



Reproductive Technology Council

Mr Michael Pervan
A/Commissioner of Health
Department of Health
1 Alvan Street
SUBIACO WA 6008

Dear Mr Pervan

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 2004-2005. 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 area of assisted reproductive technology (ART) this year has been dominated by the implementation of amendments to the HRT Act, which came into operation on 1 December 2004, bringing this State into line with the nationally consistent legislative scheme regulating human embryo research and prohibiting human cloning and unacceptable practices.

The amendments have also brought in some other important changes to the law relevant to many IVF participants, such as extending the time embryos may be stored from 3 to 10 years. Council has been kept busy developing policy and processes for the approval of genetic testing of embryos previously prohibited in WA. This led to the granting of the first approval for some procedures to go ahead in this state.

Other significant amendments implemented on the advice of Council have included the counselling requirements addressing the best interests of the child where parents who have used donated human reproductive material to form their families may consent on behalf of their minor children to the sharing of identifying information about the donor and recipients where both parties request this. Council has also been developing a framework for the counselling provisions preparing donor conceived persons to have access to identifying information once they reach 16 years of age.

During the year Council has also been working with clinics and legal services to clarify the understanding of the requirements of Section 23 of the HRT Act, addressing eligibility issues for IVF, which culminated in a public seminar being held in November 2004.

The work of the Council is not possible without the ongoing support of a significant number of people. Among these I would like to thank Dr Sandy Webb for her ongoing

expert guidance to the Council particularly in relation to the approval processes for embryo diagnostic testing and Ms Deborah Andrews for her continuing legal support and guidance. I would also like to acknowledge the ongoing financial and administrative support by the Department of Health, which are vital to enable the Council to carry out its statutory duties.

Yours sincerely

A handwritten signature in black ink, appearing to read "Prof. Michael". The script is cursive and fluid.

**Professor Con Michael AO
CHAIR
Reproductive Technology Council
26 September 2005**

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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 2004-2005, 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 2004-2005. Information reported by clinics licensed under the HRT Act, gives summary information about their activities during the financial year 2004 – 2005. 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 significantly impacted by the proclamation of the amendments to the HRT Act, which were introduced into the Western Australian Parliament on 26 June 2003. The *Human Reproductive Technology Amendment Act 2004* and the *Acts Amendment (Prohibition of Human Cloning and Other Practices) Act 2004* were proclaimed on 1 December 2004.

These amendments have brought the WA legislation into consistency with a nationally agreed legislative scheme that prohibits human cloning and other unacceptable practices (such as creating an embryo simply for research) and regulation of the use of human embryos in research. A significant implication for licensed ART clinics of the amendments to the HRT Act is that accreditation by the Reproductive Technology Accreditation Committee (RTAC) is now a legal requirement as a condition of licence.

An important change to the law for IVF participants is extending the time embryos may be stored from 3 to 10 years. Council can no longer consider applications for extension after the expiry of the storage period and clinics can no longer apply for an extension on behalf of participants. The responsibility for people with embryos in storage is to keep the clinic informed of any change of their contact details and keep track of the expiry date.

Council has been kept busy developing policy and processes for the approval of genetic testing of embryos previously prohibited in WA. This has led to the granting of the first approval for some procedures to go ahead in this state. Approval has been sought for genetic material to be exported for testing in genetics laboratories that are already operating effectively in other states. Where the embryo is to be implanted, Council approval is to be based on scientific and medical knowledge that indicates the procedure is 'unlikely to leave the embryo unfit for implantation' and there is 'a significant risk of a serious genetic abnormality or disease being present in the embryo'. Importantly these procedures can only be considered for people who are eligible for IVF under the HRT Act, that is they are unable to conceive a child for medical reasons (ie they are infertile), or their child is known to be likely to be

affected by a genetic abnormality or disease. The Council cannot approve the use of Preimplantation Genetic Diagnosis (PGD) for sex selection unless it is in association with a serious sex-linked genetic disease.

Other significant amendments implemented on the advice of Council have included the counselling requirements addressing the best interests of the child where parents who have used donated human reproductive material to form their families may consent on behalf of their minor children to the sharing of identifying information about the donor and recipients where both parties request this. Council has also been developing a framework for the counselling provisions preparing donor conceived persons to have access to identifying information once they reach 16 years of age.

The amended HRT Act now also allows approval for the use of IVF in the treatment of those whose offspring may be affected not just by a genetic disease, but also an infectious disease (such as HIV).

Section 23 of the HRT Act continued to be a focus for Council due to the difficulties confronting the clinics in assessing eligibility for IVF treatment and culminated in a very successful seminar being held in November 2004. This has contributed to assisting Council in providing guidance to clinics in their decision-making on participants' eligibility for access to IVF treatment. As a follow up to the seminar, Council and the Department of Health's Legal and Legislative services met with clinics to offer further guidance with Section 23 and the recent amendments to the HRT Act.

In its public education role the Council in collaboration with the Murdoch University participated in a public seminar on Rights of Access to Assisted Reproductive Technology (ART) – ART Law Across Jurisdictions Seminar where 300 people attended. Council has also collaborated with the clinics, KEMH Genetic Services WA, KEMH Cytogenetics Unit, the Department of Health and Genesis Support Group to plan for a Diagnostic Testing of Embryos PGD/PGS (Implementation) Seminar scheduled for August 2005 following the amendments to the HRT Act. This seminar will primarily be aimed at clinic staff and approved counsellors under the HRT Act.

The 2004/05 budget allocation for the Reproductive Technology Unit, which includes funding for all operations of the Council, was \$38,000. 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 2005

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);

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);

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);

Professor Alan Harvey, (Nominee of the Minister for Health);

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);

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*)

<p style="text-align: center;">COMMITTEES OF THE COUNCIL TERMS OF REFERENCE AND MEMBERSHIP 30 June 2005</p>
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<p style="text-align: center;">COUNSELLING COMMITTEE</p>

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); A/Professor Jim Cummins; Dr Roger Hart; Fr Joseph Parkinson; Dr Beverly Petterson; and Dr Sandra Webb (*ex officio*); 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); Ms Sue Midford; Ms Leonie Forrest; and Dr Sandra Webb (*ex officio*); Ms Antonia Clissa (*ex officio*); Ms Amalia Burmas (*ex officio*)

LICENSING AND ADMINISTRATION ADVISORY COMMITTEE
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Terms of Reference:

1. Advise the Reproductive Technology Council (Council) on matters relating to licensing under the *Human Reproductive Technology Act 1991* (HRT Act), including the suitability of any applicant and the conditions that should be imposed on any licence.
2. Advise the Council generally as to the administration and enforcement of the HRT Act, particularly disciplinary matters.
3. Advise the Council as to suitable standards to be set under the HRT Act, including clinical standards.
4. Advise the Council on any other matters relating to licensing, administration and enforcement of the HRT Act.

Membership:

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

PGD (IMPLEMENTATION) TECHNICAL ADVISORY COMMITTEE
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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; Dr Ian Walpole (until March 2005); Dr Sharron Townshend (from May 2005); Dr Steve Junk; Ms Sonja Lundie-Jenkins; Ms Daphne Andersen; and Dr Sandra Webb (*ex officio*); Ms Antonia Clissa (*ex officio*)

STAFF OF THE REPRODUCTIVE TECHNOLOGY UNIT
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Dr Sandra Webb; Senior Policy Officer (Reproductive Technology)

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

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

Ms Joy Foyle; Administrative Officer (0.25FTE)

Mrs Christine Sainty; Research Officer (Reproductive Technology) contract position from September 2004 to January 2005 while Ms Burmas was on secondment to the Department of Indigenous Affairs

Ms Gwyneth Gladstones; Research Officer (Reproductive Technology) contract position from April 2005 while Ms Burmas was on three months leave

REPRODUCTIVE TECHNOLOGY COUNCIL 2004/2005 FINANCIAL STATEMENT
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The Department of Health funds the administration of the HRT Act, including the operations of Council, which incorporates Infrastructure and Workforce Development. The 2004/05 budget allocation was \$38,000 with expenditure of \$37,393.00 for the financial year.

Income generated through the payment of application fees for licences or activities of Council 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	3,383.93	
Travel interstate Airfares Accommodation	4,781.19	
Motor vehicle/Taxis	407.14	
TOTAL	8,572.26	
Food supplies/catering	2,135.79	
Administration and clerical	960.00	
TOTAL	3,075.79	
Purchase of external services:		
Sessional fees: (External Consulting Fees) Reproductive Technology Council Council Committees: Counselling Scientific Advisory Embryo Storage Licensing and Administration Approved counsellors	21,655.00	
External consulting fees and advertising	137.50	
TOTAL	21,792.50	
Other expenses:		
Books/magazines/subscriptions	293.33	
Freight/ cartage/postal	32.06	
Printing and stationery incl. Annual Report	3,547.86	
Telecommunication expenses	80.00	
Total	3,953.25	
Less credits registrations	Nil	
TOTAL	37,393.80	
BUDGET ALLOCATION	38,000.00	

OPERATIONS OF THE COUNCIL 1 JULY 2004 TO 30 JUNE 2005
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MEETINGS, MEMBERSHIP AND STAFFING

Meetings

The Reproductive Technology Council met on nine occasions during the year, with an average attendance of 98 per cent. The Counselling Committee met on five occasions as well as three with clinic counsellors; the PGD (Implementation) Technical Advisory Committee met on eight occasions; the Scientific Advisory Committee on three occasions and the Embryo Storage Committee on three occasions.

Membership

In November 2004 Ms Leonie Forrest was appointed as the member representing the WA Law Society following the resignation of Professor Jeannette Hackett who had served on Council since November 1995. Dr Stephen Junk was appointed as deputy member representing the UWA Department of Obstetrics and Gynaecology in November 2004. Mr Hans-willem van Hall was appointed deputy member, nominee of the Minister for Community Development in April 2005 following the resignation of Mr Peter Grey Searle who had served on Council since October 2000.

Staff assisting the work of the Council

There were two short-term changes to the staff assisting the work of the Council throughout the year. The Research Officer, Ms Amalia Burmas, continued to oversee the Reproductive Technology (RT) Register and liaise with the clinics and in her role as the Deputy Executive Officer, Ms Burmas continued to provide a pivotal role to the Council and the Reproductive Technology (RT) Unit. However, Ms Burmas undertook a four-month secondment to the Department of Indigenous Affairs from September 2004 to January 2005 while continuing to work for one day per week in the RT Unit. During this time Mrs Christine Sainty was employed four days per week to carry out the research officer role. In May 2005, Ms Burmas took three months leave to travel overseas and Ms Gwyneth Gladstones undertook the Research Officer role on a full time basis. 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. This has included liaison with the Reproductive Technology Accreditation Committee (RTAC) in preparation for their accreditation visits to licensed Western Australian assisted reproductive technology clinics in 2005.

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

Dr Sandra Webb has continued to work with the Council to provide expert scientific advice and serve on the Council's Scientific Advisory and Licensing Committees. Dr Webb has also served as executive officer for the PGD (Implementation) Technical Advisory Committee.

In this financial year Council has also contracted the services of a library technician, Mr Rex Waddell to catalogue the Council's unique library collection.

The Council gratefully acknowledges-

Management support from Ms Merran Smith and Mr Tony Satti, the secretarial support from Ms Denise Jesnoewski and Ms 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 Ms 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 were not due to expire until 1 March 2006, therefore Council was not required to assess any applications for renewal this financial year. Additionally, there were no new licence applications received.

Two medical practitioners requested revocation of their Exemptions from the requirement to be licensed to carry out artificial insemination (Dr MC Hamdorf and Dr LG Green). During the year there were no new applications for Exemptions.

Information circulated to Licensees

Licensees received information concerning: the proclamation of the amendments to the *Human Reproductive Technology Act 1991* (HRT Act) concerning implementation of changes to the law relating to disclosure of identifying information in cases of donation of human reproductive material; embryo storage approval procedures; use of IVF to avoid transmission of infectious diseases such as HIV and the interface between uses of embryos that are still to be overseen by the Council and uses of embryos that are to be overseen by the NHMRC Licensing Committee (See Appendix 5); Approval For Diagnostic Testing Of Embryos and Updated Minimum Standards For ICSI Use, Screening, Patient Information And Follow-Up In WA Fertility Clinics.

Protocols, Patient Information and Consent Forms

Licensees were requested to put in place revised protocols and patient information to comply with the amendments to the HRT Act. These included revision of consent forms, patient information and development of protocols in relation to embryo storage approval procedures; disclosure of identifying information in cases of donation of human reproductive material; use of IVF to avoid transmission of infectious diseases such as HIV; and uses of embryos that are to be overseen by the Council and uses that are to be overseen by the National Health and Medical Research Council (NHMRC) Licensing Committee.

Complaints

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

EMBRYO STORAGE APPLICATIONS

During the year the Council granted extensions in response to 274 applications. Of these applications, 72 were made by the participants for whom the embryos were stored and 202 were made by clinics on behalf of participants with whom they could not make contact. Of all applications received, 128 extensions (46.7%) were repeat extensions for a set of embryos that had previously been granted an extension.

All 274 applications were received prior to the proclamation of amendments to the HRT Act on 1 December 2004. The amendments changed the initial storage period of embryos from 3 to 10 years from the time they were first stored. As a result Council received no applications that required extension after 1 December 2004. However, as it is known that there are a number of embryos in storage approaching the ten year limit Council anticipates that there will still be a demand for further extensions of the storage limit, although not at rates seen in recent years. Council will consider if it needs to alter the current application process in light of these amendments.

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 considering using the embryos in the future for their own treatment (90.8%). In 3.1 per cent of cases the applicants were planning to or in the process of donating embryos to another eligible couple. Additionally, 3.1% of cases indicated they intended to donate their embryos for research should this option became available. In one case the couple were undecided and applied for an extension to allow them more time to consider available options.

Extension applications made by clinics, on behalf of the people for whom the embryos were being extended, were usually made in cases where the clinic had lost contact with the participants (81.2%). In 4.0 per cent of cases clinics applied for extensions on behalf of participants who had consented to the donation of their embryos or were in the process of consenting for donation to another persons ART treatment.

Although in 14.8 per cent of applications the clinic had been able to contact the participants, extension to storage application forms were not returned. Consequently the clinic applied for extensions to storage on behalf of these participants. In the majority of these cases (80%) the participants were seeking an extension to the storage period of their embryos to use them in their own treatment. In the remaining cases the participants informed the clinic they were undecided (13.3%), wanted to donate the embryos to research (3.3%) or wanted them discarded (3.3%).

It was necessary to convene three meetings of the Embryo Storage Committee during the year. All three were urgent meetings for embryo sets whose storage was due to expire prior to the next Council meeting.

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

Specific Approval of Innovative Procedures

During the year the Council considered and approved one application for specific approval of innovative procedures.

I015 Blastocyst Culture

Fertility North

Approved 29/10/2004

Specific Approval of Research Procedures

In 2004-2005 there were three applications received by Council for specific approval of research procedures and one of these did not require specific approval. The other two research projects were granted approval by Council.

R022 Pilot Trial using In vitro Maturation (IVM) for Women with polycystic ovarian disease (PCOS).

Hollywood Fertility Centre

Approved 13/07/2004

R023 The Treatment of Ovarian Hyperstimulation Syndrome (OHSS) using an aromatase inhibitor and a GnRH antagonist

PIVET Medical Centre

Approved 13/01/2005

Specific Approval for Diagnostic Testing of Embryos

Following amendments to the legislation in December 2004 to allow diagnostic testing of embryos there was one application from a licensed ART clinic to undertake Preimplantation Genetic Screening (PGS) for aneuploidy, which was approved by the Council. The Council also approved an application for Preimplantation Genetic Diagnosis (PGD) for a specific condition (sex selection to avoid partial androgen sensitivity syndrome) in this financial year.

PGD 001/2005-01 – PGS (Aneuploidy)

Concept Fertility Centre

Approved 15 /03/2005

PGD 001/2005-02 – PGD for a specific condition (sex selection to avoid partial androgen sensitivity syndrome)

Concept Fertility Centre

Approved 24/05/2005

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.

RELEVANT PRESENTATIONS AND PUBLICATIONS BY COUNCIL MEMBERS AND STAFF

Council members

Associate Professor Jim Cummins

Invited plenary speaker

'State of the A.R.T. 2005. The Communicating Oocyte'

Think Tank Meeting for Clinicians and Scientists. Satellite Meeting to ESHRE 2005, Copenhagen 19-22 June 2005.

Convenor

'Rights of Access to Reproductive Technology' Public Seminar, Murdoch University, 27 May 2005. Speakers: Ms Antonia Clissa, Reproductive Technology Council; Dr Roger Hart, Reproductive Technology Council; Ms Stephanie Knox, Reproductive Technology Council; Fr Joe Parkinson, Reproductive Technology Council; Mr Richard Egan, National Civic Council. This was a component of the first year undergraduate course, *'Introduction to the Human Body'*.

Dr Roger Hart

Publications

McGurgan P, Maouris P, Hart R, Hammond I, Pavey T, Lowe B. Case Report: En caul delivery of the fetus to facilitate cell salvage. *Australian and New Zealand Journal of Obstetrics and Gynaecology*. 2004; **44**(6): 585-6.

Cutner A, Saridogan E, Hart R, Pandya P, Creighton S. Laparoscopic management of pregnancies occurring in non-communicating accessory uterine horns. *Eur J Obstet Gynecol Reprod Biol* 2004; 113(1): 106-9.

Hart R, Hickey M, Maouris P, Buckett W, Garry R. Excisional surgery versus ablation surgery for the management of ovarian endometriomata. In: *The Cochrane Library*, Issue 3, 2005 Chichester: Wiley.

Hart R, Hickey M, Maouris P, Buckett W, Garry R. Excisional surgery versus ablation surgery for the management of ovarian endometriomata. *Hum Reprod* (In Press) 2005.

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

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

Presentations

'The removal of endometriosis has no place in the management of infertility-A debate' Australian Gynaecological Endoscopy Society Conference, Perth 2005

'A histochemical study into the origins of endometriosis' Australian Gynaecological Endoscopy Society Conference, Perth 2005

'Predictive Value Of The Symptom Of Dyschezia For Rectovaginal Disease In Women Undergoing Surgery For Endometriosis' AGES Conference, Perth 2005

'Impact Of Radical Surgical Treatment Of Severe Endometriosis On Quality Of Life' Cathy Burke, Phillipe Dabourn, Krishnan Karthigasu, Raymond Garry, Roger Hart AGES Conference, Perth 2005.

'Vascular Endothelial Growth Factor (Vegf) And Angiogenin As Markers For Bone Marrow-Derived Endometrial Repair' Cathy Burke, Yourados Tesfai, Deborah Sloboda, Raymond Garry, Roger Hart, Martha Hickey. AGES Conference, Perth 2005.

'A Controlled Study Of The Effect Of Small Intramural Uterine Fibroids On The Outcome Of Assisted Conception' Yacoub Khalaf, Clare Ross, Tarek EL-Toukey, Roger Hart, Paul Seed, Peter Braude. ESHRE, Copenhagen, 2005.

Rev Dr Joseph Parkinson STL PhD

Lectures

'IVF and ART: No Frankensteins Here!' St Gertrude's College, New Norcia, Young Adult Convention, 8 October 2004

Issues in Bioethics (1), Catholic Pastoral Centre Lecture Hall, Diaconate Training Program, 26 February 2005

'What is happening in reproductive technology?' St Brigid's Centre, West Perth, Senior Religious Study Group, 16 March 2005

Issues in Bioethics (2), Catholic Pastoral Centre Lecture Hall, Diaconate Training Program, 2 April 2005

'Pastoral Issues in Reproductive Technology', St Brigid's Centre, West Perth, Senior Religious Study Group, 18 May 2005

Presentations

'Eligibility for IVF', Reproductive Technology Council's IVF Eligibility Issues Seminar, 16 November 2004

'Ethical Aspects of ART', Catholic Education Office, Leederville, Secondary Teacher In-Service Program, 4-5 November 2004

Dr Beverly Petterson

Presentation

'Exploring contemporary questions in genetics, genetic screening and therapeutic cloning' Seminar, Como Uniting Church, 18 June 2005

Staff

Dr Sandra Webb

Lectures

'Changes to the Law about Human Reproductive Technology In WA', Department of Anatomy and Human Biology, University of Western Australia, October 2004

'The Law and embryo diagnostic procedures in WA: What it says and why' Genetic Support Council of WA, 20 April 2005

Presentations

'Preimplantation genetic testing of embryos: What is it and is it preferable to pre-natal diagnosis?' Population Health Conference, Department of Health, November 2004

'Eligibility under the Human Reproductive Technology Act: Balancing rights and interests', Reproductive Technology Council Symposium on IVF Eligibility Issues, 16 November 2004

'Monitoring the Numbers of Embryos Created and Stored: In the context of the new national legislative scheme regulating human embryo research in Australia', Fertility Society of Australia Annual Scientific Meeting, September 2004

Ms Amalia Burmas

Presentations

'The Western Australian Reproductive Technology Register: Report from a Mature Data Collection', 21st Annual Conference of the European Society of Human Reproduction and Embryology (ESHRE) Copenhagen, Denmark, June 2005

'Human Assisted Reproductive Technology (ART) and the Law in WA' Murdoch University, 24 May 2005

Ms Antonia Clissa

Presentations

'Ethical Dilemmas in Assisted Reproductive Technology (ART)' Curtin University, 24 September 2004

'Human Assisted Reproductive Technology (ART) and the Law in WA' Murdoch University, 24 May 2005

'Rights of Access to Assisted Reproductive Technology (ART) – ART Law Across Australian Jurisdictions' Murdoch University, 27 May 2005

Attendance at relevant meetings by Council members with Council support

The Council sponsored the attendance of the Executive Officer and two Council members to attend the Fertility Society of Australia meeting held on 10-13 October 2004 in Adelaide and the attendance of the Executive Officer and one Council member to the Victorian Infertility Treatment Authority seminar "*Reprogenetics, Who Rules?*" Seminar on 27 October 2004. The Executive Officer was also sponsored to attend the *Access to ART Treatment Programmes* Seminar conducted by ANZICA held on 20 May 2005.

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

Seminars

IVF Eligibility Issues Seminar

This seminar was conducted on 16 November 2004 on IVF eligibility issues as part of Reproductive Technology Council's (Council) Working Group to clarify Section 23 of the *Human Reproductive Technology Act 1991* (HRT Act). The issue of eligibility has always been the subject of widespread and intense debate. There has been public discussion of these controversial issues from the time the Ethics Committee that was established by the Government to advise on reproductive technology in 1984, to the first public seminar held by the then Interim Reproductive Technology Council in 1990 to the present day. This seminar has contributed to the process of assisting Council to provide guidance for licensed clinics in assessing eligibility of people seeking treatment as well as taking into consideration the welfare and interests of participants and children to be born. A range of speakers addressed the seminar in relation to the application of Section 23 of the HRT Act. Council invited the medical director from each of the licensed ART clinics that carry out IVF to address the impact of this section of the HRT Act on their delivery of services. The following medical practitioners gave presentations: Dr John Yovich, PIVET Medical Centre, Dr Vince Chapple, Fertility North, Dr George O'Neil, Concept Fertility Centre and Dr Simon Turner, Hollywood Fertility Centre. There were 2 keynote speakers Ms Sandra Dill, ACCESS Australia Infertility Network who outlined the consumer interests and Dr John Wray, Head of Department, Community and Developmental Paediatrics, Women's & Children's Health Service, Department of Health who addressed the interests of the child. Fr Joe Parkinson, Council member and Director of LJ Goody Bioethics Centre outlined the ethical considerations in matters of IVF eligibility; Ms Colleen Brown outlined the local consumer perspective with a particular focus on same sex women; Ms Deborah Andrews, the Department of Health's Legal services clarified the intention of Section 23 of the HRT Act especially in relation to infertility due to age while Dr Sandy Webb gave a historical background of the legislation and its development. The chair for the seminar was to be Dr Maria Harries, Senior Lecturer, UWA School of Social Work and Social Policy. However, as she was taken ill, at short notice Ms Linda Savage Davis, deputy Council member and nominee of the WA Law Society kindly stepped in as chair.

Highlights

Consumer Perspective

Ms Sandra Dill drew attention to the fact that most people take for granted their ability to have a child. While for the 13 to 24 per cent of couples that would like to have a child but are not able to, it can be a very painful experience and one difficult to manage. Her view is that infertile people need medical and social choices to help them deal with infertility and noted that IVF and related treatments has provided another way for people to overcome infertility and childlessness. Ms Dill outlined that governments have argued that the costs of providing affordable access to infertility treatment are too high but she wanted it noted that the financial costs are less significant than the real costs of infertility. To support this view Ms Dill referred to findings by both the Royal College of Obstetricians and Gynaecologists and the British Infertility Counselling Association, based on papers by infertility specialists

and interviews with medical, scientific and psychological experts, that infertility costs the nation in absenteeism, poor productivity and wasted resources.

Interests of the Child

Dr Wray proposed that all prospective parents should have counselling and preparation for parenthood focussing on the best interests of their children while parents using ART should receive specific counselling about the special conditions for ART conceived children. He also drew attention to the fact that some donor conceived children yearn for their biological parent(s), half-siblings, that some donors yearn for their biological child and that somewhere the social parents and the donor's family get tangled. He also urged that it was essential to follow-up the "outcomes of pregnancy", in controlled studies.

Medical Practitioners' Perspective

Several medical directors raised the complexity for them in applying the legislation especially in relation to demand from older women wanting to access IVF treatment. The legislation states that the woman must not be infertile due to age, which has been interpreted to mean menopause occurring within the normal age range. They also highlighted the difficulties of applying the requirements of Section 23 (e) to take into consideration the welfare and interests of participants and any future children to be born from the procedure when there were no clearly stated guidelines. Dr Turner gave a very passionate view of the difficulties he faced with women seeking IVF treatment who also had many other complicating health issues, which increased the risks, associated with infertility treatment. He also stated that 30% of women who presented for fertility treatment were over 40 years age and proposed that women should be encouraged to start their families earlier by introducing government incentives and workplace support. Dr Turner was clearly of the opinion that the role of the clinician should include encouraging women to abandon treatment or discouraging them from entering treatment where the risks to health were very high.

Rights of Access to Assisted Reproductive Technology (ART) – ART Law Across Jurisdictions Seminar

This public seminar was held at Murdoch University in May 2005. Council members made up 3 out of the 4 speakers who presented to some 300 people and another Council member Dr Roger Hart chaired the seminar. The seminar included the consumer perspective, ethical issues, and the differences in legislation across Australia as well as the views of the presenter, representing the National Civic Council, the Australian Family Association and the Coalition for the Defence of Human Life. The seminar provided a forum for vigorous debate from the audience. The consumer's presentation was interactive and invited audience members to participate in a way that was more personal and emotional as a means of conveying the rollercoaster ride undertaken by those undergoing IVF treatment. The areas of contention that generated animated discussion included the issue of our society's responsibility with ART for the future ecology of the nation; that Intro Cytoplasmic Sperm Injection (ICSI) avoids a natural selection process and evidence that the genetic disability rate following ICSI is significantly higher than natural reproduction and higher than through standard IVF; that embryo screening is akin to infanticide and that social indicator studies support that children do better with a mother and a father.

Presentation at 21st ESHRE Conference Copenhagen

In June 2005, Ms Amalia Burmas, the Deputy Executive Officer, gave a poster presentation on the Western Australian Reproductive Technology Register: Report from a mature Data Collection at the 21st European Society of Human Reproduction and Embryology Conference in Copenhagen. It outlined the strengths and uniqueness of the Western Australian (WA) Reproductive Technology Register (RT Register) which is one of the most comprehensive and longest-term databases on ART procedures in the world. Its strengths include that it was established in the WA Department of Health, under the *Human Reproductive Technology Act 1991* (HRT Act), and contains data on all assisted reproductive technology (ART) procedures carried out by five ART clinics in the WA since 1993. Data collected by the RT Register includes individual treatment records on all IVF and donor insemination procedures, and identifying information on participants. Non-identifying information on donors is collected for the interests of recipients or donor conceived persons. The register allows monitoring and evaluation of ART practices, guides decision-making by policy makers and regulators, provides information to participants and donors on their treatment and facilitates long-term follow-up of participants and children. Finally WA's position of geographical isolation and history of strong support for epidemiological research has provided a valuable opportunity to conduct research through linkage to a number of other data collections.

RTC Website

The Council website has been updated throughout the year to include the amended Directions, the new policy and processes for diagnostic testing of embryos as well as information for clinics concerning the new amendments and an updated notice for Minimum Standards for ICSI use. 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 60 email inquiries generated through the website on matters relating to legislation and its amendments, eligibility for IVF, importation and exportation of human reproductive material, requests for copies of publications for research purposes, requests from other national and international jurisdictions such as Victoria, South Australia, ACT, Japan, Hong Kong and the US for information concerning how the HRT Act addresses certain matters. There have been 4,334 visits to the website, in the last financial year and of these 885 have visited more than once. The most popular documents (after the home page) identified on the site with over 2600 visits in total were the Frequently Asked Questions (FAQ's) document, the links page, the consumer page and the glossary page. The most downloaded files were the annual reports followed by the publication "Questions and Answers about the donation of human reproductive material". Throughout the year the highest activity months were April, May and June 2005 with over 1,000 visits each month and the quietest month was December 2004 with just over 500 visits.

RTAC's Revised Code of Practice

The Fertility Society of Australia's Reproductive Technology Accreditation Committee (RTAC) revised its Code of Practice guidelines in 2004 and was implemented in February 2005 for all ART Clinics in Australia. As Western Australian (WA) ART units are due for RTAC accreditation in August 2005 a special seminar was conducted on 17 June 2005 by RTAC for WA clinics in consultation with the Council to discuss the amended Code of Practice.

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 to maintain accreditation. Three (3) RTAC representatives, Dr Adrienne Pope, Dr Ossie Petrucco and Ms Sue Brown gave their presentation on the revised 2004 Code of Practice to IVF Directors and their staff. There were approximately 20 people present from the clinics as well as Council representation. Dr Pope discussed the levels of compliance, the list of compulsory actions, buildings and facilities; Ms Brown outlined the benefits and costs of a quality management systems, staff and training and Dr Petrucco discussed clinical training and competencies and risk management for OHSS and multiple pregnancy. The Code of Practice was developed to set and maintain minimum standards for clinics or centres offering ART, and to encourage continuous improvement in the quality of care offered to people accessing fertility treatment in Australia and New Zealand. The regulatory and legislative requirements of the NHMRC and Therapeutic Goods Act (TGA) were discussed as well as the Quality Management System (QMS) model of risk assessment with the emphasis having changed from prescriptive instructions to allowing ART units to determine how best to assess and manage risks. In terms of implementation of the Code of Practice 2004 (COP), accreditation using the COP 2004 will commence in 2005 with leniency during 2005. There will be no penalty if QMS is not fully introduced in 2005. However, ART clinics must provide evidence of impending introduction of QMS and in 2006 all units are required to comply.

OPERATIONS OF THE COUNSELLING COMMITTEE 1 JULY 2004 – 30 JUNE 2005

Meetings and membership

The Counselling Committee met on five (5) occasions during the year. A subgroup of the Committee also held three meetings with clinic counsellors to give consideration to the amendments to the HRT Act in order to make recommendations to Council concerning what constitutes “approved counselling” in relation to donor conceived persons who at 16 years of age may be able to access identifying donor information. Ms Suzanne Midford continued in her role as chair for the Committee. The rest of the membership remained constant and Mr Hans-willem van Hall (nominee of the Minister for Community Development) was appointed on 15 April 2005 to replace Mr Grey Searle who had taken 12 months leave from December 2003.

Key Focus Areas

The focus for the Committee has been on planning seminars and resource development for consumers.

The Committee has continued to:

- work on upgrading the RTC website as resource for participants
- plan for resource development in the form of a video for same sex parents who have used assisted reproduction for family formation
- develop information for participants concerning rights in accessing assisted reproductive technology services.
- work on conducting seminars on “IVF eligibility issues” and Diagnostic Testing of Embryos PGD/PGS Implementation Seminar especially for approved counsellors working in ART clinics
- work on the counselling guidelines for PGD
- work on counselling guidelines for offspring at age 16 and parents and donors who consent to share information

The Counsellor as an Integral Member of the Team

Early in 2004 the Counselling Committee was developing an issues paper following recommendations from the Council’s audit of counselling, clinic counsellors, and Genesis consumer support group that consideration be given to infertility counsellors becoming an integral part of the clinic team. As a result of the issues paper which included the rationale for the proposed changes as well as a literature review and consultation nationally and internationally, the Counselling Committee recommended to Council that changes to Directions be considered to support the clinic counsellor being a more integral member of the clinic team. After careful consideration the Council accepted these recommendations and advised the Commissioner of Health that this recommendation be included in the subsequent amendments to the Directions. This amendment was accepted and has been included in the Directions proclaimed on 1 December 2004 in Section 1.8 Availability of Approved Counsellors Employed by Licensed Clinics, Part 1 Approved Counsellors of Schedule 4–Counselling.

Counselling Guidelines for Diagnostic Testing of Embryos

These guidelines were developed in consultation with KEMH Genetics Services WA in accordance with Council policy and are being incorporated in the Manual for Approved Counsellors.

Approved Counsellors

Manual for Approved Counsellors

The manual was amended in the various sections such as embryo storage, diagnostic testing of embryos and access to identified donor information to reflect the amendments to the HRT Act, which were proclaimed on 1 December 2004.

Approved Counsellor Applications

The Committee received one new application during the year and two inquiries in relation to approved counsellor applications. All existing approved counsellors' terms were due for re-recognition on 30 June 2005. Letters were sent to 20 approved counsellors still on the list outlining requirements for re-recognition and 16 responded requesting a further term. Council agreed to continue to recognise the following approved counsellors for another three-year term until 30 June 2008. Sue Midford, Antonia Clissa, Patrice Wringe, Iolanda Rodino, Jill Bain, Jane Irvine, Deborah Foster Gaitskell, Rosemary Keenan, Kay Rosen, Kaye Miller, Margaret van Keppel, Helen Mountain, Elizabeth Webb, Lisa Hasard and Marion Connelly. Elyse Frankel was required to attend at least 2 Council endorsed events in the subsequent six months before Council would consider a further term of three years.

Other Counselling Committee Initiatives

Seminars

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 has agreed that a seminar be held for clinic staff and for approved counsellors in particular. The aim of the seminar will be to increase staff knowledge in the area of embryo diagnostic testing in order to be of greater assistance to potential participants. This seminar is scheduled for 10 August 2005.

REPRODUCTIVE TECHNOLOGY REGISTERS

Requests for information from the Reproductive Technology (RT) Register

A number of requests for data were made by the Department of Health in relation to the additional amendments to the HRT Act, relating to the release of identifying information on donors and donor offspring. These data extracts provided information on the number of donor offspring born in WA, for use in predicting future demand for access to identifying information.

Just prior to the lifting of the ban, in the *Research Involving Human Embryos Act 2002*, prohibiting the use of excess IVF embryos created after 5 April 2002 for embryo research, information was requested from the Australian Family Association. Specifically, information was sought on the number of embryos in storage in Western Australia and the number of those created prior to 5 April 2002.

Information was also sought from the RT Register by a Western Australian parliamentarian on the average number of IVF cycles each woman undertakes. This request was in response to the federal Government's announcement that it was considering altering Medicare funding for IVF treatment by restricting the number of subsidised cycles a woman could access per year.

The Reproductive Technology Council (Council), as part of its continuous monitoring of Ovarian Hyper-stimulation Syndrome (OHSS), accessed data from the RT Register looking at trends in OHSS rates. Council recognised the importance of examining OHSS especially as stimulation medications were becoming more effective.

Research involving RT Register data

During the year data was requested by Dr Liz Milne, from the Institute of Child Health Research, for a study she was conducting looking at childhood cancers. Dr Milne was investigating factors that may increase the risk of a child developing cancer and sought information from the RT Register to identify children who had been born through ART and the specifics of the treatments they had received.

Dr Webb, from the Department of Health, also sought summary data from the RT Register for a paper presented at the Fertility Society of Australia 2004 Annual Meeting. This research examined trends in the creation and use of embryos, specifically to provide information to regulators who were examining the effects of the national *Research Involving Human Embryos Act 2002* on embryo usage.

Voluntary Register of Information about Donation in Assisted Reproduction

There have been a total of 93 requests for applications to join the register since the Voluntary Register (VR) was launched in November 2002 to the end of June 2005. The VR has 51 registrants and 42 application forms not returned. The registrants have included 29 parents of donor-conceived offspring compared to 20 in the previous year, 19 donors compared to 15 in the previous year and 3 donor-conceived adults with no further registrations this year. Since November 2002, 25 parents of donor-conceived offspring, 15 donors and 2 donor-conceived adults have requested application forms to join the register, which have not been returned.

SIGNIFICANT DEVELOPMENTS IN ASSISTED REPRODUCTIVE TECHNOLOGY DURING THE YEAR

AMENDMENTS TO WA'S HUMAN REPRODUCTIVE TECHNOLOGY ACT 1991

Amendments to WA's *Human Reproductive Technology Act 1991* (HRT Act) were passed in State Parliament on 1 July 2004 and proclaimed on 1 December 2004. Significantly these amendments brought the WA legislation into consistency with a nationally agreed legislative scheme that prohibits human cloning and other unacceptable practices (such as creating an embryo simply for research) and regulates the use of human embryos in research.

Donating Embryos For Research

The donation of embryos for research provides another option for people who have responsibility to make decisions about the embryos (usually the couple for whom they were created) where these have been created for use in fertility treatment and are no longer required. Options now include requesting that the embryos be removed from storage and allowed to die; donating the embryos to another couple for treatment; or, as a consequence of the recent amendments, the embryos may now be donated for use in research or in the training of clinic staff etc.

The use of embryos in research is strictly regulated and requires a licence issued by the National Health and Medical Research Council's (NHMRC) Embryo Research Licensing Committee. The consent for the donation of embryos to research must be a two-step process. First the embryos must be declared to be 'excess ART embryos' and further consent to use the embryos must be quite separate and explicitly relate to a particular project. To be licensed, the research must use the minimum number of embryos required, have prior approval by a Human Research Ethics Committee, and be expected to contribute to a 'significant advance in knowledge or improvement in technologies for treatment'.

Changes Relating To Embryo Storage

The amendments now extend the time embryos may be stored from 3 to 10 years from the time they were first stored. This is of particular significance to many IVF participants. There has also been clarification concerning who may apply to the Reproductive Technology Council (Council) for an extension. The Council may grant an extension on a case by case basis, but there must be 'special reasons' for them to do so.

Applications cannot be considered after the expiry of the storage period and clinics are no longer able to apply for an extension. There is greater responsibility on people with embryos in storage to keep the clinic informed of any change in their contact details and to keep track of the expiry date. Licensed ART Clinics will attempt to contact people with stored embryos at least three months prior to the expiry date, to remind them of their responsibility and the consequences if no extension is obtained (that is, the embryos must be removed from storage and allowed to die if no further instructions are obtained from the people responsible for the embryos). In those cases where there has been a request made for an extension to the storage period, as a matter of protocol Council will notify the relevant licensee that an application has been received. Once Council has met to consider the application, the licensee will also be notified of Council's decision.

Diagnostic Testing of Embryos

The amendments, which now permit the Council to approve the genetic testing of embryos, previously prohibited in WA, led to the granting of the first approval for some procedures to go ahead in this state. The Council appointed the Preimplantation Genetic Diagnosis (PGD) (Implementation) Committee to advise the Council on a suitable framework for the approval of PGD under the HRT Act, both generally and for specific cases; the factors that it should consider when deciding whether to approve PGD; the standards for facilities, staffing and technical procedures and on the ongoing process of approval once the implementation phase is over. In consultation with the PGD Committee, the Council developed a policy and advice for clinics concerning the approval for the diagnostic testing of embryos.

Where the embryo is to be implanted, Council approval is to be based on scientific and medical knowledge that indicates the procedure is 'unlikely to leave the embryo unfit for implantation' and there is 'a significant risk of a serious genetic abnormality or disease being present in the embryo'. There is a distinction between pre-implantation genetic diagnosis (PGD), where pre-existing diagnosis indicates that an embryo is at a significant risk of being affected by a serious genetic condition, and pre-implantation genetic screening (PGS), carried out in categories of participants thought to be at higher than average risk of conceiving abnormal embryos (also known as aneuploidy screening). Each clinic must apply for approval to conduct aneuploidy screening, but this is not required on a case by case basis. Whereas for single gene defects and translocations the clinics must apply to Council for PGD for individual cases, based on support of a clinical geneticist (accredited by the Human Genetics Society of Australasia (HGSA)) who has assessed the risk and seriousness of the condition to be tested for and discussed relevant issues with the participants requesting the testing. There is not a specific list of conditions that are generally approved for PGD testing.

Importantly these procedures may only be considered for people who are eligible for IVF under the HRT Act, that is they are unable to conceive a child for medical reasons (ie they are infertile), or their child is known to be likely to be affected by a genetic abnormality or disease. The Council cannot approve the use of PGD for sex selection alone, unless it is in association with a serious sex-linked genetic disease.

Changes To The Criteria For Eligibility For IVF

Another change of great importance to some participants is that the amended HRT Act now allows approval for the use of IVF in the treatment of those whose offspring may be affected not just by a genetic disease, but an infectious disease (such as HIV).

RTAC Accreditation

A significant implication for licensed ART clinics of the amendments to the HRT Act is that accreditation by the Reproductive Technology Accreditation Committee (RTAC) is now a legal requirement as a condition of licence.

Disclosure Of Identifying Information In Cases Of Donation Of Human Reproductive Material

The law relating to disclosure of identifying information in cases of donation of human reproductive material has had two significant amendments. Firstly, donor-

conceived persons upon reaching the age of 16 may request identifying information about the donor following approved counselling. This was a recommendation made by the Select Committee report to the WA Parliament in 1999. Secondly, parents who have used donated human reproductive material to form their families may consent on behalf of their minor children for sharing of identifying information about the donor and recipients where both parties request this. This is to follow counselling to address, in particular, what may be in the best interests of the child. Council has been developing guidelines for Counselling in consultation with the Counselling Committee and approved counsellors employed by ART clinics.

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 is required to report to the Council of Australian Governments (COAG) and table reports in the Australian Parliament by 19 December 2005. The Committee is 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 has 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) would allow it to comment very broadly on the terms of reference of the Committee, however the Council will be limiting its submission to areas where it has practical experience of relevance.

SUMMARY REPORTS FROM RELEVANT CONFERENCES/SEMINARS ATTENDED BY COUNCIL MEMBERS

Annual Scientific Meeting Of The Fertility of Society of Australia – Adelaide, 10-13 October 2004.

Council Member: Professor Jim Cummins

I thank the RTC for their sponsorship of my travel and conference expenses. The following summarises what I felt were the most relevant points of the meeting from the plenary sessions that I attended.

Serono Symposium International, ‘Unravelling Fetal Programming and the Influence of ART’ 10 October 2005.

This symposium addressed the Barker Hypothesis on the Foetal Origins of Human Disease, proposed over a decade ago.

Julie Owens from the University of Adelaide first summarised the concept.

The main points were:

- Low birth weight (and possibly very high birth weight) appears to be associated with increased risks of coronary heart disease and syndrome X later in life. This is significant for ART given the tendency for low birth weight, even among singletons.
- There may be a period of ‘catch-up’ neonatal growth, which in turn appears to link with poor glucose control later in life.
- Restricted foetal growth patterns are affected by nutrition, altitude and behaviour (especially substance abuse)

Carol Bower and Michele Hansen presented their results from the WA Midwife reports and compared them with other published results. The worrying trends are:

- Increases in risks of prenatal mortality, low birth weight and preterm birth and a 30–40% increase in birth defects.
- Increase in the incidence of an imprinted gene defect (Beckwith–Wiedemann syndrome). The aetiology is unclear: *in vitro* exposure or a different subset of the population seeking ART?
- Patients should be counselled about the risks, and ART programs should aim at singleton pregnancies.

Emma Whitelaw from the University of Sydney discussed the epigenetic regulation of phenotype during pregnancy. Most of this covered the animal models and molecular biology of genome imprinting, which while informative for me as a biologist, is not especially relevant for the RTC (except noting the Beckwith–Wiedemann syndrome discussed above).

Vivienne Moore from the University of Adelaide reviewed the influence of diet in pregnancy on neonatal outcomes. Much information has been gleaned from epidemiology and natural ‘experiments’ such as the Dutch famine during WWII.

- Low birth weight is a significant predictor of later obesity and cardiovascular disease.

- Dieting and particularly unbalanced diets (e.g. Adkins) while attempting to become pregnant can have knock-on effects but the evidence is unclear. Some diets might affect folate metabolism, with effects on neural tube formation, DNA methylation and hence gene imprinting.

Daniel Dumesic from the University of Wisconsin discussed their animal model of polycystic ovarian (PCO) disease based on prenatal androgenization of female rhesus monkeys. These models promise to throw light on carbohydrate metabolism and insulin function in controlling PCO and optimising follicular development.

Chris O'Neill from the Royal North Shore Hospital discussed the regulation of survival in the preimplantation embryo, with emphasis on apoptosis (controlled cell death) and embryo viability.

- Stress during IVF may artificially 'select' embryos that have defective apoptotic pathways.
- Suppression of apoptosis and the use of growth factors to 'stimulate' growth to the blastocyst stage may therefore have negative long-term effects as abnormal embryos may be grown preferentially.

David Gardner (Colorado), Michelle Lane (University of Adelaide) and Henry Leese (York) all discussed the role of IVF culture systems on embryo growth and outcomes and ART programs. As these followed a common theme I will summarise the main points.

- All culture systems distort 'normal' embryo metabolism, generally reducing oxidative (mitochondrial) metabolism and increasing the reliance on glycolysis. This is important as it is now known that—at least in mice—there is a transient phase of mitochondrial DNA (mtDNA) replication, which can be affected by toxic environmental factors such as homocysteine, and disturbances to mtDNA copy number can have marked knock-on effects on whole body metabolism in later development (McConnell and Petrie 2004).
- Current sequential culture systems, while better than single-systems, still only approximate the embryo's requirements and probably lack many of the key features seen (or suspected) *in vivo*. However, implantation rates of 60% or better should be possible with good screening and selection.
- Success in IVF programs requires a holistic approach: it is pointless to concentrate on one issue (e.g. culture media) while ignoring the other matters (stimulation regimens, timing, embryo transfer skills). In the laboratory, concentration on maintaining high quality airflow and reduction in temperature and pH fluctuations seem important.
- Aneuploidy screening is of doubtful long-term benefit in terms of improving implantation rates for older women or those with a poor IVF history (*this theme came up several times in the FSA, too*). See a recent report on whole-genome amplification (Handyside, Robinson et al. 2004).
- As embryos move through the first five days of development they become increasingly resilient. Thus the 1–2 cell stage is particularly vulnerable although, as the genome is not yet activated, insults may not emerge until later in development, appearing as aneuploidy or failed implantation.

- One main toxin in current embryo culture systems is ammonia produced by amino acid breakdown. This could be a problem in pregnancy for women on high-protein low-carbohydrate diets.
- High oxygen levels are embryotoxic. In fact, much early pregnancy in humans (perhaps the whole first trimester) occurs at low oxygen levels and the metabolic rate and amino acid uptake of 'good' embryos are surprisingly low, perhaps to reduce the mutagenic and toxic effects of oxygen-derived free radicals.
- There are no good animal models of human embryo development.
- Analysing the human (or any animal) embryo proteome is a major challenge: 12% of the genome is devoted to cell signalling pathways that are probably critical to normal development and yet current systems require at least 1 mg of protein for analysis. This would represent around 8000 'normal' human embryos.
- Henry Leese discussed regulation and the role of the HFEA in the UK. There is a trade-off in the oscillating cycles of regulation and 'downregulation': as audit levels and requirements for reporting perceived 'risks' increase, trust and empathy between clinics and regulators decline (Turner 2001).
- While follow-up of ART outcomes is important, in the UK this is difficult because of confidentiality issues.
- In the UK there are 30,000 cycles per year (1 in 80 babies born) costing A\$5100 per cycle, with a 'take-home baby' rate of 22% per cycle started.

Michael Davies (University of Adelaide) discussed the perspective of twin and multiple pregnancies in ART and general obstetrics, but I did not get much new information from this.

Fertility Society of Australia 11-13 October 2004

Highlights

Marilyn Renfree (University of Melbourne) gave a wonderful talk on male gonadal differentiation using a marsupial model. The advantage of this mammal is that much development occurs outside the uterus, while being suckled in the pouch. There was not much of direct relevance to the RTC, however.

David Gardner again outlined embryo culture systems and argued strongly that ART programs should now be aiming at single embryo transfers. However, the downside of doing blastocyst culture is that ~5% of couples will end up with no viable embryos for transfer.

Graham Burton (Cambridge) discussed the nutrient supply to the human conceptus. There were (to me) some eye-openers.

- The foetal-maternal blood supply to the placenta does not become established until week 12; before that time the capillaries in the chorionic villi are blocked with plugs of foetal cells. Most nutrient flow to the foetus is histotroph (uterine 'milk' secretions) that get taken up by the yolk sac (often assumed to be vestigial in the human).
- Early foetal development (the first trimester) is in a low-oxygen environment (probably to reduce toxicity). 'True' oxidative metabolism and full

haemochorial placentation and blood flow does not commence until after the first trimester.

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Reprogenetics –Whose Rules Apply? Symposium- Melbourne, 27 October 2004

Council Members: Dr Beverly Petterson and Ms Antonia Clissa

Council sponsored the attendance of Dr Petterson and Ms Clissa at this symposium held by the Infertility Treatment Authority (ITA) of Victoria to discuss the future of reproductive and genetic technologies and what the implications of these would be for the future role of regulatory bodies. There were four internationally recognised keynote speakers. Professor Alan Trounson, Monash University, outlined the future possibilities for reproductive and genetic technologies in a challenging and passionate style. He highlighted his views concerning the future of scientific approaches to infertility, prolonging the natural reproductive cycle in women and what might lie ahead in the areas of genetics and stem cell sciences. The Hon Barry Jones AO reflected on the issues faced by government with emerging technologies. Professor Tony Coady, Melbourne University, Rev Brian Carey from the Ethics Committee at the Epworth Hospital and Dr Leslie Cannold, Melbourne University, outlined ethical considerations and Dr Marie Karamesinis provided a consumer perspective from the Genetic Support Network of Victoria. Ms Angela McNab, Chief Executive of the Human Fertilisation and Embryology Authority (HFEA) in the UK gave the keynote address of the issues confronting HFEA and the challenges in the UK with regulation. The challenging issues included posthumous use of gametes, saviour siblings, sex selection and therapeutic cloning. She outlined how HFEA has regulated rapidly changing technologies and highlighted the benefits of regulation to include public debate/awareness, evolving science and safer practice, patient/public confidence and promoting a culture of responsibility. In terms of looking to the future, Ms McNab included the importance of putting patients at the centre, increased transparency, risk management in clinics, new technologies and risk reduction, using a risk based approach and regulating in a global market (reproductive freedom versus exploitation and risk). Dr Helen Szoke, recent past Chief Executive Officer of ITA provided an Australian regulatory perspective and that the purpose of regulation in this area is to protect the public interest and to reflect a view about the standard of protection to be afforded to the embryo and to the children who are born as a result of these procedures. She also highlighted the lessons to be learnt from the short history of regulation in Australia. The first is that governments usually take a long time to make the final decision to pass laws about the use of reproductive technology (except Victoria, where only four years lapsed between the birth of the first IVF baby in Victoria and the passage of legislation). The second aspect is that different cultures as

well as different political considerations will affect the type of regulation that any jurisdiction puts into place. Dr Szoke outlined a continuum of the different levels of regulation, from permissive to restrictive and that the most restrictive regimes are those where religious mores determine what can and cannot be done. Professor Marcia Neave AO is the person charged with the responsibility for the review of Victorian legislation and presented three different approaches to regulation - self-regulation, legislative regulation which prohibits and permits certain practices and a framework legislation which gives a regulatory authority power to pass regulations and/or change definitions as new technologies are discovered or current legislative provisions are found to be inadequate. She suggested that it would also be possible to design a model, which includes elements of each of above models. However, ultimately, the questions to be asked about any particular approach are the same: Are the purposes of the legislation clear?; Does the law adequately protect the vulnerable?; Can the regulatory model respond adequately to technological change?; Does the regulatory model adequately reflect community values and balance competing interests?; Does the model of regulation contain adequate mechanisms to ensure compliance and prevent abuse?; Professor Neave stated that a model which satisfied all these requirements would allay community concerns about 'rogue science', while allowing the advancement of knowledge and the treatment of infertile couples.

Access to ART Treatment Programmes Seminar, Melbourne, 20 May 2005.

Executive Officer: Ms Antonia Clissa

Ms Clissa was sponsored to attend the *Access to ART Treatment Programmes* seminar conducted by ANZICA, addressing the needs of single women, women with psychiatric issues, women with disability and older women. Dr. Helen Szoke, C.E.O. Equal Opportunity Office (Victoria) addressed the seminar and outlined the lack of legislative consistency across Australian jurisdictions except for permitting embryo research and banning human cloning. She also outlined that the RTAC Code of Practice and the NHMRC Ethical Guidelines on ART in Clinical Practice and Research issued in September 2004, both mandate counselling for those undergoing assisted reproduction procedures. The limits of counselling, gaining informed consent and taking into consideration the welfare and interests of participants and potential children were also discussed. The seminar also highlighted the issues with inconsistent legislation across Australia, which includes reproductive tourism, inequity of access to various procedures and increased expense to participants.

REPRODUCTIVE TECHNOLOGY IN THE PRESS

The material presented in the following section, *Reproductive Technology in the Press*, has been derived through articles reported in the media. The Reproductive Technology Council (Council) has included this material to provide a snapshot of issues in reproductive technology that have gained media attention in the previous year. The Council does not necessarily agree with what has been reported and gives no assurance as to 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

On 17 June 2005 a National Legislation Review Committee was appointed to review the *Prohibition of Human Cloning Act 2002* and the *Research Involving Human Embryos Act 2002*. The committee's main task is to review the two Acts of Parliament, which set out regulatory frameworks banning human cloning and regulating research involving excess human embryos created through assisted reproductive methods.

In March 2005 John Howard decided not to extend the restrictions on the therapeutic use of embryos left over from fertility treatment. A national law passed in December 2002 banned the use of embryonic stem cells for therapeutic cloning. The three year ban had meant that only embryos created before 5 April 2002 could be used for research. Now scientists can use excess IVF embryos created after that date, although it is still illegal to create embryos solely for research.

The Australian Governments plans to limit Medicare funding were put on hold with the Federal Government now planning a review of IVF funding rather than cuts to the procedure. Health Minister Tony Abbott had aimed to limit funding to three cycles in a year for infertile women, with those over 42 allowed no more than three funded treatments.

Western Australia

On 1 July 2004 the State Parliament of WA passed the *Human Reproductive Technology Amendment Act 2004* that allows WA licensed fertility clinics to screen embryos for genetic diseases as well as chromosomal abnormalities. Preimplantation genetic diagnosis (PGD) will permit couples with a family history of certain genetic diseases to screen embryos and implant those free of the disease-causing genes. It can also be used by couples who have had repeated IVF failures due to chromosomal abnormalities. The procedure can be used for sex-selection, but only to select embryos free of X-linked genetic diseases. Under the amended legislation, donor conceived persons at age 16 will be able to find out the identity of donors who contribute sperm or eggs, providing the donor has been informed about changes to the legislation or the donor has already given consent to supplying identifying information.

In March 2005 new NHMRC guidelines ruled that it is unethical for couples to choose the sex of their baby through ART clinics. Sydney IVF and IVF Australia confirmed that they would no longer allow couples to select an embryo of a particular sex. They had been the country's only centres offering sex selection of embryos for social reasons. Sex-selection for couples whose children might suffer

from sex-linked genetic diseases is still allowed.

Victoria

In May 2005 the Victorian Law Reform Commission issued draft recommendations about access to assisted reproductive technology. Recommendations include establishing the right of women and men to use their dead partners eggs or sperm if written permission is given beforehand; giving lesbians and single women the right to have in vitro fertilization (IVF) treatment; allowing couples to create 'saviour siblings'; and automatically banning people convicted of a violent or sexual offence from receiving IVF treatment. Recommendations focus on the rights of the child. The Infertility Treatment Act 1995 has previously been criticised as irrational, ambiguous and difficult to administer, leading doctors into making decisions on whether a woman is suffering from physical or psychological infertility. In 2000 the Federal Court ruled that the State's infertility laws were in breach of the Federal Discrimination Act 1984. This earned lesbians and single women the right to IVF if they could prove they were medically infertile, however the law has not yet been amended to reflect that. The Victorian Infertility Treatment Authority (ITA) has said that allowing all women to use IVF and donor insemination, including lesbians and single women, would bring Victoria into line with most other states. The ITA has also asked for the legislation to be clarified on the issue of whether self-insemination is a criminal offence, something else that the Act is not clear about.

In just over a year The Infertility (Medical Procedures) Act 1984 will allow donors who have registered with the Infertility Treatment Authority to contact children conceived with their

human reproductive material on or after July 1, 1988. This will be permitted once the donor conceived person has reached 18 years of age even if they unaware that they were conceived using a donor. Doctors are hoping that the Victorian Government will amend the law to protect donor conceived persons who may not have been informed that they were conceived using a donor. The first persons affected by the law are due to turn eighteen in 2006. Surveys have shown that only a third of donor conceived persons have been told that their conception involved a donor. Melbourne IVF chairman, Dr John McBain said parents should be encouraged to tell children of their history.

New Zealand

The New Zealand Law Commission published a new report into parenthood called 'New Issues in Legal Parenthood', which recommends a number of changes to existing laws. The proposals focus on the importance of children 'having clear rules about who were their parents and who had legal responsibility for them', especially the small number of children born through ART. One of the suggested legal reforms was to give donors of eggs and sperm legal parenthood status, which could mean that a child has three parents. The Commission also asked for there to be a section on the birth certificate of a child conceived using donor gametes or surrogacy that can indicate that 'extra information' is available about a person's parentage.

UK

The Human Fertilisation and Embryology Association (HFEA) now allows fertility clinics to screen IVF embryos for familial adenomatous polyposis (FAP), a genetic form of bowel cancer. Babies would normally

have a 50% chance of inheriting the disease from parents carrying the genes for FAP. Preimplantation genetic diagnosis (PGD) was previously only approved for untreatable disorders such as cystic fibrosis and Huntington's disease.

From 1 April 2005 a new law under the Human Fertilisation and Embryology (HFE) Act 1990 gives children born in UK from donated eggs, sperm and embryos the right to trace their biological parents when they reach the age of eighteen.

In May 2005 the British Medical Journal reported that Britain's House of Lords had ruled that couples can use IVF to create babies, 'saviour siblings', to help cure sick siblings. The five judges ruled that HFEA has the power to licence both PGD and tissue typing on embryos used in the treatment for IVF.

Gay and lesbian couples will get easier access to fertility treatment following a review of the *Human Fertilisation and Embryology Act 1990* by the House of Commons Science and Technology Committee. The Department of Health plans to make changes to the law partly because of 'changes in societal attitudes' since the 1990 Act was passed, and partly because of the new Civil Partnerships Bill. Entering a 'civil partnership' means that same sex couples have similar rights and responsibilities to those of married couples.

USA

The US Food and Drug Administration (FDA) is to introduce new rules about who can donate sperm. Men who have had homosexual sex within the five years prior to them wanting to make an anonymous donation will not be allowed to do so, however they would

not be prevented from making a sperm donation to a friend or family member. The FDA says that gay men are collectively more likely to be HIV-positive than other men. Gay rights groups condemned the new rules for being discriminatory and difficult to enforce.

France

A new law allows scientists to create embryonic stem cells from spare IVF embryos for the development of treatments for serious disease. It is estimated that there are 120,000 frozen IVF embryos in France that have accumulated over the past 15 to 20 years, of which about 55% could be used for research.

Italy

The Italian referendum failed in June 2005 with only 25.9% of registered voters participating. The referendum would have repealed some aspects of the law, approved in 2004, that dictates that embryos be given the full status of human beings; allows fertility treatments only for heterosexual couples who live together and are of child-bearing age; bans the use of donated sperm or eggs; prohibits prenatal screening for abnormalities and prohibits doctors from freezing embryos or using them for scientific research. The Italian law is said to be the most restrictive in Europe.

Israel

Israeli parents can now apply for permission to select an embryo of the opposite sex if they already have at least four children of the same sex. In a new directive passed on 19 May 2005 the Israeli Health Ministry authorised social sex selection when "there is a real danger of substantial harm to the mental health of the parents or parent, or of the child destined to be born, if the desired procedure is not performed".

All preimplantation genetic diagnosis (PGD) procedures so far in Israel have been done to avoid passing on serious genetic conditions. A new seven-member committee comprised of experts in law, medical genetics and obstetrics, a social worker and a clergyman will consider each request. The Commissioner for Future Generations Shlomo Shoham criticized the decision as “another step on the road to severe moral deterioration”.

United Nations

In March 2005 the United Nations General Assembly voted to ban all forms of human cloning, including therapeutic cloning. Australia voted to support the resolution. The Declaration is open to interpretation and several countries including the UK, Belgium, Singapore and Korea are already ignoring the ban.

ART Data

Australia

The AIHW report, Assisted Reproductive Technology was released on 1 October 2004 with details of fertility treatments delivered in 2002 in Australia and New Zealand and their outcomes. It reported that ART-conceived babies now account for 3% of all births in Australia. The number has more than doubled in the last ten years. Many negative health indicators for babies born using ART have reversed over a two year period. The babies are healthier, with higher birth weights, longer gestational ages and fewer perinatal deaths than ART babies born just two years earlier. The average age of women having treatment was 35.2 yrs. The success rates varied according to age but overall 18% of women using their own fresh embryos go on to have a baby, while the rate dropped to 13% for women using frozen embryos.

Europe

The latest statistics reported in *Human Reproduction* April 2005 show that 3.9% of all births in Denmark are a result of IVF, probably the highest proportion in the world. Next is Slovenia with 3.2%. Finland, Norway, Iceland and Sweden all report that more than 2% of births are IVF births. The results are from 2001 figures, indicating that current levels would be higher.

USA

A study by the Centre for Disease Control and Prevention showed that after the age of 40 years women using IVF and associated technologies only have 4-11% chance of falling pregnant. This compares to a 37% success rate in women under 35 years of age.

ART Risks

Beckwith-Wiedemann Syndrome

A study carried out at the Murdoch Children's Research Institute in Melbourne and published in the *American Journal of Human Genetics* has shown that children born through IVF have a 1 in 400 risk of being diagnosed with the rare genetic growth disorder Beckwith-Wiedemann Syndrome (BWS). The general prevalence of the syndrome ranges from 1 in 15,000 to 1 in 35,000. The study was based on a sample of thirty seven babies born in Victoria between 1983 and 2003, all of whom were diagnosed with the syndrome. Results of this study were presented at the Genetics and Population Health conference, Fremantle WA in 2004.

Beckwith-Wiedemann syndrome is the only rare genetic ‘imprinting’ disorder linked to the use of Assisted Reproductive Technology (ART), according to researchers at University College in London, in the largest study carried out so far. The study also showed that no particular method of

ART was linked to the increased risk of BWS. The researchers suggest the problem could be in the culture media, or the parents may be naturally infertile because of a genetic abnormality.

Birth Defects

Perth researchers from the Telethon Institute for Child Health Research have shown that babies conceived through IVF and related procedures were between 30 and 40% more likely to have birth defects although the reason why is unknown. The review of 25 international studies was published in the journal *Human Reproduction*. About 3% of babies who are conceived naturally are born with defects.

Research published in the journal *Fertility and Sterility* by scientists at the Reproductive Institute of Chicago showed that extracting a cell from an 8-cell embryo to test for genetic disorders does not cause birth defects. The study concluded that PGD babies are no more likely to suffer birth defects than babies born after natural conception.

Long Term Health

In November 2004 the Medical Research Council of the UK issued a report 'Assisted reproduction; a safe, sound future', which reviewed the scientific evidence for potential health effects of new and existing ART. It highlighted the risk of implanting several embryos at a time, and pointed out that even single IVF pregnancies are more likely to have complications and poorer outcomes for mother and child than naturally conceived pregnancies. The report concluded that the evidence for the long-term health of IVF babies is 'relatively weak' compared to other well-established clinical techniques, and identified the need for better evaluation and research to determine the safety, efficacy and

effectiveness of all existing and new ART techniques.

A review of 169 high-quality studies undertaken at John Hopkins University, USA, the largest review ever of IVF children, has shown that there appear to be no notable problems with overall health, development and psychosocial skills, childhood cancers, major malformations and growth abnormalities. However, the results from children conceived using ICSI were inconclusive.

Single Embryo Transfer

At the Annual Conference of the Fertility Society of Australia in Adelaide, October 2004, Professor David Gardner, scientific director of the Colorado Centre for Reproductive Medicine in the US, said governments should ensure that couples having IVF treatment for the first time only have a single embryo transferred. Regulations only allowing single instead of multiple embryo transfers would prevent the health risks associated with multiple births.

Belgian researchers reported at the 21st Annual Conference of European Society for Human Reproduction and Embryology (ESHRE) in June 2005, that babies born following single embryo transfer (SET) are as healthy as singleton babies born after a spontaneous conception. They found little difference in birth weight or gestational age, and stillbirth was the same in both groups. SET pregnancies however did report more cases of hypertension than spontaneous pregnancies (7.6% as opposed to 4.6%).

Dual Embryo Transfer

A Danish study reported that the major health risks for IVF singleton babies came from being the surviving twin from a dual embryo transfer. Dr Anja

Pinborg from the Fertility Clinic at the Rigshospitalet, University of Copenhagen, said her team had studied data collected between 1995 and 2001 from eleven Danish fertility clinics. The findings included that: 10.4% of all the IVF singletons born originated from a twin gestation in early pregnancy; a clear correlation between the incidence of neurological problems in these babies and the time of onset of spontaneous reduction; the risk of child death within the period of follow up was higher in the survivors of a vanishing twin than in those born from a single gestation. Dr Pinborg advised that patients should be informed that vanishing twins are a considerable risk factor in IVF twin pregnancies and a relatively common consequence of dual embryo transfer.

Parenting

A University of Melbourne study found that mothers of babies, who conceived through IVF treatment, as well as those who had a caesarean delivery, are more likely to have parenting problems. They found that about 1.7% of babies in the general community were born with reproductive assistance, yet the proportion of mothers with IVF babies entering early parenting centres was about six times higher than this. The researchers say it suggests that women who have undergone IVF treatment may not receive adequate help once the baby is born, and clinicians should be made aware of this.

Research

Growth factor GM-CSF

Adelaide researchers have experimented with adding a protein, the growth factor GM-CSF, to the conventional growth medium of mouse embryos. Adding GM-CFS, which is produced by a range of mammals including humans, appears to increase the survival of IVF embryos.

Preliminary studies have shown that GM-CFS more than doubled the chances of human embryos surviving to the blastocyst stage.

Gulf war veterans

A study of 40,000 servicemen undertaken at the London School of Hygiene and Tropical Medicine and funded by the British Ministry of Defence showed that Gulf war veterans take longer to conceive and are more likely to be infertile than servicemen who had not served in the Gulf. Fertility problems in men who had previously fathered children suggest they may have suffered sperm damage. Researchers questioned 24,379 Gulf veterans and 18,439 servicemen who had not served in the Gulf.

Dnmt3L

Researchers from the Monash Institute of Medical Research and the Walter and Eliza Hall Institute have been testing variations in the gene Dnmt3L in fertile and infertile men. They found that 'switching off' this gene renders male mice infertile, and have now begun testing men for variations in the gene in fertile and infertile men. Researchers from the USA had previously discovered an absence of the same gene causes early miscarriage in female mice.

REC8

Researchers from The Peter MacCallum Cancer Centre in Melbourne accidentally discovered the gene REC8 that appears to regulate fertility in mice. Reporting in the journal *Developmental Cell*, they said REC8 has a role in repairing genetic material damaged during radiation therapy.

Human Embryo Research Grants

Australia

The Prince of Wales Hospital diabetes transplant unit, in collaboration with

IVF Australia, was granted a licence from the NHMRC to produce six stem cell lines using up to 100 human embryos created before 5 April 2002. Embryonic stem cells have the potential to be converted into all types of body tissue, but the procedure is controversial, as it requires the eventual destruction of the embryos. The transplant unit hopes to develop new treatments for insulin-dependent diabetes.

The NHMRC has given a \$200,000 grant to Adelaide University's Department of Obstetrics and Gynaecology to compare the health of South Australia's IVF babies with those naturally conceived.

UK

In February 2005 HFEA gave Ian Wilmut of Edinburgh's Roslin Institute a licence to produce cloned human embryos for research into the degenerative disorder motor neurone disease (MND). In therapeutic cloning, which became legal in the UK in 2001, cells are taken from people with the disease and used to create cloned embryos carrying the disease. Stem cells carrying the genetic defect are then extracted from the embryos for research, after which the embryos are destroyed.

In August 2004 the Human Fertility and Embryology Authority (HFEA) granted a one-year license, the first in Europe, to researchers at the University of Newcastle in the UK to create human embryos from which they will extract stem cells for medical research. Using embryos left over from IVF procedures they plan to harvest insulin-producing cells from the embryos and then transplant the cells into diabetic patients. Britain legalised therapeutic cloning in 2001, becoming the first country in the world to do so.

USA

In March 2005 Harvard University granted permission for researchers to create cloned human embryos from which to harvest embryonic stem cells to use in research into diseases such as diabetes and Parkinson's disease.

Advances in Technology

Ovarian autotransplantation

In a procedure reported in the journal *Cancer*, a 29-year-old woman at the Leiden Medical Centre in the Netherlands undergoing treatment for cervical cancer has had her left ovary transplanted into her left upper arm. In the procedure, known as 'ovarian autotransplantation', the ovary forms blood vessels much faster than a strip of ovarian tissue. The aim was to ensure the woman kept her fertility after having radiotherapy treatment. Doctors hoped to be able to harvest eggs for IVF treatment from it.

Stem Cells-Somatic nuclear Transfer

Following the announcement in March 2004 that Korean scientists had succeeded in creating 31 cloned human embryos, they then cultivated 11 embryonic stem cell lines perfectly matched to a patient's own tissue in May 2005 using a method called 'somatic nuclear transfer'. The research was published in the journal *Science* in March 2005. The donated cells used to make the cloned embryos were from volunteers with spinal cord injuries, Type 1 diabetes or a genetic immune system disorder called hypogammaglobulinaemia. With this method they transfer genetic material from a somatic cell (non-reproductive cell) of a patient into a donated egg from which the nucleus had been removed.

Stem Cells from 4-day-old Embryos

It was reported in the November 2004 issue of the journal *Nature* that a

Chicago IVF clinic has developed a new method of obtaining embryonic stem cells from four-day-old human embryos at the morulae stage without killing the embryos, a method that scientists suggest could bypass ethical objections. All previous embryonic stem cell lines have been created from older embryos at the blastocyst stage. With the new method it may become possible for couples seeking IVF treatment to have their child's embryonic stem cells removed to create a stem cell line that could be used for future medical treatment.

Ovarian Tissue Cryopreservation

The world's first baby was born in a Belgian Hospital to a woman who had frozen ovarian tissue re-implanted following treatment with chemotherapy and radiotherapy for Hodgkin's lymphoma. The tissue was removed seven years ago, immediately before the treatment, and frozen. It was reimplanted last year and within months she had resumed her normal menstrual cycle and ovulation. Dr Jacques Donnez who published the study in *The Lancet Online* recommended that the procedure should be offered to young female cancer patients facing the risk of premature infertility.

Israeli researchers reported that a second woman had become pregnant after an ovary tissue transplant. She had some ovarian tissue frozen after she had undergone a first course of chemotherapy for non-Hodgkin's lymphoma. Subsequent courses of chemotherapy pushed her into early menopause. When she was clear of the cancer, her strips of frozen tissue were replanted into her ovaries. The transplanted tissue responded to IVF drugs whereas the original ovarian tissue didn't. Eggs were harvested from the transplanted tissue for her IVF treatment.

Egg Freezing

Researchers at the University of Michigan Comprehensive Cancer Centre are developing a new technique whereby women may have their eggs frozen before they begin cancer treatment by a method called 'vitrification'. Egg freezing has up to now proved to be a difficult technique, as freezing and thawing egg cells tends to create ice crystals, damaging the eggs. In the new technique the egg is almost instantly thawed, reducing the damage done by the process. Researchers have so far tested the technique on mouse eggs, and are achieving a high survival rate. They are now developing a clinical technique that can be used in humans.

Sperm-Sorting

Australian researchers from the University of Newcastle and Sydney-based Life Therapeutics have developed a sperm-sorting machine that filters out sperm with DNA damage associated with infertility. The machine is based on the principle that sperm with the most negatively charged membranes have the least DNA damage, and the researchers believe that these sperm have matured properly. The sorter will soon be tested in two clinical trials of women undergoing IVF treatment.

'Serial nuclear transfer'

Researchers from Melbourne's Monash Institute and the Genetics Australia Cooperative cloned a cow using a new technique known as 'serial nuclear transfer' (SNT). The Holstein-Friesian calf was born in December 2004. In the new procedure the cells used to create the calf underwent two rounds of nuclear transfer in the cloning process instead of the normal one, before they developed into an embryo ready for implantation into a surrogate cow. Dolly the sheep, born in 1997, was created using the method 'standard

nuclear transfer'. They say this new technique improves the chances of success. SNT is still in the research stage. Australia's first cloned cow, Suzi, was born in 2000 but died of acute mastitis in July 2004.

Umbilical Stem Cells

Research presented by Professor Gesine Kögler of the University of Dusseldorf, Germany at an Academy of Science Symposium on Stem Cells in Canberra in May 2005 showed that a rare stem cell isolated in umbilical cord blood can turn into bone, cartilage, blood, nerve cells, and liver and heart tissue in animals. The researchers say these stem cells are a promising alternative to using embryonic stem cells as a new source of tissue.

Embryonic stem cells of mice develop ovarian structures containing eggs

Researchers from Melbourne's Monash Immunology and Stem Cell Laboratories developed a process using the embryonic stem cells of mice to develop ovarian structures containing eggs. Further studies are needed to see if the eggs are normal and capable of fertilization. This could eventually be used to develop eggs for infertile women that contain their own genetic material.

Growing Eggs and Sperm

Researchers from the University of Sheffield's centre for stem cell biology in England announced that they had converted human embryonic stem cells into primordial germ cells (precursor cells) that create eggs and sperm. In the future infertile couples may be able to 'grow' their own sperm and eggs.

Human eggs grown for first time using stem cells scraped from surface of women's ovaries

Human eggs were grown in the laboratory for the first time using stem

cells scraped from the surface of women's ovaries it was reported in the *Journal of Reproductive Biology and Endocrinology* in May 2005. The researchers took surface cells from the ovaries of five women aged 39 to 52, which were then used in experiments where they were grown in the laboratory for five to six days. Some of them developed into mature human eggs capable of being fertilized. The research, undertaken at the University of Tennessee, raises the possibility of providing a source of donor eggs for IVF and embryonic stem cell research, and for delaying menopause.

Infertility Health Issues

Lifestyle factors and IVF Success

It was reported at the Fertility Society of Australia's Annual Scientific Meeting in Adelaide in October 2004 that lifestyle factors, such as a healthy diet and exercise and quitting smoking, are as important as medical intervention in ensuring IVF success. Previous conferences had focused on medical advancements in fertility.

A Dutch study published in the journal *Human Reproduction* showed that smoking and being overweight affected IVF success rates. Doctors from twelve centres in the Netherlands investigated the success rates of the first cycle of IVF treatment in more than 8400 women and their medical records from between 1983 and 1995. The researchers believe that smoking alone adds ten years to a woman's reproductive age, and the live birth rate for smokers was 28% lower than that of non-smokers.

Fertility experts warn that one in three Australian couples will be infertile within a decade because of our sedentary lifestyle and increasing obesity. One in seven couples now has trouble conceiving naturally. Professor

Bill Ledger, a UK fertility expert from Sheffield University warned it is possible that infertility in Europe could double in the next decade. Factors contributing to the alarming rise in infertility include obesity, declining sperm quality, stress, use of illicit drugs, environmental pollutants, delaying having children and sexual diseases such as chlamydia.

Weight

Danish research on 1558 men, average age nineteen, found that being either overweight or underweight affected both sperm count and sperm concentration. The study was done at various hospitals and universities in Denmark and published in the journal *Fertility and Sterility* in October 2004.

A study on women at Boston IVF, USA, found that obese women (with Body Mass Index - BMIs over 35) had little more than a one in four chance of becoming pregnant, as compared to a better than one in four for women with healthy weight. Overweight women had irregular periods and lower ovulation rates. Embryos were also less likely to implant in overweight women.

Passive Smoking

Canadian research published in the journal *Human Reproduction* indicated that passive smoking can be as damaging to a woman's chances of becoming pregnant as being the actual smoker. The study involved 225 women undergoing fertility treatment and showed passive smoking could decrease the chances of conceiving by 50%.

Sperm

The Melbourne-based, government-funded organization 'Andrology Australia' is testing the sperm of 5500 men across Australia to determine how many men over 40 are involuntarily

infertile, that is they are in a relationship and are trying but failing to have children, and have not had a vasectomy. It has been suggested that age plays a greater role in sperm decline than previously thought.

Polycystic ovarian syndrome

Dr Robert David, a researcher into obesity, said the incidence of polycystic ovarian syndrome (PCOS), a pre-diabetic condition that affects many obese women is increasing and obesity is causing infertility in women. The number of women over 25 who are overweight or obese has increased by 15% in the last 10 years. He predicts that up to 50% of all Australian women could become infertile within 10 years. The fertility specialist Dr David Knight said that women with PCOS have irregular menstrual cycles and often failed to ovulate.

Findings published in the *Australian and New Zealand Journal of Obstetrics and Gynaecology* showed that the incidence rate of polycystic ovary syndrome (PCOS) is actually 12%, although it is normally quoted at between 5 and 10%. It was reported that PCOS is the most common hormonal disorder in Australian women and one of the leading causes of infertility. The exact cause of PCOS is unknown but it can lead to infertility, weight gain, diabetes, heart disease, excessive facial hair and acne.

Pelvic inflammatory disease

A study from the University of Pittsburgh's Graduate School of Public Health and published in the *American Journal of Public Health* tracked more than 600 women, aged between 14 and 37 who had symptoms of pelvic inflammatory disease (PID), for about three years. They found their risk of becoming infertile as a result of repeated attacks of PID dropped by

60% when they used condoms during sex. PID is the most common preventable form of infertility in women.

Chlamydia

A report released by the National Centre in HIV Epidemiology and Clinical Research showed that record numbers of women are suffering from chlamydia in Australia, with the rate more than doubling over the last four years. Sexually transmitted diseases are threatening the fertility of a generation of young women. Left untreated, chlamydia can cause pelvic inflammation, ectopic pregnancy, and infertility.

Pregnancy-induced hypertension

Korean researchers found that pregnancy-induced hypertension (PIH) occurs more often in women needing donor eggs to conceive. Researchers found that using an unrelated donor's egg carried a 5.4 fold increased risk, whereas using a sibling egg only caused a 2.2 fold increased risk. They believe the immune system is likely to play an important role in PIH in these women. When PIH is more severe, and called pre-eclampsia it can be very serious and kills 3-5 women and 500-600 babies a year.

Genistein

Lynn Fraser, Professor of Reproductive Biology at King's College London suggests that eating some foods may affect a woman's chance of getting pregnant, because chemicals in them affect the ability of sperm to fertilise an egg. The chemical genistein found in soya products and leguminous vegetables, particularly in combination with other chemicals found in hops and industrial products causes the acrosome reaction to occur too early causing the sperm to be infertile by the time they reach an egg.

Social Issues

Public Awareness and Consultation

The Human Fertility and Embryology Authority (HFEA), set up in 1991 to regulate and licence the provision of fertility treatments in the UK, launched an online consultative panel called 'Fertility Views' in June 2005, to gather views and experiences of people who have had, are undergoing, or who are preparing for fertility treatment. British couples who have had fertility problems are being asked to help improve the quality of services provided across the UK.

The Birmingham Post and the Midlands Fertility Service launched a 'Funded Fertility Treatment for All' campaign. The regional newspaper offered its readers the chance to 'win' free fertility treatment in the campaign designed to raise awareness of infertility. Three couples are to have IVF treatment funded by the newspaper. The Director of the Midlands Fertility Service said the overwhelming response showed that more money should be invested in fertility treatment on the National Health Service (NHS).

Egg and Sperm Donation

On November 11, 2004 the Human Fertilisation and Embryology Authority (HFEA) in the UK launched a public consultation on sperm and egg donation entitled 'The Regulation of Donor Assisted Conception'. It was seeking views on issues such as limiting the number of children per donor, how donor's characteristics should be matched with patients, and how much compensation donors should be paid.

'UK Donor link' a voluntary register launched in April 2004 that enables people conceived in the UK using donated eggs, sperm or embryos to contact their donors and biological half-siblings has reported successful matches of ten adults in their 40s and

50s with their half-siblings. The Department of Health funds the registry and offers genetic testing to match offspring with donors and other biologically related offspring who are also registered with the service. The register was created following campaigning by donor-conceived people wanting to know more about their biological origins.

Two studies published in the journal *Human Reproduction* showed that community attitudes are tending towards more openness about sperm donation. The studies looked at how much information the parents believed a donor-conceived child should be given about their background. In the study from the Netherlands the majority of the couples 'pointed to the right of the child to know its genetic origins'. In the UK study 39% of couples were inclined towards openness. Researchers found that while there were growing trends towards being more open about sperm donation, not all parents were comfortable with being open.

Lesbians

Lesbians in Victoria are now allowed to inseminate themselves at home using sperm screened for disease at a fertility centre. If the procedure fails four times the women can be deemed infertile and granted full access to IVF services in that state. Under new guidelines both the women and the donors will be given counselling. Melbourne IVF and the Royal Women's Hospital provide this service. However, despite similar laws, lesbians in South Australia (SA) are unable to access the same treatment, as doctors there fear losing their licenses if they perform any parts of a fertility treatment illegally. The South Australian Health Minister agreed that the Reproductive Technology Act was due for review and the SA Council on

Reproductive Technology would advise the Government. The Lesbian Parenting SA spokeswoman said the Victorian arrangement should be explored for SA.

Counselling

An IVF eligibility issues seminar held in Perth in November 2004 examined the medical, legal and ethical aspects of access to IVF with a focus on the consumer perspective and the psychosocial development of children born following IVF treatment. A common theme was that these issues are often complex and that there is a lack of strong longitudinal studies looking at the interests of the child.

Parentage

IVF twins born in 2001 have become the first children in Britain to have five parents after the High court in the UK took three years to decide on their legal status. The children began as surplus embryos in an IVF clinic and were later 'adopted' by an infertile couple. The woman could not carry the pregnancy for medical reasons so used her 44-year-old mother as a surrogate. As a result the twins have a biological mother and father, an adopted mother and father and a surrogate mother who is also their adopted grandmother.

IVF Adoption

It was reported in March 2005 that a 41-year old woman was pregnant with Spain's first adopted embryo. She was unlikely to conceive naturally as she had had chemotherapy. The foetus was from an embryo frozen seven years ago. There are 30,000 frozen embryos stored in fertility clinics in Spain. The embryo adoption programme, set up in 2004 at the Marques Clinic in Barcelona, aims to match women who want to have children with the surplus embryos produced by couples undergoing IVF treatment. Although the Catholic

Church bans ART it supports the embryo adoption programme.

With the support of the Government, Christian groups in USA are cooperating with IVF clinics in arranging for frozen embryos to be given to childless couples in a controversial programme called 'Snowflakes'. However, since only about 2% of an estimated 400,000 frozen embryos in IVF clinics are given to other couples, it is not really a solution of what to do with the embryos. Many IVF parents have mixed feelings about adopting out their excess embryos.

Multiple Births

Many couples are asking IVF specialists to help them conceive twins by implanting more than one embryo at a time. However, the specialists warn that there are too many risks associated with multiple births. There is a much higher chance of a healthy baby from a single embryo and a twin pregnancy trebles the risk of death and abnormality.

Sex Selection

A survey of 561 American women published in the journal *Fertility and Sterility* in March 2005 showed that almost 41% of women treated at IVF clinics would choose their baby's sex if sex selection was offered at no extra cost. The women who had no children already were about evenly split on whether they would choose boys or girls.

Excess Embryos

A Western Australian study of 235 couples published in the *Medical Journal of Australia* found that they would prefer their excess embryos to be destroyed or donated to research rather than be donated to another couple. Dr Peter Burton Scientific Director of the

Concept Fertility Centre, and Dr Katherine Sanders of the University of Western Australia conducted the study.

In a similar study, Dr Sheryl De Lacey of the University of Adelaide Reproductive Health Research Centre found that after undergoing successful IVF treatment most couples choose to dispose of their excess stored embryos rather than donate them to another couple. Some couples farewelled the embryos in a ceremony or had them implanted at a time when they were unlikely to survive.

Sperm Shortages

A chronic shortage of donor sperm at Perth fertility clinics is leading single women to advertise for donors in suburban newspapers. In September 2002 it became legal for infertile single women to access IVF treatment. Clinics report that the shortage is due to a growing demand from single career women and potential donors' concern new legislation would force them to reveal their identity to any future offspring. Changes to the *Human Reproductive Technology Act 1991* that came into effect on December 1, 2004 gives donor conceived persons at age 16 access to donor identifying information following counselling. Urgent appeals for more sperm donors have also been made in Queensland South Australia and Tasmania

Queensland and Victorian state MPs under 45 were asked to donate their sperm to fertility clinics for IVF treatments in the hope that they would become community role models. In 1998 law changes meant that donors must be prepared to release their identity to the recipient and since then stocks have dwindled.

In January 2005 the Department of Health in the UK launched a new

national campaign called 'Give Life, Give Hope', aimed at increasing public awareness about the need for egg and sperm donation, and to encourage potential donors to come forward. UK fertility clinics reported a decline in the numbers of people coming forward to donate gametes since the announcement that rules about anonymity would be changing. The changes meant that anyone born from donations made after April 1, 2005 would be able to ask for identifying information about the donor, when they reached 18 years of age.

Surrogacy

It was reported that Australian infertile couples, single women and gay couples are flying to the USA for surrogate babies. The Los Angeles fertility agency 'The Egg Donor Program' has helped more than 200 Australian couples have children by finding egg donors and surrogate mothers. Another company, 'Egg Donation Inc', has helped gay Australian couples to have a child at a cost of \$170,000 for fees and expenses. Fertile Australian women are also going to the USA where they can legally sell their eggs for up to \$20,000 a cycle.

Reproductive Tourism

Thousands of European couples are travelling to Eastern Europe seeking either quicker or cheaper fertility treatment, and to Spain for egg donation because women are allowed to sell their eggs there.

Case Reports

Posthumous Use of Sperm

In the first ruling of its kind in Australia a 36-year old Victorian woman was told she could not be impregnated with her dead husband's sperm using IVF. She had been married for more than 8 years and a Victorian Supreme Court ruling in 1998 had allowed her to have his

sperm taken and stored at the Royal Women's Hospital following his death in a car accident. The judge ruled that the Infertility Treatment Act 1995 banned the proposed procedure unless written the husband had given consent before his death.

Embryo Mix-up

A Californian woman was awarded \$US1 million (\$A1.4 million) after a fertility specialist accidentally implanted her with the wrong embryos and then hid the mistake until her baby was 10 months old. The embryos had been intended for a married couple that underwent IVF treatment on the same day using the husband's sperm and a donated egg. The couple is now seeking custody of the 3 year-old son the Californian woman has raised since birth.

Saviour Siblings

Sydney IVF used preimplantation genetic diagnosis (PGD) to screen embryos for a Tasmanian couple whose 4 year old son has a rare immune deficiency known as hyper IgM syndrome. They hoped to conceive a child free of the syndrome as well as providing a tissue match for their son who's only chance of a normal life was a bone marrow transplant. Nobody in his family had a direct tissue match and it took 18 months to develop a test to screen the embryos for hyper IgM.

In the UK a 6-year old boy was cured of a rare blood disorder, Diamond Blackfan anaemia following transplants from a baby brother who was created to give him tissue-matched healthy blood cells. The disorder is normally fatal. The parents received preimplantation genetic diagnosis from a Chicago clinic after failing to get permission to create a saviour sibling from British authorities.

Preimplantation Genetic Diagnosis

The world's first IVF baby was born in Sydney after scientists from the Royal North Shore Hospital and Sydney IVF used preimplantation genetic diagnosis (PGD) to choose an embryo to be implanted that was free from Rhesus factor disease. In the first reported use of PGD for this purpose, they were able to test whether or not there would be an incompatibility between the mother's blood and the baby's blood. Rhesus factor disease develops when a mother with RhD-negative blood has a foetus with the opposite type, RhD-positive, inherited from the father. While the first birth is usually unproblematic, the mother develops antibodies that attack subsequent RhD-positive babies through the placenta, usually during delivery. About 300 Australian babies are born each year with this potentially fatal condition.

Surrogacy

A South Australian couple spent \$80,000 travelling to the ACT to have a surrogate child. However, South Australian (SA) law doesn't recognize them as a family even though they are the genetic parents. The couple had tried IVF treatment for 8 years, but was unable to conceive. A cousin agreed to carry a child for them for no fee. Although they had three frozen embryos in storage in SA the law forced them to travel to the ACT where such surrogacies are permitted. In the ACT they underwent an IVF cycle to produce a new embryo, which was implanted in the surrogate. There was no egg or sperm donation involved and the couple is asking for 'altruistic gestational surrogacy' to be legalised in SA, so they can have any future children through surrogacy in their own State. They are also requesting that genetic parents be recognized on the baby's birth certificate.

In Arizona, USA, a surrogate mother who had five embryos implanted gave birth to five boys, and declined any payment from the genetic parents because of the expenses they would face. The couple had been trying to start a family for more than a decade. Five embryos were implanted in the hope that one of them would develop.

Ovarian Hyperstimulation Syndrome

A 33-year-old woman who was undergoing IVF treatment died in the UK two days after commencing treatment. An inquest into her death found it was due to ovarian hyperstimulation syndrome (OHSS). She apparently developed a blood clot that caused a massive heart attack from which she died. Mild symptoms of the syndrome may affect up to 20% of women undergoing treatment, however, very rarely the symptoms are more severe and are potentially fatal. This is believed to be the first woman to die as a result of IVF treatment in the UK, and only three other women have died from the same condition since IVF treatment began in 1978.

In the UK a woman received 'substantial' agreed damages after she had been left brain-damaged after developing OHSS as a result of IVF treatment. Following a series of strokes she now has great difficulty with speech, mobility, reasoning and decision-making.

APPENDIX 1

LICENCES AND EXEMPTIONS

<p>LICENCES CURRENT UNDER THE HUMAN REPRODUCTIVE TECHNOLOGY ACT AT 30 JUNE 2005</p>
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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.

Pivet Australia Pty Ltd, LEEDERVILLE –
Practice and Storage Licences.

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

<p style="text-align: center;">MEDICAL PRACTITIONERS WITH AN EXEMPTION FROM THE REQUIREMENT TO BE LICENSED TO CARRY OUT ARTIFICIAL INSEMINATION: AUGUST 31 2004</p>
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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 June 2005

Name	Professional Address	Telephone Number
Ms Jill Bain*	57 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 Elyse Frankel	Perth and Hills Division of General Practice, 48A James Street Guildford PO Box 354 GUILDFORD WA 6935 27 Alvan Street, Mount Lawley WA 6050	0414 764 663 0414 764 663 Fax (08) 9473 1754
Ms Lisa Hasard	Pivet Medical Centre, 166-168 Cambridge St, Leederville WA 6007	(08) 9382 1677 Fax (08) 9382 4576
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*	69 Clontarf St, Sorrento WA 6020	(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*	Keogh Institute for Medical Research, A Block 3 rd Floor, QE Medical Centre, Nedlands WA 6009 64 Farrington Road, Leeming WA 6149 – Private Practice	(08) 9346 2008 (08) 9389 7212 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, 166-168 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

‘APPROVED COUNSELLORS’

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 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 2004/2005

OPERATIONS OF LICENSEES FOR THE FINANCIAL YEAR 2004/2005

BACKGROUND

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

All information was submitted in a collated form and referred to the financial year, which ended at 30 June 2005. 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 2004/05 financial year, 61 men donated semen to WA Storage Licensees. Of these, 24 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). The age distribution of donors (Table 1) indicates that the majority (87.0%) were over 30 years of age. This continues the general trend seen over the last twelve years, towards a greater number of older donors (figure 2). Where the marital status of the donor was known, in 47.8% the donor was married or in a de facto relationship, 30.4% were single and 21.7% were divorced or separated.

Reporting by Exempt practitioners and the Sperm Banks indicated that during the year no donor semen was supplied to WA Exempt practitioners, however, one interstate medical practitioner was supplied with donor semen during the year, with the approval of the Reproductive Technology Council (Council) under Direction 6.2. This approval was based on an undertaking by that practitioner to ensure that all recipients were fully informed about requirements of the Act, and knew in particular that information about outcomes of treatments would be provided to the WA Reproductive Technology Register. In the course of submitting their Annual Reports three Exempt practitioners requested revocation of their Exemptions, leaving 16 exempt practitioners, as detailed in Appendix 1.

Embryo storage

Table 3 shows that the total number of embryos in storage at the end of the year was 13362. 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, this rate is still lower than the 1996 to 2002 figures. The reduced rate of embryos put into storage has occurred despite the significant

increase (23.4%) in the number of oocyte pick up cycles commenced in 2004/05. This may be a result of the greater use of stored embryos through frozen embryo transfer (FET) cycles, with the proportion of FET cycles on the increase since 1993 and now approaching fifty percent (45.1%) of all cycles with embryo transfer. Under the HRT Act (Direction 8.4) where participants have more than two embryos in storage, the licensee must not allow the creation of any further embryos.

A total of 4820 embryos were stored following treatment and 3572 stored embryos were used in treatments during the year. In all 419 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 1366 women began oocyte retrieval cycles for IVF, 695 began FET and 2 began GIFT procedures.

A total of 3552 cycles were begun for IVF, frozen embryo transfer or GIFT, a substantial increase on the previous year (3092). As illustrated in figure 4, of all cycles begun, 2070 (58.3%) were for IVF and 1479 (41.6%) were for frozen embryo transfer. GIFT cycles accounted for only 3 of the cycles begun.

Of the 2073 cycles begun for fresh IVF or GIFT with ovarian stimulation, 88.6% proceeded to oocyte retrieval and 73.1% proceeded to transfer fresh embryos or gametes (figure 5). Of the 1479 frozen embryo transfer cycles begun, 1246 (84.2%) proceeded to transfer.

Overall, donated human reproductive material was involved in 4.6% of all IVF or GIFT cycles with oocyte retrieval during the year. In 3.4% of cycles donor semen was used (62 cycles); donor eggs were used in 1.2% of cycles (23 cycles) and there were no IVF cycles with fresh embryos donated. A higher proportion of frozen embryo transfer cycles (8.5%) involved use of donated gametes or embryos. Donor embryos were used in 1.6% of all FET cycles with transfer (23 cycles); donor eggs in 3.4% (51 cycles) and donor semen in 3.5% (52 cycles).

Of all 1835 IVF treatment cycles with successful oocyte retrieval, 827 (45.1 %) used intra-cytoplasmic sperm injection (ICSI). As illustrated in Figure 6, use of ICSI appears to be levelling off with the proportion of IVF cycles in which ICSI is used remaining relatively stable in recent years. Fresh or frozen sperm retrieved from the epididymis or testis was used in 148 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, 77 women were treated with fresh IVF transfer and 30 with frozen transfer. The results for this year indicate the number of public patients treated is slightly higher than last year. During the year 111 fresh IVF and 115 FET treatment cycles were commenced. This year 34 of the IVF cycles involved micro-manipulation (ICSI). Of all the 226 cycles for public patients only 2 cycles reported using donated gametes or

embryos, with both using donor semen. In addition, there were 10 cycles reported as using assisted hatching.

There were 92 artificial insemination (10 DI, 82 AIH) treatments between 1 July 2004 and 30 June 2005, for public patients.

Intra-uterine insemination (IUI)

The Council is continuing to monitor IUI carried out by licensees and Exempt practitioners. A total of 1573 IUI cycles were reported by five Practice licensees and two Exempt practitioners. The overall ongoing clinical pregnancy rate per treatment cycle carried out was 7.8% (123 ongoing pregnancies), and of the pregnancies, 10 were singleton (89.4%), 11 were twin (8.9%), one was a triplet (0.8%) and the plurality of one pregnancy was unknown.

The information provided showed that 80.7% of the IUIs used the partner's sperm and 19.3% used donor sperm. Of all cycles carried out, the majority (59.8%) did not involve the use of ovulation induction. Clomid was used in only 5.7% of the cycles, and gonadotrophins were used in 34.5% of the cycles.

The set of triplets reported followed gonadotrophin stimulation using donor sperm (DI). Of the eleven sets of twins reported, ten followed ovulation induction by gonadotrophins and one set of twins occurred following a natural cycle. Only one of the sets of twins were a result of DI and the remaining 10 occurred after IUI using the partner's semen.

Serious morbidity and mortality in women undergoing treatment

Overall the five clinics reported a total of 30 cases of severe ovarian hyper-stimulation relating to 2073 IVF and GIFT stimulation cycles (1.4% stimulation cycles, with a clinic range of 1.0–2.6%). The average number of follicles above 12cm for women who were affected by severe ovarian hyperstimulation was 17.4 (with a median of 15.5).

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

Counselling

There were 1109 counselling sessions provided by the licensed clinics during 2004-2005, according to the annual reporting forms, compared to 1025 sessions in the previous year. This represents an increase of 8%. Just over eighty eight per cent (88.34%) of participants who had counselling had one session of counselling. Of those seeking treatment that had a single session of counselling over eighty five per cent (85.5%) had information counselling while almost 15 per cent of participants accessed support or therapeutic counselling. This was consistently the case in all the licensed clinics. Of those accessing more than one session of counselling over 22 percent (22.75%) were seeking counselling for support, over 23 per cent (23.44%) were seeking counselling in relation to a matter associated with infertility and just over 5% sought counselling to manage a crisis.

The majority of the counselling took place on site at the clinics. Only one clinic reported not charging participants a fee for counselling. One clinic reported conducting telephone counselling sessions during the year and providing telephone follow-up to participants who had unsatisfactory treatment outcomes or pregnancy loss. Counselling concerning issues of donation for donors or recipients made up almost thirty-five per cent (34.8%) of all counselling compared to 32.5 per cent in the previous year. For one IVF clinic over 75% of all counselling offered for the year was pertaining to issues of donation.

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 283 fresh and 237 frozen embryo cycles. The use of the procedure ranged from being used in 8.7% to 23.3% of all cycles (fresh and frozen) with transfer. The overall pregnancy rate following assisted hatching was 17.5%, with quite a varied rate between clinics, ranging from 8.3% to 23.5%.

Data from the four clinics with approval to carry out blastocyst culture indicated the procedure was used in 457 fresh and 312 frozen embryo cycles. The use of the procedure between clinics varied greatly from 4.4% to 54.0% of cycles (fresh and frozen) commenced. The majority of the cycles (77.4%) 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.

Research

R001 Use of granulosa cell co-culture in assisted reproduction procedures
PIVET Medical Centre
Approved 25/05/93
In abeyance

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, 11 patients treated to date

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 the last year

I 002 Use of SAIZAN (Growth Hormone) in ovulation induction
PIVET Medical Centre
Approved 23/11/93
The 2005 report indicated use in 43 cycles for 32 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

I015 Extended culture and blastocyst transfer
Fertility North
Approved 29/10/2004
Information reported in summary data above

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

No new changes to routine practice of licensees were reported at the time of annual report submission by licensees. However, a number of routine changes, predominantly to patient information sheets were received throughout the year.

Complaints

A total of 16 formal complaints were reported by clinics for issues including accounting, clinical and ultrasound services.

Figure 1: Semen Donors in WA

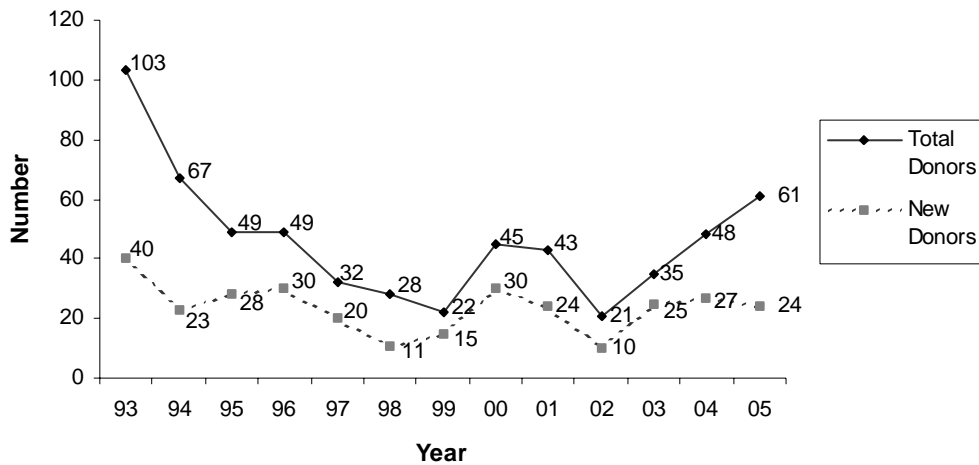


Figure 2: Ages of Semen Donors

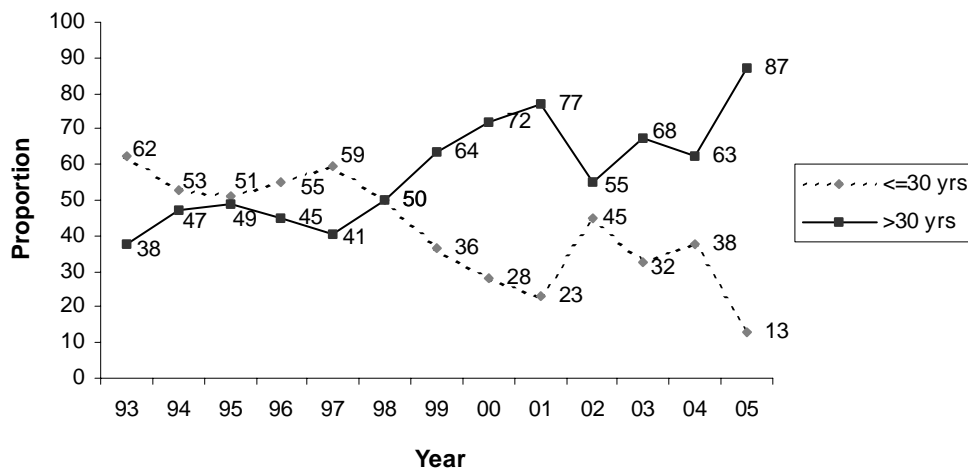


TABLE 1: 2004/05 SEMEN DONOR AGES

Age of Donor (years)	Number (%)
18-25	4 (6.6)
26-30	4 (6.6)
31-35	12 (19.7)
36-40	21 (34.4)
41-49	16 (26.2)
50 +	4 (6.6)
Total	61 (100)

Figure 3: Trends in Embryo Storage

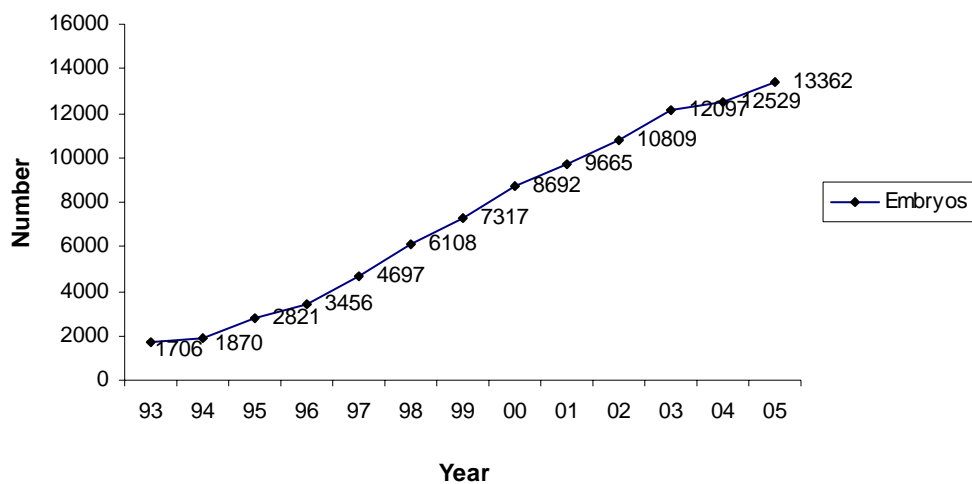


TABLE 2: DISPERSAL OF STORED EMBRYOS 2004/2005

	No of embryos
Embryos in storage 30/06/04	12529
Embryos created from IVF	4820
Transferred into WA clinics from interstate	69
Transferred between clinics in WA	83
Transferred to clinics outside WA (Patients moving interstate/overseas)	65
Used in frozen embryo transfer treatments	3572
Allowed to succumb with consent of couples	419
Embryos in storage 30/06/05	13362

Figure 4: ART Treatment Trends

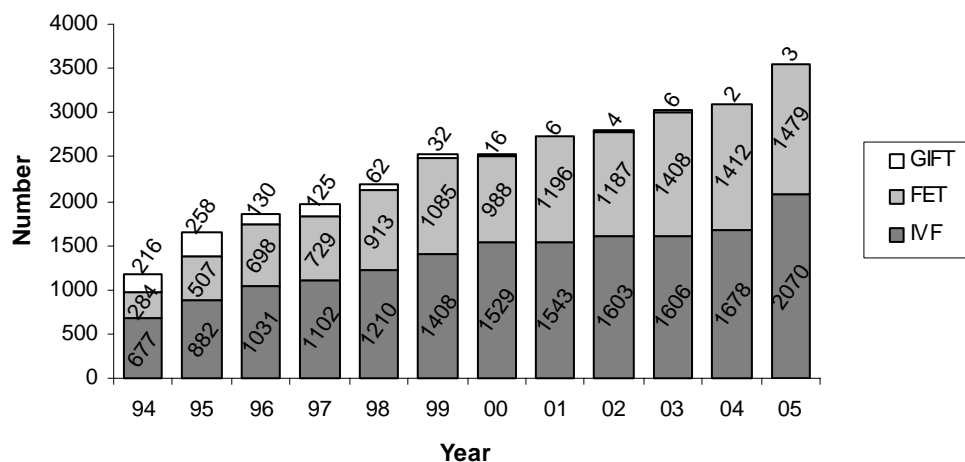


Figure 5: IVF (fresh) and GIFT Treatments

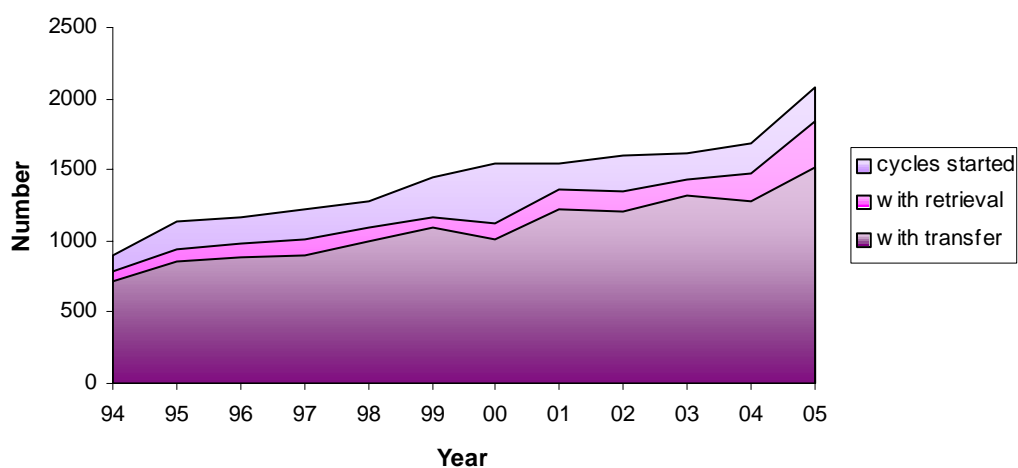


Figure 6: IVF cycles using ICSI

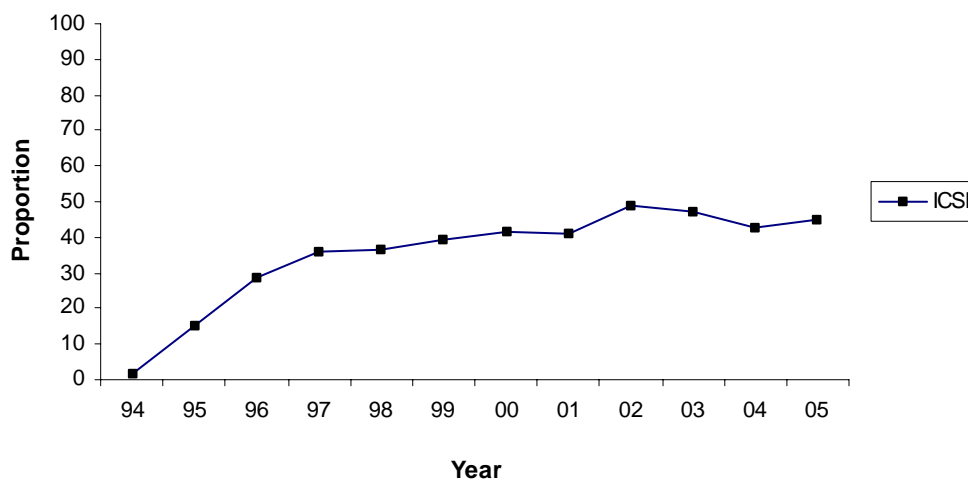


TABLE 3: 2004/05 IVF and GIFT TREATMENTS

	IVF (fresh)	IVF (frozen)	GIFT	TOTAL
Women treated	1366	695	2	2063
Cycles begun	2070	1479	3	3552
Cycles with egg retrieval	1835	-	1	1836
Cycles with gamete or embryo transfer	1515	1246	1	2762
Cycles with embryos storage	1029	-	0	1029
Number of cycles using donor:				
Semen	62	52	0	114
Eggs	23	51	0	74
Embryos	0	23	-	23
Total	85	126	0	211
Number of cycles from which human reproductive material was donated:				
Eggs donated	27	-	0	27
Embryos donated	0	-	-	0
Breakdown of treatment cycle details				
Cycles with IVF/GIFT same cycle	0	-	0	0
Cycles with surgical sperm aspiration	148	-	0	148
Cycles with ICSI*	827	-	-	827
Cycle with Fallopian embryo/egg transfer	3	0	1	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				
	00/01	01/02	02/03	03/04	04/05	00/01	01/02	02/03	03/04	04/05
IVF	87	77	50	65	77	126	114	71	82	111
GIFT	0	0	0	0	0	0	0	0	0	0
FET	19	64	39	27	30	101	142	127	104	115
TOTAL	106	141	89	92	107	227	256	198	186	226

APPENDIX 4

REPORT FROM THE REPRODUCTIVE TECHNOLOGY REGISTER: JANUARY 1 TO DECEMBER 31 2003

<p>REPORT FROM THE REPRODUCTIVE TECHNOLOGY REGISTER: 1 JANUARY TO 31 DECEMBER 2003</p>

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. The 2003 calendar year data represents 10 complete years of data collection. A separate report will be published which will provide a summary of 2003 data as well as a complete review of data from the Reproductive Technology Registers over ten years. This report will be available through the Department of Health and on the Reproductive Technology Council website at www.rtc.org.au.

APPENDIX 5

INFORMATION CIRCULATED TO LICENSEES

INFORMATION FOR CLINICS ON THE PROCLAMATION OF THE RECENT AMENDMENTS TO THE HUMAN REPRODUCTIVE TECHNOLOGY ACT 1991.

Background

Recent amendments to the Human Reproductive Technology Act 1991 (HRT Act) will come into operation 1 December 2004. All the amendments contained in the Human Reproductive Technology Amendment Act 2004 and the Acts Amendment (Prohibition of Human Cloning and Other Practices) Act 2004 will come into operation on that day. Those amendments will have significant impacts on your clinic's operations, which I first alerted you to in July 2004 following passage of the amendments.

Updated Directions to be given by the Commissioner of Health also commence on 1 December 2004. The revisions to the previously Gazetted Directions (1997) reflect the amendments to the HRT Act and otherwise incorporate earlier changes in policy which you have been aware of for some time, or reflect editing which has been carried out to make the Directions clearer.

The Directions may appear quite different but, other than as required by amendments to the HRT Act, there are no policy changes which you would be unaware of already.

This *Information for Clinics on the Proclamation of Recent Amendments to the HRT Act* (Information for Clinics) is to ensure that you are aware of the implications for your own clinic practices, as the required changes to your clinical practice or administration procedures must be in place by 1 December 2004.

Dealt with in this Information for Clinics are:

- Establishment of processes and standards for implementation of changes to the law relating to disclosure of identifying information in cases of donation of human reproductive material;
- Development and implementation of changes to embryo storage approval procedures;
- Development and approval of protocols for use of IVF to avoid transmission of infectious diseases such as HIV; and
- In relation to uses of embryos, an outline of appropriate responses to uses that are still to be overseen by the Reproductive Technology Council (Council) and uses that are to be overseen by the National Health and Medical Research Council (NHMRC) Licensing Committee.
-

If you have any queries or need any assistance, please contact staff of the Reproductive Technology Unit (RT Unit) or the Council.

Copies of the revised Directions will be sent to you as soon as they have been published in the Government Gazette and they will also be readily available from the State Law Publisher's web site as soon as they have been issued. An electronic version of the compiled HRT Act will also be available from the same web site, within a week of proclamation of the amendments.

You should now put in place revised protocols and patient information, as required to comply with the changes.

Please provide the Council with copies of your revisions by Friday 21 January 2005, in time for consideration at the February meeting of the Council (8 February 2005).

The establishment of approval processes for diagnostic testing of embryos (including pre-implantation genetic diagnosis (PGD)) is not covered in this document, as it is dealt with in full in a separate document.



**CA MICHAEL AO
CHAIR
Reproductive Technology Council
29 November 2004**

INFORMATION FOR CLINICS – AMENDMENTS TO THE HUMAN REPRODUCTIVE TECHNOLOGY ACT 1991 EFFECTIVE FROM 1 DECEMBER 2004

1. Implementation of changes to the law relating to disclosure of identifying information in cases of donation of human reproductive material.

Amendments

Sections 49(2), (2a), (2b), (2c), (2d), (2e), (2f) of the *Human Reproductive Technology Act 1991* (HRT Act)

Revised Directions to be issued by the Commissioner of Health on 1 December 2004

Direction 8.5.

Effects

i) Donor offspring, upon reaching the age of 16, may be given identifying information about the donor.

Donor offspring, upon reaching the age of 16 and having undertaken approved counselling have the right to identifying information about the donor in circumstances where:

- The reproductive material was donated after the amendments come into effect (1 December 2004);
- The donation was made before 1 December 2004, but the Commissioner of Health is satisfied that there is clear evidence that the donor was informed that disclosure of identifying information was likely should there be a future change in the legislation; or
- The donation was made before 1 December 2004, but the donor on or after 1 December 2004 gave consent to the use.

ii) Parents who have used donated human reproductive material may consent on behalf of their minor children for sharing of identifying information.

Parents who have used donated human reproductive material to form their families may consent on their own behalf and on behalf of their minor children for sharing of identifying information about the donor, the recipients and the child where both the donor and recipient request this and in so far as it does not disclose the identity of any participant who has not given consent. This is to follow counselling (approved by the Commissioner of Health on advice from the Council) to address, in particular, what may be in the best interests of the child.

Implications and Actions for Licensees

i) Donations made after 1 December 2004.

For all donors who donate human reproductive material after 1 December 2004, licensees must ensure that the donors have consented to the material being used in the knowledge that the law provides that identifying information may be released to a

donor offspring aged 16 or over (Direction 4.2 refers to this). No donated human reproductive material should be accepted unless the donor is aware that identifying information will be provided to mature donor offspring if requested by the offspring and has consented to the future use of the material in this knowledge.

Donors should also be advised that once the donation has been used they will not have any opportunity to prevent the future release of identifying information to the donor offspring.

Licensees need to update patient information and consent forms explaining the impact of the amendments.

ii) Donations made prior to 1 December 2004 and used prior to 1 December 2004.

There will be no retrospective right to identifying information for offspring conceived using material donated before the commencement of the amendments, unless the donor had donated with knowledge that identifying information may be provided to offspring in the future. It is only where the donation was made with the knowledge that identifying information may be provided, or with the consent of these donors, that this information may be shared. In other words information may be provided in situations where there is clear evidence that the donor was aware at the time of the donation that information may later be provided to any resulting child.

This latter provision of information will be a matter of evidence, based on the records of the clinic at the time the donation was made. If a clinic considers that the donor had been provided with adequate information about possible future changes to the release of identifying information, the clinic should provide evidence of this to the Commissioner of Health for consideration. The Commissioner must be satisfied that the donor was adequately informed.

iii) Donations made prior to 1 December 2004 and not yet used.

Clinics with stored reproductive material donated prior to 1 December 2004 should attempt to contact the donors to seek a new consent to the use of the donated material. The new consent should either be given after 1 December 2004 (following appropriate information about the impact of the amendments), or should clearly indicate that the donor is aware that changes in the law will allow identifying information about the donor to be provided to a mature donor offspring.

Where the donor(s) cannot be found, or do not consent to the release of identifying information, their donated material should not be used again, except in circumstances established under new Direction 8.5 (b), (c) and (d).

The effect of the exceptions in these Directions 8.5 (b) and (c) is not that any donor offspring conceived using the donated material under these circumstance has a right to identifying information about the donor without the donor's consent. The donated material may be used under these exceptional circumstances, but any offspring conceived will not have a right to access to identifying information about the donor at age 16.

The circumstances where donated material can be used without the donor giving consent to the release of identifying information are:

- where an embryo was developed prior to 1 December 2004 using donated material and is in storage;

- where woman who has a child conceived using donated material prior to 1 December 2004 wishes to undergo a further donor treatment with the aim of having a full sibling to the existing donor child.

Material donated before 1 December 2004 may also be used where there was clear evidence that, at the time of the donation, the donor was advised about the possibility of changes in the law relating to provision of identifying information. In this case information can be provided to a mature donor offspring if requested. Before the donated material is used, the clinic must ensure the Commissioner of Health is satisfied about the adequacy of the information that was provided to the donor at the time of the donation.

Licensees need to update patient information and all relevant consent forms explaining the impact of the amendments.

iv) Sharing Identifying Information where children are under 16 years.

For children under 16 years each donor and recipient needs to consent to sharing identifying information and the parent needs to consent on behalf of the child. There must be “approved counselling” of all parties (which may include the child). In the interim the licensee can apply to the Commissioner of Health (via the Council) for approval concerning counselling and include the details of counselling proposed and by whom.

v) Counselling for New Donors and Recipients.

Counselling for new donors and recipients must explore issues concerning potential release of their identifying information to a donor offspring aged 16 or over.

2. Embryo storage approval procedures.

Amendments

Sections 3, 24, 28A, 53W(2)(a)(i,) of the HRT Act.

Revised Directions to be issued by the Commissioner of Health on 1 December 2004

Part 6

Effects

These amendments have significant implications relating to the storage of embryos, in relation to both the duration of permitted storage, persons who may apply for any extension to this and the removal of embryos from storage at expiry of permitted storage.

Implications and Actions for Licensees:

i) The maximum period of allowed storage of an embryo or an egg undergoing fertilisation is now 10 years. This amendment applies to all embryos regardless of when they were created. It remains unlawful for a licensee to store an embryo beyond its permitted storage period. Where embryos have already been extended by form 8 or 9 beyond 10 years, their storage term expires on the date specified by Council in the most recent extension.

ii) On the written application of an eligible person the Council may, if it considers there are special reasons in a particular case, grant an extension to permitted storage. Patients may apply for extension to the storage period of their own embryos, through the revised Form 8 application set out in the revised Directions, and Council will consider these on a case-by-case basis.

Other than where embryos have been donated for a use requiring a licence from the NHMRC (eg embryos donated for research), after 1 December 2004 clinics will no longer be able to apply for extension of the storage limit for patients using Form 9s.

iii) A licensee may allow an embryo to succumb without being subject to liability if the permitted storage period has ended and no application for extension is made, as long as they have taken reasonable steps *three months* before the end of the storage period to notify each person for whom an embryo is being stored that the storage period is coming to an end. (S 24(3) and (4)).

Council remains unable to approve applications to extend storage after expiry of the approved storage limit.

Changes to patient information and clinic protocols/ administrative processes are required.

3. Use of IVF to avoid transmission of infectious diseases such as HIV.

Amendments

Section 23(a)(ii) of the HRT Act

Effects

This amendment means IVF treatment can now be carried out where it would benefit a couple or woman whose child would otherwise be likely to be affected by a disease other than a genetic disease (eg an infectious disease such as HIV or Hepatitis)

Implications and Actions for Licensees:

Licensees may choose to introduce new practices to treat these eligible patients with IVF (or AIH) to avoid transmission of an infectious disease, such as HIV. At this stage, Council considers the protocols used for infection control and sperm washing to be “innovative procedures”. A clinic proposing to offer these treatments should make an appropriate application to the Council for approval prior to commencement.

Therefore, when applying for approval to carry out IVF, ICSI or IUI to avoid transmission of an infectious disease such as HIV the following need to be demonstrated:

- The reason for wanting to introduce the procedure;
- If the procedure is to be used on specific groups of patients the criteria for inclusion;
- Details on whether the procedure is used in other reputable clinics (nationally or internationally);
- Whether the procedure is expected to be successful in the clinic (eg training of staff to undertake the procedure);
- Safety and Effectiveness of the procedure based on research reports in the internationally peer-reviewed literature;
- Any risks of the procedure and outcomes.

4. The interface between uses of embryos that are still to be overseen by the Council and uses of embryos that are to be overseen by the NHMRC Licensing Committee

Amendments

Sections 53T(1) ('proper consent'); 53T(2); 53W (2) and (4) of the HRT Act.

Revised Directions to be issued by the Commissioner of Health on 1 December 2004

Revised Directions 4.3, 3.8 – 3.10

Effects

Embryos that are no longer required for the treatment of the persons for whom they were created may be determined by those persons to be "excess ART embryos".

All uses of excess ART embryos, other than certain 'exempt uses' that are defined in section 53W of the HRT Act (and set out below) require an NHMRC Licence.

Implications and Actions for Licensees:

- i) A licensee wishing to use an excess ART embryo for any purpose other than an exempt use should contact the NHMRC Licensing Committee for guidance on procedures for applying for a licence for that use.

Revised Directions 4.3, 3.8, 3.9 and 3.10, set out details of the requirements for consent to donation of excess ART embryos for research..

- ii) All uses of embryos within clinical practice and all 'exempt uses' are to be overseen by the Council. The Council will oversee the following 'exempt uses' of excess ART embryos:

- Storage; removal from storage; and allowing to succumb;
- (See section 2 above for more information on storage)
- Transport;
- Observation only;
- Some diagnostic procedures;
- Donation to another couple for treatment.

Persons eligible to apply for extensions to storage of excess ART embryos will depend on whether these are to be donated for another couple or research. This is covered in more detail in part 2 herein (Embryo storage).

Where a diagnostic procedure on an embryo is to be carried out the requirements and approval processes will differ depending on whether the embryo to be tested is an excess ART embryo or not. This is covered in detail in separate information already provided to clinics by the Council: *(Approval for diagnostic testing of embryos: Advice to clinics, November 2004).*



Reproductive Technology Council

**TO: LICENCE SUPERVISORS AT ALL CLINICS LICENSED UNDER
THE *HUMAN REPRODUCTIVE TECHNOLOGY ACT 1991* TO
PERFORM IVF PROCEDURES**

**FROM: PROFESSOR CA MICHAEL AO
CHAIR
REPRODUCTIVE TECHNOLOGY COUNCIL**

DATE: 24 MAY 2005

**RE: MINIMUM STANDARDS FOR ICSI USE, SCREENING, PATIENT
INFORMATION AND FOLLOW-UP IN WA FERTILITY CLINICS**

The Reproductive Technology Council (Council) wishes to inform clinics licensed under the *Human Reproductive Technology Act 1991* (HRT Act) that treatment by intra-cytoplasmic sperm injection (ICSI), when carried out in compliance with the attached standards, is not considered an 'innovative practice' and specific approval of the Council is not required.

The Council still needs to be satisfied that the criteria set out in Schedule 5 Part 2 to the Directions are met however, in deciding whether ICSI may be considered routine under particular circumstances. Licensees will need to ensure that if they are to carry out ICSI in the permitted circumstances, the procedure to be followed is set out in a detailed manual for which Council approval is obtained (in accordance with Direction 9.2 and 9.3) and that the documentation set out in Schedule 5 is provided to the Council (on request).

Following the recent amendments to the HRT Act, the Council may approve the diagnostic testing of embryos and the use of ICSI prior to pre-implantation genetic diagnosis is included in these standards. The European Society for Human Reproduction and Embryology (ESHRE), in its 'Best Practice Guidelines for Clinical PGD/PGS testing', strongly recommends the use of ICSI prior to polymerase chain reaction (PCR) and finds it an acceptable alternative to conventional insemination for fluorescence in situ hybridisation (FISH) cases.

Recent amendments to the HRT Act may now also allow the use of IVF to avoid transmission of an infectious disease and the use of ICSI under these circumstances is included in the standards. However, other aspects of such treatments (such as infection control procedures) will require consideration and approval by the Council and your HREC, as innovative practices.

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

Please note the attached *Minimum standards for ICSI*, which set the standards under which ICSI may be considered to be a routine procedure, not requiring the specific approval of the Council. At the 24 May 2005 meeting Council agreed to add to the minimum standards the use of ICSI where there is a history of polypronuclear oocytes.

Please apply to the Council for specific approval in the usual manner, in the event you wish to introduce the use of ICSI in circumstances outside these standards or involve any other innovative procedures.



CA MICHAEL AO
CHAIR
Reproductive Technology Council
24 May 2005

Attachment

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

May 2005

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.

Bonduelle et al, 2005 A multi-centre cohort study of the physical health of 5-year-old children conceived after intracytoplasmic sperm injection, in vitro fertilization and natural conception. *Human Reproduction* 20(2): 413-419.

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-Wiedemann 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.

May 2005

- 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 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.
- 2.7 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**).
- 2.8 '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.

2.9 '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.

2.10 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. Follow-up 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.

5. Protocols 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.

APPROVAL FOR DIAGNOSTIC TESTING OF EMBRYOS

ADVICE TO CLINICS

Reproductive Technology Council

November 2004

BACKGROUND

The *Human Reproductive Technology Amendment Act 2004* and the *Acts Amendment (Prohibition of Human Cloning and Other Practices) Act 2004* is expected to come into operation on 1 December 2004. Both of these Acts amend the *Human Reproductive Technology Act 1991* (the HRT Act).

The amendments to the HRT Act will permit the diagnostic testing of embryos (including pre-implantation genetic diagnosis (PGD) and pre-implantation genetic screening (PGS)) to be undertaken in Western Australia. The relevant legislative provisions are set out in attachment 1.

All diagnostic procedures carried out on an embryo must have the prior approval of the Reproductive Technology Council (Council).

The *Approval for Diagnostic Testing of Embryos - Advice for Clinics* (Advice for Clinics) provides information for clinics about the approval processes for all diagnostic testing involving embryos.

Applications for approval should be made using the application form provided by the Council. This may be available on the Council's web site or sent on request.

The Advice for Clinics does not deal with diagnostic procedures that may be carried out on unfertilised eggs or eggs undergoing fertilisation, such as the testing of polar bodies removed prior to the formation of two pronuclei. Such testing is however regulated under the HRT Act and requires Council approval. An application for approval to test unfertilised eggs or eggs undergoing fertilisation should be made as an application for approval for an innovative procedure.

CATEGORIES OF TESTING

The HRT Act places different requirements on approval of each of the two broad categories of diagnostic testing that may be undertaken on embryos, depending on whether the diagnostic procedures are to be carried out prior to implantation or on embryos that are not to be implanted.

Pre-implantation procedures

Where the embryo is to be implanted the Council must be satisfied, based on scientific and medical knowledge, that the procedure is 'unlikely to leave the embryo unfit for implantation' and there is 'a significant risk of a serious genetic abnormality or disease being present in the embryo'.

Diagnostic testing carried out prior to implantation is generally intended to allow selection of embryos that do not have an abnormality or disease for implantation. A distinction may be made between pre-implantation genetic diagnosis (PGD), where pre-existing diagnosis indicates that an embryo is at a significant risk of being affected by a serious genetic condition, and pre-implantation genetic screening (PGS), carried out in categories of patients

thought to be at higher than average risk of conceiving abnormal embryos (also known as aneuploidy screening).

Diagnosis in excess ART embryos

Most uses of excess ART embryos are subject to a licensing requirement that is to be administered by the National Health and Medical Research Council.

One exception to this requirement is in relation to excess ART embryos that are being tested as 'part of diagnostic investigations conducted in connection with the assisted reproductive technology treatment of the woman for whom the excess ART embryo was created'. The Council can approve diagnostic testing of an embryo in this circumstance if the embryo is not suitable for implantation (solely on the basis of its biological fitness).

ELIGIBILITY

Participants who are seeking genetic testing of embryos must be eligible to receive IVF treatment in accordance with the requirements in section 23 of the HRT Act.

FACTORS TO BE CONSIDERED BY THE COUNCIL IN DECIDING WHETHER TO APPROVE PRE-IMPLANTATION GENETIC TESTING

In deciding whether to approve a pre-implantation diagnostic procedure on an embryo, the Council will consider:

- the risk and severity of the condition that is to be tested for;
- the safety and reliability of the procedures to be used in the embryology and the genetics laboratories;
- the availability of counselling and other support and coordination services.

The seriousness of a genetic disease should be considered in the broad context of the environmental and personal factors of the participants who are seeking the diagnostic testing.

THE CONDITION THAT IS TO BE TESTED FOR

Conditions that may be tested for fall into two categories:

- pre-implantation genetic screening (PGS, eg aneuploidy screening), and
- testing for single gene defects and translocations (pre-implantation genetic diagnosis (PGD)).

Aneuploidy

Aneuploidy refers to the occurrence of one or more extra or missing chromosomes. This can have serious consequences for a single cell or an entire organism. Chromosomal aneuploidy may lead to infertility, pregnancy loss – such as miscarriage or stillbirth – the death of a child, as well as a number of birth defects, genetic syndromes and/or mental retardation.

The Council considers that aneuploidy is a serious genetic abnormality.

The process that results in eggs or sperm having extra or missing chromosomes is an unpredictable and unpreventable accident of nature. There are, however well identified indicators of circumstances in which there is a significant risk of aneuploidy.

PGS or aneuploidy screening may be approved for the following categories of people who are eligible for the IVF program and who are considered to be at significant risk of producing an embryo that is chromosomally abnormal:

- women over 35 years of age providing eggs; or
- women with >2 miscarriages; or
- women with >2 failed IVF attempts where embryos have been transferred; or
- women referred by a clinical geneticist with a family history of aneuploidy not caused by translocations or other chromosomal rearrangements.

Each clinic will need to apply for approval to conduct aneuploidy screening, but this will not be required on a case by case basis. An application seeking approval based on the above criteria should include copies of the relevant clinical protocols.

Aneuploidy screening may be approved in additional circumstances on a case by case basis. The clinic requesting approval on different criteria to those outlined above should provide relevant scientific and medical data in support of the additional/different criteria.

Single gene defects and translocations

The increased knowledge about the human genome has contributed to a greater awareness of the contribution of genetics to many diseases (or the response that a person has to those diseases). One small DNA alteration in a critical gene can lead to a severe inherited disease, a predisposition to chronic diseases or greater vulnerability to an infectious disease.

There are a vast number of conditions that may result from a genetic defect and a variety of factors that may indicate a risk of transmission of the defect.

There is not a specific list of conditions that will be approved for testing for by PGD.

The Council will approve PGD for individual cases, based on support of a clinical geneticist (accredited by the Human Genetics Society of Australasia (HGSA)) who has assessed the risk and seriousness of the condition to be tested for and discussed relevant issues with the participants requesting the testing.

An application for approval of testing for a single gene defect or translocation should be made by the clinic and include a report from the clinical geneticist addressing the following questions as relevant:

- Is there a significant risk of a serious genetic abnormality or disease in the context of the family that is requesting the testing?
- What is the genetic abnormality or disease that is to be tested for?
- What experience with, and attitude to, the abnormality or disease does the family requesting the testing have?
- What factors indicate that there is a risk that the embryo will be affected by the genetic abnormality or disease?
- What is the level of impairment to body functions and structures that is usually associated with the abnormality or disease?
- What difficulties would a person with the abnormality or disease be expected to have in participating in the activities such as learning and applying knowledge, communication, mobility, self care, employment and community, social and civic life?

- What is the level of support that would be required by a person who has the abnormality of disease?
- What are the prospects for new and longer term treatments and interventions for the condition?
- What is the capacity of the family who are requesting the testing to provide the level of support required by a child with the abnormality or disease?
- What clinical genetic and diagnostic data is to be used in the testing procedure?
- What other testing options are available?
- What level of information will be possible from the test, in terms of interpretation, sensitivity and specificity (includes error)?
- Has the person requesting the testing been provided with counselling about the potential impact of testing and contact information for other persons or organisations that have experience with the condition?

The persons who are seeking to have their embryos tested may include a statement about the impact of the abnormality or disease from their own perspective in the application.

An application for genetic testing should contain only de-identified information about any participant. Care must also be taken not to disclose any non-relevant personal, private or confidential matters.

Additional matters

Sex selection

The use of an embryo diagnostic procedure for sex selection alone is not permitted.

Although genetic testing for other purposes may provide information about the sex of an embryo, information conveyed to participants should not include information about the sex of the embryo, unless this is relevant to the genetic abnormality or disease.

Carrier embryos

Carrier embryos are those embryos where the condition itself will not be present, but where a person resulting from the embryo would be at risk of passing on the disease or illness to subsequent offspring.

There may be circumstances where it would be appropriate to provide information to participants about the carrier status of tested embryos, with the approval of the Council, particularly where a carrier may be symptomatic for the disease state.

An application for approval of the genetic testing should include a request for approval to disclose information about the carrier status of embryos tested to the participants.

Export for testing

Clinics will be permitted to export genetic material for testing elsewhere, if that testing and the testing facility has been approved by the Council. Genetic material may not be exported for testing elsewhere if that testing has not been approved by the Council.

SAFETY AND RELIABILITY OF PROCEDURES— Standards for facilities, staffing and technical procedures.

Guidelines on the appropriate standards for facilities, staffing and technical procedures are provided below. Each clinic must apply for approval to undertake the testing using the application form provided by the Council, which includes information to allow the Council to assess the capacity of the clinic to meet the following guidelines relating to the safety and reliability of the procedures.

General approval of ICSI

The Council has extended the general approval of ICSI to include use to develop embryos that will be genetically tested. This improves the reliability of genetic testing by minimising the risk of contamination of biopsied material.

Guidelines for embryology laboratories

Approval for the embryo biopsy procedures and any other new or amended embryology procedures (such as the use of extended culture to enable the transfer of fresh embryos following biopsy and diagnosis) will be required from the Council. The normal processes of specific approval should apply, including a requirement for prior approval from a Human Research Ethics Committee.

In deciding whether a diagnostic test is 'unlikely to leave the embryo unfit for implantation' (unlikely to harm the embryo), it is necessary to consider the safety and reliability of biopsy procedures to be undertaken in the embryology laboratory.

The standards for approval of embryology laboratories and procedures are as follows:

- Laboratories must be licensed under the HRT Act and maintain accreditation by the Reproductive Technology Accreditation Committee (RTAC)
- Laboratories must participate in a QA program recognised by RTAC or NATA
- The biopsy procedure to include setting up of micro-tools on an inverted microscope, placing oocyte/embryo in micro-droplets for the procedure, removal of cell/polar body, placing cell into appropriate transport container

- The biopsy techniques to be used may be acid Tyrode's or laser, as approved by the Council
- Biopsy may be in the form of polar body biopsy, embryo biopsy (at day 3) or blastocyst as approved by the Council
- Staff performing the biopsy must have demonstrated competency in:
 - the proposed biopsy technique
 - placing the cell(s) in transport vessel, in the case of single gene defects; and,
 - fixing of cell(s) on a slide in the case of chromosome analysis

through documented evidence of training and use, such as in an animal model or under a licence issued by the NHMRC Licensing Committee.

- Laboratories must demonstrate competency in transfer of cell(s)/polar body(s) to a testing laboratory in a state capable of being analysed and free from contaminants
- Where the cell(s) are to be couriered interstate/overseas for genetic testing, laboratories must demonstrate that the proposed courier system is safe, accurate and efficient (including quick 'turn-around')
- Where cell(s) from a day 3 embryo are to be couriered interstate/overseas for genetic testing with the intention of the embryo(s) being transferred in the same cycle, the laboratory/centre must have approval to undertake blastocyst culture as part of clinical procedures
- Embryo(s) from which biopsies have been taken may not be transferred with any other (non-biopsied) embryos in the same treatment cycle

Guidelines for genetic testing laboratories

The Council understands that WA clinics are unlikely to establish their own genetic testing facilities, at least in the short term, and will send biopsied material to genetic testing laboratories outside of WA. As the genetic testing laboratories are not themselves subject to licensing under the HRT Act, approval should include approval for the facility to which the material will be transferred for testing.

The standards for approval of genetics laboratories and procedures are as follows:

Labs performing Pre-implantation genetic diagnosis- aneuploidy screening (PGD-AS) or other Fluorescence in situ Hybridisation (FISH) based tests

- Laboratories must be accredited by the National Association of Testing Authorities (NATA), (or working towards accreditation within the NATA 3 year cycle) to carry out the type of testing being undertaken.

- Laboratories must meet all relevant NATA and National Pathology Accreditation Advisory Council (NPAAC) requirements for testing.
- Laboratories must participate in an accredited quality assurance program (QAP) for FISH, preferably with a PGD component, which may be offshore.
- Laboratories should adhere to the standards set by the European Society for Reproduction and Embryology (ESHRE) (see ESHRE website) unless otherwise approved by the Council.
- All PGD testing should conform with the Australian standard for PGD-AS (if any).

Standards for Labs performing PGD by molecular genetic methods

- Laboratories must be NATA accredited (or working towards accreditation within the NATA 3 year cycle) to carry out the type of testing being undertaken.
- Laboratories must meet all relevant NATA and NPAAC requirements for testing.
- Laboratories must participate in an accredited QAP for molecular genetics, preferably with a PGD component, which may be offshore.
- Laboratories should adhere to the standards set by the European Society for Reproduction and Embryology (ESHRE) (see ESHRE website) unless otherwise approved by the Council.
- All PGD testing should conform with the Australian standard for PGD-by molecular techniques (if any).

COUNSELLING AND OTHER SUPPORT AND COORDINATION SERVICES

The Council considers that participants in IVF must have access to accurate information and counselling about any proposed genetic testing of embryos.

In the case of single gene defects and translocations a genetic consultation with a clinical geneticist who provides a report to the Council as required in the application for approval is mandatory. The consultation may also involve a genetic counsellor who is accredited by the HGSA as required.

In the case of aneuploidy screening, participants must have a consultation with the clinic counsellor (an 'approved counsellor' under the HRT Act), to assist in understanding the ramifications of genetic testing in the IVF setting.

Approved counsellors providing counselling in a clinic that offers aneuploidy screening should have some understanding of genetics, as ideally also should embryologists and nurses, so that they can adequately assist couples undergoing PGD or aneuploidy screening. This would not replace the role of the clinical

geneticist or trained genetic counsellor as being the main source of complex genetic information where this is requested, required or recommended.

An application for approval of genetic testing of embryos should include details of the availability and qualifications of staff employed by the clinic to provide information about the testing and counselling.

Coordination of services

The Council is concerned at the number of steps that any participant must go through in the course of undergoing embryo diagnostic procedures, involving a range of professional services, ranging from genetics services, to the local ART clinic and perhaps an interstate genetics laboratory.

Clinics offering embryo diagnostic procedures must put in place a named staff member whose role it is to act as 'PGD coordinator' and coordinate the information relating to each person undergoing the procedures and respond the patient queries about progress with their testing. This person may be the clinic counsellor, a nurse or other person. The role of the PGD coordinator is set out in more detail in the flowcharts at Attachment 2.

An application for approval of genetic testing of embryos must include details of the person who is to act as the PGD coordinator.

Record keeping

To allow comprehensive follow-up of outcomes after PGD or aneuploidy screening, conditions on approvals will require the following additional data items be provided by the Clinic for inclusion in the Registers maintained under the HRT Act.

- # embryos biopsied;
- # embryos damaged (unfit for implantation);
- reason for genetic testing (aneuploidy screening or PGD);
- # embryos successfully screened;
- and list of gene defects tested for.

The new data items will allow the calculation of rates of damage to the embryo and no-diagnosis, reason for the test (aneuploidy testing or PGD) and diseases tested for.

DIAGNOSTIC TESTING OF EXCESS ART EMBRYOS

The scope of diagnostic testing of excess ART embryos that is permitted under the HRT Act is very narrow. The diagnostic testing must be part of clinical practice. Approval to undertake assessment should be on the same basis as approval for an innovative procedure ie on a clinic by clinic basis. Conditions on the approval should address issues such as counselling, information giving and reporting and record keeping. Applications for approval of these procedures must also be made using the application form provided by the Council.

FRAMEWORK FOR THE APPROVAL OF EMBRYO TESTING

The *Framework for Approval of Embryo Diagnostic Procedures* (the Framework) at Attachment 3 summarises the advice set out above.

Part A of the Framework sets out the guidelines for genetic testing of embryos intended for implantation.

Part B of the Framework sets out the guidelines for diagnostic testing of excess ART embryos.

APPLICATION FOR APPROVAL

An application to the Council for approval to undertake testing of an embryo should be made on the *Application for Approval to Carry Out Embryo Diagnostic Procedures* that is attached at Attachment 4.

The application form is also available on the Council's website (www.rtc.org.au) or can be emailed on request. The application includes instructions for the completion and lodging of the forms.

Diagnostic testing of embryos (including Pre-implantation genetic diagnosis (PGD)): Relevant sections of the amended HRT Act 1991.

7. Offences relating to reproductive technology

- (1) A person, whether or not a licensee, must not cause or permit —
 - (b) a diagnostic procedure to be carried out upon or with a human egg undergoing fertilisation, or any embryo, not being a procedure which is —
 - (i) authorised by the Code; or
 - (ii) specifically approved by the Council.

14. Functions of the Council

- (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).

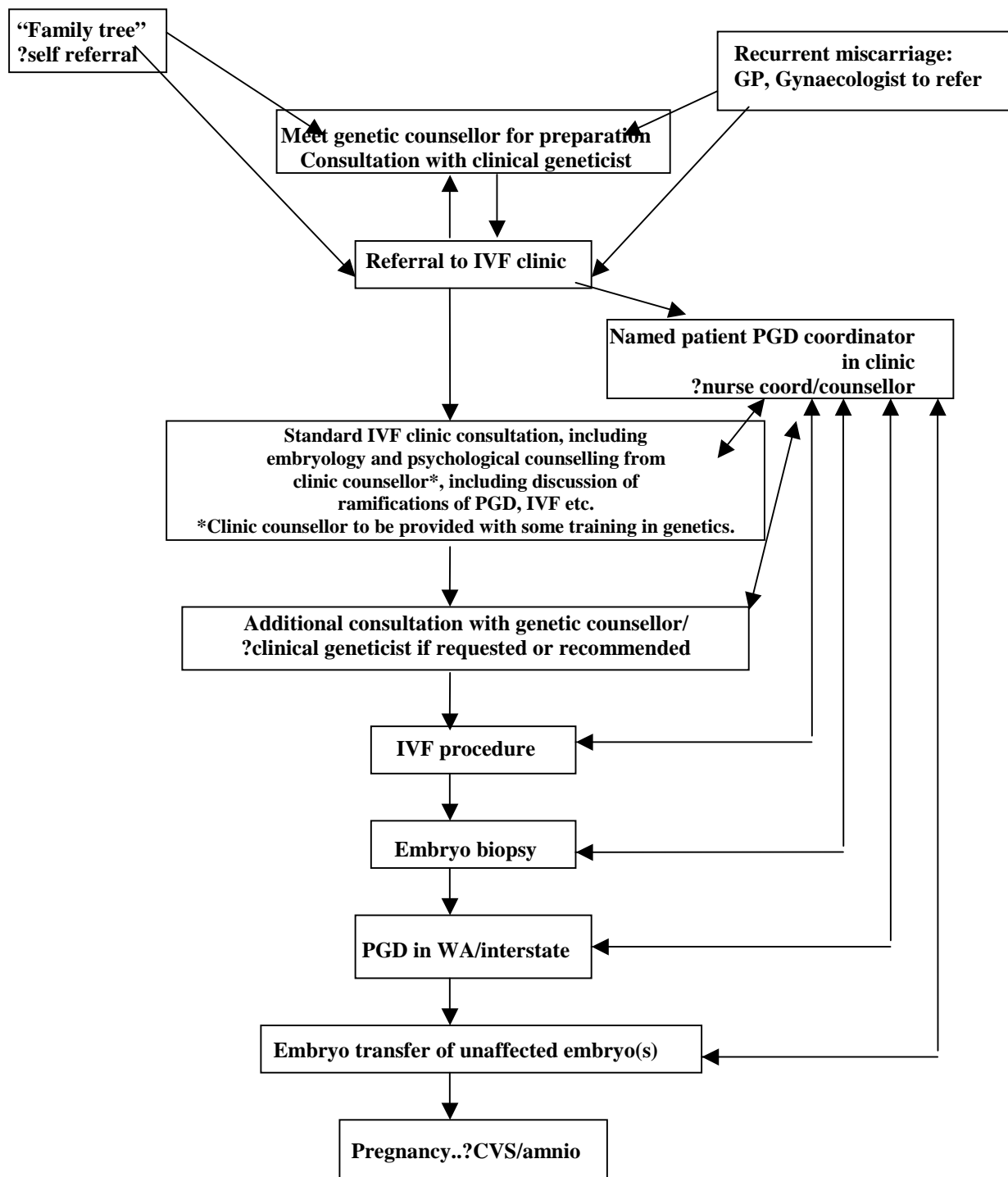
Excerpts from 53W. Offence — use of excess ART embryo

- (2) A use of an excess ART embryo by a person is an “**exempt use**” for the purposes of subsection (1) if —
 - (d) the use is carried out by a licensed ART centre, and —
 - (i) the excess ART embryo is not suitable to be placed in the body of the woman for whom it was created where the suitability of the embryo is determined only on the basis of its biological fitness for implantation; and
 - (ii) the use forms part of diagnostic investigations conducted in connection with the assisted reproductive technology treatment of the woman for whom the excess ART embryo was created;
 - (f) the use is of a kind prescribed by the Commonwealth Human Embryo regulations for the purposes of section 10(2)(f) of the Commonwealth Human Embryo Act.
- (4) In subsection (2) —
 - “**diagnostic investigation**”, in relation to an excess ART embryo, means any procedure undertaken on embryos for the sole purpose of diagnostic investigations for the direct benefit of the woman for whom it was created;

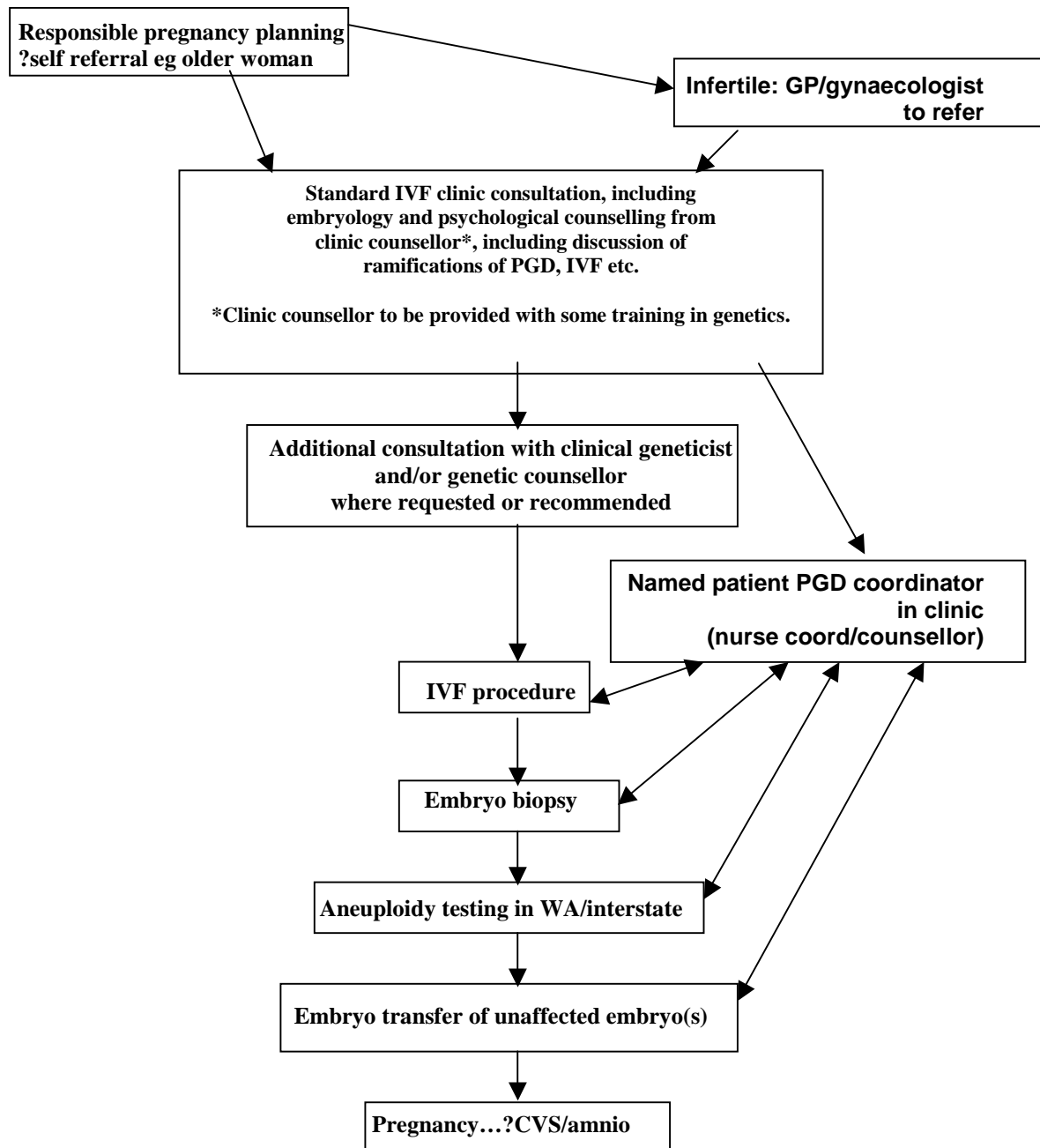
FLOW CHARTS

FLOW CHARTS FOR COORDINATION OF PRE-IMPLANTATION EMBRYO DIAGNOSTIC PROCEDURES IN WA: TWO SCENARIOS

A. PGD WHERE PRE-EXISTING DIAGNOSIS INDICATES SIGNIFICANT RISK OF A SERIOUS GENETIC CONDITION IN THE EMBRYO



B. PROCEDURES TO BE CARRIED OUT IN CATEGORIES OF PATIENTS AT HIGHER THAN AVERAGE RISK OF CONCEIVING ABNORMAL EMBRYOS (ANEUPLOIDY SCREENING)



A. Pre-implantation diagnostic procedures

May only be offered where participants are eligible for IVF under the HRT Act:

Either they are unable to conceive a child due to medical reasons OR their child would otherwise be likely to be affected by a genetic abnormality or disease.

Clinics seeking authorisation should obtain a copy of the *Application for Approval to Carry Out Embryo Diagnostic Procedures*.

A.1 Diagnostic procedures to be carried out in categories of patients thought to be at higher than average risk of conceiving abnormal embryos.

1. Generally authorised under the Act, under certain conditions

- a) Initially general authorisation will be clinic by clinic, but all to the same standards.
- b) Criteria for eligibility:
 - women over 35 years of age providing eggs; or
 - women with >2 miscarriages; or
 - women with >2 failed IVF attempts where embryos have been transferred; or
 - women referred by a clinical geneticist with a family history of aneuploidy not caused by translocations or other chromosomal rearrangements; or
 - otherwise as approved on a case by case basis by the Council.'

A.2 Diagnostic procedures to be carried out where pre-existing diagnosis indicates that an embryo is at a significant risk of being affected by a serious genetic condition.

1. Case by case approval

- (a) Applications for approval must be made on the proforma provided.
- (b) Support from a clinical geneticist accredited by the Human Genetics Association of Australasia
- (c) A report from the clinical geneticist addressing the following questions as relevant:
 - Is there a significant risk of a serious genetic abnormality or disease in the context of the family that is requesting the testing?
 - What is the genetic abnormality or disease that is to be tested for?
 - What experience with, and attitude to, the abnormality or disease does the family requesting the testing have?
 - What factors indicate that there is a risk that the embryo will be affected by the genetic abnormality or disease?
 - What is the level of impairment to body functions and structures that is usually associated with the abnormality or disease?
 - What difficulties would a person with the abnormality or disease be expected to have in participating in the activities such as learning and applying knowledge, communication, mobility, self care, employment and community, social and civic life?
 - What is the level of support that would be required by a person who has the abnormality of disease?
 - What are the prospects for new and longer term treatments and interventions for the condition?
 - What is the capacity of the family who are requesting the testing to provide the level of support required by a child with the abnormality or disease?
 - What clinical genetic and diagnostic data is to be used in the testing procedure?
 - What other testing options are available?
 - What level of information will be possible from the test, in terms of interpretation, sensitivity and specificity (includes error)?
 - Has the person requesting the testing been provided with counselling about the potential impact of testing and contact information for other persons or organisations that have experience with the condition?

Conditions:

Conditions:

-
- | | |
|---|---|
| <p>(a) Any participant whose embryos are to be tested must meet criteria for eligibility for the testing that are set by the Council.</p> | <p>(a) Council approval for the testing must have been obtained</p> |
| <p>(b) Any licensee proposing to carry out such tests must have prior approval from the Council for all stages of the procedures involved in the biopsy and ongoing culture of the embryos (innovative practices), to ensure that the procedures are 'unlikely to leave the embryo unfit for implantation';</p> | <p>(b) Any licensee proposing to carry out such tests must have prior approval from the Council for all stages of the procedures involved in the biopsy and ongoing culture of the embryos (innovative practices), to ensure that the procedures are 'unlikely to leave the embryo unfit for implantation';</p> |
| <p>(c) The types of genetic tests to be carried out and the laboratories where they are to be performed must be approved by the Council to ensure that the tests are feasible and likely to be safe and effective; and</p> | <p>(c) The types of genetic tests to be carried out and the laboratories where they are to be performed must be approved by the Council to ensure that the tests are feasible and likely to be safe and effective; and</p> |
| <p>(d) Reporting and record keeping requirements must be complied with.</p> | <p>(d) Reporting and record keeping requirements must be complied with.</p> |
| <p>(e) Counselling, information giving and consent requirements must be complied with.</p> | <p>(e) Counselling, information giving and consent requirements must be complied with.</p> |

2. Extensions to the criteria for eligibility:

Clinics may apply to the Council for any extension to the criteria for eligibility for this testing.

This request should detail why the extension is needed and provide documented evidence that the requirements of the Act that there be a 'significant risk of a serious genetic abnormality or disease being present in the embryo' would still be met..

B. Diagnostic procedures involving excess ART embryos

Note: To be eligible for Council approval Clinics must comply with s 53W(2)(d)(ii) , ie the diagnostic procedure to be carried out must be in connection with the ART treatment of the woman.

If the diagnostic procedure is to be carried out as part of a Quality Assurance program approval MUST be sought from the National Health and Medical research Council.

Generally authorised under the Act, under certain conditions.

General authorisation to be granted clinic by clinic.

Clinics seeking authorisation should obtain a copy of the *Application for Approval to Carry Out Embryo Diagnostic Procedures*.

Conditions:

1. That the embryo to be tested is unfit for implantation on the basis of its biological fitness for implantation (as required by s.53W(2)(d)(i)); and
 2. That the procedure also complies with s 53W(2)(d)(ii), is in connection with the ART treatment of the woman.
 3. Reporting and record keeping requirements set out on approval must be complied with.
 4. Counselling, information giving and consent protocols on approval must be complied with.
-

APPLICATION FORM FOR APPROVAL UNDER THE *HUMAN REPRODUCTIVE TECHNOLOGY ACT 1991* (HRT ACT) FOR A DIAGNOSTIC PROCEDURE TO BE CARRIED OUT UPON OR WITH AN EMBRYO

Name of Licensee:

Licence Supervisor:

(Full name)

PGD Coordinator:

(Full name)

Address:

Tel:

Fax:

Is approval being sought to undertake **aneuploidy screening** prior to implantation?

☐ yes* ☐ no

***If yes please complete Part A & Part B.**

Is approval being sought to undertake **genetic testing for a specified condition** prior to implantation?

☐ yes* ☐ no

***If yes please complete Part A & Part C.**

Is approval being sought to undertake **diagnostic testing on an excess ART** embryo?

☐ yes* ☐ no

***If yes please complete Part D.**

For office use only

Reference No:

Issued:

(Date):

Signed:

(Chairman, Reproductive Technology Council)

INSTRUCTIONS:

- This form is available electronically on the Reproductive Technology Council website www.rtc.org.au/forms.
- The information requested may be printed or typed in the shaded boxes or provided as attachments.
- Please do not include patient identifying information in the application.
- The application may be submitted:
 - by e-mail to the Executive Officer antonia.clissa@health.wa.gov.au; or
 - by post to:

**The Executive Officer
The WA Reproductive Technology Council
189 Royal Street
EAST PERTH WA 6004
Telephone: (08) 9222 4260
Facsimile: (08) 9222 4236**

PART A: APPROVAL OF TECHNICAL PROCEDURES.

Item 1: BIOPSY PROCEDURES

Do you have specific approval from the Reproductive Technology Council to undertake the relevant embryo biopsy procedures?

☐ yes ☐ no*

***If no please provide details of the procedures intended to be used by reference to the following standards.**

- Laboratories must be licensed under the HRT Act and maintain accreditation by the Reproductive Technology Accreditation Committee (RTAC).
- Laboratories must participate in a QA program recognised by RTAC/NATA.
- The biopsy procedure to include setting up of microtools on an inverted microscope, placing oocyte/embryo in microdroplets for the procedure, removal of cell/polar body, placing cell into appropriate transport container.
- HREC approval for the procedure(s) to be used.
- The biopsy techniques to be used may be acid Tyrode's or laser as approved by the Council.
- Biopsy may be in the form of polar body biopsy, embryo biopsy (at day 3) or blastocyst as approved by the Council.
- Staff performing the biopsy must have demonstrated competency in:
 - the proposed biopsy technique;
 - placing the cell(s) in transport vessel, in the case of single gene defects; and
 - fixing of cell(s) on a slide in the case of chromosome analysis.

Provide attachments if necessary and note the attachment numbers in this box.

Item 2: EXTENDED BLASTOCYST CULTURE

Are you intending to use extended blastocyst culture?

☐ yes* ☐ no

***If yes do you have specific approval from the Reproductive Technology Council to undertake extended blastocyst culture?**

☐ yes ☐ no*

***if no please provide details of the procedure intended to be used as required for a standard application for specific approval.**

Provide attachments if necessary and note the attachment numbers in this box.

-----end of Part A-----

PART B: APPROVAL TO UNDERTAKE ANEUPLOIDY SCREENING

Item 1: Criteria to be applied to undertake aneuploidy screening.

Are you seeking approval for screening against the following standard criteria?

- The woman or couple is eligible for IVF under the HRT Act; and
 - women over 35 years of age providing eggs; or
 - women with >2 miscarriages; or
 - women with >2 failed IVF attempts where embryos have been transferred; or
 - women referred by a clinical geneticist with a family history of aneuploidy not caused by translocations or other chromosomal rearrangements.

☐ yes ☐ no*

*If no please provide details of the criteria to be applied and the scientific or medical justification for the criteria.

Provide attachments if necessary and note the attachment numbers in this box.

Item 2: GENETIC TESTING

Please provide details of the proposed testing and the testing facility to be used by reference to the following standards.

- Laboratories must be accredited by the National Association of Testing Authorities (NATA), (or working towards accreditation within the NATA 3 year cycle) to carry out the type of testing being undertaken.
- Laboratories must meet all relevant NATA and National Pathology Accreditation Advisory Council (NPAAC) requirements for testing.
- Laboratories must participate in an accredited quality assurance program (QAP) for FISH, preferably with a PGD component, which may be offshore.
- Laboratories should adhere to the standards set by the European Society for Reproduction and Embryology (ESHRE) (see. ESHRE website) unless otherwise approved by the Council.
- All PGD testing should confirm with the Australian standard for PGD-AS (if any).

Provide attachments if necessary and note the attachment numbers in this box.

Item 3: Details of information and counselling to be provided in respect of screening.

Provide attachments if necessary and note the attachment numbers in this box.

-----end of Part B-----
PART C: APPROVAL TO UNDERTAKE TESTING FOR A SPECIFIC CONDITION

Item 1: Details of condition to be tested for.

Does the application have the support of a clinical geneticist who has assessed the risk and seriousness of the condition to be tested for?

☐ yes ☐ no

Please attach a report from a clinical geneticist addressing the following questions as relevant:

- Is there a significant risk of a serious genetic abnormality or disease in the context of the family that is requesting the testing?
- What is the genetic abnormality or disease that is to be tested for?
- What experience with, and attitude to, the abnormality or disease does the family requesting the testing have?
- What factors indicate that there is a risk that the embryo will be affected by the genetic abnormality or disease?
- What is the level of impairment to body functions and structures that is usually associated with the abnormality or disease?
- What difficulties would a person with the abnormality or disease be expected to have in participating in the activities such as learning and applying knowledge, communication, mobility, self care, employment and community, social and civic life?
- What is the level of support that would be required by a person who has the abnormality or disease?
- What are the prospects for new and longer term treatments and interventions for the condition?
- What is the capacity of the family who are requesting the testing to provide the level of support required by a child with the abnormality or disease?
- What clinical genetic and diagnostic data is to be used in the testing procedure?

- What other testing options are available?
- What level of information will be possible from the test, in terms of interpretation, sensitivity and specificity (includes error)?
- Has the person requesting the testing been provided with counselling about the potential impact of testing and contact information for other persons or organisations that have experience with the condition?

Item 2: GENETIC TESTING

Please provide details of the proposed testing and the testing facility to be used by reference to the following standards.

- Laboratories must be NATA accredited (or working towards accreditation within the NATA 3 year cycle) to carry out the type of testing being undertaken.
- Laboratories must meet all relevant NATA and NPAAC requirements for testing.
- Laboratories must participate in an accredited QAP for molecular genetics, preferably with a PGD component, which may be offshore
- .
- Laboratories should adhere to the standards set by the European Society for Reproduction and Embryology (ESHRE) (see .ESHRE website) unless otherwise approved by the Council.
- All PGD testing should conform with the Australian standard for PGD-by molecular techniques (if any).
- Laboratories must demonstrate competency in transfer of cell(s)/polar body(s) to a testing laboratory in a state capable of being analysed and free from contaminants.
- Where the cell(s) are to be couriered interstate/overseas for PGD analysis, laboratories must demonstrate that the proposed courier system is safe, accurate and efficient (including quick 'turn-around').

Provide attachments if necessary and note the attachment numbers in this box.

Item 3: Additional statement from the person requesting testing (optional)

Provide attachments if necessary and note the attachment numbers in this box.



-----end of Part C-----

PART D: APPROVAL FOR DIAGNOSTIC PROCEDURE ON EXCESS ART EMBRYOS

Item 1: Detail of procedure to be carried out.

Provide attachments if necessary and note the attachment numbers in this box.




Item 2: Criteria by which an embryo will be identified as unfit for implantation.

Provide attachments if necessary and note the attachment numbers in this box.



Item 3: Details of how the procedure will benefit the woman for whom it is undertaken.

Provide attachments if necessary and note the attachment numbers in this box.



Item 4: Is approval being sought for the procedure to be part of general clinical practice?

☐ yes* ☐ no

*If yes please provide a copy of the relevant sections of the clinical protocol.

Provide attachments if necessary and note the attachment numbers in this box.

-----end of application-----

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.]