Reproductive Technology Council

Western Australian Reproductive Technology Council

Annual Report

1 July 2011 to 30 June 2012

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Reproductive Technology Council

Mr Kim Snowball
Chief Executive Officer
Department of Health
189 Royal Street
EAST PERTH WA 6004

Dear Mr Snowball

It is with pleasure that I submit the Reproductive Technology Council (Council) Annual Report for the financial year 2011 to 2012. This report sets out details of reproductive technology practices in Western Australia and the activities of Council, as required by the *Human Reproductive Technology Act 1991* (HRT Act). It is in a form suitable for submission to the Minister for Health and also, as is required, to be laid by the Minister before each House of Parliament.

This year Council has focused on the renewal of practice and storage licences for fertility clinics. Council assessed applications from the seven licensed clinics and recommended that all licences were renewed for three years.

Council members reviewed a range of applications for approval under the HRT Act and the *Surrogacy Act 2008*. This included applications for embryo storage extension, genetic testing of embryos, consideration of waivers, research proposals and surrogacy arrangements. One birth was reported under the *Surrogacy Act 2008*.

This year Council provided submissions regarding donor-assisted conception practices to the 57th Parliament of Victoria, Law Reform Committee and to the Parliament of New South Wales, Legislative Assembly Committee on Law and Safety.

It is not possible for Council to operate effectively without the support of a number of people who provide their expertise and time to attend to Council matters. I especially wish to thank Council and committee members for their ongoing commitment. Finally, I recognise the ongoing financial contribution and administrative support provided by the Department of Health.

Yours sincerely

CA Michael AO
Chair
Reproductive Technology Council

September 2012

Contents

Executive Summary

This annual report was prepared by the Reproductive Technology Council (Council) for the Chief Executive Officer (CEO), Department of Health, to comply with the requirements of Section 5(6) of the *Human Reproductive Technology Act 1991* (HRT Act). The CEO is required to submit the report to the Minister for Health, to be laid before Parliament. The annual report outlines the use of assisted reproductive technology in Western Australia (WA), and the operation of Council for the financial year from 1 July 2011 to 30 June 2012 (this year).

Council has an important role as an advisory body to the Minister for Health and to the CEO on issues related to assisted reproductive technology, and the administration of the HRT Act and the *Surrogacy Act 2008* (Surrogacy Act). Council is also responsible for licensing assisted reproductive technology services and monitoring standards of practice.

Renewed practice and storage licences were issued to the seven fertility clinics that provide assisted reproductive technology services in WA. Fertility clinics were visited and an extensive review of clinic documents was undertaken as part of the licensing renewal process.

Council members reviewed a range of applications for approval under the HRT Act and Surrogacy Act. Council approved 16 applications to extend embryo storage, 28 applications for genetic testing of embryos, and six surrogacy applications.

Council responded to the 57th Parliament of Victoria, Law Reform Committee *Inquiry into Access by Donor-Conceived People to Information about Donors*. Council was also invited to provide a submission to the Parliament of New South Wales, Legislative Assembly Committee on Law and Safety's inquiry into the inclusion of donor details on the register of births.

This year the budget allocation to Council was $59,050 and the expenditure was $25,840. The financial statement, which outlines the distribution of expenses, is provided in this annual report. Council has a long record of remaining within the allocated budget, and predicts that expenditure for the next financial year will also remain within budget.

Data collected from the annual reports submitted by WA licensees for 2011-2012 show that 3,603 women underwent in vitro fertilisation (IVF) treatment, which is 6% more than in the previous year. Fertility clinics undertook 5,575 IVF treatment cycles this year, which is 9% more than in the previous year.

A total of 1,250 intrauterine inseminations were undertaken, which represents a reduction of 1% compared to the previous year.

The number of embryos in storage at 30 June 2012 was 17,312 compared to 17,771 for the previous year. Inconsistencies were identified in the submitted embryo storage report for one clinic. The matter could not be resolved within the required timeframe. Therefore, embryo dispersal numbers may not be complete for this year. Consequently, this clinic will be audited by authorised officers to confirm embryo numbers.

There were 16 reported cases of morbidity (complications) associated with artificial fertilisation procedures. There were no reports of mortality (deaths) in association with fertility treatment.

A total of 2,189 couples or individuals received counselling, which represents a 13% decrease from the previous year. Most counselling consisted of a single session and involved the provision of information.

Clinics that provide surrogacy services reported six surrogacy applications in total and one clinic reported a surrogacy birth for this year.

The number of people accessing assisted reproductive technology, and the number of treatment cycles, have grown steadily over the years. This is in line with national trends.

The effective operation of Council requires the significant and dedicated support of Council and committee members, and the ongoing financial and administrative support provided by the Department of Health. This support is essential to enable Council to meet the responsibilities set out in the HRT Act and the Surrogacy Act, and to ensure the effective regulation of these Acts.

Introduction

This annual report provides a comprehensive account of the activities of Council for the past financial year. Council regulates assisted reproductive technology practices in WA, as set out in the HRT Act and the Surrogacy Act. The report is structured around the legal requirements and major activities of Council. The report outlines the operation of Council, significant technical and social trends in relation to assisted reproductive technology, and the activities of licence holders.

Council Functions

The functions of Council are outlined in Section 14 of the HRT Act and include:

- the provision of advice to the Minister on issues relating to reproductive technology, and the administration and enforcement of the HRT Act
- the provision of advice to the CEO of Health on matters relating to licensing, administration and enforcement of the HRT Act
- the review of the Directions and guidelines to govern assisted reproductive technology practices and storage procedures undertaken by licensees, and thereby to regulate the proper conduct, including counselling provision, of any reproductive technology practice
- the promotion of research, in accordance with the HRT Act, into the causes and prevention of all types of human infertility and the social and public health implications of reproductive technology
- the promotion of informed public debate on issues arising from reproductive technology, and communication and collaboration with similar bodies in Australia and overseas.

The Minister for Health determines Council membership and is required to ensure that Council comprises individuals with special knowledge, skills and experience in assisted reproductive technology. Therefore, Council also has members who are consumer representatives and members with expertise in public health, ethics and law.

Membership of Council and Council Committees

This section provides biographies of the Council Chair and Council Committee Chairs, a list of Council membership for this year, and the terms of reference and membership of the various Council committees.

Council Chair and Council Committee Chairs

Professor Con Michael

Professor Con Michael is Chair of the Reproductive Technology Council and Chair of the Licensing and Administration Advisory Committee. Professor Michael is the Consultant Medical Advisor for St John of God Healthcare Inc. and Emeritus Professor of Obstetrics and Gynaecology at the University of Western Australia. He is a fellow of the Royal Australian and New Zealand College of Obstetricians and Gynaecologists, a Director of the Australian Medical Council, and a member of the Australian Health Practitioner Regulation Agency Management Committee. In 2001, Professor Michael was named an Officer of the Order of Australia.

Reverend Brian Carey

The Reverend Brian Carey is Chair of the Embryo Storage Committee. Reverend Carey is a Minister of the Uniting Church in Australia and has extensive involvement in bioethics at both a State and national level, including presenting papers on the full range of ethical and medical subjects at conferences and universities. Reverend Carey was the applied ethicist for the State of Victoria's Bio-technology Committee and a member of the Stem Cell Working Group. He was a member of Monash Medical Centre and Epworth Hospital's Human Research Ethics Committee for over twenty years. He is currently a member of the Ethics Committees of both the Department of Health (WA) and the Western Australian Genetics Council.

Associate Professor Jim Cummins

Associate Professor Jim Cummins is Chair of the Scientific Advisory Committee. He is an Associate Professor in Anatomy at Murdoch University. As a reproductive biologist, he has been involved with assisted reproduction since 1981 when he helped to establish the Queensland Fertility Group. Associate Professor Cummins is a member of the editorial board of a number of professional journals – *Human Reproduction; Reproduction, Fertility and Development,* and *Reproductive Biomedicine Online*. He is a member of the Fertility Society of Australia and the Society for Reproductive Biology.

Ms Suzanne Midford

Ms Suzanne Midford is Chair of the Counselling Committee. As a specialist clinical psychologist and Clinical Director of Perth Psychological Services, she has a wide range of expertise in the field of surrogacy, donation of human gametes, disclosure issues in donation, and broader issues related to reproductive technology. Ms Midford is a director on the National Board of the Australian Clinical Psychology Association and an educator for the postgraduate Clinical Psychology program at the University of Western Australia. Her many years of involvement in reproductive technology include research, expert witness testimony, and the provision of professional development and education.

Dr Beverly Petterson

Dr Beverly Petterson is Chair of the Preimplantation Genetic Diagnosis (PGD) Advisory Committee. She is a senior honorary research fellow at the Institute for Child Health Research, and a member of the Western Australian Register of Developmental Anomalies Advisory Committee and the Western Australian Cerebral Palsy Register Advisory Committee. Dr Petterson was a lecturer in Anatomy and Human Biology at the University of Western Australia, teaching and researching in genetics. She has served as the chair of the Tertiary Entrance Examination examining panel for human biology and has been a long-term member of the Human Genetics Society of Australasia.

Reproductive Technology Council Members

Professor Con Michael, Chair (nominee of the Minister for Health representing the Australian Medical Association)

Dr Simon Clarke (nominee of the Royal Australian and New Zealand College of Obstetricians and Gynaecologists)

Associate Professor Jim Cummins (nominee of the Minister for Health)

Ms Justine Garbellini (nominee of the Health Consumers' Council WA)

Professor Roger Hart (nominee of The University of Western Australia, School of Women's and Infants' Health)

Ms Anne-Marie Loney (nominee of the Minister for Child Protection)

Dr Brenda McGivern (nominee of the Law Society of Western Australia)

Dr Joe Parkinson (nominee of the Minister for Health)

Dr Beverly Petterson (nominee of the Minister for Health)

Ms Patrice Wringe (nominee of the Department for Communities, Office of Women's Interests)

Adjunct (Adj) Associate Professor Mo Harris (Executive Officer *ex officio*, Senior Policy Officer, Department of Health).

Reproductive Technology Council Deputy Members

Ms Jane Baker (nominee of the Minister for Child Protection)

Dr Peter Burton (nominee of The University of Western Australia, School of Women's and Infants' Health)

Reverend Brian Carey (nominee of the Minister for Health)

Dr Angela Cooney (nominee of the Australian Medical Association)

Dr Andrew Harman (nominee of the Law Society of Western Australia)

Ms Kari Johnson (nominee of the Health Consumers' Council WA)

Ms Suzanne Midford (nominee of the Department for Communities, Office of Women's Interests)

Dr David Miller (nominee of the Minister for Health)

Dr Kathy Sanders (nominee of the Minister for Health)

Dr Lucy Williams (nominee of the Royal Australian and New Zealand College of Obstetricians and Gynaecologists)

Mrs Sue Laing (Deputy Executive Officer *ex officio*, Senior Policy Officer, Department of Health)

Ms Jen Parker (Deputy Executive Officer *ex officio*, Senior Policy Officer, Department of Health)

Ms Frances Powell (Deputy Executive Officer *ex officio*, Senior Policy Officer, Department of Health).

Counselling Committee

Terms of Reference

The committee's terms of reference are to:

- establish standards for approval of counsellors as Approved Counsellors, as required by the Code of Practice or Directions of the HRT Act for counselling within licensed clinics, and for counselling services available in the community
- recommend to Council those counsellors deemed suitable for Council approval or interim approval, and reconsider those referred back to the committee by Council for further information
- monitor and review the work of any Approved Counsellor
- convene training programs for counsellors if required
- establish a process whereby counsellors may have approval withdrawn or may appeal a Council decision
- report annually as required by Council for its annual report to the CEO of Health, including information on its own activities and information reported to it by Approved Counsellors
- advise and assist 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
- advise Council on matters relating to access to information held on the IVF and Donor Registers
- advise Council on psychosocial matters relating to reproductive technology as Council may request.

Membership

Ms Suzanne Midford (Chair), Ms Jane Baker, Ms Justine Garbellini, Ms Anne-Marie Loney, Ms Iolanda Rodino, Ms Patrice Wringe, Adj Associate Professor Mo Harris (*ex officio*) and Ms Frances Powell (*ex officio*).

Embryo Storage Committee

Terms of Reference

The committee's terms of reference are 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 Council, and to provide to the next meeting of Council details of all decisions made since the previous meeting
- provide other advice or carry out other functions relating to the storage of embryos, as instructed by Council.

Membership

Reverend Brian Carey (Chair), Dr Brenda McGivern, Ms Suzanne Midford, Ms Patrice Wringe, Adj Associate Professor Mo Harris (*ex officio*) and Ms Jen Parker (*ex officio*).

Licensing and Administration Advisory Committee

Terms of Reference

The committee's terms of reference are to:

- advise Council on matters relating to licensing under the HRT Act, including the suitability of applicants and conditions that should be imposed on any licence
- advise Council generally as to the administration and enforcement of the HRT Act, particularly disciplinary matters
- advise Council as to suitable standards to be set under the HRT Act, including clinical standards
- advise Council on any other matters relating to licensing, administration and enforcement of the HRT Act.

Membership

Professor Con Michael (Chair), Professor Roger Hart, Ms Suzanne Midford, Dr Joe Parkinson, Ms Patrice Wringe, Adj Associate Professor Mo Harris (*ex officio*) and Mrs Sue Laing (*ex officio*).

Preimplantation Genetic Diagnosis (PGD) Advisory Committee

Terms of Reference

The committee's terms of reference are to:

- advise Council on factors that it should consider when deciding whether to approve PGD, both generally and for specific cases
- advise Council on standards for facilities, staffing and technical procedures
- advise on how the ongoing process of approval of PGD should be managed effectively by Council
- monitor outcomes of diagnostic procedures involving embryos
- advise on other relevant matters as requested by Council.

Membership

Dr Beverly Petterson (Chair), Dr Peter Burton, Dr Ashleigh Murch, Dr Sharron Townshend, Adj Associate Professor Mo Harris (*ex officio*) and Mrs Sue Laing (*ex officio*).

Scientific Advisory Committee

Terms of Reference

The committee's terms of reference are to:

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

Membership

Associate Professor Jim Cummins (Chair), Dr Peter Burton, Professor Roger Hart, Dr Joe Parkinson, Dr Beverly Petterson, Dr Kathy Sanders, Adj Associate Professor Mo Harris (*ex officio*) and Ms Frances Powell (*ex officio*).

Operations of Council

Meetings

Council met on nine occasions during the year, with attendances reaching quorum at all meetings. The Counselling Committee met on six occasions. The Preimplantation Genetic Diagnosis (PGD) Advisory Committee met on two occasions, with several applications for PGD being assessed out of session. The Embryo Storage Committee met on one occasion, with several applications being considered out of session. The Licensing and Administration Advisory Committee met on two occasions. The Scientific Advisory Committee did not meet this year; however, members provided expert advice when required.

Reproductive Technology Unit

The Department of Health's Reproductive Technology Unit provides the following administrative support to Council:

Executive Officer, Senior Policy Officer, Adjunct Associate Professor Mo Harris (Doctor of Philosophy, Registered Nurse, Registered Midwife)

Deputy Executive Officer, Senior Policy Officer, Mrs Sue Laing (Bachelor of Science (Hons), Master of Philosophy, Postgraduate Diploma in Health Sciences)

Deputy Executive Officer, Senior Policy Officer, Ms Jen Parker (Bachelor of Science (Health Promotion), Registered Nurse)

Deputy Executive Officer, Senior Policy Officer, Ms Frances Powell (Bachelor of Health Science).

Practice and Storage Licences

Practice or storage facilities must renew their licence every three years. Council provides advice to the CEO regarding the licensing of fertility clinics. All clinics applied to renew their licence this year. The Executive Officer and a Deputy Executive Officer of Council visited all the fertility clinics as part of the licensing review process. Council members Dr Joe Parkinson and Ms Patrice Wringe also visited a number of clinics to meet with clinic staff and licensees.

An extensive review of each clinic's documentation was undertaken as part of the licence renewal process. The Australian Health Practitioner Regulation Agency (AHPRA) registers were accessed to confirm the professional registrations of relevant personnel. In addition, facilities were required to demonstrate compliance with the Fertility Society of Australia Reproductive Technology Accreditation Committee (RTAC) Code of Practice (RTAC 2010) and RTAC Certification Scheme (RTAC 2010). RTAC requires that all standards are audited every three years. Fertility service providers must use a JAS-ANZ (Joint Accreditation System – Australia and New Zealand) accredited certification body for RTAC certification. Laboratories were also required to demonstrate compliance with the National Association of Testing Authority standards. All seven clinics had their licences renewed by the CEO on recommendation of Council. Details of practice and storage licence holders are listed in Appendix 1.

Exempt Practitioners

A medical practitioner who is an exempt practitioner must ensure that minimum standards for practice, equipment, staff and facilities comply with those required for good medical practice. In addition, they must comply with any requirements established under the HRT Act.

An application for exemption must be made in the prescribed format and include evidence of registration as a medical practitioner, and a written undertaking by the medical practitioner to comply with the Directions. Medical practitioners, who meet the requirements of the HRT Act, may provide artificial insemination procedures if they have a licence exemption.

No new applications were received this year and three exemptions were revoked by the CEO at the request of the exempt practitioners. A list of exempt practitioners is available on the Council website www.rtc.org.au

Applications to Council

Council is required to approve certain assisted reproductive technology practices, including the storage of embryos beyond 10 years, diagnostic testing of embryos, surrogacy applications, innovative procedures, and research projects. The following sections describe the activities for this year.

Embryo storage applications

Council approval is required for the storage of embryos beyond the authorised 10 year time limit. An extension may be granted under section 24(1a) of the HRT Act if Council considers there are special circumstances. Applications must be made by eligible participants (those for whom the embryos were created or donor recipients). Storage of gametes beyond the authorised 15 year time limit also requires Council approval. This year Council received 16 applications for extension of the authorised embryo storage period and 20 applications to extend the authorised sperm storage period. Table 1 shows the number and length of approved storage extension periods for embryos and sperm for this year.

Table 1: **Approved applications for extension of embryo and sperm storage**

	Length of storage extension (years)					
	≤1	2	3	4	5	Total
Embryos	5	6	3	0	2	**16**
Sperm	0	0	0	0	20	**20**

Preimplantation genetic testing

Council approves applications for genetic testing of embryos. Preimplantation genetic diagnosis (PGD) can be used where there is a known risk for serious genetic conditions. Preimplantation genetic screening (PGS) tests for abnormal numbers of chromosomes (aneuploidy), where there can be either extra or missing chromosomes, in the developing embryo. This can be a common cause of pregnancy loss. PGS for patients thought to be at risk of conceiving abnormal embryos does not require specific Council approval. However, application to Council must be made when general approval requirements are not met. There may be additional circumstances where aneuploidy screening may be appropriate and these are considered by Council on a case by case basis.

Each application for genetic testing of embryos is supported by a letter from a clinical geneticist. Council approval may be subject to the advice of the PGD Advisory Committee. In addition, a laboratory test (a feasibility study) may be required to determine if it is possible to test embryos for the specific genetic condition.

This year, a total of 28 applications for genetic testing were approved (24 for PGD, three for combined PGD and PGS, one for PGS). The genetic conditions that were approved for PGD are listed in Table 2.

Table 2: **Genetic condition**

Condition	n
Autosomal dominant polycystic kidney disease	1
Brain lung thyroid syndrome	1
Carbamyl phosphate synthetase deficiency	1
Cerebral cavernous malformation	1
Cystic fibrosis	7
Fragile X syndrome	2
Haemophilia B	1
Holt-Oram syndrome	1
Huntington disease	2
Myotonic Dystrophy type 1	1
Neurofibromatosis type 1	1
Translocations	8

All diagnostic procedures for a fertilising egg or an embryo must have Council approval. General approval may be provided in the Directions or specific approval may be given in a particular case (Sections 7(1)(b), 14(2b), 53(W)(2)(d) and 53(W)(4) of the HRT Act).

Surrogacy applications

The Surrogacy Act sets out the requirements for a surrogacy arrangement and prescribes the processes. The Surrogacy Regulations 2009 outline the requirements for an application, including medical assessments, psychological assessment and legal advice for surrogacy participants. Council received and approved a total of six applications for this year.

Innovative procedures

Innovative procedures must be approved by Council under Direction 9.4. New and innovative procedures are monitored through the approval process and annual reporting. Approved innovative procedures are listed in Table 3.

Table 3: **Approved innovative procedures**

Procedure	Clinic
Assisted hatching	Concept Fertility Centre Fertility Specialists of WA
In vitro maturation	Concept Fertility Centre Fertility Specialists of WA

New technology and techniques may eventually become widely adopted procedures and, with time, become considered routine rather than innovative. However, a licensee is required to demonstrate they have sufficient expertise with the procedure. The Scientific Advisory Committee recommended that the procedure of oocyte cryopreservation should no longer be considered as innovative. No applications for innovative procedures were received this year.

Research applications

Research projects undertaken by licensees, other than research on excess embryos requiring a National Health and Medical Research Council licence, must receive Council approval. General Council approval has been granted for some types of research, including surveys of participants or research involving additional testing of samples collected at the time of a procedure. Specific approval is required for all other research projects. Summary information indicating the current status and related matters of any Council approved research project must be submitted with the licensee's annual report.

This year Council approved the following three research projects:

- Professor C Bower, Telethon Institute for Child Health Research. Significant adverse health outcomes in children conceived following assisted reproductive technology treatment. Approved by Council on 18 October 2011.
- Professor R Hart. The long term consequences of assisted reproduction on development of the offspring: a prospective cohort study. Approved by Council on 21 February 2012.
- Professor R Hart. Administration of granulocyte colony-stimulating factor (G-CSF) to an unresponsive endometrium in an IVF cycle. Approved by Council on 16 May 2012.

National Health and Medical Research Council Licences

Differences between State and Commonwealth legislation have led to uncertainty regarding the authority of the National Health and Medical Research Council (NHMRC) to license and monitor research on excess embryos from assisted reproductive technology. Research that requires an NHMRC licence is not being undertaken in WA. The legal uncertainty for legislators, researchers and licensees will need to be resolved by amendment of the HRT Act.

Complaints to Council

Council received one formal complaint regarding an alleged contravention of the HRT Act by a licensee. Authorised officers undertook an investigation and a determination is yet to be finalised.

Finances

The budget allocation to Council was $59,050, with expenditure totalling $25,840. The financial statement in Appendix 2 outlines the distribution of expenses. Council has a long record of remaining within the allocated budget, and predicts that expenditure for the next financial year will also remain within budget.

Council's Role as an Advisory Body

Council has a prescribed role to promote informed public debate and discussion on assisted reproductive technology, and to communicate and collaborate with similar bodies in Australia and overseas. Another primary function of Council, also set out in the HRT Act, is to advise the CEO and Minister for Health on matters relating to assisted reproductive technology.

This year Council contributed to a range of legislative reviews. It responded to the 57th Parliament of Victoria, Law Reform Committee's *Inquiry into Access by Donor-Conceived People to Information about Donors*. Council also responded to an invitation to provide a submission to the Parliament of New South Wales, Legislative Assembly Committee on Law and Safety's inquiry into the inclusion of donor details on the register of births.

Particular attention has been given to the posthumous use of gametes, which is not allowed in this State. A small working party, led by Dr Joe Parkinson, has been established to explore the legal, ethical and social dimensions of the posthumous use of gametes. This work will help to make a clearer distinction between the posthumous collection and the posthumous use of gametes. Importantly, it will provide a broad conceptual framework for future discussions and informed public debate.

Council members Dr Brenda McGivern and Dr Joe Parkinson were invited speakers at a public seminar 'Giving Life after Death: The posthumous collection and use of gametes' held at Murdoch University, Perth. The seminar was organised by Council member Associate Professor Jim Cummins.

Council provides opportunities for all Approved Counsellors to participate in on-going professional development. The Counselling Committee arranged two professional development sessions this year. Ms Sue Midford presented 'Counselling for Matches on the Voluntary Register' on 29 September 2011 and also facilitated a surrogacy round-table discussion on 15 March 2012. Both education sessions were well attended and highly rated by the participants. A list of Approved Counsellors is available from the Council website www.rtc.org.au

Council members are all active in the field of assisted reproductive technology. The next section lists the publications and presentations of Council members. It demonstrates the level of activity, expertise and commitment to scientific endeavour, and social and ethical debates related to reproductive technology.

Publications and Presentations

Publications

Costello MF, Misso ML, Wong J, **Hart R**, Rombauts L, Melder A, Norman RJ, Teede HJ. (2012). The treatment of infertility in polycystic ovary syndrome: a brief update. *Australian and New Zealand Journal of Obstetrics and Gynaecology.* 52(4): 400-403.

Chua W, Boothroyd C, Walls M, **Hart RJ**. (2012). Slow freeze versus vitrification for embryo cryopreservation (Protocol). *Cochrane Database of Systematic Reviews*, Issue 1. Art. No.: CD009589. DOI: 10.1002/14651858.CD009589.

Gladstones GH, **Burton PJ**, Mark PJ, Waddell BJ, Roberts P. (2012). Immunolocalisation of 11ß-HSD-1 and -2, glucocorticoid receptor, mineralocorticoid receptor and Na+ K+-ATPase during the postnatal development of the rat epididymis. *Journal of Anatomy*. 220(4): 350-362.

Hart R. (2012). Periodontal disease: could this be a further factor leading to subfertility and is there a case for a pre-pregnancy dental check-up? *Women's Health*. 8(3): 229-230.

Hart R, Doherty DA, Pennell CE, Newnham IA, Newnham JP. (2012). Periodontal disease: a potential modifiable risk factor limiting conception. *Human Reproduction*. 27(5): 1332-1342.

Koh SA, **Sanders K**, Deakin R, **Burton P**. (2011). No effect of paternal age on clinical pregnancy rate in donor insemination cycles. *Human Reproduction*, Proceedings of the 14th World Congress on Human Reproduction. Melbourne, Australia.

Kroon B, **Hart RJ**, Wong BMS, Ford E, Yazdani A. (2012). Antibiotics prior to embryo transfer in ART. *Cochrane Database of Systematic Reviews*, Issue 3. Art. No.: CD008995. DOI: 10.1002/14651858.CD008995.pub2.

Misso ML, Wong J, Teede HJ, **Hart R**, Rombauts L, Melder AM, Moss J, Norman RJ, Costello MF. (2012). Aromatase inhibitors for PCOS: a systematic review and meta-analysis. *Human Reproduction Update*. 18(3): 301-312.

Peate M, Meiser B, Cheah BC, Saunders C, Butow P, Thewes B, **Hart R**, Phillips KA, Hickey M, Friedlander M. (2012). Making hard choices easier: a prospective, multicentre study to assess the efficacy of a fertility-related decision aid in young women with early-stage breast cancer. *British Journal of Cancer*. 106(6): 1053–1061.

Rodino IS, **Burton PJ**, **Sanders KA**. (2011). Mating by proxy: a novel perspective to donor conception. *Fertility and Sterility*. 96(4): 998-1001.

Stewart LM, Holman CDJ, **Hart R**, Finn J, Mai Q, Preen DB. (2011). How effective is in vitro fertilization, and how can it be improved? Author reply. *Fertility and Sterility*. 96(6): e168.

Tang H, Hunter T, Hu Y, Zhai SD, Sheng X, **Hart RJ**. (2012). Cabergoline for preventing ovarian hyperstimulation syndrome. *Cochrane Database of Systematic Reviews*, Issue 2. Art. No.: CD008605. DOI: 10.1002/14651858.CD008605.pub2.

Presentations

Harris M. Data collection; the good, the bad and the ugly. Fertility Symposium, The University Club of Western Australia, Perth, 11 February 2012. Invited speaker.

Harris M. Evidence-based practice. Law and ethics. Edith Cowan University, Perth, 17 April 2012. Invited speaker.

Hart R. Primary amenorrhea and hypogonadotrophic hypogonadism. International Federation of Fertility Societies, Guangzhou, China, 2011. Invited speaker.

Hart R. The management of endometriosis in the subfertile woman. RANZCOG Annual Scientific Meeting, Melbourne, 29 November 2011. Invited speaker.

Hart R. Early life influences upon male and female reproductive development in a Western Australian population.14th World Congress on Human Reproduction, Melbourne, Australia, 2 December 2011. Invited speaker.

Hart R. Polycystic ovary syndrome – Early life origins. Fertility Symposium, The University Club of Western Australia, Perth, 11 February 2012. Invited speaker.

Hart R. Lifestyle interventions in infertility. CREI trainee weekend, Sydney, 5-6 May 2012. Invited speaker.

Hart R. Therapies for bad eggs. SEED Meeting – The Oocyte, Sydney, 2012. Invited speaker.

Hart R. Social egg freezing is a good thing! SEED Meeting – The Oocyte, Sydney, 2012. Invited speaker.

McGivern B. Posthumous Reproduction: A Legal Perspective. Giving life after death: The posthumous collection and use of gametes. Public forum, Murdoch University, Perth, 17 May 2012. Invited speaker.

Midford S. Disclosure: How, why and when to tell your child about their origins? Surrogacy Australia Conference 2012, Melbourne, 26-27 May 2012. Invited speaker.

Parkinson J. Posthumous Reproduction: An Ethical Perspective. Giving life after death: The posthumous collection and use of gametes. Public forum, Murdoch University, Perth, 17 May 2012. Invited speaker.

Developments in Reproductive Technology

Single embryo transfer

Australian fertility clinics were early adopters of voluntary single embryo transfer to reduce the incidence of multiple pregnancies and births and the associated increase in adverse outcomes. Single embryo transfer is a continuing trend, now accounting for 70% of cycles, with a significant reduction in multiple pregnancies. Notably, pregnancy rates have remained stable (Wang et al 2011). This change in practice is also associated with a $47.6 million saving in health care expenditure, due to a reduction in multiple births associated with assisted reproductive technology from 18.8% in 2002 to 8.6% in 2008 (Chambers et al 2011).

Fertility treatment and birth defects

A recent Australian study of 308,974 births, between 1986 and 2002, examined the relationship between infertility, fertility treatments (assisted reproductive technology), and birth defects (Davies et al 2012). The risk of birth defects was 8.3% for the assisted reproductive technology group compared to 5.8% for the unassisted conception group. Intracytoplasmic sperm injection was associated with an increased risk of birth defects. A history of infertility, with or without assisted reproductive technology treatment, was also associated with an increased risk of birth defects. However, the causal relationship is not clear, as it is difficult to identify and account for other underlying factors that may influence the results of the study. It is also important to note that the developments in assisted reproductive technology are rapid and in the past 10 years there have been significant changes in laboratory and clinical practice. It is vital that prospective population studies are encouraged.

Microarray technology for embryo testing

Technological developments in preimplantation genetic testing include array-Comparative Genomic Hybridization (aCGH) and Single Nucleotide Polymorphism (SNP) arrays.

Array-Comparative Genomic Hybridization (aCGH): The human genome is the complete set of DNA, including the genes. Abnormal copies of DNA associated with each chromosome can be identified using aCGH, by comparing the entire genome with normal DNA. The advantage of aCGH over previous techniques is that all the chromosomes can be analysed in a single test. In addition, the test can be completed in less than 24 hours, which is within the time-frame of a fresh cycle embryo transfer.

Single Nucleotide Polymorphism (SNP) arrays: The basic building blocks of DNA (nucleotides) have natural variations at certain points of the genome called single nucleotide polymorphisms (SNPs). The differences are often seen in the DNA between genes and can be used to identify genes that are associated with a disease. SNP arrays can examine all the 23 human chromosomes, link the source of an abnormality to the sperm or the egg, and identify if the abnormality occurred before or after fertilisation. However, there is ethical concern around disclosure of information because the test may find unanticipated genetic anomalies and new mutations (HFEA 2012).

Novel techniques for the prevention of mitochondrial DNA disorders

The United Kingdom Nuffield Council on Bioethics (2012) has published an ethical review of interventions that may, in the future, prevent inheritable mitochondrial disorders. These incurable disorders are usually passed from mother to child and can result in progressive disability and death. The review examined experimental techniques to remove the affected mitochondrial DNA by using part of a healthy donor egg. Considerable work is required to establish the feasibility and safety of clinical applications and current legislation does not permit therapeutic application of these techniques.

Legislative Inquiries

The *Inquiry into Access by Donor-Conceived People to Information about Donors* was a continuation of an inquiry by the Law Reform Committee, which started during the 56th Parliament of Victoria. The report of the Law Reform Committee was published in March 2012 (Parliament of Victoria 2012). This inquiry examined the rights of donor-conceived people to access information about their donors, and issues related to donor-conceived people who have different rights, depending on when gametes were donated. The committee made 30 recommendations, which included introduction of legislation to allow all donor-conceived people to obtain identifying information about their donor. Further recommendations related to the option for contact vetoes for those involved in donor conception prior to 1998 and possible counselling needs.

An inquiry by the Parliament of New South Wales (NSW) Legislative Assembly, into the inclusion of donor details on the register of births, is being conducted by the Committee on Law and Safety. The inquiry will also consider how donor details are recorded in other Australian jurisdictions and the implications of changes in current practice. The Committee's inquiry follows a recent District Court judgement in relation to a private arrangement with a known sperm donor.

Cross-border reproductive care

Cross-border reproductive care (CBRC) is an emerging and rapidly growing social trend, where people travel to different states or countries to access assisted reproductive technology. The reasons why people access CBRC are complex. They may include variations in laws, limited access to treatment due to age or sexual orientation, lengthy waiting times or the cost of assisted reproductive technology. However, a common reason for people turning to CBRC is to bypass legal restrictions, such as selecting the sex of embryos for non-medical reasons, or commercial surrogacy (Whittaker 2011). Empirical studies are needed to examine this complex area of assisted reproductive technology in the context of interstate trends and particularly transnational trends (e.g. Australia–America and Australia–Asia).

Reproductive Technology and Voluntary Registers

The Reproductive Technology Registers

Information on assisted reproductive technology in WA is provided to the Department of Health by licensees and exempt practitioners, as set out in Schedule 2 Part 2 of the Directions under the HRT Act. Data relating to assisted reproductive technology are collected annually, by pro-forma, from each fertility service provider in WA. In addition, clinics regularly submit their electronic data to the Department of Health, which maintains this mandatory data collection.

The Reproductive Technology Registers enable ongoing monitoring of practice and provide an important resource for epidemiological research. Appendix 3 provides summary data from the annual reports of the fertility clinics in WA.

The Voluntary Register

The Voluntary Register provides a service for participants of donor conception (donor-conceived adults, recipients, and donors) in WA who wish to access their donor and/or recipient information. This includes people born from donor-assisted conception before 2004 as there is no legislated authority to access information about their donor. Relevant non-identifying information can be provided and identifying donor information can be provided to a donor-conceived person who is over 18 years of age. Release of information can only be provided with consent and after professional counselling. The Voluntary Register applications for each financial year are shown in Table 4.

Table 4: **Voluntary Register applications 2002–2012**

Year	Donor	Recipient	*DCA	Total
2002	10	13	1	24
2003	7	10	2	19
2004	3	7	0	10
2005	7	5	2	14
2006	4	10	1	15
2007	8	15	2	25
2008	6	11	2	19
2009	7	4	4	15
2010	4	7	2	13
2011	10	7	2	19
Total	**66**	**89**	**18**	**173**

*DCA: Donor-conceived adult

Links between participants are established by the donor code. Matches from the Voluntary Register are taken to mean that participants have chosen to release identifying information, and intend to undertake the required counselling with the intention of making contact with each other. Table 5 shows the total number of matches identified and contacts made from the Voluntary Register.

Table 5: **Number of links between participants 2002–2012**

	Matched	Contacted
Parent recipient and donor	6	4
Half siblings	8	3
Total	**14**	**7**

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Appendix 1: Licence Holders

Practice and Storage Licences:

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

Fertility Specialists South Pty Ltd
trading as Fertility Specialists South
1st Floor 764 Canning Hwy
APPLECROSS WA 6153

In Vitro Laboratory Pty Ltd
trading as Concept Fertility Centre
Concept Day Hospital
218 Nicholson Road
SUBIACO WA 6008

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

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

The Keogh Institute for Medical Research
Sir Charles Gairdner Hospital
2 Verdun Street
NEDLANDS WA 6009
(Artificial insemination only)

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

Appendix 2: Financial Statement

The Department of Health funds the administration of the HRT Act, including the operations of Council. The 2011-2012 Council budget allocation was $59,050, with expenditure totalling $25,840 for the financial year. Council has a long record of remaining within the allocated budget and anticipates that the 2012-2013 budget will support Council's capacity to meet all Council functions set out in the HRT Act.

Expenditure by category 2011-2012	Expenditure ($)	Income ($)
Staff or Council:		
Training, registration, course fees, interstate travel	4,794	
Food supplies and catering	1,872	
Administration and clerical	0	
Purchase of external services:		
Reproductive Technology Council sessional fees	14,764	
Other expenses:		
Books, magazines and subscriptions	0	
Freight, cartage and postal	0	
Stationery and printing, including annual report	3,413	
Equipment and maintenance	997	
Total	**25,840**	**59,050**

Appendix 3: Operations of Licence Holders

The aggregated data, tables, graphs, analysis and interpretation of data presented in this appendix have been provided by the Performance, Analysis and Quality Division of the Department of Health. Data are presented on the activities of licence holders for this year and assisted reproductive technology trends for the past 10 years.

Background

Fertility clinics licensed under the HRT Act are required to submit reports at the end of each financial year. This section outlines the information submitted by licensees. Six clinics in WA have storage licences and practice licences authorising artificial fertilisation procedures including in vitro fertilisation (IVF). One licensee has a storage licence and a practice licence for the provision of artificial insemination.

Assisted Reproductive Technologies in WA

Assisted reproductive technologies are procedures that are used to help women become pregnant (Wang et al 2011). The most recent report from the Australian Institute of Health and Welfare, National Perinatal Epidemiology and Statistics Unit found that assisted reproductive technology was used by 3.6% of women who gave birth in Australia (Li et al 2011).

The procedure of IVF involves the fertilisation of oocytes (eggs) in a laboratory and placing the embryo (fertilised egg) in the uterus. This procedure can be either a fresh cycle, where the embryo is not cryopreserved (frozen), or a thaw cycle where the embryo is thawed and transferred to the uterus.

A total of 3,603 women underwent IVF treatment this year. This represents an increase of 6% (n=217) compared to the previous year. There were 5,575 treatment cycles compared to 5,110 during the previous year. This is an increase of 9% compared to the previous year. Table 6 provides an overview of the initiated cycles.

Table 6: **IVF treatments**

	IVF fresh	IVF thaw	Total
Women treated	2,365	1,238	**3,603**
Treatment cycle	3,345	2,230	**5,575**
Cycle with oocyte retrieval	2,928	-	**2,928**
Cycle with embryo transfer	2,374	2,042	**4,416**
Cycle with embryo storage	1,880	-	**1,880**

Fresh IVF transfer techniques included 156 surgical sperm aspirations and 1,765 intracytoplasmic sperm injection (ICSI) procedures, where a single sperm is directly injected into an oocyte and the fertilised egg is transferred to the uterus.

There was one gamete intrafallopian transfer (GIFT). This is a procedure where mature oocytes and sperm are placed directly into the fallopian tubes so that in vivo fertilisation may take place. The use of this procedure has been in decline for several years (Wang et al 2011).

A total of 1,250 intrauterine insemination (IUI) treatment cycles was reported by six licensees and two exempt practitioners. This represents a small reduction (15) in the number of IUI treatment cycles compared to the previous year (n=1265). The overall clinical pregnancy rate per treatment was 7% (83 ongoing pregnancies). Of the 83 ongoing pregnancies, 80 (96%) were singleton pregnancies and three were pregnancies with unknown plurality. The partners' sperm were used for 81% of procedures and donor sperm were used for 19% of procedures. Hormones that stimulate ovulation were used in 67% of cycles (Gonadotrophin 46%; Clomid 21%) and 33% were natural cycles.

A donation cycle is defined as an assisted reproductive technology treatment cycle in which a woman intends to donate, or donates her oocytes to others. A donation cycle may result in the donation of either oocytes or embryos (Wang et al 2011). A total of 65 IVF donor cycles were reported for the donation of oocytes (48 cycles) and embryos (17 cycles). There were a total of 434 embryo transfers that used donated sperm (n=229), oocytes (n=94), and embryos (n=41). The total number of sperm donors for this year was 102, with 24 being new donors.

Embryo storage

The number of embryos in storage, as of 30 June 2012, was reported as *17,312. The dispersal of embryos for this year is shown in Table 7.

Table 7: **Dispersal of stored embryos**

Embryo dispersal	**n**
Embryos in storage 30/06/11	17,771
Embryos created from IVF	5,320
Used in frozen embryo transfer treatments	3,222
Transferred between clinics in WA	176
Transferred to clinics outside WA	86
Transferred from interstate	78
Embryo disposition (disposal)	2,549
Embryos in storage 30/06/12	***17,312**

*Inconsistencies were identified in the annual report of embryo storage data for one clinic. The matter could not be resolved within the required timeframe. Consequently, this clinic will be audited by authorised officers to confirm embryo numbers. Therefore, embryo dispersal numbers provided in Table 7 may be incomplete.

Public Fertility Clinic Referrals

This year 128 patients from King Edward Memorial Hospital Fertility Clinic were referred to Concept Fertility Clinic. The clinic undertook a total of 221 treatment cycles with 78 women having IVF with fresh embryo transfer and 27 women having IVF with thawed embryo transfer.

Serious morbidity and mortality

Clinics are required to provide information regarding complications of assisted reproductive technology treatment. There were 16 reported cases of morbidity (complications) associated with artificial fertilisation procedures. In 12 of the 16 reported cases, the cause of morbidity was excessive stimulation of the ovaries (ovarian hyperstimulation syndrome (OHSS)). Four women were considered to have serious morbidity (one secondary to OHSS, two secondary to embryo transfer and one secondary to egg collection). There were no reports of mortality in association with fertility treatment.

Counselling

A total of 2,189 couples or individuals received counselling, which represents a 13% decrease from the previous year (n=2,502). Most participants (82%) received a single counselling session and the majority of these sessions involved information counselling (77%), while the remaining participants received support counselling (22%). Therapeutic counselling accounted for 1% of the sessions. Of the 18% of participants who had more than one session, 37% had support counselling and 52% had information counselling. Counselling for donors and donor recipients accounted for 37% of all sessions. There were 810 donor counselling sessions representing a decrease of 13% from the previous year.

Assisted Reproductive Technology Trends in WA

This section presents the last 10 years of assisted reproductive technology data collected in WA to illustrate trends in assisted reproductive technology.

Treatment trends for assisted reproductive technology are shown in Figure 1 for fresh transfer cycles.

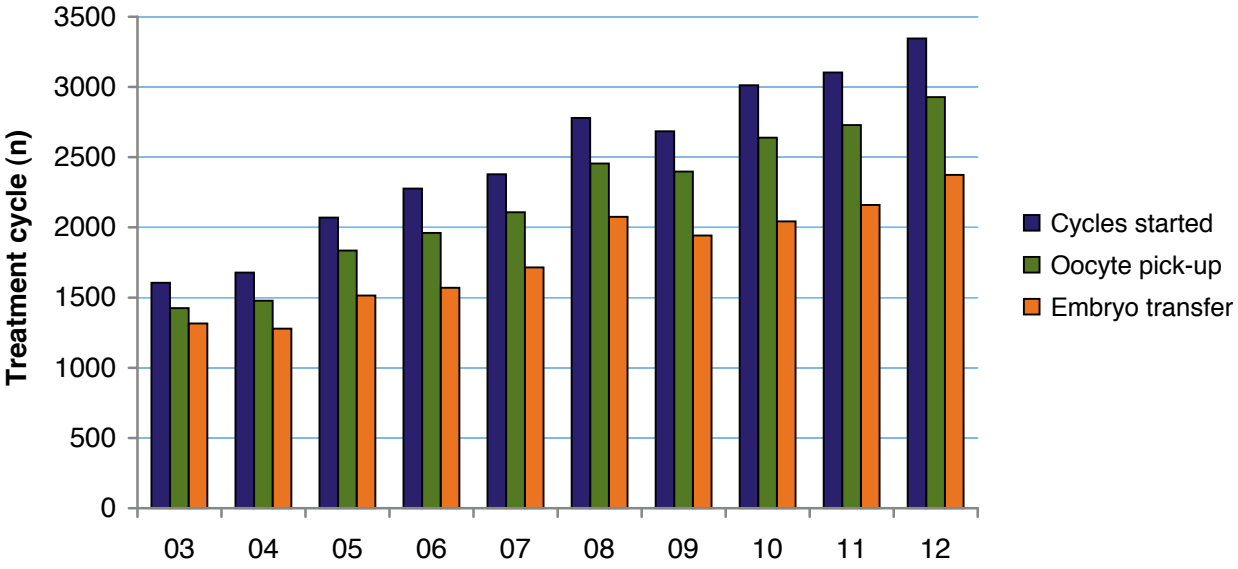

Figure 1: **Progression of fresh IVF cycles by year 2003–2012**

Figure 2 shows the progression of thawed embryo cycles.

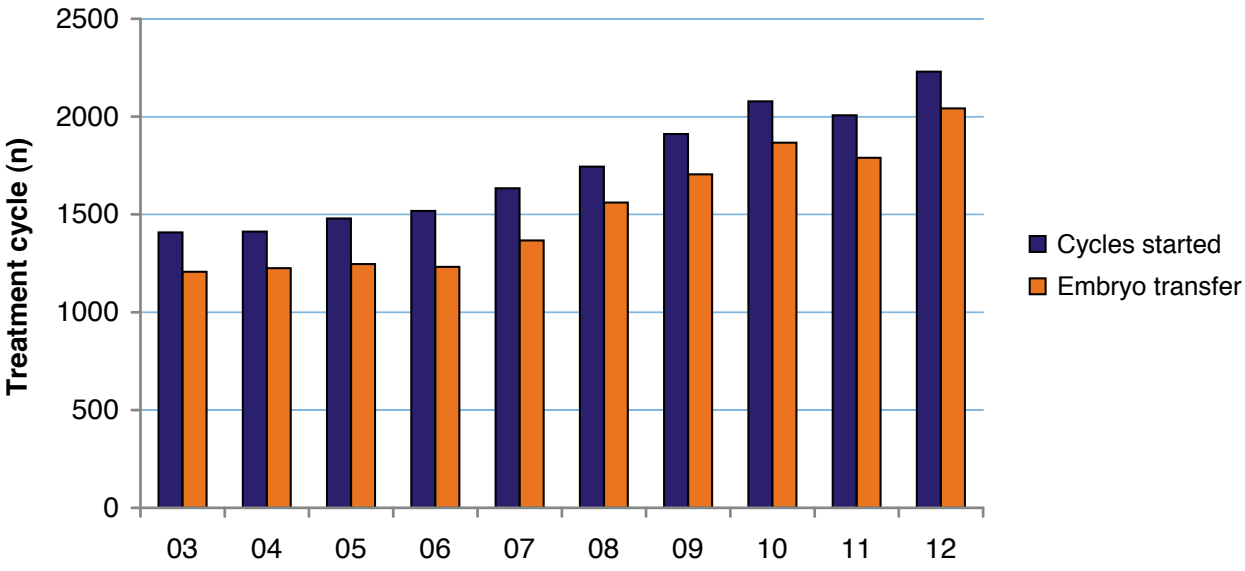

Figure 2: **Progression of thawed embryo cycles by year 2003–2012**

There has been a steady increase in the number of treatment cycles and this is in line with national trends of a 10% increase per year (Wang et al 2011). The proportion of fresh to thaw IVF treatment cycles has remained steady over the past eight years at approximately 60% of cycles.

The number of IVF procedures where ICSI was used is shown in Figure 3. International and national statistics show that the use of ICSI has increased over the past decade. Australia-wide, 73% of fresh oocyte recipient cycles used ICSI procedures (Wang et al 2011).

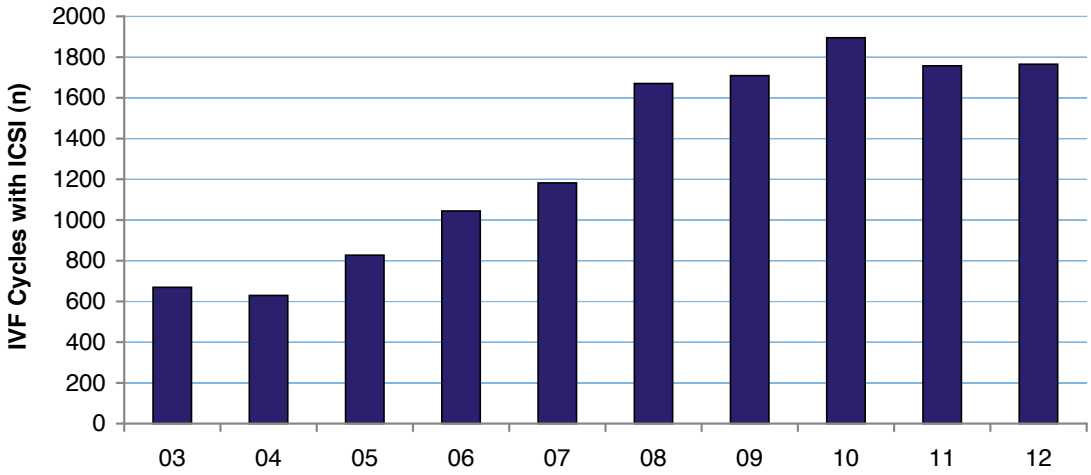

Figure 3: **Number of IVF cycles with ICSI by year 2003–2012**

The number of sperm donors has gradually increased over the past 10 years (Figure 4). Men in the 41-50 years age range represent the largest group of donors. The minimum age for sperm donation is 18 years and while there is no legal upper age limit for sperm donation, most clinics recommend the ideal age range of 18 to 50 years.

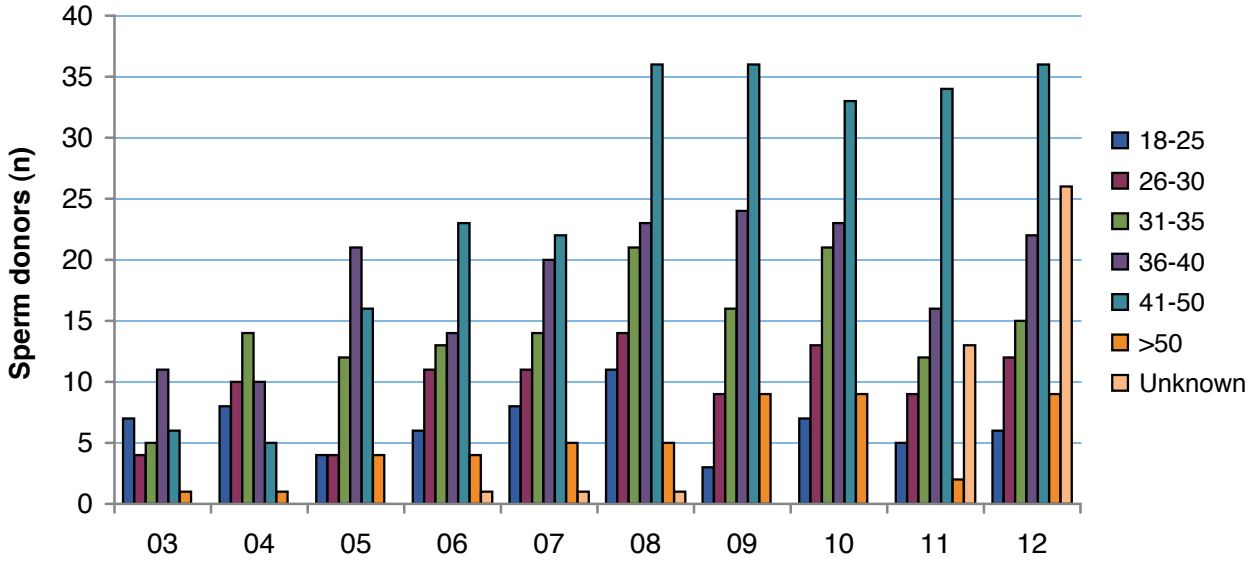

Figure 4: **Number of sperm donors by age group and year 2003–2012**

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EAST PERTH WA 6004

HP012524 SEP'12