein.

ART AND LEGISLATION

Australia

Stem Cell Research & Cloning

The legislatively mandated review of the Australian *Prohibition of Human Cloning Act 2002* and *Research Involving Human Embryos Act 2002* (Weekend Australian, 24/12/2005) was led by the late, former Federal Court judge, John Lockhart. Lockhart supported Somatic Cell Nuclear Transfer (SCNT) also known as Therapeutic Cloning, under strict ethical and scientific regulation. Despite opposition from prominent political and religious figures, Joanna Knott, Convenor of the Coalition for the Advancement of Medical Research in Australia, believes therapeutic cloning would enable Australia to be on par with other countries such as Singapore, Japan, South Korea and Britain (The West Australian, 20/12/2005).

The Lockhart Review suggested therapeutic cloning be allowed for research, training and clinical purposes. The review also declared that despite some viewing this process as unethical, it should not necessarily be deemed illegal. Opposition to this procedure could hamper Australia's biotechnology industry (Australian Financial Review, 20/12/2005).

Other recommendations from the review included the potential use of animal eggs; altering the definition of a human embryo; supporting the establishment of a stem cell bank; and banning reproductive cloning where an embryo clone would be allowed to develop into a baby. Additionally, the review believed the prohibition of creating human embryos for processes other than natural or assisted reproduction should remain (Australian Financial Review, 20/12/2005). The review also supported suggestions from Griffith University (Qld) research, which claims similar results can be obtained through the use of adult, as compared to embryonic, stem cells (Courier Mail, 21/12/2005).

Therapeutic Cloning, also called Somatic Cell Nuclear Transfer (SCNT), involves researchers making embryonic stem cells by transferring the nucleus of an adult cell into an unfertilised human egg that has had its own nucleus removed. If successful, the resulting cell begins to divide as a normal human embryo, creating embryonic stem cells (ES cells) that have the same genetic composition as the donor of the original adult cell (The Australian, 21/11/2005). SCNT, also known amongst scientists as disease-specific stem cell research, could enable healthy organs to be cloned for a donor's own body (The West Australian, 20/12/2005).

Significantly, SCNT cannot be utilised to develop a human being, as stem cells derived from the inner mass of an early embryo cannot give rise to a placenta and would not develop into a baby even if implanted in a woman's uterus (Sydney Morning Herald, 19/12/2005). However, this process will enable research into disorders such as heart, motor neurone, Alzheimer's and Parkinson's disease and debilitating conditions, such as spinal cord injury (The Weekend Australian, 24/12/2005).

Australia To Continue Therapeutic Cloning Ban

Australia's Cabinet has decided to keep in place a federal ban on therapeutic cloning research, rejecting the advice of an expert review published last year. Last December, a six-member Legislative Review Committee, chaired by the now deceased John Lockhart, a former Federal Court judge, recommended that the existing laws on cloning and stem cell research should be relaxed. But Prime Minister John Howard said last Friday that 'after careful reflection, the government is not disposed to make any changes to the existing national legislative framework for research involving human embryos'. In Australia, *the Research Involving Human Embryos Act* and *the Prohibition of Human Cloning Act*, both passed in 2002 after much debate, together ban reproductive cloning, prevent scientists from cloning embryos to obtain stem cells and restrict them to research on surplus IVF embryos created before the acts were passed, and donated by IVF patients who no longer require them. All research must operate under a licensing scheme administered by the National Health and Medical Research Council (NHMRC). However, the laws had a built-in three-year 'sunset clause', which means the debates needed to be revisited. The Lockhart Review showed that there was 'clearly overwhelming support from the general public and the medical and scientific communities for maintaining a strong regulatory framework' in the area but also clear support for 'augmentation of the current system to allow research, within a rigorous ethical framework, into emerging scientific practices that will assist in the understanding of disease and disability'. On this basis, the Lockhart Committee recommended that while human reproductive cloning should be banned, cloning technology should be permitted to produce embryos for stem cell research. The Cabinet's decision to ignore the findings of the Lockhart Review has attracted criticism from supporters of therapeutic cloning. The move is due to be discussed at the July 2006 meeting of Council of Australian Governments (COAG), at which Victorian Premier Steve Bracks and Queensland Premier Peter Beattie are expected to argue against the ban (BioNews, 25/06/2006).

Frozen Embryo Storage

Victorian IVF clinics have discarded more than 6600 embryos since state laws came into effect in 1998 and banned embryo storage beyond 5 years. Previously, embryos created in IVF clinics could be stored indefinitely. Monash IVF managing director Donna Howlett stated that an increasing awareness of stem cell research has meant the number of couples donating embryos to research has grown from 30% to 60% in the past year. Melbourne IVF spokesman John McBain said that while the proportion of couples donating their unused embryos to research was growing, donating embryos to others couples was not. The Age found that only 5% of couples choose to donate their embryos to couples that have

been unsuccessful in creating an embryo through IVF (The Age, 26/09/2005).

Western Australia

First WA PGD Baby Born

Maisy Waters is a landmark child – the first IVF baby born in February 2006 after being screened in WA for genetic defects using a once banned test. As an embryo, she was screened in a Perth laboratory for diseases, including Down syndrome, before being implanted into her mother. Pre-implantation genetic screening (PGS) and pre-implantation genetic diagnosis (PGD) were outlawed until changes to state legislation last year. Apart from the Waters family, another 15 WA couples are now expecting babies following genetic screening through Perth's Concept Fertility Clinic. Concept's reproductive biologist, Bruce Bellinge said four couples were expecting babies after having PGD to rule out a single gene disease (The West Australian, 24/03/2006).

Stem Cell Research & Cloning

Eminent WA medical scientists are pressuring the State Government to allow embryos to be cloned for use in controversial research. WA Nobel Prize winner Barry Marshall and IVF specialist Anne Jequier both believe the State is lagging the rest of Australia in medical research in this area. Professor Marshall supports the legalisation of therapeutic cloning under strict conditions. Professor Marshall's view will carry weight with Premier Alan Carpenter, who recently appointed him and fellow Nobel laureate Robin Warren as roving ambassadors to promote WA's fledgeling biotechnology sector. Professor Marshall, who was on the Lockhart committee, hoped MPs would get a conscience vote on therapeutic cloning, like that over the abortion drug RU-486 (The West Australian, 25/04/2006).

Natural Fertility Treatment

A natural fertility treatment, which claims success rates higher than IVF through less invasive methods, will soon be available across Australia. In the US, the world leader in NaProTechnology, the treatment is recording a 60-80% success rate among infertile couples. IVF success rates in some Australian clinics are up to 35%. Perth-based Dr Amanda Lamont claims that approximately 60% of her successful couples had previously failed to conceive through IVF. Treatment is also a fraction of the cost of IVF – about $3000 over 18 months compared with between $3000 and $8000 for a one-month IVF cycle (Sunday Times, 16/10/2005).

RESEARCH

Australia

Obesity & Conception

Fertility experts and obstetricians are seeing a rise in infertility and pregnancy complications associated with obesity. Canberra Hospital's acting director of obstetrics and gynaecology, David Knight, estimated that in about a third of women he saw with infertility problems, obesity was one of the barriers to them falling pregnant. Sydney-based fertility specialist Dr Anne Clarke said "one of the things a lot of people don't realise is that being overweight can affect whether women ovulate, and also impacts on the miscarriage rate" (Canberra Times, 3/10/2005).

Obese and overweight pregnant women are placing themselves and their babies at increased risk reports the Medical Journal of Australia

(Adelaide Advertiser, 16/01/2006), which published results from research conducted at Brisbane's Mater Mothers' Hospital (Hobart Mercury, 16/01/2006). The ability to conceive is reportedly reduced by obesity and obese women are more likely to experience menstrual disorders. "Obesity is occurring at a younger age, the problem increases with time, and women are becoming pregnant later in life", reported the journal's editor (Canberra Times, 16/01/2006). The risks for babies include birth defects, prematurity, respiratory distress syndrome, hypoglycaemia and neonatal intensive care admission. Maternal risks include gestational diabetes, hypertension, caesarean delivery and extended hospital stay (The Age, 16/01/2006). Pre-pregnancy counselling has been recommended for all women to be included in a general public health effort to reduce obesity rates (Northern Territory News, 16/01/2006).

Perth Obstetrician Simon Turner has caused controversy by developing a policy at a Perth clinic that refuses IVF treatment to women who are overweight or over 45 years as he believes IVF is too much of a health risk and a waste of resources (The West Australian, 17/03/2006).

Anti-inflammatory Use and Conception

Research has shown women may be increasing their chances of miscarriage by taking non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen and aspirin, particularly around the time of conception, according to Dr Michael Cooper from the University of Sydney. Even after adjusting for factors such as previous miscarriage, education, maternal age, race, vitamin use and smoking, research has found those who use NSAIDs had an 80% increased risk of miscarriage (The Age, 14/11/2005).

Depression Risk to Older IVF Mothers

Older mothers, particularly those who conceive through IVF may be at increased risk of developing depression during pregnancy or after the baby is born, according to Sydney Psychiatrist Maire-Paule Austin. She states that many are older career women and are used to a structured environment that a baby changes dramatically (Daily Telegraph, 15/11/2005).

New Zealand

IVF Children May Be Taller

A New Zealand study has found that children born through IVF may grow to be as much as four centimetres taller as adults compared to their naturally conceived counterparts. Surprisingly, the study also found that IVF children had lower levels of 'bad' cholesterol and higher levels of 'good' cholesterol, which may mean a lower risk of adult heart disease (The Age, 6/09/2005).

United Kingdom

Embryonic Stem (ES) Cells

Researchers from Kingston University (UK), working alongside the University of Texas, stated umbilical cord blood could be a source of cells with all the potential of stem cells derived from embryos but without their ethical dilemmas. The researchers were able to make these cells proliferate by using microgravity, a technique developed by NASA for the International Space Station. This allows them to grow rapidly and in three dimensions. Despite some scepticism by other stem cell scientists, cord-blood-derived embryonic-like stem cells, (CBE); can differentiate

into all three basic types of tissue. But the factor that makes this development most exciting is that the stem cells are derived from umbilical cord blood. "Cord blood is great because it is normally disposed of. It's ethically very acceptable to most of the world," says Dr McGuckin. With 100 million babies born every year, "you have 100 million times a chance to find cells that have the same immunology as you and won't be rejected when they are transplanted into you." The results of the research have been published in the journal 'Cell Proliferation' (New Scientist, 18/08/2005).

Scientists at the Universities of Edinburgh and Milan have created the world's first pure nerve stem cells from embryonic stem cells. "This is incredibly exciting in terms of curing disease," says Dr Steven Pollard. "We may be able to create the disease in a dish. If we do that, we'll be able to better understand the disease and also to test drugs." The leader of the research team, Professor Austin Smith, says "we're already talking with the bio- technology and bio-pharmaceutical companies about taking these cells into screening systems for new drugs. Hopefully that will come to pass within two to three years." The possibility of therapies for diseases like Parkinson's from human embryos is far more remote, says Professor Smith, "That's a much more difficult and longer- term thing" (BBC, 16/08/2005).

Researchers from Britain's Newcastle University have won an appeal to overturn an HFEA ban on the fusion of two eggs to create one egg to be fertilized in an IVF program. The nuclear DNA of the fused egg will be from a woman whose mitochondria (from outside the cell nucleus) carries a genetic disease. Another woman with healthy mitochondria will donate the rest of the egg. The fused egg will then be fertilized with sperm from the first woman's husband and then implanted into her womb, in an attempt to have a child who will not inherit the genetic disease (Canberra Times, 30/01/2006).

Pre-Implantation Genetic Diagnosis

UK doctors are set to test embryos for a rare form of inherited eye cancer, after the Human Fertilisation and Embryology Authority (HFEA) granted a license to a team at University College Hospital (UCH) in London last week. Four couples will use preimplantation genetic diagnosis (PGD) to try and avoid passing on the genetic condition retinoblastoma to their children. The news comes a week after the HFEA revealed its plans to launch a public consultation on the use of PGD to test for late-onset and 'lower penetrance' genetic disorders (BBC News online, 18/8/2005).

PGD involves taking a single cell from a 2-4 day old embryo created using in vitro fertilisation (IVF), performing a genetic or chromosome test on that cell, and then returning one or two unaffected embryos to the womb. Retinoblastoma is a cancer of the retina caused by a mutation in a gene called RB1. People with this faulty gene have a 50 per cent chance of passing it on to any child, and it causes tumours in 90 per cent of those who inherit it. Affected people also have a greatly increased risk of developing another type of cancer during their lifetime (BBC News online, 18/8/2005).

HFEA Attacked Over PGD

Slate's bioethics correspondent has made a scathing attack on this month's decision by the UK's fertility regulator to allow pre-implantation genetic diagnosis for flawed embryos. William Saletan says that the decision by the

Human Fertilisation and Embryology Authority (HFEA) shows that the "slippery slope" is a reality and that it can be measured in three ways. The first is "penetrance", the probability that a gene will lead to a disease. The old standard was that a 90% probability would justify PGD. Now a 30-80% is enough. The second scale is treatability. The old standard was that screening was only allowed when treatments would be "awful or unreliable". But now a mere risk of failure, not a certainty of failure, is enough. The third scale is age of onset. Originally PGD was allowed only for diseases which were present in a child when it was born. Now the diseases for which PGD is allowed can show up at the age of 40. The HFEA even asks whether PGD should be used to screen out diseases which will not develop until a person is 70 or 80. Saletan complains that the criteria for destroying selected embryos are not only changing and slippery but subjective. "Significant anxiety" in the carriers of the gene is also reason enough for PGD, according to Dame Suzi Leather, the head of the HFEA (Slate, 19/05/2006).

Parents Warned Over Speculative Cord Blood Banking

The Royal College of Obstetricians and Gynaecologists (RCOG) reports that there is little evidence to recommend the practice whereby private companies collect and store umbilical cord blood for up to twenty years - at a charge of up to £1500 - for possible future use. The RCOG committee called for increased funding into the NHS bank so that more samples could be collected and those in need could have better access. They warned that there is currently 'insufficient evidence' to recommend private collection and storage. Demand for private cord blood banks has increased recently with around 11,000 British couples opting to store their child's blood using companies such as the UK Cord Blood Bank, Smart Cells and Future Health (BioNews 18/06/2006).

Mysteries of Adult Cell Reprogramming Unravelled

UK and US researchers say they are close to identifying a 'cocktail' of proteins that could convert adult cells into embryonic-like stem cells capable of growing into any type of body tissue. Scientists based at Edinburgh University have shown that a protein called 'Nanog' is key to this reprogramming process, while a team from Princeton University, New Jersey, has identified some of the proteins that work with Nanog. Both studies appear in the latest issue of Nature. Following the cloning of Dolly the sheep, scientists have been searching for proteins involved in the 'reprogramming' of the genetic material of an adult cell, that help transform it into an embryonic state. Such research could eventually lead to an alternative to the use of embryonic stem (ES) cells in the search for new disease therapies. The Edinburgh team has now shown that a gene called Nanog - named after the mythical Celtic land of the ever-young, Tir nan Og - is the key to the reprogramming process. The scientists first created mouse ES cells that produce four times the usual amount of Nanog protein. When they fused these cells with mouse nervous tissue cells, the hybrid cells transformed into ES cells 200 times more efficiently than normally happens in such fusion experiments. Team leader Austin Smith says that several other genes are probably involved, but that the identification of Nanog will hopefully speed up the search. The US study reported alongside the Nanog findings represents a significant step towards

this goal, since the researchers have developed a new way to identify other reprogramming genes (BioNews 18/06/2006).

USA

Embryo Research

A new, embryo-free technology may be in the making for stem cell research. Scientists fused adult skin cells with laboratory-grown embryonic stem (ES) cells, and then saw the hybrid cells revert back to an embryonic state. If perfected, this technology could provide a way to obtain ES cells for research and therapeutic applications without the need to use human eggs and embryos. Researchers at Harvard University Medical School in Massachusetts performed the work. They found that when they fused adult skin cells with ES cells, the resulting hybrid cells acted like ES cells. When injected into mice, they formed tumours called teratomas. They contained the chemical markers of ES cells, and when cultured, the cells differentiated into the three basic types of cell. However, the researchers also emphasise that the technology is at an early stage of development. Researcher Kevin Eggan acknowledged that a major technical barrier remains, because the resulting cells have twice the normal number of chromosomes (The Washington Post 22/8/2005).

Twins and Early Menopause

Female twins are up to four times more likely to go through early menopause than other women, a study of twins born in Britain and Australia has found. Professor of reproductive medicine at Cornell University, New York, Roger Gosden joined teams in Brisbane and London to do the study. Approximately 1% of women have gone through menopause by the age of 40, but the study found among twins was between 3-5%. By 45 years, the study found more than 15% of twins experienced menopause, compared with only 4.5% of the general female population. The average age of menopause among all women is about 51 years (Sydney Morning Herald, 21/10/2005).

Germany

Infertility & Acupuncture

A German study examined more than 100 infertile women who had 30-minute acupuncture sessions immediately after IVF treatment and again 3 days later. Pressure was applied to the key fertility areas of the liver, spleen, kidneys and stomach. A second group had the needles applied to random areas. One-third of those from the first group became pregnant, compared with just one-sixth of the others. IVF success rates are usually one in four. Another related Danish study found almost 40% of women became pregnant if acupuncture was performed on the same day as IVF treatment (The Sunday Times, 14/05/2006). It is thought that acupuncture sessions increase blood flow to the uterus and help balance the hormones critical for conception (The Courier Mail, 12/05/2006).

Belgium

ICSI

A Belgium study has found children born as a result of the intracytoplasmic sperm injection (ICSI) develop a higher IQ than children conceived naturally. The Belgian researcher stated that IVF couples were more likely to be especially dedicated parents willing to devote extra attention to their children. Doctors told an international fertility conference in Copenhagen that IVF children are brighter, more likely due to psychological factors, rather than

biological (The West Australian, 2/07/2005).

Norway

IVF Pregnancy Complication Link

Norwegian research suggests that IVF may increase the risk six fold of a potentially dangerous complication of pregnancy, placenta praevia, compared to those who had conceived naturally. This condition involves the placenta covering all or part of the cervix, blocking a baby's passage through the birth canal. It can cause haemorrhaging in the mother and increases the risk of premature birth and problems during delivery. Researchers have estimated from over 845,000 cases that the risk rose from approximately 3 in 1000 pregnancies to 16 in 1000 for women who undergo IVF (BBC News Online, 25/05/2006). The researchers were not sure why IVF increased the risk of placenta praevia, however, suggested that it could be related to a woman's anatomical factors that contributed originally to the infertility, rather than to the IVF procedure itself. Alternatively, it has been reported that embryos may be placed lower in the uterus to improve implantation rates (The Australian, 26/05/2006).

ADVANCES IN TECHNOLOGY

Australia

Reduction in Multiple Births with Single Embryo Transfer

Improvements in IVF technologies over recent years have reduced the incidence of multiple pregnancies in women undergoing IVF treatment. The Assisted Reproduction Technology in Australia and New Zealand reported that the number of IVF cycles between 2002 and 2003 increased by 9%, whilst the resulting number of multiple pregnancies dropped from 19.4% to 18.1%. This may predominantly be due to a reduction in the number of embryos transferred per cycle (Adelaide Advertiser, 16/02/2006). Multiple births are becoming less common because of a code of practice, introduced into clinics in 2005, which advised against more than one embryo being implanted in women under 35 or more than two embryos in women over 40 (The West Australian, 18/02/2006).

A study conducted by Sydney IVF has found that women who have a single embryo transferred via IVF face lower risks and have a higher chance of taking a baby home. Latest figures suggest that more women are undergoing single embryo transfer, compared to two embryo transfers. In fact, at Monash IVF in 2005, more than half of all transfers were single embryo (Sunday Age, 29/01/2006).

A drop in the number of twins and triplets born through ART led to fewer premature births and a reduction in the number of low birth weight babies (The Australian, 16/02/2006).

Sperm Sorter

Australian scientists have developed a machine to sort the good sperm from bad and are trialling it on infertile couples. The sperm sorter, invented by University of Newcastle scientists John Aitken and Chris Ainsworth is designed as a rapid way of isolating sperm free of DNA damage. Professor Aitken said the machine was based on the principle that the sperm with the most negatively charged membranes had the least DNA damage. The sperm sorter is smaller than a shoe box in size and has the benefit of not subjecting sperm to the trauma of centrifugation, which involves forces 500 times the force of gravity (Courier Mail, 2/11/2005).

Egg Maturation Technique

Women who get seriously sick from IVF treatment will soon be offered a less invasive technique in Melbourne. Unlike traditional IVF, the method does not use large doses of hormones. Instead, women's eggs are "matured" for 1-2 days in a Petri dish in the laboratory before fertilisation. Professor Alan Trouson pioneered the technique -which could benefit up to 20% of IVF patients – at Monash IVF in the early 1980s, but the popularity of traditional IVF overshadowed it. Countries such as Canada, Taiwan, Korea has used this technique since the 1980s. Britain is expected to begin using this method this year following an expected easing of regulation. This technique is expected to suit 2 main categories of IVF participants – those who do not tolerate taking large doses of hormones and those with Polycystic Ovarian Syndrome. The technique is expected to be available in Australia mid-year (The Age, 13/04/2006).

IVF babies more likely to be boys study finds

Women undertaking IVF treatment are more likely to give birth to a boy. A study by IVF Australia embryologist Jean Scott found that embryos conceived using the IVF technique and grown for a longer period of time had a higher chance of being male. Her findings were presented to an annual meeting of the European Society of Human Reproduction and Embryology in Prague. The study looked at live birth sex ratios for assisted reproductive technology pregnancies following a technique called blastocyst culture, where the embryo is grown for five days before being transferred back to the woman. Researchers found that if a couple had IVF, where the egg and sperm are mixed outside the body, rather than intra-cytoplasmic sperm injection, where a single sperm is selected and directly injected into an egg, and the embryo was grown to a blastocyst before being transferred back to the woman, there was a 56 per cent chance the child would be a boy. IVF Australia director Dr Ric Porter said the predominance of male babies reflected the fact the doctors would select the embryo that was dividing fastest and these tended to be male. (The Sun-Herald, 25/06/2006)

USA

Pharmacological Advances

Organon USA in Roseland, New Jersey, announced the availability of a 900 IU presentation of Follistim(R) AQ Cartridge (follitropin beta injection) for use with the Follistim Pen(R), a pen injection device allowing accurate, fine-tune dosing of fertility medication in 25 IU increments for patients undergoing ART procedures, such as IVF. Now physicians have more flexibility in prescribing and patients have more flexibility in self-administering this convenient and easy-to-use formulation of Follistim(R) AQ Cartridge. Unlike other follicle stimulating hormone (FSH) products on the market, the Follistim(R) AQ Cartridge does not require mixing and is delivered through a unique fine-needle, pen injection device (PRNewswire, 24/08/2005).

United Kingdom

DIY Male Fertility Test

British researchers have unveiled the world's first do-it-yourself fertility test for men, which is reportedly 95% accurate and takes just 75 minutes. The simple over-the-counter kit, known as Fertell, simulates the journey sperm must make to fertilise an egg. It also tests sperm quantity and motility. The test's creator, University of Birmingham's Professor Chris Barratt states "all the man has to do is produce

a sample, push a button and twist a switch and he will be able to assess that he has enough sperm that can swim to fertilise an egg." Fertell will be sold in Britain for the approximate Australian equivalent of $189 and will be sold with a companion test, which can tell women if they are fertile within 30 minutes (The West Australian, 06/01/2006).

Fertility Clock

A simple test telling women how many years they have left to start a family has been developed. The test detects how close women are to menopause by measuring hormone levels. The mail order kit, developed by Professor Bill Ledger of UK's Sheffield University, is already being hailed as a breakthrough as big as the oral contraceptive pill (Daily Telegraph, 14/10/2005).

ART HEALTH ISSUES

Sperm Allergies

Women have been reminded of a study, conducted 10 years ago, which found that some women might be allergic to their partner's sperm. This may be a factor to consider in those couples with unexplained infertility. The study identified semen allergies in about 15 percent of the study population of 1,073 women. The allergy is not usually to the spermatozoa, but rather, it's to a protein in the semen. It's often something that both men and women are unaware of. Semen is composed of a number of substances, including ascorbic acid, calcium, cholesterol, chlorine, nitrogen, purine, sodium, uric acid and zinc. Typical allergic reactions include swelling, burning, itching, hives or plummeting blood pressure. In some cases, semen allergies may also be responsible for infertility. According to Karisa Matthews, M.D., a Californian gynaecologist, as many as one-quarter of couples with fertility problems have semen allergies and end up conceiving with ART.

Physical treatments for such reactions include desensitization injections, in which women are administered with shots of protein from their partner's semen, similar to allergy injections, which can gradually annul the allergic effect by slowly increasing the amount of semen exposed to (myDNA News, 23/02/2006).

SOCIAL TRENDS & ISSUES

Australia

Age and ART

An Australian Institute of Health and Welfare review of ART reinforced the national trend of women delaying motherhood into their forties. The delay could be the result of social, educational and economic factors, as well as increased access to ART (Adelaide Advertiser, 09/12/2005).

Research from the National Perinatal Statistical Unit confirms women undergoing ART were, on average, almost 5 years older than those conceiving unassisted (Sun Herald, 19/02/2006). Trends also demonstrate increases in the number of people undergoing fertility treatment, however, the chances of women over 40 having babies still remain low (less than 5%). Yet women as old as 55, and men as old as 87, have been recently reported to utilise IVF in Australia (The West Australian, 18/02/2006).

Women aged 43 or older will no longer be accepted for IVF treatment in a Sydney IVF clinic. Howard Smith, the director of Westmead Fertility Centre, believes the policy is more humane than allowing women to continue with treatment that would almost inevitably

fail. Dr Smith stated that of the 250 women aged 43 and over that the clinic has treated during the past 5 years, only 2 had had a baby. Federal Health Minister, Tony Abbott has proposed that women aged 42 or older should be allowed a maximum of three Medicare-funded IVF attempts (Sydney Morning Herald, 18/11/2005).

Delaying Parenthood Trend

The Commonwealth sponsored Fertility Decision Making Project has found that couples may be postponing childbirth in the erroneous belief that IVF technology will counteract family planning troubles. More than 60% of the project's respondents had expectations of success with IVF that do not reflect the true picture of fertility failure rates, especially for older women. The trend to delay parenthood has contributed to falling fertility rates because women's reproductive cycles are finite and cannot always accommodate delays in family planning (The Australian, 21/07/2005). Researchers from the Australian Institute of Family Studies believe a public awareness campaign is necessary to alert young adults to the pitfalls of postponing having children, and to let them know IVF is unlikely to be a successful fallback option, especially as they approach their 40's. They additionally believe the media may unwittingly provide a false sense of security, by publishing mainly success stories, which may encourage a delay in parenthood (The Age, 10/09/2005).

An Australia wide advertising campaign is scheduled to commence within the next year that warns about the consequences of delaying parenthood. The Fertility Society of Australia (FSA) has decided the Fertility Protection Project campaign is needed and will warn of the difficulties older women encounter when trying to conceive. It will also educate about reduced fertility associated with smoking, obesity and sexually transmitted infections, including Chlamydia. The campaign will be both federally and state funded and includes television, radio and print advertisements (The Age, 23/02/2006).

Egg Freezing

A Queensland Fertility Group doctor has labelled "Reproductive Insurance" the trend of freezing eggs whilst a woman is in her 20's and in her reproductive prime for use later in life when the woman is actually ready, financially and socially to have a child (The West Australian, 11/01/2006). However, women are being cautioned against freezing their eggs in an attempt to delay childbirth, with experts warning the success rate is very low. IVF Directors Group chairman, Professor Michael Chapman outlines the public message should be to have your children at a younger age and then develop your career afterwards (Sun Herald, 22/01/2006). Egg freezing was previously something only women with cancer were encouraged to do, to safeguard their fertility against the consequences of chemotherapy. However, it is currently becoming a favourable option for "socially infertile" women (The Age, 25/03/2006).

Cryopreservation of Ovarian Tissue for Cancer Sufferers

Women diagnosed with cancer can keep dreams of motherhood intact through a pioneering program to freeze ovarian tissue. The Monash IVF (Melbourne) program seeks to fast track the development of a process to thaw ovarian tissue and utilise the immature eggs it contains to produce a successful pregnancy. Doctors would need to ensure the tissue contained no

cancer cells before being used to create new life. This process is not available to women wanting to delay having children or to defer menopause (Adelaide Advertiser, 26/04/2006).

Increasing ART Cost With Age

Federal Health Minister Tony Abbott appointed an expert ART committee of six prominent medical professionals to review the cost-effectiveness, societal impact, clinical appropriateness and public funding of IVF (Canberra Times, 6/7/2005).

A University of NSW report has demonstrated that IVF is 3-4 times more expensive for women over 40 years. The costs dramatically increase if over 42 years of age (The West Australian, 19/12/2005). The estimated cost of ART to the Federal Government, private insurers and parents for women aged 42 years is $182,794.00. Much of the cost has shifted from individuals to the government with the introduction of the Medicare Safety Net in January 2004, which pays 80% of out-of-pocket medical expenses past a certain threshold. Health Minister, Tony Abbott had suggested limiting Medicare funding for IVF for women older than 42 years to 3 cycles, as a cost saving incentive, arguing that IVF for this age bracket has limited success. However, overall, IVF represented less than 1% of Medicare benefits paid in 2004 (The Australian, 19/12/2005).

Concept Fertility Centre biologist, Dr Bruce Bellinge, replied to suggestions that IVF treatments should be limited by age as offensive and discriminatory. He stated, "if you try to suggest treating older women is less cost-effective and shouldn't be done, then we should seriously consider not doing heart transplants on older people". In perspective, less than 10% of women over 42 were seeking reproductive technology treatment and only consumed 0.2% of the nation's private and public annual expenditure in health care (The West Australian, 19/12/2005). Another argument against age-limiting IVF includes the fact that for approximately $2000 in health spending, the Government will get back a human being who will probably spend the majority of his or her life paying tax (Sun Herald, 08/01/2006). In addition to economic cost when making policy decisions, however, it should also be important to consider, community values, ethical practice and clinical factors (Adelaide Advertiser, 19/12/2005).

Interestingly, the Federal Government recently walked away from its previous plans to limit Medicare funding for older IVF participants due to political backlash. Treasurer Peter Costello made it clear that the Government would not revisit this issue, irrespective of what the appointed committee of experts found (The Age, 08/05/2006).

Stigma with IVF

Research from Macquarie University suggests a stigma is still associated with fertility difficulties and utilising IVF to conceive in Australia (Sun Herald, 8/01/2006).

Egg & Sperm Donor Shortage

The Department for Reproductive Medicine at Sydney's Royal Hospital for Women announced it might face closure in 2006 due to a reduction in sperm and egg donors. IVF Australia stated similar concerns. However, in September 2005, shortly after the public announcement, a promising surge of public interest allayed fears. Possible reasons for the shortage of donors include the facts that donors are

not financially rewarded and they must be willing to be contacted by potential offspring (Sun Herald, 25/09/2005).

Anonymous 'Egg Bank' Request

A NSW medical professional has made a public plea for an egg bank to be set up to ease the trauma associated with finding an egg donor. Her rationale is that anonymous sperm banks exist, so should egg banks. An egg bank could alleviate the personal trauma associated with trying to locate a willing donor (Sun Herald, 19/02/2006).

Same-Sex Parenting

The Victorian Law Reform Commission published a literature review that examined 18 substantial studies of children born through ART, which showed that the psychosocial development and academic achievement of children born into lesbian families is no different from that of children born into heterosexual families. The Commission argued it is in the best interests of children for the law to recognise the reality that children are being born to single women and women in same-sex relationships as the result of ART provided in clinics and privately arranged self-insemination. However, the legislation has not been amended in light of the decision. It continues to be interpreted restrictively so that a woman without a male partner can only undergo treatment if a doctor is satisfied she is clinically infertile Status of children legislation fails to recognise the reality of many children's families. Where a child is born through ART to a woman in a same-sex relationship, the non-birth mother is not recognised as a legal parent of the child and consequently cannot assume the full range of parental obligations or powers in respect of the child. This has important implications for children, affecting their rights to child support and inheritance (BioNews, August 2005). The Victorian Law Reform Commission is reviewing current legislation, with a final report due out in late 2006. Its interim recommendations include allowing lesbian and single women to undergo fertility treatment and allowing children to contact their biological sperm-donor fathers but not allowing sperm donors to initiate contact (The Age, 03/03/2006).

Surrogacy

The Victorian Infertility Treatment Authority (ITA) has supported recommendations to overturn legislation that stipulates a woman must be infertile to become a surrogate mother. However, they have supported that surrogacy remain altruistic, with the commissioning couple covering the surrogate's medical expenses. The Victorian Law Reform Commission has described the law as irrational and has urged the Victorian State Government to review it. Neither the commission nor the authority would comment on whether surrogacy should be prohibited, but both agree the legislation needs to be clarified (The Age, 31/01/2006).

Multiple Births

Australian Twin registry deputy director, Sue Treloar, has revealed that the number of non-identical twins born in Australia has risen due to the increased number of women delaying parenthood and using IVF (Sunday Tasmanian, 12/03/2006).

USA

Sex Selection

Thousands of couples are travelling to clinics in the US where they can choose the sex of their next child. Dr Jeffrey Steinberg, the leading figure in American commercial sex selection, says that half of his clients come from

countries where the controversial procedure is banned, such as Australia, Germany, Britain and Canada. Over the past three years he has treated 2,000 couples. The American Society for Reproductive Medicine says sex selection of embryos is clearly ethical when the method is used to prevent genetic disease. But the professional group discourages its use for choosing one gender over another. The group says the practice risks reinforcing sexism in society and diverts medical resources from real medical needs (AFP, 14/05/2006).

Sperm Donation

Men who have had sex with men (MSM) in the past 5 years have been denied the ability to anonymously donate sperm under Food & Drug Administration (FDA) guidelines, developed in May 2005. The FDA's Guidance Document for sperm donor eligibility recommends, rather than mandates, the exclusion of anonymous MSM donors, but many sperm banks across America have put the ban into place. The FDA considers MSM a high-risk group for HIV and other STI's. In view of the routine, rigorous screening and testing procedures for anonymous sperm donors, some groups have labelled the FDA guidelines as unnecessarily restrictive and biased (Choice Magazine, 2005).

Same-Sex Parenting

In 2005, a study published in the journal *Child Development* confirmed what earlier generations of researchers have asserted: that parents' sexual orientation has no negative effect on the development of their children. The study found that children with same-sex partners were identical to those with opposite-sex parents in nearly every area analysed (Planned Parenthood Federation, 2006). This reiterates Australian findings.

Embryo Donation

The American Fertility Association announced the release, in print and online, of new educational brochures that simplify the complexity of embryo donation - both for the donor of unused embryos following IVF treatments, and for the recipient of donated embryos. Fertility clinics across the country received a total of 20,000 copies of these brochures to distribute this much-needed resource to their patients (The American Fertility Association, New York, 23/02/2006).

Pre-Implantation Genetic Diagnosis

An investigation conducted by the Sydney Daily Telegraph has revealed that at least 14 couples from Australia have undergone IVF in the USA to select the gender of their child. Sex-selection PGD is currently banned in Australia. Similarly, it is banned in Britain, Europe, Asia and Canada (Daily Telegraph, 27/02/2006).

United Kingdom

Delaying Parenthood

British fertility experts have claimed that women are increasingly seeking inappropriate IVF treatment because they do not have the time or inclination for a sex life and want to "diarise" their busy lives. Wealthy career women in their 30's and 40's are resorting to "medicalised conception" despite being fertile and before they have extensively tried to conceive naturally. Many believe IVF offers the best chance of immediate pregnancy (The West Australian, 26/09/2005).

Britain's Oldest Mum

Britain's oldest expectant mother has defended her to decision and conveyed her delight to be expecting a child at 62 years. Dr Patricia Rashbrook, a child psychiatrist, is seven months pregnant with her fourth child, a boy. She has

paid $16,857 for a donor egg and IVF treatment in Russia, one of the few countries to offer IVF treatment to women older than 50 years (Sunday Telegraph, 07/05/2006).

Saviour Sibling Approval

A couple in Britain are the first to be given approval to create a "saviour sibling" through genetic screening to help their seriously ill daughter, Charlotte. The couple want stem cells to transplant into 20-month-old Charlotte, who was diagnosed at 5 months with diamond blackfan anaemia, a condition where inadequate amounts of red blood cells are produced by the bone marrow. Utilising IVF technology, Doctors will implant an embryo with tissue cells that match Charlotte's. When the resultant baby is born, umbilical stem cells will be taken and transplanted into Charlotte, in the hope of treating her disease (The West Australian, 06/05/2006).

Single 63-Year old Dad of Triplets

The first man in the UK to have children without a female partner, Ian Mucklejohn's children, now five years old, were born to an American surrogate mother when he was 58. He recently took the boys to the US to meet their genetic mother and the woman who brought them to term. Now 63, he told the BBC that his experience has been very positive. He feels that the boys will not regret not having a mother because he plays both roles adequately (BBC News Magazine, 17/05/2006).

Towards A World without Autism

A British IVF clinic wants to create autism-free babies for couples who fear that they might have an affected child. A team at University College London says that boys are four times more likely to have autism than girls, so embryos would be screened to eliminate the boys. A prospective couple would only be allowed to have the procedure if autism had inflicted severe suffering upon the family. The proposal to the UK's fertility watchdog, the Human Fertilisation and Embryology Authority, is a controversial one because autistic children can live long and healthy lives. A spokesman for the British Council of Disabled People said: "Screening out autism would breed a fear that anyone who is different in any way will not be accepted. Screening for autism would create a society where only perfection is valued" (London Times, 18/06/2006).

Romania

IVF Mother at 67

The child of the 67-year-old Romanian woman who became the world's oldest mother via IVF has had her first birthday. Ms Iliescu, who created an international debate when she conceived through donor eggs and sperm, believes parenthood is not as difficult as she expected despite her age (Adelaide Advertiser, 18/01/2006). She has reportedly stated that her age has had little impact on the controversial pregnancy, her daughter's health or her ability to care for her child (The West Australian, 18/01/2006).

CASE REPORTS

Widow Wins Access to Husband's Sperm

A Victorian widow won the right to try to have her dead husband's baby in a legal first for the state. The Civil and Administrative Tribunal gave the woman permission to take stored sperm from her husband interstate where she can use IVF services. Under Victorian IVF law, a man must give consent for his partner to use his sperm or to take it interstate to another IVF

service. The woman's lawyer says her client's husband died in a car accident seven years ago and she is delighted with the decision (ABC News Online, 20/12/2005).

Sydney Clinic Fallout

One of Australia's biggest and most profitable IVF companies have experienced a mass departure of staff. Up to 15 staff, including the company's founder and clinical director, from IVF Australia's Sydney clinic have resigned and started up a new clinic, called Next Generation Fertility, due to what they viewed as an increasingly corporate focus of the company (Sun Herald, 10/07/2005). Shortly after the split, additional conflict arose due to the discovery that a former IVF Australia employee downloaded patient database records to his iPod. The database was utlised to send out letters to over 8000 clients, introducing the new Next Generation clinic. The Supreme Court did not prosecute the staff member involved or Next Generation (The Australian, 4/08/2005).

IVF Pioneer Dies Tragically

South Australian IVF pioneer Professor John Kerin (61) was killed tragically at his farm property in January 2006. The world-renowned clinician has been responsible for more than 2000 IVF babies during his career and his team produced South Australia's first IVF twins and frozen embryo pregnancy (Adelaide Advertiser, 27/01/2006).

Frozen-Egg Baby Welcomed

A baby conceived using a woman's frozen eggs has been born in Victoria. The birth is the first for Melbourne and the second in Australia. Melbourne IVF chairman Lyndon Hale said the birth, which came after 6 attempts at the clinic to thaw frozen eggs and fertilise them, was good news for the growing number of single women who were freezing their eggs to preserve their fertility until they met a partner. Egg freezing has been trialled for years, however, Melbourne IVF senior research scientist Debra Gook said the egg freezing worked in this instance because the clinic has changed the way it froze eggs and used a stronger concentration of anti-freeze solution (The Age, 12/04/2006).

Sperm Donor Crisis in Scotland

All of Scotland's five fertility clinics are struggling and one has closed for lack of sperm donors. A recent law has given people in the UK the right to trace their biological father. As soon as it came into effect sperm donation stopped. At the moment in all of Scotland there is only one active sperm donor. Infertility Network UK, a lobby group, has begun calling for a nationwide recruitment campaign (London Times, 04/06/2006) (BioEdge 9/05/2006).

KOREA

Korean stem cell scientist Hwang Woo-suk

The number of eggs used by disgraced Korean stem cell scientist Hwang Woo-suk keeps climbing. He originally claimed that he had used only 427 eggs to produce 11 human embryonic stem cell lines. This claim has been proven fraudulent. In January, investigators from Seoul National University disclosed that he had used 2,061 eggs from 129 donors. A month later, the National Bioethics Committee found that he had gathered 2,221 eggs from 119 donors. And now police prosecutors say that the number is 2,236 eggs from 136 donors. Hwang did not act alone. It also appears that Hanyang University Medical Center gave eggs to Hwang without obtaining the consent of the donors. This was a

clear violation of a Korean bioethics law (Korea Times, 15/05/2006).

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New Technique Will Improve Embryo Test Success Rates

A new technique is set to improve the success rate of preimplantation genetic diagnosis (PGD), the testing of embryos for gene mutations that cause disease. The new test called 'preimplantation genetic haplotyping (PGH) has already been approved by the UK's fertility regulator and tried seven times, resulting in five currently healthy pregnancies. In PGH, instead of detecting the mutation itself, scientists look at a set of nearby DNA 'markers' that can distinguish the chromosome with the faulty version of the gene from one carrying the healthy version. In order to do this, the scientists first increase the amount of DNA available to test, using a new method called multiple displacement analysis. One of the advantages of PGH is that it can be offered to families carrying rare mutations, as well as those with more common, previously identified mutations. It also means that for families affected by an X-linked disease, such as Duchenne muscular dystrophy (DMD), doctors will be able to distinguish affected male embryos from unaffected ones - potentially increasing the number of healthy embryos that can be returned to the womb (BioNews, 18/06/2006).

Egg Freezing Moves Closer

A new product unveiled at the ESHRE conference could allow women to freeze their eggs so that they can become pregnant at a time of their choosing. Dr Masashige Kuwayama, of the Kato Ladies Clinic in Tokyo, says that a technique first used for cattle and sheep might lead to a dramatic improvement in success rates for pregnancies from frozen eggs. Existing techniques result in a pregnancy with only 1 in 100 eggs. The Japanese method, which uses a kind of antifreeze to keep ice crystals from forming in the egg, will increase this rate to 10 in 100 (BBC, 19/06/2006).

No Physical Health Problems For ICSI Children:

Researchers from Belgium have presented evidence at ESHRE to show that children born from intracytoplasmic sperm injection (ICSI) are still developing well 8 years after birth. Some previous studies have reported slight developmental delays - in both cognitive and motor functions - in children born after ICSI. This study, however, looked at physical characteristics of the children, rather than their social and cognitive development. There were 24.1 per cent of ICSI children with a 'minor congenital malformation', compared with 17.2 per cent of the controls. However, when the results were reassessed by an Australian team - using a different set of definitions - the percentages of major and minor malformations decreased dramatically in both groups, showing that it was perhaps the case that the Belgian groups had a wider definition of what constituted a malformation than other groups would use. And, even though major malformations were found more frequently in the ICSI children, most of these were able to be easily corrected by minor surgery. Dr Florence Belva, a paediatrician and research assistant at the Centre for Medical Genetics at the Vrije University of Brussels, pointed out that it was a small study and that there is a need for a larger, multi-centre follow-up study (BioNews 18/06/2006).

ESHRE Continues Human Cloning Ban

ESHRE at its annual conference again renewed its moratorium on human reproductive cloning. ESHRE began a voluntary five year moratorium on the cloning of human babies in 1999, in response to developments in animal cloning and fears that these skills could be transferred and used in attempts to clone humans. At the annual ESHRE conferences over the last two years (since the original five year moratorium ended) the organisation, which represents more than 4000 international fertility experts, has continued the moratorium. This year, the Executive Committee has decided to continue the moratorium for at least a further year, saying that in the light of data from animal cloning, it would be 'totally irresponsible, as well as unethical, to start human reproductive cloning' (BioNews 18/06/2006).

Three Million IVF Babies Born Worldwide

Data presented at the annual ESHRE conference has shown that more than three million babies have been born using IVF and other assisted reproductive technologies (ART) since the world's first IVF baby was born in 1978. Data were first collected on the number of ART births worldwide in 1989 and in that year only about 30,000 babies were born following ART. Two years ago, that figure had risen to 200,000 babies in a year. This year's data, from the International Committee for Monitoring Assisted Reproductive Technologies (ICMART), includes reports from 52 countries, and covers almost 600,000 IVF cycles and 122,000 newborn babies. The data does not include information on most African nations or many Asian countries. The data also showed that huge variation exists in the availability of ART treatments - and their success rates - across the countries represented. Last year it was reported that there was a decline in the number of twin births following the use of ARTs, and a fall from 3.6 per cent to 1.3 per cent of triplet births - this is a trend that appears to be continuing, with SET being favoured in many countries (BioNews 25/06/2006).

Therapy For Stress-Related Infertility

A study by scientists at Emory University in Atlanta, Georgia, US, has revealed that stress-related infertility can be reversed by cognitive behavioural therapy (CBT). The researchers, who presented their findings at the annual ESHRE conference, suggest that CBT may prove effective and enable women to avoid having to have what might be expensive and unnecessary fertility treatment. Professor Sarah L Berga, the lead author of the study, concluded that in some women, CBT would offer a 'holistic treatment that is safe, cost-effective and easy to implement' (BioNews 25/06/2006).

Sheep Womb Transplant Success

Swedish scientists, who presented their findings at the annual ESHRE conference, have successfully transplanted uteruses in sheep, an achievement that paves the way for women who do not have a womb to bear their own children (BioNews 25/06/2006).

IVF Embryo Culture Link To Genetic Disorder

New research on mouse embryos suggests that laboratory culture conditions can affect the activity of several genes. The findings, presented by US scientists at the annual ESHRE conference add to evidence that IVF methods might increase the risk of

some rare genetic 'imprinting' disorders. However the team, based at the University of California, caution that their results are preliminary, and that further research is needed. The scientists hope that their studies will eventually lead to better culture media for IVF procedures (BioNews 25/06/2006).

Vasectomies Linked To Genetic Sperm Damage

Vasectomies can cause chromosomal abnormalities in sperm, say a team based at Chulalongkorn University in Bangkok, Thailand. The researchers, who presented their findings at the annual ESHRE conference, say that the genetic damage is caused by the original vasectomy, rather than reversal operations. The scientists say that men should consider freezing healthy sperm before they undergo the procedure. Two years ago, researchers from Queen's University, Belfast showed that men who have undergone vasectomies and then had a reversal operation produce much less sperm than fertile men who have never had a vasectomy. The team also showed that the pregnancy success rate using intracytoplasmic sperm injection (ICSI) was more than 50 per cent lower for the vasectomised men. The new study confirms that vasectomies, even when successfully reversed, could affect sperm quality as well as quantity. They also found that rate of abnormalities dropped with time after a reversal operation - that is, the longer ago the reversal, the better the chances of producing normal sperm (BioNews 25/06/2006).

New Egg Test May Increase IVF Success Rate

Italian scientists presented research at the annual ESHRE conference showing that eggs can be screened - before they are fertilised - for chromosomal abnormalities that might reduce IVF success rates. Ana Pia Ferraretti and colleagues, from SISMER (Societa Italiana Studi di Medicina Della Riproduzione) in Bologna, Italy, looked at chromosomes contained in the 'first polar body' - a small cellular structure, surrounded by a membrane, that is expelled from the developing egg during cell division and which contains the same number of chromosomes as the egg. By doing this, they found they could select healthy eggs with the correct number of chromosomes. Italy's laws on human fertilisation and embryology, passed in December 2003 and said to be the most restrictive in Europe, were passed to counter the country's reputation for being the 'Wild West' of fertility treatments. The law restricts the provision of fertility treatments to 'stable heterosexual couples' who live together and are of childbearing age, and who are shown to be clinically infertile. Research using human embryos is prohibited, as well as embryo freezing, gamete donation, surrogacy, and the provision of any fertility treatments for single women or same-sex couples. The law also says that no more than three eggs can be fertilised at any one time, and that any eggs fertilised must all be transferred to the uterus simultaneously, increasing the risk of multiple births. Preimplantation genetic diagnosis and prenatal screening for genetic disorders are banned. As Italian doctors are banned from discarding or freezing surplus embryos, this new research may go some way to helping infertile women in Italy (BioNews 25/06/2006).

Free UK Fertility Treatment 'Would Boost Economy'

Research presented at the annual ESHRE conference suggests that the benefits that would come from the UK's government providing free

fertility treatment to enable couples to have children would outweigh the initial costs. Based on these findings, the researchers argue that the National Health Service (NHS) should fund three cycles of IVF, as was recommended by the National Institute of Health and Clinical Excellence (NICE) in 2004. Professor William Ledger, from the University of Sheffield in the UK, assessed the average cost of creating a child using fertility treatment and compared this to the benefit the government would obtain over the child's lifetime. This led Professor Ledger to state that the costs of IVF are in fact 'trivial' and 'truly insignificant' in terms of what the child gives to society (BioNews 25/06/2006).

Concern Over 'IVF Identity Fraud'

Dr Luca Sabatini, from the Centre for Reproductive Medicine at St Bartholomew's Hospital in London, UK, told the annual ESHRE conference that fertility clinics across Europe should take more steps to protect themselves against identity fraud by prospective patients. Fraud such as this would make consent forms for one of the couple irrelevant, for example, but was probably done to avoid having to 'start again' and have the preliminary investigations undertaken - including an assessment as to the welfare of the prospective child - for the new partner. The research team surveyed 70 of the licensed clinics in the UK, the sample including both NHS-funded and private units. Overall, the questionnaire results showed that 53 per cent of clinics did not feel that they had enough protection from identity fraud. Final results will be sent to clinics to encourage them to see identity fraud as a serious issue and perhaps to standardise methods of patient identification (BioNews 25/06/2006).

APPENDIX 1

LICENCES AND EXEMPTIONS

LICENCES CURRENT UNDER THE *HUMAN REPRODUCTIVE TECHNOLOGY ACT* AT 30 JUNE 2006

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

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

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

JL Yovich Pty Ltd, PIVET Medical Centre, LEEDERVILLE –
Practice and Storage Licences.

Fertility North Pty Ltd, JOONDALUP –
Practice and Storage Licences.

MEDICAL PRACTITIONERS WITH AN EXEMPTION FROM THE REQUIREMENT TO BE LICENSED TO CARRY OUT ARTIFICIAL INSEMINATION AT 30 JUNE 2006

Exemptee No	***Name***	***Suburb***	***Post Code***
E023	Dr PK Bairstow	Bunbury	WA 6230
E034	Dr RT Chapman	Katanning	WA 6317
E027	Dr DP Day	Kelmscott	WA 6111
E001	Dr ZN Dorkhom	Bunbury	WA 6230
E050	Dr R Kirk	Carnarvon	WA 6701
E046	Dr TP Knight	Mandurah	WA 6210
E024	Dr DN Lawrance	Kelmscott	WA 6111
E025	Dr HH Leslie	Exmouth	WA 6707
E016	Dr KA McCallum	Kalgoorlie	WA 6430
E003	Dr KT Meadows	Collie	WA 6225
E051	Dr WD Patton	Rockingham	WA 6168
E017	Dr C Russell-Smith	Kwinana	WA 6167
E022	Dr BGA Stuckey	Nedlands	WA 6009
E029	Dr JM Vujcich	West Perth	WA 6050
E028	Dr RJ Watt	Mandurah	WA 6012
E049	Dr M Zafir	Albany	WA 6330

APPENDIX 2

APPROVED COUNSELLORS

APPROVED COUNSELLORS AT 30 JUNE 2006

Name	Professional Address	Telephone Number
Ms Jill Bain*	57A Canning Beach Road, Applecross WA 6153 – Private Practice	Tel / Fax (08) 9364 3665.
Ms Marion Connelly	Concept Fertility Centre c/- KEMH Bagot Rd Subiaco WA 6008	(08) 9383 2388 Fax (08) 9381 3603
Ms Deborah Foster-Gaitskell*	62 Churchill Avenue, Subiaco WA 6008 – Private Practice Hollywood Fertility Centre, Hollywood Private Hospital Monash Avenue, Nedlands, WA 6009	(08) 9271 3582 Fax (08) 9388 3740 (08) 9346 7100 Fax (08) 9386 1463
Ms Jane Irvine	Roe Street Centre for Human Relationships-FPWA, 70 Roe St, Northbridge WA 6003	(08) 9228 3693 Fax (08) 9227 6871
Ms Rosemary Keenan*	6 The Lakes Mews, Karrinyup Lakes Lifestyle Village Gwelup WA 6018	(08) 94478365
Ms Sue Midford*	324 Huntriss Road, Woodlands WA 6018 2/36 Ormsby Tce, Mandurah WA 6210 Suite 7/401 Oxford St, Mt Hawthorn WA 6016	Tel (08) 9581 6545 (Appointments) Fax (08) 9446 8483
Dr Kaye Miller	Palm Springs Medical Centre, 3 Halliburton Drive, Warnbro WA 6169	(08) 9593 2033 Fax (08) 9593 1913
Ms Helen Mountain	C/ Genetic Services of WA King Edward Memorial Hospital Centre for Women's Health Bagot Road, Subiaco 6008	(08) 9340 1525 Fax (08) 9340 1678
Ms Iolanda Rodino*	64 Farrington Road, Leeming WA 6149 – Private Practice Keogh Institute for Medical Research A Block, 3rd Floor QE Medical Centre Nedlands. WA 6009	(08) 9389 7212 (08) 9346 2008 Fax (08) 9380 6387
Ms Kay Rosen	36 Carnarvon Crescent, Mt Lawley WA 6050 – Private Practice	(08) 9444 1617 Fax (08) 9242 5882
Ms Margaret van Keppel*	267 Walcott Street, North Perth WA 6006 – Private Practice Pivet Medical Centre, 166 Cambridge St, Leederville WA 6007 Hollywood Fertility Centre, Hollywood Private Hospital, Monash Ave, Nedlands WA 6009	(08) 9443 3655 Fax (08) 9443 8665 (08) 9382 1677 Fax (08) 9382 4576 (08) 9346 7100 Fax (08) 9386 1463
Ms Elizabeth Webb	Fertility North, Suite 213, Specialist Medical Centre, Joondalup Health Campus, Shenton Ave Joondalup WA 6027 Mental Health Unit, Joondalup Health Campus Shenton Ave, Joondalup WA 6027	(08) 9400 9965 (08) 9400 9788 Fax (08) 9400 9069

*** Qualified to assist with child-related 'Telling Issues' associated with donor conception.**

The professional address is provided first followed by an alternate address if applicable.

INFERTILITY COUNSELLING: THE ROLE OF 'APPROVED COUNSELLORS' UNDER THE *HUMAN REPRODUCTIVE TECHNOLOGY ACT 1991* (WA)

When experiencing infertility or involved in its treatment through assisted reproduction (such as IVF and donor insemination), individuals and couples can, at various times, need or want to see a counsellor. This may be to discuss personal issues, seek assistance in decision making, or to seek support. For example those dealing with the psycho–social issues of infertility, or those considering the donation or use of donated human reproductive material (eg sperm donors) may wish to seek this support. Counselling is an accepted and useful resource for those experiencing the difficult emotional and psycho–social processes that most people experience in these situations.

Counselling is to distinguished from

- the information which is given to everyone seeking treatment;
- the normal relationship between the clinician and the person seeking treatment; and
- the process of assessing people for treatment.

The aims of counselling are to provide people with the opportunity

- to explore personal and family issues related to infertility;
- to understand the personal implications of the available treatment options;
- to seek help in making decisions about treatment that is acceptable to them; and
- to seek support before, during and after treatment.

Whilst the benefits of counselling are generally recognised, consumers are not obliged to accept counselling. The exception to this is when individuals and couples are considering treatment using gametes or embryos from donors who are known to them. In this case, the donors and recipients, and any spouse or partner, must attend counselling. In addition, fertility clinics are encouraged, but not obligated, to make counselling available for all donors of human reproductive material (such as sperm donors) or donor insemination patients. The list of 'Approved Counsellors' must be made available to them. Counselling assists with the better understanding of the complex issues involved in donation, for both the potential donors and recipients.

Counsellors who assist people seeking infertility treatment need to have a knowledge and understanding of the complex issues involved. For this reason the Western Australian Reproductive Technology Council recognises some counsellors as 'Approved Counsellors' under *the Human Reproductive Technology Act 1991 (Act).*

'Approved counsellors' must be qualified and experienced counsellors, who also possess a significant knowledge of the issues associated with fertility and infertility. They must also demonstrate evidence of keeping up to date with technological developments. A list of 'approved counsellors' is provided overleaf. Counsellors on this list include those working in fertility clinics licensed under the Act as well as those working in the general community. Clinic counsellors must also become members of ANZICA, the Australian New Zealand Infertility Counsellors' Association. See website www.anzica.org

In Western Australia all fertility clinics are licensed under the Act, and must provide access to counselling to all people undergoing IVF treatment, with some counselling being provided at no extra cost in the overall treatment fee. There is currently an entitlement to counselling at the rate of one hour per IVF treatment cycle, plus one additional hour when the decision is made to withdraw from further IVF treatment.

For further information please contact your Doctor or

The Executive Officer
Reproductive Technology Council
189 Royal Street
East Perth WA 6004
Phone (08) 9222 4260 Fax (08) 9222 4236
Email: Antonia.Clissa@health.wa.gov.au

APPENDIX 3

OPERATIONS OF LICENSEES FOR THE FINANCIAL YEAR 2005/2006

OPERATIONS OF LICENSEES FOR THE FINANCIAL YEAR 2005/2006

Background

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

All information was submitted in a collated form and referred to the financial year, which ended at 30 June 2006. 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 the licences.

Semen storage and donation

During the 2005/06 financial year, 72 men donated sement to WA Storage Licensees. Of these, 19 were new donors. This is a further increase in the total number of donors from 2002 when the lowest numbers of donors was recorded (illustrated in figure 1). However, the number of new donors for this financial year is lower than last year. Since the 2003/04 financial year there has been a decrease in the number of new donors, this may coincide with the introduction of amendments to legislation in December 2004, requiring any new donors to consent to release of their identifying information to any offspring conceived from their donation. Therefore, the demonstrated increase in donor numbers would indicate that clinics are retaining their established donors.

The age distribution of donors (Table 1) indicates that the majority (76.1%) were over 30 years of age, with 38% being over 40. Although, the proportion of donors over 30 is not as high as last financial year, over the last thirteen years there appears to be a general trend away from young donors towards older donors (figure 2). Where the marital status of the donor was known, in 70.9% the donor was single, 27.3% were married or in a de facto relationship and 1.8% were divorced or separated.

Reporting by Exempt Practitioners and Storage Licensees indicated that during the year donor semen was supplied to two WA Exempt practitioners. As detailed in Appendix 1, there were 16 exempt practitioners at the end of the 2005/2006 financial year with no exempt practitioners requesting revocation of their exemptions this year.

Embryo storage

Table 3 shows that the total number of embryos in storage at the end of the year was 14,047. The total number of embryos in storage has continued to increase since 1993 (as illustrated in figure 3). Although there has been a 6.6% increase in embryos in storage in the last financial year, the rate of increase has slowed down over the past three years. Largely this increase, in the number of embryos in storage, is due to the growing number of people undertaking IVF as demonstrated by the rise in the number of oocyte pick up cycles commenced, which this year increased by 10.0% from last financial year. It is expected that these embryos will either be used in IVF or for research. The Reproductive Technology Council is also aware that there are a small number of participants who have completed treatment and are continuing to store their embryos as they are finding it difficult to make a decision about the embryos. Council is currently developing strategies to address this issue.

A total of 4881 embryos were stored following treatment and 3623 stored embryos were used in treatments during this year. In all 580 embryos were allowed to succumb at the request of the participants.

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

Table 4 shows that during the last financial year 1420 women began oocyte retrieval cycles for IVF, 762 began FET and 1 began GIFT procedures.

A total of 3796 cycles were begun for IVF, frozen embryo transfer or GIFT, a further increase on the previous year (3552). As illustrated in figure 4, of all cycles begun, 2276 (60.0%) were for IVF and 1518 (40.0%) were for frozen embryo transfer. GIFT cycles accounted for only 2 of the cycles begun.

Of the 2278 cycles begun for fresh IVF or GIFT with ovarian stimulation, 86.1% proceeded to oocyte retrieval and 69.0% proceeded to transfer fresh embryos or gametes (figure 5). Of the 1518 frozen embryo transfer cycles begun, 1232 (81.2%) proceeded to transfer.

Overall, donated human reproductive material was involved in 5.3% of all IVF or GIFT cycles with oocyte retrieval during the year. In 3.8% of cycles donor semen was used (75 cycles); donor eggs were used in 1.2% of cycles (24 cycles) and there were 5 IVF cycles with fresh embryos donated. A higher proportion of frozen embryo transfer cycles (14.0%) involved use of donated gametes or embryos. Donor embryos were used in 2.6% of all FET cycles with transfer (32 cycles); donor eggs in 6.3% (78 cycles) and donor semen in 5.1% (63 cycles).

Of all 1960 IVF treatment cycles with successful oocyte retrieval, 1044 (53.3 %) used intra-cytoplasmic sperm injection (ICSI). As illustrated in Figure 6, use of ICSI has increased since the last financial year. Since its introduction in WA in 1994, the early increase in use of ICSI may be explained by ICSI becoming a mainstream practice in cases of male fertility problems and poor fertilisation. The ongoing but gradual increase in ICSI, may be a result of the changing demographic presenting for ART treatment. Fresh or frozen sperm retrieved from the epididymis or testis was used in 142 of the ICSI treatment cycles.

Treatment of patients referred from the Public Fertility Clinic

During the year a number of patients from the King Edward Memorial Hospital (KEMH) Infertility Clinic were referred for treatment at the Concept Fertility Centre, which reported on the treatments and their outcomes. As can be seen from Table 5, 81 women were treated with fresh IVF transfer and 24 with frozen transfer. The results for this year indicate the number of public patients treated is similar to last year. During the year 130 fresh IVF and 97 FET treatment cycles were commenced. This year 40 of the IVF cycles involved micro-manipulation (ICSI). Of all the 227 cycles for public patients, only 1 cycle reported using donated gametes or embryos, in this case donor semen was used. In addition, there were 14 cycles reported as using assisted hatching. No cycles used extended culture or embryo diagnostic testing.

There were 120 artificial insemination (8 DI, 112 AIH) treatments between 1 July 2005 and 30 June 2006, for public patients.

Intra-uterine insemination (IUI)

The Council is continuing to monitor IUI carried out by licensees and exempt practitioners. A total of 1774 IUI cycles were reported by five Practice licensees and two Exempt practitioners. The overall ongoing clinical pregnancy rate per treatment cycle carried out was 7.7% (137 ongoing pregnancies), and of the pregnancies where plurality was known, 80 were singleton (92.0%), 6 were twin (6.9%), one was a triplet (1.1%).

The information provided showed that 82.0% of the IUIs used the partner's sperm and 18.0% used donor sperm. Of all cycles carried out, the majority (58.3%) did not involve the use of ovulation induction. Clomid was used in only 5.6% of the cycles, and gonadotrophins were used in 36.1% of the cycles.

The set of triplets reported followed gonadotrophin stimulation using husbands/partner sperm (AIH). Of the six sets of twins reported, one followed a natural cycle, one followed a clomid cycle and the other four sets resulted from ovulation induction by gonadotrophins. All sets of twins were a result of AIH.

Serious morbidity and mortality in women undergoing treatment

Overall the five clinics reported a total of 32 cases of severe ovarian hyper-stimulation relating to 2278 IVF and GIFT stimulation cycles (1.4% stimulation cycles, with a clinic range of 0.7–2.7%). The average number of follicles above 12cm for women who were affected by severe ovarian hyperstimulation was 17.1 (with a median of 16).

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

Counselling

There were 1090 counselling sessions provided by the licensed clinics during 2005/06, according to the annual reporting forms, compared to 1109 sessions in the previous year. This represents a 1.7% decrease for this financial year. Just over eighty per cent (80.55%) of participants who had counselling only had one session of

counselling. Of those over ninety one percent (91.3%) had information counselling, while the remaining participants (8.7%) accessed support or therapeutic counselling. Of those 228 accessing more than one session of counselling, the majority (51.8%) were seeking information counselling, while a significant proportion (43.4%) were seeking counselling for support, 2.6% were seeking counselling in relation to a matter associated with infertility and 2.2% sought counselling for other personal matters not related to infertility. From the clinic reports it appears that the majority of participants who are undertaking ART treatment are only accessing one session of information counselling, and a small number of participants are accessing multiple counselling sessions for support and therapeutic counselling.

Counselling concerning issues of donation for donors or recipients, (which is mandatory under the Reproductive Technology Accreditation Committee Code of Practice) made up thirty-six per cent (36%) of all counselling, which represents a 1.2% increase from that recorded in the previous year. For one IVF clinic, almost 68% of all counselling offered for the year was related to issues of donation. The majority of the counselling took place on site at the clinics. Only one clinic reported not charging participants a fee for counselling. All clinics reported the clinic counsellors conducting telephone counselling sessions during the year, while only 3 clinics provided telephone follow-up by the clinic counsellors for participants who had unsatisfactory treatment outcomes.

Approved research and innovative practices

Three clinics with approval to carry out assisted hatching provided data showing that this procedure had been used in a total of 311 fresh and 218 frozen embryo cycles. The use of the procedure ranged from being used in 8.5% to 29.0% of all cycles (fresh and frozen) with transfer. The overall pregnancy rate following assisted hatching was 23.5%, with quite a varied rate between clinics, ranging from 18.3% to 24.9%.

Data from the four clinics with approval to carry out blastocyst culture indicated the procedure was used in 646 fresh and 473 frozen embryo cycles. The use of the procedure between clinics varied greatly from 4.3% to 58.5% of cycles (fresh and frozen) commenced. The majority of the cycles (59.7%) were carried out in one clinic. A variety of factors, including patient selection, may explain this considerable range in use of blastocyst culture.

Current approved research and innovative practices.

Under the *Human Reproductive Technology Act 1991*, specific approval from the Reproductive Technology Council is required for clinics to carry out embryo diagnostic testing, research projects and innovative practices. Licensees report information on the progress of each of these approvals each year. Indicated below are projects with current approval.

Research Projects

R001 Use of granulosa cell co-culture in assisted reproduction procedures
PIVET Medical Centre
Approved 25/05/93
Not active in 2005/06

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

R016 Does ICSI increase the risk of major birth defects?
TVW Telethon Institute for Child Health Research
Approved 24/11/98
In abeyance

R019 Phase III, Multicentre open label randomised trial to assess the efficacy and convenience of orgalutron
PIVET Medical Centre
Approved 08/08/00
Initial data analysis of the study group was completed in 2003, however ongoing data is still being collected from frozen embryos generated in the study cycles.

R022 Pilot trial using *in vitro* maturation for women with PCOS
Hollywood Fertility Centre
Approved 13/07/2004
Study continuing

Innovative clinical/laboratory practices

I 001 Improvement of IVF in severely oligospermic patients using partial zona dissection (PZD) and subzonal spermatozoal injection (SUZI)
PIVET Medical Centre
Approved 20/05/93
Not active in 2005/06

I 002 Use of SAIZAN (Growth Hormone) in ovulation induction
PIVET Medical Centre
Approved 23/11/93
The 2005/06 report indicated use in 99 cycles for 69 women

I 008 Assisted Hatching
PIVET Medical Centre
Approved 13/11/00
Information reported in summary data above

I009 Assisted hatching
Concept Fertility Centre
Approved 06/02/01
Information reported in summary data above

I010 Blastocyst transfer
Concept Fertility Centre
Approved 20/03/01
Information reported in summary data above

I011 In vitro culture of human embryos to Blastocyst stage
Pivet Medical Centre
Approved 19 /06/01
Information reported in summary data above

I012 Assisted Hatching
Hollywood Fertility Centre
Approved 20/03/01
Information reported in summary data above

I013 Blastocyst Transfer
Hollywood Fertility Centre
Approved 23/09/03
Information reported in summary data above

I014 ART treatment for couples where the male is HIV positive
Concept Fertility Centre
Approved 08/06/04
In abeyance

1015 Extended culture and blastocyst transfer
Fertility North
Approved 29/10/2004
Information reported in summary data above

Diagnostic Testing of Embryos

Listed below are approvals for embryo diagnostic testing approved in the 2005/06 financial year only.

PGD 003/2005-01 PGS (Aneuploidy)
PIVET Medical Centre
Approved 12/07/2005

PGD 014/2005-01 PGS (Aneuploidy)
Hollywood Fertility Centre
Approved 12/07/2005

PGD 001/2005-03 (Balanced Translocation**)**
Concept Fertility Centre
Approved 12/07/2005

PGD 001/2005-04 (Myotonic Dystrophy)
Concept Fertility Centre
Approved 12/07/2005

PGD 001/2005-05 (Balanced Translocation)
Concept Fertility Centre
Approved 12/07/2005

PGD 001/2005-06 (Duchenne's Muscular Dystrophy)
Concept Fertility Centre
Approved 20/09/2005

PGD 001/2005-07 (Spinal Muscular Atrophy)
Concept Fertility Centre
Approved 01/11/2005

PGD 001/2005-08 (Fragile X)
Concept Fertility Centre
Approved 13/12/2005

PGD 001/2006-01 (Huntington's Disease)
Concept Fertility Centre
Approved 14/03/2006

PGD 001/2006-02 (Reciprocal Translocation)
Concept Fertility Centre
Approved 14/03/2006

PGD 001/2006-03 (Charcot-Marie-Tooth Neuropathy 1)
Concept Fertility Centre
Approved 16/05/2006

PGD 001/2006-04 (Haemophilia)
Concept Fertility Centre
Approved 20/06/2006

PGD 014/2005-02 (Fragile X)
Hollywood Fertility Centre
Approved 16/08/2005

PGD 014/2005-03 (Fragile X)
Hollywood Fertility Centre
Approved 16/08/2005

PGD 014/2005-04 (Balanced Translocation)
Hollywood Fertility Centre
Approved 20/09/2005

PGD 014/2005-05 (Kallman Syndrome**)**
Hollywood Fertility Centre
Approved 14/03/2006

PGD 014/2005-06 (Balanced Translocation)
Hollywood Fertility Centre
Application withdrawn 23/11/2005

PGD 014/2005-07 (Balanced Translocation)
Hollywood Fertility Centre
Approved 13/01/2006

PGD 014/2005-08 (Aneuploidy of Non-viable embryos)
Hollywood Fertility Centre
Approved 13/01/2006

PGD 014/2006-01 (Balanced Translocation)
Hollywood Fertility Centre
Approved 14/03/2006

PGD 014/2006-02 (Robertsonian Translocation)
Hollywood Fertility Centre
Approved 14/03/2006

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

Licensees reported no new changes to routine practice of licenses at the time of annual report submission. However, throughout the year the licenses reported a number of routine changes, predominantly to patient information sheets and consent forms.

Complaints

A total of 28 formal complaints were reported by clinics for issues including accounting, clinical management and communication of information.

Figure 1: Semen Donors in WA

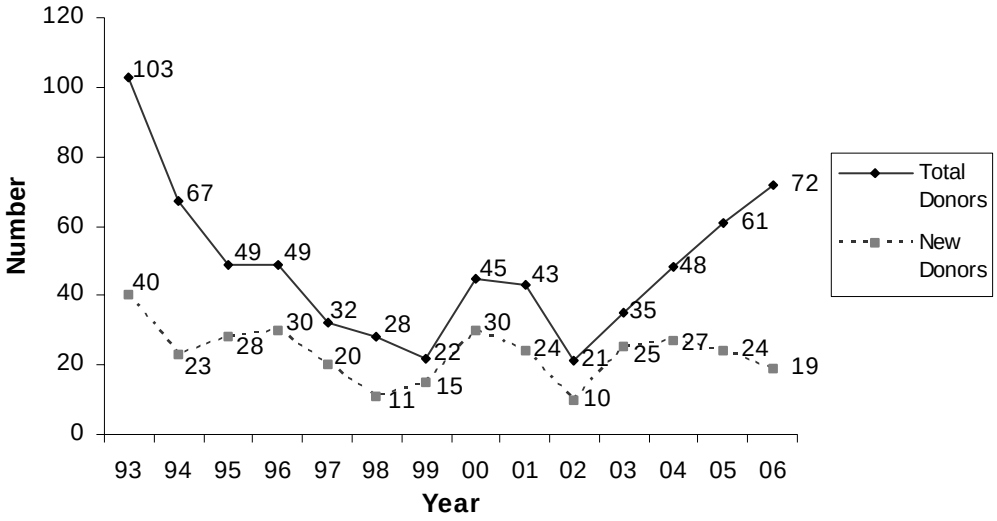

Figure 2: Ages of Semen Donors

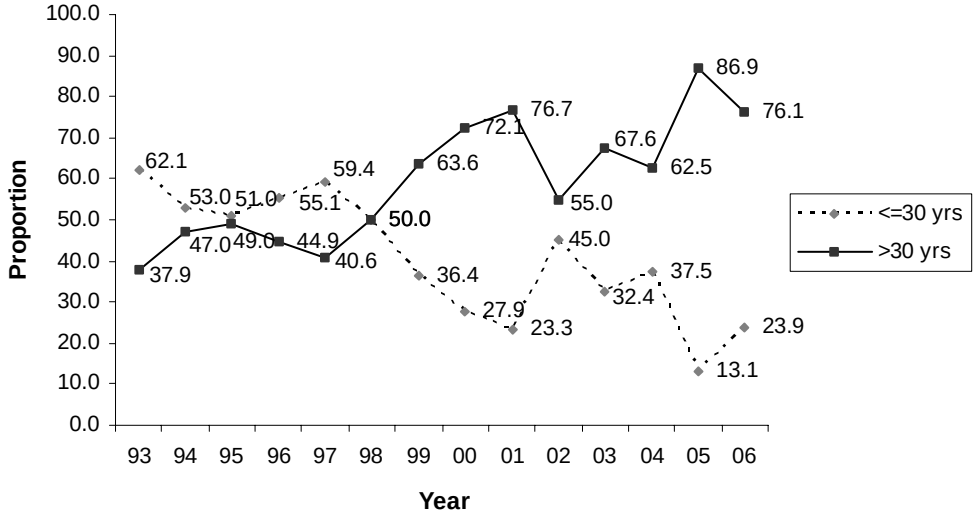

TABLE 1: 2004/05 SEMEN DONOR AGES

Age of Donor (years)	Number (%)
18-25	6 (8.5)
26-30	11 (15.5)
31-35	13 (18.3)
36-40	14 (19.7)
41-49	23 (32.4)
50 +	4 (5.6)
Total	**71* (100)**

* The age of one donor was unknown

Figure 3: Trends in Embryo Storage

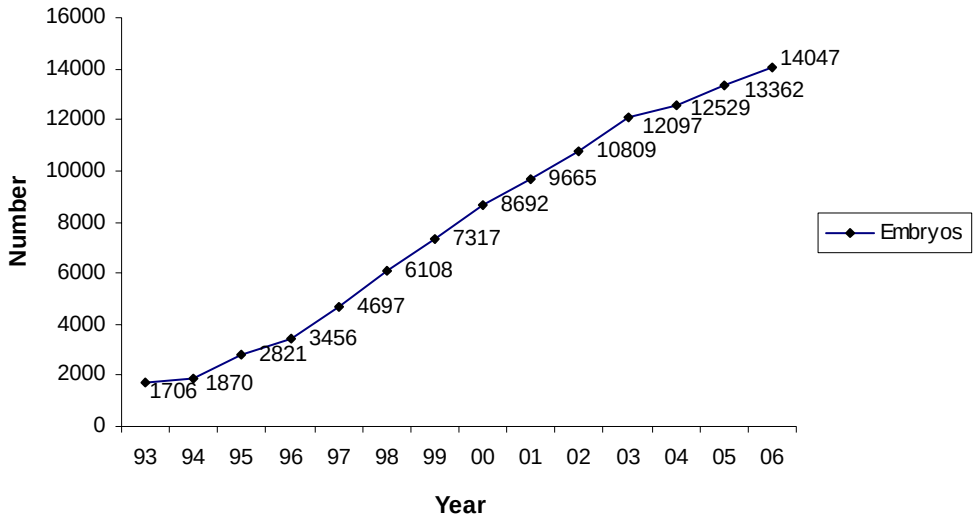

TABLE 2: DISPERSAL OF STORED EMBRYOS 2004/2005

	No of embryos
Embryos in storage 30/06/05	**13362**
Embryos created from IVF	4881
Transferred into WA clinics from interstate	116
Transferred between clinics in WA	94
Transferred to clinics outside WA (Patients moving interstate/overseas)	109
Used in frozen embryo transfer treatments	3623
Allowed to succumb with consent of couples	580
Embryos in storage 30/06/06	**14047**

Figure 4: ART Treatment Trends

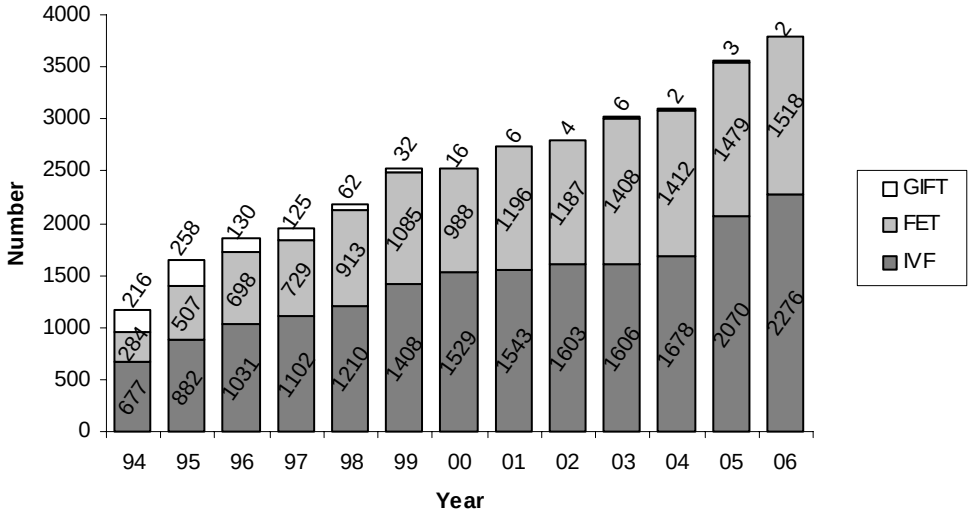

Figure 5: IVF (fresh) and GIFT Treatments

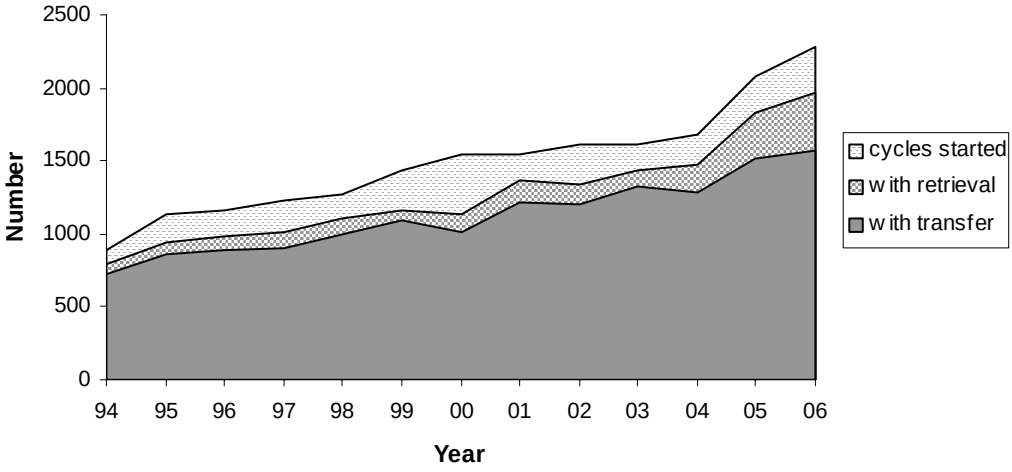

Figure 6: IVF cycles using ICSI

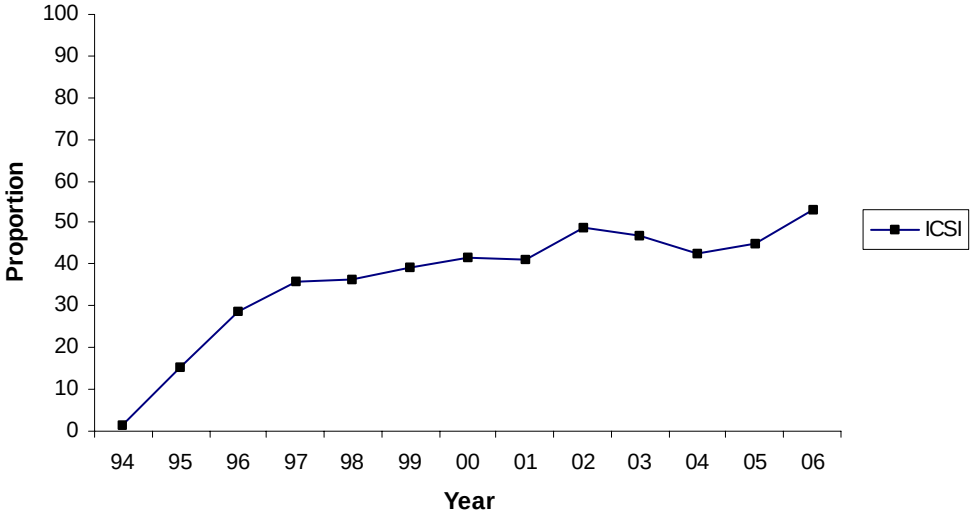

TABLE 3: 2004/05 IVF and GIFT TREATMENTS

	IVF (fresh)	IVF (frozen)	GIFT	TOTAL
Women treated	1420	762	1	-
Cycles begun	2276	1518	2	3796
Cycles with egg retrieval	1960	-	2	1962
Cycles with gamete or embryo transfer	1570	1232	2	2804
Cycles with embryos storage	963	-	0	963
Number of cycles using donor:				
Semen	75	63	0	138
Eggs	24	78	0	102
Embryos	5	32	-	37
Total	104	173	0	277
Number of cycles from which human reproductive material was donated:				
Eggs donated	43	-	0	43
Embryos donated	5	-	-	5
Breakdown of treatment cycle details				
Cycles with IVF/GIFT same cycle	0	-	0	0
Cycles with surgical sperm aspiration	142	-	0	142
Cycles with ICSI*	1044	-	-	1044
Cycle with Fallopian embryo/egg transfer	2	0	2	4

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

TABLE 4: IVF AND RELATED TREATMENT OF PUBLIC PATIENTS

	No. of Patients					No. of Treatment Cycles				
	01/02	02/03	03/04	04/05	05/06	01/02	02/03	03/04	04/05	05/06
IVF	77	50	65	77	81	114	71	82	111	130
GIFT	0	0	0	0	0	0	0	0	0	0
FET	64	39	27	30	24	142	127	104	115	97
TOTAL	**141**	**89**	**92**	**107**	**105**	**256**	**198**	**186**	**226**	**227**

APPENDIX 4

REPORT FROM THE REPRODUCTIVE TECHNOLOGY REGISTER

REPORT FROM THE REPRODUCTIVE TECHNOLOGY REGISTER

Registers of assisted reproductive technology treatments were established under the *Human Reproductive Technology Act 1991* (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 has been collected since 8 April 1993. Recently, data reporting to the Reproductive Technology (RT) Register has been reviewed and as a result a new data structure and system of reporting implemented. Therefore, all reported data since the 2003 calendar year has been provided in a different format, with some alterations to the fields collected. The new data structure for treatment data, which outlines the fields currently being collected, is located in the next section.

The RT Register will be publishing the summary review of assisted reproductive technology data from the register over the ten years, from 8 April 1992 until 31 December 2003. This report will also include detailed information on 2003 and 2004 calendar year data, with the addition of new information not previously collected. This report will be available through the Department of Health and on the Reproductive Technology Council website at www.rtc.org.au.

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 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.	Char-8
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 TO LICENSEES

Reproductive Technology Council

Dear Licensee

Minimum Standards for ICSI Use

An additional indication for use of ICSI as a routine procedure has been brought to the Reproductive Technology Council's (Council) attention. Evidence has been provided that in cases where there are low numbers of oocytes available for attempted fertilisation the proportion of failed fertilisations was lower after ICSI than standard IVF.

Council has agreed to extend the Minimum Standards for ICSI Use to include cases where there is an expectation that only one or two oocytes will be available for attempted fertilisation. This includes cases where participants choose to have single or dual oocyte collection.

A copy of the amended **Minimum Standards for ICSI Use** has been attached for your reference. The amendment may be found at Item 2.6.

Yours sincerely

CA Michael AO
CHAIR

Reproductive Technology Council

23 February 2006

Att

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

January 2006

1. BACKGROUND

ICSI has been shown to be effective for male factor infertility and it also brings advantages in relation to PGD procedures and in the avoidance of transmission of infectious diseases.

To date studies reporting long term follow up of children conceived by ART are few and the available evidence concerning difference in outcomes between those conceived by IVF compared to ICSI are conflicting. In deciding to continue to limit the routine application of ICSI in IVF, the Council notes that the following concerns remain with the use of both ICSI and IVF:

1.1 Plural births present the greatest risk of mortality and morbidity following both IVF and ICSI (Devroey and Van Steirteghem, 2004).

1.2 ICSI and IVF infants are more likely to be born preterm and of low birthweight compared to spontaneously conceived infants (Bonduelle et al, 2004; Schieve et al, 2002).

1.3 An increased risk of birth defects following ART treatment has been previously suggested but remained controversial (Hansen et al, 2002). The Council has noted that a recently published systematic review supports the existence of an increased risk of birth defects. The review examined 25 studies from around the world that compared birth defects in IVF and/or ICSI infants to spontaneously conceived infants (Hansen et al, 2005). Two thirds of the studies reviewed showed a 25% or greater risk of birth defects in IVF or ICSI babies. Meta-analysis of the study results suggested a statistically significant 30-40% increased risk of birth defects associated with assisted reproductive technology. Unfortunately there are limited data examining the risk of birth defects in ICSI infants separately. A sub-group analysis of the 5 studies with ICSI data revealed a 30% increased risk of birth defects in ICSI compared to spontaneously conceived infants. However, this sub-group analysis included only 4000 ICSI births, 85% of which were contributed by a single study.

1.4 The European multi-centre cohort study of ICSI infants (published since the meta-analysis was performed) found that ICSI infants were 2.54 (95% CI 1.13-5.71) times more likely to be diagnosed with a major malformation by 5 years of age than spontaneously conceived infants after adjusting for maternal age, educational level, social class, maternal smoking and drinking and number of previous pregnancies. ICSI boys in particular had an excess risk of uro-genital malformations. These may be attributable to paternal genetic factors rather than the ICSI procedure itself (Bonduelle et al, 2005).

1.5 There is evidence for an increased risk of imprinting disorders in ICSI and IVF children, although these disorders remain extremely rare (Cox et al, 2002; De Baun et al, 2003; Halliday et al, 2004).

1.6 Assessment of a number of ICSI and IVF cohorts at 5 years of age have shown that these children experienced greater morbidity in the first 5 years and had significantly more surgical interventions compared to spontaneously conceived children. Hearing, vision and growth were similar for both groups (Bonduelle et al, 2004; Bonduelle et al 2005).

There is potential for ICSI to lead to the inheritance of conditions associated with male infertility (eg mutations in the cystic fibrosis gene and micro deletions on the Y chromosome) that in turn affect fertility of male offspring. Prenatal testing has provided evidence of a significant increase in *de novo* sex and autosomal chromosome aberrations after ICSI, which is related to low sperm counts (Devroey and Van Steirteghem, 2004). Although ICSI is allowed in the treatment of male infertility appropriate investigations into the cause of the infertility and counselling about the risk of infertility in male offspring are recommended.

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

REFERENCES:

Bonduelle et al, 2004 Medical follow-up study of 5-year-old ICSI children. RBM Online 9(1):91-101.

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Cox et al, 2002 Intracytoplasmic sperm injection may increase the risk of imprinting defects. Am J Hum Genet 71, 162-164.

DeBaun et al, 2003 Association of in vitro fertilization with Beckwith-Weidemann syndrome and epigenetic alterations of LIT1 and H19. Am J Hum Genet 72, 150-160.

Devroey and Van Steirteghem, 2004 A review of ten years experience of ICSI. Human Reproduction Update 10(1): 19-28.

Halliday et al, 2004 Beckwith-Wiedemann syndrome and IVF: a case-control study. Am J Hum Genet. 2004 Sep; 75(3): 526-8.

Hansen et al, 2002 The risk of major birth defects after intracytoplasmic sperm injection and in vitro fertilization. The New England Journal of Medicine 346(10): 725-730.

Hansen et al, 2005 Assisted reproductive technologies and the risk of birth defects – a systematic review. Human Reproduction 20(2): 328-338.

Schieve et al, 2002 Low and very low birth weight in infants conceived with use of assisted reproductive technology. The New England Journal of Medicine 346(10): 731-737.

2. CURRENTLY ACCEPTABLE MINIMUM STANDARDS FOR ICSI USE (INCLUDING THE USE OF RETRIEVED SPERM)

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

2.2 The HRT Act has been clarified to allow the use of IVF to avoid the transmission of a genetic abnormality or a disease (including infectious diseases) and ICSI may be used under these circumstances. However other aspects of the procedures will require approval from the Council as innovative practices.

2.3 The use of ICSI prior to pre-implantation genetic diagnosis is now permitted under these standards. The use of ICSI prior to polymerase chain reaction (PCR) is strongly recommended and it is an acceptable alternative to conventional insemination for fluorescence in situ hybridisation (FISH) cases.

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

- Very low numbers of motile sperm with normal appearance
- Unexplained azoospermia; azoospermia due to ejaculatory disorders (eg retrograde ejaculation, aspermia); or acquired testicular failure (eg mumps, orchitis, radiotherapy or chemotherapy)
- Absence of sperm secondary to blockage or abnormality of the ejaculatory ducts
- Frozen sperm collected prior to cancer treatment that may be limited in number and quality
- A history of polypronuclear oocytes

2.5 ICSI may also be used in cases where there the following have been documented-

- Problems with sperm binding to and penetrating the egg
- Antisperm antibodies of sufficient quantity and /or quality to prevent fertilisation
- Prior repeated low fertilisation rate or fertilisation failure with standard IVF culture and fertilisation methods.

2.6 ICSI may be used in cases where there is an expectation that only one or two oocytes will be available for attempted fertilisation. This includes cases where participants choose to have single or dual oocyte collection.

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

2.8 Use of immature sperm
It is currently a condition of all Practice Licences that any surgically retrieved sperm from the epididymis or testis used in ICSI by a WA clinic is independently motile, released from the seminiferous epithelium by spontaneous spermiation, with normal head morphology (regular oval shape lying within the parameters 3-5 microns long and 2-3 microns wide).

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

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

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

3. MINIMUM STANDARDS FOR REQUIRED SCREENING PRIOR TO ICSI

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

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

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

4. MINIMUM STANDARDS FOR FOLLOW-UP OF ICSI USE BY LICENSEES

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

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

4.3 In accordance with Direction 2.6 of the Human Reproductive Technology Act (1991) licensed clinics are required to report each ART cycle to the Commissioner of Health, including whether ICSI was used in the cycle.

5. PROTOCOLS REGARDING ICSI TO BE SET OUT IN A PROTOCOL MANUAL

5.1 Where ICSI is to be carried out in the permitted circumstances, Licensees need to ensure that the procedures to be followed are set out in the detailed manual for which Council approval is obtained (Directions 9.2 and 9.3).

5.2 Documentation is to be provided to the Council (on request) showing that the procedure to be adopted:

- complies with relevant professional standards, such as of the NHMRC and RTAC
- has not been rejected by a relevant HREC
- is used in other reputable, nationally or internationally recognised clinics
- is reported in international peer-reviewed literature, indicating safe and successful outcome, based on good research
- is expected to be, or is currently, successful in the local clinic (eg. details of results or relevant staff training undertaken)
- is considered a necessary element of the routine practice in the clinic.

Reproductive Technology Council

NOTICE TO LICENSEES

TO: **LICENSEES UNDER THE *HUMAN REPRODUCTIVE TECHNOLOGY ACT 1991* (the HRT Act)**

FROM: **Professor Con Michael AO**
Chair
Reproductive Technology Council

DATE: **24 February 2006**

RE: **COOLING OFF PERIOD FOR COUNSELLING IN CASES OF KNOWN OOCYTE DONATION**

Background
At it's meeting on 13 December 2005, the Reproductive Technology Council (Council) considered the recommendation of the Counselling Committee to reduce the cooling off period for counselling for cases of known oocyte donation to a minimum of three months.

This recommendation was based on consultation with consumers and clinic counsellors. It is becoming evident that with the revised and more rigorous requirements of the RTAC Code of Practice fewer women are able to undertake fresh embryo transfer. Therefore for those women requiring known egg donors they may have to wait up to 12 months before being able to progress their treatment due to the 6 month cooling off period for counselling (Part 2, Schedule 4 to the HRT Act) (see **attachment 1**) and the RTAC requirement for a 180 day quarantine period for screening purposes. Whereas in the case of known sperm donation, the cooling off period for counselling can occur concurrently with the RTAC requirement of the 180 day quarantine period. Council understands this wait may be of concern to some patients, particularly as there is also an increasing trend of advanced maternal age.

Recommendation
Council has agreed with the Committee's recommendation that the cooling off period for counselling in cases of known oocyte donation be reduced to a minimum of three (3) months to be applied in addition to the RTAC requirement for a 180 days quarantine period in relation to a fertilised oocyte (RTAC Code of Practice – 9.9 (see attachment 2).

Please note that this variation to Part 2, Schedule 4 of the Directions under the HRT Act applies only to known egg donation and NOT known sperm donation.

Professor Con Michael AO, Chair Reproductive Technology Council

HUMAN REPRODUCTIVE TECHNOLOGY ACT 1991

DIRECTIONS

Given by the Commissioner of Health to set the standards of practice under the *Human Reproductive Technology Act 1991* on the advice of the WA Reproductive Technology Council

SCHEDULE 4

PART 2 - PSYCHO-SOCIAL PREPARATION FOR PARTICIPANTS PRIOR TO KNOWN DONATION

The following counselling/psycho-social preparation is required to be provided prior to any artificial fertilisation procedure where a donor is known to the recipients, in accordance with the requirements in Direction 5.8.

- Counselling must be provided by an approved counsellor;
- Counselling should preferably be provided before the medical assessment of the participants;
- Information that has been approved by the Council in accordance with the Directions should be provided to each participant;
- Initial counselling should include a minimum of three hours counselling in three individual sessions during which the recipient (and spouse or de-facto spouse, if any) and donor (and spouse or de-facto spouse, if any) should be seen separately and then together;
- A six month cooling off period should be allowed following the completion of initial counselling before the donated material is used in an artificial fertilisation procedure;
- At the end of the cooling of period each participant should have further contact with the approved counselor to ensure her/his continued willingness to proceed;
- An exit interview with an approved counselor must be provided for participants who are not proceeding with the program;
- All counseling should be face to face unless this is very difficult to arrange. If face to face counselling cannot be arranged the approved counsellor may conduct the counselling by phone or video-link;
- Counselling of a person who is not resident in WA may be provided by an interstate or overseas counsellor who is a member of the Australian and New Zealand Infertility Counsellors Association (ANZICA) (or equivalent);
- The costs of counselling would generally be borne by recipients.

Issued 20 NOVEMBER 2004

CODE OF PRACTICE FOR ASSISTED REPRODUCTIVE TECHNOLOGY UNITS
Fertility Society Of Australia
Reproductive Technology Accreditation Committee
(revised February 2005)

Testing of donors and samples

9.9 Donor screening tests

It is recommended that mandatory screening tests for donor suitability be carried out at a NATA/IANZ-accredited laboratory. Mandatory tests are the minimum tests required for the release for supply of gametes/embryos, and are determined by the TGA in consultation with industry. The following mandatory tests may be changed or extended as required and determined by the TGA:

- human immunodeficiency virus (HIV) types 1 and 2
- hepatitis C virus
- hepatitis B virus
- human T-cell lymphotropic virus type 1
- syphilis
- microbiological contamination testing.

There must be a documented procedure for the taking of laboratory samples for medical screening of donors. Blood and semen samples for laboratory testing of donors must be taken within an appropriate time of the first donation. Documented procedures must detail the laboratory screening tests required, and the rationale for inclusion, before gametes/embryos can be released for supply.

Documentation should include the acceptance and rejection criteria for individual screening tests. The documented procedure must include the requirement that sperm supplied by a donor is able to be cryostored for 180 days. At the end of this quarantine period, the donor is required to be retested for HIV, hepatitis B and hepatitis C. Where any of these tests is confirmed as positive, the sperm is to be discarded unless specific consent for use by the recipient has been obtained.

In the case of donated oocytes, RTAC recommends that the documented procedure should allow for the oocytes to be fertilised and the embryos cryostored for 180 days. At the end of this quarantine period, the donor is required to be retested for HIV, hepatitis B and hepatitis C. Where any of these tests is confirmed as positive, the embryos are to be discarded unless specific consent for use by the recipient has been obtained.

Oocyte donation with embryo formation followed by fresh embryo transfer may be considered appropriate by an ART unit. The documented procedure must include a risk assessment for infectious disease transmission (particularly HIV). The documentation must include the requirement that recipients are to be informed before signing the consent form of the risks of using fresh embryo transfer (even when the donor is known to them). Where screening protocols change during the life of the gametes/embryos in storage, the donor is required to be retested with the new screening test protocol.

Where the gamete/embryo specifications require mandatory tests additional to those noted above before release for supply, records must demonstrate that the gametes/embryos have met the requirements for these additional tests. Permanent records of screening test results must be retained.

Reproductive Technology Council

NOTICE TO LICENSEES

TO: **LICENSEES UNDER THE *HUMAN REPRODUCTIVE TECHNOLOGY ACT 1991* (the HRT Act)**

FROM: **Professor Con Michael AO**
Chair
Reproductive Technology Council

DATE: **8 May 2006**

RE: **OOCYTE CRYOPRESERVATION**

Background

The Reproductive Technology Council (Council) gave consideration to this matter at its meeting on 11 April 2006 following advice received concerning this matter.

Collection and Storage of Oocytes

Legal advice received indicates that the collection and storage of mature oocytes through oocyte cryopreservation, is considered a storage procedure under the *Human Reproductive Technology Act 1991* (the HRT Act*).* Therefore, it is subject to the general provisions under the HRT Act and Directions, such as consents and information giving as well as the specific requirements of gamete storage in Part 6 of the Directions. The eligibility criteria under Section 23 of the HRT Act are **not** applicable to storage procedures.

Oocyte Cryopreservation as an Innovative Procedure

At its meeting, Council also determined that the oocyte cryopreservation procedure meets the criteria for an innovative procedure given the associated technology is relatively new and patients would need to be appropriately informed of the risks and benefits. In accordance with Direction 4.1 information to be provided prior to effective consent must be in a written form approved by Council and Direction 3.7, requires that the licensee must ensure that participant(s) give a separate consent to each innovative procedure, diagnostic procedure or research that is subject to approval of Council.

Licensees of ART clinics will therefore require specific approval from Council for this innovative procedure firstly to carry out this procedure and secondly at the time of intended use of the stored oocytes. This is in accordance with Section 20 of the HRT Act and Section 9 of the Directions.

Future Use

In terms of the potential future uses of these cryopreserved oocytes, in cases where the oocytes are used for ART treatment, at the time of the IVF procedure, participants will need to meet the eligibility criteria for IVF treatment (under Section 23 of the HRT Act). For other potential uses of cryopreserved oocytes, such as nuclear transfer, it is recommended that licensees consult with Council prior to intended use to identify whether the specific use is subject to any legislative requirements at that time. For example, currently nuclear transfer (to create a clone) is **not** permitted under the Commonwealth *Prohibition of Human Cloning Act 2002*.

Requirements

Licensees of ART clinics will require specific approval from Council:

- firstly to carry out this procedure and
- secondly at the time of intended use of the stored oocytes.

Licensees must also submit to Council the relevant proposal, ethics approval, consent forms and patient information for Council approval.

Professor Con Michael AO, Chair Reproductive Technology Council

Reproductive Technology Council

NOTICE TO LICENSEES

TO: **LICENSEES UNDER THE HUMAN *REPRODUCTIVE TECHNOLOGY ACT 1991* (the HRT Act)**

FROM: **Professor Con Michael AO**
Chair
Reproductive Technology Council

DATE: **Effective from 16 May 2006**

RE: **COOLING OFF PERIOD FOR PSYCHO SOCIAL PREPARATION IN CASES OF KNOWN EMBRYO DONATION**

Background

At its meeting on 16 May 2006, the Reproductive Technology Council (Council) considered the "cooling off" period for psycho-social/counselling preparation in cases of known embryo donation. In reaching its decision Council took into account legal advice and the discussion held at its meeting of 13 December 2005 where the Counselling Committee recommended the reduction of the cooling off period for cases of known oocyte donation to a minimum of three months.

Members recognised that in embryo donation people may be more attached to their embryos (than in gamete donation), especially if they have had children from the same set of embryos. However, it was acknowledged that in the decision-making concerning the future of stored embryos participants often deliberated for a longer period of time about their options and the consequences of each option before deciding to donate. Additionally, it was noted that recipients seeking donated embryos tended to be older and that it was preferable for them to undergo the treatment as soon as possible.

Therefore the Council agreed that for those participants deciding to undergo IVF treatment with known donor embryos they are required to have a minimum of three (3) months cooling off period following the psycho-social preparation/counselling before proceeding with treatment. The RTAC requirement for the 180 day quarantine period for screening purposes still applies. However, Council accepted that in the majority of cases of embryo donation the quarantine period would have been met, as generally embryos would have been in storage for over 6 months.

Recommendation

Council has agreed that the cooling off period for psycho-social preparation/counselling in cases of known embryo donation (Part 2, Schedule 4 to the HRT Act) (see attachment 1) be reduced to a minimum of three (3) months. This will be in addition to the RTAC requirement for a 180 days quarantine period for screening purposes. (RTAC Code of Practice – 9.9) (see attachment 2).

Con. Michael

Professor Con Michael AO, Chair Reproductive Technology Council

HUMAN REPRODUCTIVE TECHNOLOGY ACT 1991

DIRECTIONS

Given by the Commissioner of Health to set the standards of practice under the *Human Reproductive Technology Act 1991* on the advice of the WA Reproductive Technology Council

SCHEDULE 4

PART 2 - PSYCHO-SOCIAL PREPARATION FOR PARTICIPANTS PRIOR TO KNOWN DONATION

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- Counselling must be provided by an approved counsellor;
- Counselling should preferably be provided before the medical assessment of the participants;
- Information that has been approved by the Council in accordance with the Directions should be provided to each participant;
- Initial counselling should include a minimum of three hours counselling in three individual sessions during which the recipient (and spouse or de-facto spouse, if any) and donor (and spouse or de-facto spouse, if any) should be seen separately and then together;
- A six month cooling off period should be allowed following the completion of initial counselling before the donated material is used in an artificial fertilisation procedure;
- At the end of the cooling of period each participant should have further contact with the approved counselor to ensure her/his continued willingness to proceed;
- An exit interview with an approved counselor must be provided for participants who are not proceeding with the program;
- All counseling should be face to face unless this is very difficult to arrange. If face to face counselling cannot be arranged the approved counsellor may conduct the counselling by phone or video-link;
- Counselling of a person who is not resident in WA may be provided by an interstate or overseas counsellor who is a member of the Australian and New Zealand Infertility Counsellors Association (ANZICA) (or equivalent);
- The costs of counselling would generally be borne by recipients.

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Testing of donors and samples

9.9 Donor screening tests

It is recommended that mandatory screening tests for donor suitability be carried out at a NATA/IANZ-accredited laboratory. Mandatory tests are the minimum tests required for the release for supply of gametes/embryos, and are determined by the TGA in consultation with industry. The following mandatory tests may be changed or extended as required and determined by the TGA:

- human immunodeficiency virus (HIV) types 1 and 2
- hepatitis C virus
- hepatitis B virus
- human T-cell lymphotropic virus type 1
- syphilis
- microbiological contamination testing.

There must be a documented procedure for the taking of laboratory samples for medical screening of donors. Blood and semen samples for laboratory testing of donors must be taken within an appropriate time of the first donation. Documented procedures must detail the laboratory screening tests required, and the rationale for inclusion, before gametes/embryos can be released for supply.

Documentation should include the acceptance and rejection criteria for individual screening tests. The documented procedure must include the requirement that sperm supplied by a donor is able to be cryostored for 180 days. At the end of this quarantine period, the donor is required to be retested for HIV, hepatitis B and hepatitis C. Where any of these tests is confirmed as positive, the sperm is to be discarded unless specific consent for use by the recipient has been obtained.

In the case of donated oocytes, RTAC recommends that the documented procedure should allow for the oocytes to be fertilised and the embryos cryostored for 180 days. At the end of this quarantine period, the donor is required to be retested for HIV, hepatitis B and hepatitis C. Where any of these tests is confirmed as positive, the embryos are to be discarded unless specific consent for use by the recipient has been obtained.

Oocyte donation with embryo formation followed by fresh embryo transfer may be considered appropriate by an ART unit. The documented procedure must include a risk assessment for infectious disease transmission (particularly HIV). The documentation must include the requirement that recipients are to be informed before signing the consent form of the risks of using fresh embryo transfer (even when the donor is known to them). Where screening protocols change during the life of the gametes/embryos in storage, the donor is required to be retested with the new screening test protocol.

Where the gamete/embryo specifications require mandatory tests additional to those noted above before release for supply, records must demonstrate that the gametes/embryos have met the requirements for these additional tests. Permanent records of screening test results must be retained.

Reproductive Technology Council

NOTICE TO LICENSEES

TO: **Licensees under the *Human Reproductive Technology Act 1991* (HRT Act)**

FROM: **Professor Con Michael AO**
Chair, Productive Technology Council

RE: **Direction 7.7- IVF treatment to avoid the transmission of an infectious disease**

Background

The Reproductive Technology Council (Council) gave consideration to the process for approvals of applications under Direction 7.7 at its meeting on 16 May 2006. Direction 7.7 states: *The licensee must ensure that an IVF procedure directed at reducing the risk of transmission of an infectious disease, such as HIV or hepatitis, is not undertaken without the prior approval of the Council*.

Recommendation

The Council determined that the requirement for application would vary depending on the mode of transmission of a disease.

Viruses not transmitted through reproductive bodily fluids

For viruses not typically transmitted through sexual intercourse, eg Hepatitis C, if clinics standard protocols for infection control are adequate general approval is granted to treat these patients with IVF and therefore an application under Direction 7.7 is not required.

Viruses transmitted through reproductive bodily fluids

For viruses transmitted through sexual intercourse, including Hepatitis B and HIV, an application under Direction 7.7 is required. Based on consideration of this application Council will determine whether general approval or specific approval (as an Innovative Practice) is required. This applies regardless of whether the IVF procedure is being used to reduce the risk of transmission of the infectious disease or not.

As part of the application the following information should be supplied:

- Risks of transmission of the infectious disease to the embryo
- Protocol on infection control to be used
- Patient information and consent forms applicable to the case

Clinics who have already been granted specific approval as an Innovative Procedure to undertake treatment of patients at risk of transmitting a specific infectious disease are not required to re-apply.

Con. Michael

Professor Con Michael AO, Chair Reproductive Technology Council

APPENDIX 6

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

FUNCTIONS OF THE COUNCIL

The general functions of the Reproductive Technology Council are covered in section 14 of *the Human Reproductive Technology Act 1991*, and in effect set its Terms of Reference. Amendment of the Act in 2004 for excess ART embryos to be donated for research the Council to grant approval for diagnostic procedures upon a human embryo where the embryo is intended for use in the treatment a woman and that the Council is satisfied on the basis of existing scientific and medical knowledge that the diagnostic procedure is unlikely to leave the embryo unfit for implantation and where the diagnostic procedure is for the genetic testing of an embryo, there is a significant risk of serious genetic abnormality or disease being present in the embryo.

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:

"**5(6).** A report on the use of human reproductive technology in the State during the preceding financial year shall be furnished annually by the Council to the Commissioner who shall thereafter submit the annual report required by clause 11 of the Schedule to the Minister who shall, within 14 sitting days after submission of that report, cause copies of it to be laid before each House of Parliament";

and from the Schedule-

"**Annual Report on Reproductive Technology**

11. (1) The report to be furnished by the Council to the Commissioner of Health on the use of reproductive technology in the State and the operations of the Council in the preceding year ending 30 June shall be so furnished by such a date as, in the opinion of the Commissioner, will enable the Commissioner to submit an annual report to the Minister not later than 30 September in each year.

(2) The report to be furnished by the Council to the Commissioner, and the annual report to be submitted to the Minister, under subclause (1)-

(a) shall set out-

(i) any significant developments in the use of, or in the procedures or techniques used in, reproductive technology during the year, whether in the State or elsewhere;

(ii) details of research specifically approved by, or being conducted with the prior approval of, the Council during that year;

(iii) in statistical terms, the activities of persons licensed under this Act and carried on during that year; and

(iv) any discernible social trends that became apparent during that year and are, or may be, attributable to the use of reproductive technology;

(b) shall contain particulars of-

(i) any contravention of this Act, or of any terms, condition or direction relating to a licence or exemption; and

(ii) any other matter within the responsibilities of the Council or the Commissioner,

that is, in the opinion of the Council or of the Commissioner, of significance to the public interest;

and

c) shall, if that is practicable, be combined with any annual report that may be required to be submitted in relation to this Act under the *Financial Administration and Audit Act 1985."*

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