Reproductive Technology Council

Western Australian Reproductive Technology Council

Annual Report

1 July 2013 to 30 June 2014

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Reproductive Technology Council

Professor Bryant Stokes
A/Chief Executive Officer
Department of Health
189 Royal Street
EAST PERTH WA 6004

Dear Professor Stokes

It is with pleasure that I submit the Reproductive Technology Council (Council) Annual Report for the financial year 2013 to 2014. This report sets out details of assisted reproductive technology (ART) practices in Western Australia (WA) 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.

Council members reviewed a range of applications for approval under the HRT Act and the *Surrogacy Act 2008* (Surrogacy Act). This included applications for embryo storage extension, genetic testing of embryos, surrogacy arrangements and research proposals.

Council provided submissions to the Government of South Australia (review of ART regulations), the Department of Health, Western Australia (review of the Surrogacy Act 2008) and to the National Health and Medical Research Council (NHMRC: review of ethical guidelines of ART).

Council also convened an extraordinary meeting this year to finalise a position statement for the posthumous use of gametes.

This year Council provided a seminar 'Problems with International Commercial Surrogacy' which examined this growing trend and the legal problems that can occur. In collaboration with the University of Western Australia (UWA), Council convened a joint seminar 'Law, policy and evidence about children's interest in genetic relatives in the era of open disclosure' which explored ART laws and ethics.

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 2014

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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 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 ART in WA, and the operation of Council for the financial year from 1 July 2013 to 30 June 2014.

Council has an important role as an advisory body to the Minister for Health and to the CEO on issues related to ART, the administration of the HRT Act and the Surrogacy Act. Council is also responsible for providing advice on licensing matters for ART services and monitoring standards of practice.

Council members reviewed a range of applications for approval under the HRT Act and Surrogacy Act. Council approved 21 applications to extend embryo storage and 43 applications for genetic testing of embryos. Four surrogacy applications were received and approved.

A practice licence and a storage licence were issued by the CEO to a new fertility clinic "Fertility Great Southern" on the advice of Council.

Council approved the renewal of recognition as approved counsellor for nine applicants and granted conditional approval for one new applicant.

Council finalised a position statement on the posthumous collection of gametes and the posthumous use of gametes.

This year Council provided a submission to the Government of South Australia's proposed Assisted Reproductive Treatment Variation Regulations, 2014. The proposed changes to the legislation will enable governance of a Donor Conception Register. Council provided a submission to the review of the NHMRC Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research (2007). Council also provided a submission to review the operation and effectiveness of the Surrogacy Act.

The budget allocation to Council for this year was $61,400 and the expenditure was $42,462. 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 2013-2014 show that 3,866 women underwent *in vitro* fertilisation (IVF) treatment, which is 6% more than in the previous year. Fertility clinics undertook 5,791 IVF treatment cycles this year, which is 6% more than in the previous year.

A total of 1,147 intrauterine inseminations were undertaken, which represents an increase of 3% compared to the previous year.

There were 24 reported cases of morbidity (complications) and no reports of mortality (deaths) in association with fertility treatment.

A total of 1,915 couples or individuals received counselling, which represents a 10% decrease from the previous year. Most counselling consisted of a single session and involved the provision of information.

The number of embryos reported in storage at 30 June 2014 was 20,323.

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 an account of the activities of Council for the past financial year. Council regulates ART 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 and outlines the operation of Council, significant technical and social trends in relation to ART, 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 for Health 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 ART 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 ART. Council 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 Council and Chair of the Licensing and Administration Advisory Committee. Professor Michael is Emeritus Professor of Obstetrics and Gynaecology at the UWA. He is also a Fellow of the Royal Australian and New Zealand College of Obstetricians and Gynaecologists, a Director of the Australian Medical Council, a member of the Australian Health Practitioner Regulation Agency Management Committee, Chair of the WA Medical Board and Medical Board of Australia. 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

Adjunct Associate Professor Jim Cummins is Chair of the Scientific Advisory Committee. As a reproductive biologist, he has been involved with assisted reproduction since 1981, when he helped to establish the Queensland Fertility Group. Adjunct 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 Iolanda Rodino

Ms Iolanda Rodino is Chair of the Counselling Committee. Ms Rodino graduated from the UWA in 1992. She practises as a clinical psychologist in Perth, WA and has extensive experience in the fields of infertility, pregnancy and post birth clinical services. Ms Rodino is a doctoral candidate in the School of Anatomy, Physiology & Human Biology and School of Psychology, UWA. Her research interests include the areas of third party reproduction, disordered eating and the emotional impact of stress on fertility.

Associate Professor Kathy Sanders

Associate Professor Kathy Sanders is Chair of the Preimplantation Genetic Diagnosis (PGD) Advisory Committee. Associate Professor Sanders has a BSc (Hons) and Doctor of Philosophy (UWA). She was appointed lecturer in the School of Anatomy, Physiology & Human Biology at UWA in 2002 and teaches human biology and reproductive biology to undergraduate science and medical students. Her current role includes academic coordinator of the Bachelor of Philosophy (Honours) program. Associate Professor Sanders' research centres around the impact and interaction of stress on reproductive processes; the stress buffering effects of supportive social relationships on reproductive health outcomes; and issues surrounding the use of donated gametes and embryos.

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)

Ms Antonia Clissa (nominee of the Department for Communities, Office of Women's Interests)

Adjunct 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)

Rev Dr Joe Parkinson (nominee of the Minister for Health)

Associate Professor Kathy Sanders (nominee of the Minister for Health)

Dr Mo Harris (Executive Officer *ex officio*, Manager, Reproductive Technology Unit, Department of Health).

Reproductive Technology Council Deputy Members

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)

Dr Michele Hansen (nominee of the Minister for Health)

Ms Rachael Oakley (nominee of the Department for Communities, Office of Women's Interests)

Dr Peter Roberts (nominee of the Minister for Health)

Ms Iolanda Rodino (nominee of the Health Consumers' Council WA)

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

Vacant position (nominee of the Minister for Child Protection)

Mrs Vickie Rogers (Deputy Executive Officer, Senior Policy Officer, Department of Health)

Dr Laila Simpson (Deputy Executive Officer, 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 Iolanda Rodino (Chair), Ms Justine Garbellini, Ms Anne-Marie Loney, Dr Elizabeth Webb, Dr Mo Harris (*ex officio*) and Mrs Vickie Rogers (Deputy *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 Michele Hansen, Dr Andrew Harman, Ms Antonia Clissa, Dr Mo Harris (*ex officio*) and Dr Laila Simpson (Deputy *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, Rev Dr Joe Parkinson, Dr Mo Harris (*ex officio*) and Mrs Vickie Rogers (Deputy *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

Associate Professor Kathy Sanders (Chair), Dr Peter Burton, Dr Ashleigh Murch, Dr Sharron Townshend, Dr Mo Harris (*ex officio*) and Mrs Vickie Rogers (Deputy *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

Adjunct Associate Professor Jim Cummins (Chair), Dr Peter Burton, Dr Michele Hansen, Dr Andrew Harman, Professor Roger Hart, Rev Dr Joe Parkinson, Associate Professor Kathy Sanders, Dr Mo Harris (*ex officio*) and Dr Laila Simpson (Deputy *ex officio*).

Operations of Council

Meetings

Council met on 12 occasions during the year, with attendances reaching quorum at all meetings. In addition, Council convened an extraordinary meeting to finalise a position statement for the posthumous collection of gametes and the posthumous use of gametes. The Counselling Committee met on five occasions. The PGD Advisory Committee met on two occasions, with the majority of applications for PGD being approved out of session. The Embryo Storage Committee met on two occasions, with most applications for extension of storage being approved out of session. The Scientific Advisory Committee met on three occasions, with additional business conducted out of session. The Licensing and Administration Advisory Committee met on one occasion.

Memberships

Outgoing and in-coming members

Ms Jane Baker resigned 31 March 2014 as deputy member (nominee of the Minister for Child Protection) and member of the Reproductive Technology Council Counselling Committee.

Ms Antonia Clissa was appointed member (nominee of the Department for Communities, Office of Women's Interests), 24 December 2014.

Ms Rachael Oakley was appointed deputy member (nominee of the Department for Communities, Office of Women's Interests), 2 December 2014.

Ms Iolanda Rodino was appointed deputy member (nominee of the Consumer Health Council) and Chair of the Reproductive Technology Council Counselling Committee, 23 July 2013.

Reproductive Technology Unit

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

Executive Officer, Manager, Dr Mo Harris (Registered Nurse, Registered Midwife, Doctor of Philosophy).

Deputy Executive Officer, Senior Policy Officer, Mrs Vickie Rogers (Registered Nurse, Registered Midwife, Master of Midwifery).

Deputy Executive Officer, Senior Policy Officer, Dr Laila Simpson (Bachelor of Health Science (Hons), Doctor of Philosophy)

Practice and storage licences

Practice or storage facilities must renew their licence every three years. In addition, facilities must comply with the Fertility Society of Australia Reproductive Technology Accreditation Committee (RTAC) Code of Practice (RTAC 2010a) and Certification Scheme (RTAC 2010b). Each year all critical criteria and a third of good practice criteria and Quality Management Systems are audited. All standards are audited every three years. Fertility service providers must use a Joint Accreditation System - Australia and New Zealand accredited certification body for RTAC certification. Laboratories are also required to demonstrate compliance with the National Association of Testing Authority standards. Details of fertility clinics are listed in Appendix 1 and on the Council website www.rtc.org.au.

Accredited fertility clinics may be granted a licence by the CEO, following the advice of Council. This year one practice licence and one storage licence were issued to Fertility Great Southern. This newly established fertility clinic is based in Denmark.

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 applications for a licence exemption and no applications to revoke a licence exemption were received this year. A list of exempt practitioners is available on the Council website www.rtc.org.au.

Approved Counsellors

Council received 10 applications for renewal of approved counsellor status. On the advice of the Counselling Committee nine applicants were approved for a period of three years. One applicant did not meet the requirements for renewal of approved counsellor status as set out in the Directions and consequently Council did not approve the application. One counsellor did not apply for renewal of approved counsellor status. A list of approved counsellors is available on the Council website www.rtc.org.au.

Council received two applications for recognition as an approved counsellor under the HRT Act. On the advice of the Counselling Committee one applicant was granted conditional approval, with on-going requirements for training and supervision. The second applicant did not meet the eligibility criteria for an approved counsellor.

Applications to Council

Council is required to approve certain ART practices, including the storage of embryos beyond 10 years, the storage of gametes beyond 15 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).

This year Council received 21 applications for extension of the authorised embryo storage period, compared to 30 applications the previous year. Table 1 shows the number of applications and the duration of approved storage extension that were granted for this year.

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

	Length of storage extension (years)					
	≤1	2	3	4	5	Total
Applications (n)	4	12	4	0	1	**21**

Storage of gametes beyond the authorised 15 year time limit also requires Council approval. Council received 13 applications. Nine applications were approved for an additional five years and four applications for an additional 10 years of storage.

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 the developing embryo for either extra or missing chromosomes (aneuploidy). This can be a common cause of pregnancy loss. Preimplantation genetic screening does not require specific Council approval when there are known risk factors for aneuploidy. However, 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 PGD 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 43 applications for genetic testing were approved (18 for PGD; 20 for both PGD and PGS; five for PGS). The genetic conditions that were approved for PGD are listed in Table 2.

Table 2: **Genetic conditions approved for PGD**

Condition
Alpha thalassemia
Charcot-Marie-Tooth disease
Congenital adrenal hyperplasia
Cystic fibrosis
Fragile X syndrome
Hereditary amyloidosis
Holt-Oram syndrome
Hypokalemic periodic paralysis
Myotonic dystrophy
Neurofibromatosis
Pericentric inversion
Translocations
Von Hippel-Lindau disease
Wiskott-Aldrich syndrome
X-linked AP1S2

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 surrogacy arrangements and prescribes the processes. The *Surrogacy Regulations* 2009 outline the requirements for an application, including medical assessments, psychological assessment, Counselling requirements and legal advice for surrogacy participants. Council received and approved four surrogacy applications this year.

Innovative procedures

Innovative procedures must be approved by Council under Direction 9.4. New and innovative procedures are monitored through approval and annual reporting. There were no applications for innovative procedures this year.

Research applications

Research projects undertaken by licensees, other than research on excess embryos requiring a NHMRC licence, must receive Council approval. General Council approval has been granted for research such as surveys of participants and research involving additional testing of samples collected at the time of a procedure. Specific approval is required for all other research projects. Progress reports of Council approved research projects must be submitted with the licensee's annual report. This year Council approved the following research projects:

- Dr M Hansen: Ecological Study – embryo culture conditions and birth defects. Extension of a previous study of ART, 23 January 2014.
- Dr M Harris: An exploratory study of participants' experiences and views of altruistic surrogacy arrangements, 21 January 2014.

National Health and Medical Research Council Licences

Differences between State and Commonwealth legislation have led to uncertainty regarding the authority of the NHMRC to license and monitor research on excess embryos from ART. Research that requires an NHMRC licence is not being undertaken in WA. The legal uncertainty will need to be resolved by amendment of the HRT Act.

Complaints to Council

Council received one formal complaint, which was referred to the CEO for investigation by an authorised officer.

This year, the CEO issued a Summary Determination to one clinic in response to a contravention of the HRT Act. The clinic endeavoured to show cause why effect should not be given to the Summary Determination. As a consequence of this and the corrective steps the clinic had since taken, lesser penalties were imposed including a reprimand, specified action to be taken (reporting the matter to the RTAC and corrective action taken), certain requirements as to conduct (concerning compliance with the Act), and a one year period of monitoring.

Finances

The budget allocation to Council was $61,400, with expenditure totalling $42,462. 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 ART, and to communicate and collaborate with similar bodies in Australia and overseas. Another function of Council is to advise the CEO and Minister for Health on matters relating to ART.

A working party, led by Rev Dr Joe Parkinson, was established in 2012 to explore the legal, ethical and social dimensions of the posthumous collection, and use, of gametes. This year Council continued its deliberations to finalise a position statement, which was provided to the Minister for Health.

Council responded to the Government of South Australia's targeted consultation on the Assisted Reproductive Treatment Variation Regulations, 2014. The Regulations are intended to provide governance for a donor conception register. The Regulations will also enable persons who are donor-conceived to apply for access to identifying information about their donor.

Council provided a submission to a review of the NHMRC Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research, 2007.

Council also provided a submission to a review of the operation and effectiveness of the Western Australia Surrogacy Act.

Council hosted a special event on 23 October 2013 with guest lecturer Mr Michael Nicholls esq. QC, a specialist in international family law, and medical ethics. Mr Nicholls presentation 'Problems with International Commercial Surrogacy' examined this growing trend and the legal problems that can occur. The event attracted a multi-disciplinary audience of over 30 people.

A half day seminar was hosted on 30 May 2014 by Council in collaboration with the Faculty of Law, UWA. Professor Jenni Millbank, a leading international expert on gender, sexuality and law provided the keynote address. Professor Millbank's presentation, 'Law, policy and evidence about children's interest in genetic relatives in the era of open disclosure', explored complex issues related to donor-assisted conception. The seminar also included a panel discussion with Professor Millbank, Justice Jeremy Curthoys, Rev Dr Joe Parkinson and Ms Antonia Clissa. A total of 42 people attended the event.

Council has an advisory role as to the content and uses of the Reproductive Technology Registers established under the HRT Act. This year the Scientific Advisory Committee reviewed the information that is provided to the registers by licensees. This will inform future developments of the Reproductive Technology Registers.

Publications and presentations

Council members are active in the field of ART. This 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

Chambers GM, Lee E, Hoang VP, **Hansen M**, Bower C, Sullivan EA. Hospital utilization, costs and mortality rates during the first 5 years of life: a population study of ART and non-ART singletons. *Human Reproduction*. 2014 Mar;29(3):601-10. PubMed PMID: 24310618.

Hart R. Is there a place in infertility practice for the use of oil-based tubal flushing? *The Australian & New Zealand Journal of Obstetrics & Gynaecology*. 2014 Feb;54(1):1-2. PubMed PMID: 24471842.

Hart R. The reproductive consequences of childhood cancer treatment [Commentary]. *British Journal of Obstetrics and Gynaecology* 2014; *In press*.

Hart R, Doherty DA, Frederiksen H, Keelan JA, Hickey M, Sloboda D, *et al*. The influence of antenatal exposure to phthalates on subsequent female reproductive development in adolescence: a pilot study. *Reproduction*. 2014;147(4):379-90. PubMed PMID: 24025997.

Hickey M, **Hart R**, Keelan JA. The relationship between umbilical cord estrogens and perinatal characteristics. *Cancer Epidemiology, Biomarkers & Prevention.* 2014 Jun;23(6):946-52. PubMed PMID: 24636976.

Koh SA, **Sanders K**, Deakin R, **Burton P**. Male age negatively influences clinical pregnancy rate in women younger than 40 years undergoing donor insemination cycles. *Reproductive Biomedicine Online*. 2013 Aug;27(2):125-30. PubMed PMID: 23768621.

Malacova E, Kemp A, **Hart R**, Jama-Alol K, Preen DB. Long-term risk of ectopic pregnancy varies by method of tubal sterilization: a whole-population study. *Fertility & Sterility.* 2014 Mar;101(3):728-34. PubMed PMID: 24388203.

Oakley R. From bereaved to conceived, creating life after death through posthumous assisted reproduction. *Precedent.* 2014 (122):4-9.

Thomson A, **Roberts P**, Bittles A. Navigating the maze: ethics approval pathways for intellectual disability research. *Journal of Medical Ethics*. 2013 Aug 20;10.1136/medethics-2012-100899. PubMed PMID: 23963255.

Stemp M, **Roberts P**, McClements A, Chapple V, Natalwala J, Black M, *et al*. Serum concentrations of the biomarkers CA125, CA15-3, CA72-4, tPSA and PAPP-A in natural and stimulated ovarian cycles. *The Asian Pacific Journal of Reproduction.* 2014;3(2):90-6.

Presentations

Chaplyn K, Coall D, **Burton P, Roberts P, Williams L**. Influence of anti-mullerian hormone levels on oocyte yield and pregnancy rate. The 5th Congress of the Asian Pacific Initiative in Reproduction (ASPIRE), Brisbane, Australia, 4 April 2014.

Hansen M,Charles A, Kurinczuk J, de Klerk N, **Burton P,** Bower C. ART and birth defects in Western Australia. Annual Conference of the Fertility Society of Australia, Sydney, Australia, 1-4 September 2013.

Hart R. Early life influences on testicular function in adulthood using the Western Australian pregnancy (Raine Cohort). 29th Annual meeting of the European Society of Human Reproduction and Embryology (ESHRE), London, UK, 8-10 July 2013.

Harris M. Regulation of IVF: The past, the present, the future. Fertility Nurses Society, Perth, Australia, 9 November 2013. Invited speaker.

Harris M. Dealing with the Reproductive Technology Council. The University Club of Western Australia, Perth, Australia, 30 March 2014. Invited speaker.

Liu Y, **Roberts P**, Ali J, Chapple V, Matson P. Morphometric analysis of human oocytes following intracytoplasmic sperm injection (ICSI). *Proceedings of the WA Endocrine and Reproductive Sciences Symposium,* Perth, Western Australia, August 2013.

Liu Y, **Roberts P,** Matson P**,** Ali J. The effect of pre-and post-fertilisation process on human pre-implantation embryo development. Scientists in Reproductive Technology Western Australia (SIRTWA) Postgraduate Symposium, Perth, Western Australia, September 2013.

Liu Y, Chapple V, **Roberts P,** Matson, P. The prevalence and morphokinetics of human embryos demonstrating reverse cleavage when viewed using the Embryoscope™ time lapse video system. The 5th Congress of the Asian Pacific Initiative in Reproduction (ASPIRE), Brisbane, Australia, 4 April 2014.

Liu Y, Chapple V, **Roberts P**, Ali J, Matson, P. Changes in the size of human oocytes following ICSI: observations made using the Embryoscope™ time-lapse system. The 5th Congress of the Asian Pacific Initiative in Reproduction (ASPIRE), Brisbane, Australia, 4 April 2014.

Matson P, McEvoy A, **Roberts P**, Yap K, Chapple V. The relationship between semen quality and the halosperm G2 kit results. Proceedings of the Fertility Society of Australia (FSA), Sydney, Australia. 1-4 September 2013.

McEvoy A, **Roberts P**, Yap K, Matson P. Air-dried semen is stable in storage prior to testing sperm DNA fragmentation with the halosperm G2 kit, unlike semen snap-frozen in liquid nitrogen. Endocrine and Reproductive Biology Society of Western Australia's Endocrine and Reproductive Sciences Symposium. Perth, Western Australia, August 2013.

McEvoy A, **Roberts P**, Yap K, Matson P. The development of a simplified method of semen storage for the testing of sperm DNA fragmentation. Scientists in Reproductive Technology Western Australia (SIRTWA) Postgraduate Symposium, Perth, Western Australia, September 2013.

McEvoy A, **Roberts P**, Yap K, Matson P. The development of a simplified method of semen storage for the testing of sperm DNA fragmentation. Edith Cowan University Research Week, Perth, Western Australia, 2013.

Peirce K, Matson P, **Roberts P,** Ali J. The Use of human blood products and alternatives in assisted reproduction. Scientists in Reproductive Technology Western Australia (SIRTWA) Postgraduate Symposium, Perth, Western Australia, September 2013.

Rodino I. Byrne S, **Sanders K.** Disordered eating attitudes and behaviours in women undergoing infertility treatment in Western Australia. Proceedings of the Fertility Society of Australia (FSA), Sydney, Australia. 1-4 September 2013.

Rodino I. Surrogacy counselling demystified. Surrogacy Australia Workshop, Perth, Australia, 26 October 2013. Invited speaker.

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Developments in Reproductive Technology

Mitochondrial donation

The United Kingdom Human Fertilisation and Embryology Authority published its third scientific review of the safety of techniques to prevent inheritable mitochondrial disorders (HFEA 2014). These incurable disorders are passed from mother to child and can result in progressive disability and death. The techniques for removing the affected mitochondrial DNA, by using part of a healthy donor egg, have been subject to extensive scientific evaluation and ethical debates. This third review concluded there were no safety issues, however further experiments and assessments are required before the procedures are made available as a clinic treatment.

Elective frozen embryo transfer

The elective cryopreservation of all embryos (freeze all) for later planned embryo transfer, rather than a fresh embryo transfer, has been the subject of recent debate. Some studies have found an increase in pregnancy rates and live births for frozen embryos, when compared to fresh embryo transfers (Evans et al 2014). This may be due to embryos that survive the freezing process being more robust and the lining of the womb being better prepared to receive the embryo. Further, there may be a reduced risk of ovarian hyperstimulation syndrome (OHSS) particularly for women who are predisposed to this condition (Weinerman & Mainigi 2014). However, the use of historical data, lack of standardised selection criteria, and lack of robust experimental and clinical outcome data, limits the conclusions that can be drawn from these observations. Prospective studies are required to further inform clinical practice.

Legislation & regulation

The New South Wales (NSW) Government published its response to the NSW Legislative Assembly Committee on Law and Safety report on donor assisted conception (Parliament of NSW 2014a). Legislative amendments will provide for donor-conceived status to be recorded in the register of births. In addition, a consent-release model for pre-2010 donor information will be developed in consultation with stakeholders.

A report of the review of the New South Wales Assisted Reproductive Technology Act (NSW ART Act) 2007 was published in May 2014 (Parliament of NSW 2014b). The Ministry considered that the objectives of the legislation remain valid and current. The report recommended collection of more detailed donor information, and a donor limit of five families rather than five women. There were a number of recommendations regarding posthumous use of gametes. Where gametes are stored within the lifetime of the individual, the written consent of the gamete provider for posthumous use should remain a requirement of the NSW ART Act. Further consultation about the posthumous collection of gametes and subsequent use by the partner of the deceased was recommended.

Reproductive Technology and Voluntary Registers

The Reproductive Technology Registers

Information on ART 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 ART is collected annually from each fertility service provider in WA. In addition, clinics submit their electronic data to the Department of Health.

The Reproductive Technology Registers enable ongoing monitoring of practice and provide an important resource for epidemiological research. Appendixes 3 and 4 provide summary data from the annual reports of the fertility clinics in WA.

The Voluntary Register

The Voluntary Register provides a service for donor-conceived adults and for parents of donor-conceived children to connect with genetic relatives. Access to identifying information can only be provided with the mutual consent of the genetically related people (matches) who must also have joined the Voluntary Register. All the people involved must also undergo mandatory counselling prior to the release of identifying information. Donor-conceived adults (≥18 years old), parents of donor-conceived children (<18 years old), and donors may join the Voluntary Register.

Current registrations as of 30 June 2014 include 27 donor-conceived adults, 89 parents of donor-conceived children, and 67 donors. To-date, there have been 27 matches, with 14 commencing the required counselling and subsequent contact (Table 3).

Table 3: **Voluntary Register: number of matches between participants**

	Matched	Contacted
*DCA and donor	3	2
Parent and donor	12	8
Half siblings	12	4
Total	**27**	**14**

*DCA = Donor-conceived adult

Details of the Voluntary Register are advertised by the Department of Health in the West Australian four times a year to promote awareness of the service. This year the Voluntary Register was also advertised in the Medical Journal of Australia.

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Appendix 1: Practice and storage licence holders

Concept Fertility Centre
Concept Day Hospital
218 Nicholson Road
SUBIACO WA 6008

Fertility Great Southern
Unit 5/3 Mount Shadforth Road
DENMARK WA 6333

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

Fertility Specialists South
1st Floor 764 Canning Hwy
APPLECROSS WA 6153

Fertility Specialists of Western Australia
Bethesda Hospital
25 Queenslea Drive
CLAREMONT WA 6010

Hollywood Fertility Centre
Hollywood Private Hospital
Monash Avenue
NEDLANDS WA 6009

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

PIVET Medical Centre
166-168 Cambridge Street
LEEDERVILLE WA 6007

Appendix 2: Financial Statement

The Department of Health funds the administration of the HRT Act, including the operations of Council. The 2013-2014 Council budget allocation was $61,400 with expenditure totalling $42,462 for the financial year. Council has a long record of remaining within the allocated budget and anticipates that the 2014 -2015 budget will support Council's capacity to meet all Council functions set out in the HRT Act. Table 4 shows the financial statement for the 2013-2014 annual report.

Table 4: **Financial statement for the 2013-2014 annual report**

Expenditure by category 2013–2014	**Expenditure ($)**	**Income ($)**
Staff or Council:		
Training, registration, course fees, interstate travel	9,311	
Food supplies and catering	2,651	
Administration and clerical	83	
Purchase of external research services:	4,3500	
Reproductive Technology Council sitting fees	18,252	
Other expenses:		
Stationery and printing, including annual report	4,363	
Equipment and maintenance	416	
RTC special event seminar	3,036	
Total	**42,462**	**61,400.00**

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 ART trends for the past 10 years in WA. In some instances percentages do not add up to 100% and this is specifically due to rounding to whole numbers.

Background

Fertility clinics licensed under the HRT Act are required to submit summary reports at the end of each financial year. This section outlines the information submitted by licensees and exempt practitioners. Seven clinics in WA have Storage Licences and Practice Licences authorising artificial fertilisation procedures including IVF. One licensee has a storage licence and a practice licence for artificial insemination only.

Assisted reproductive technologies in Western Australia

Assisted reproductive technologies have evolved over the last three decades into mainstream medical interventions that have resulted in the birth of more than five million babies worldwide (ICMART 2008). The most recent report from the Australian Institute of Health and Welfare, National Perinatal Epidemiology and Statistics Unit, estimated that in 2011 ART was used by 3.8% of women who gave birth in Australia (Li et al 2013).

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 3,866 women underwent IVF treatment in WA this year. This represents an increase of 6% (n=228) compared to the previous year. There were 5,791 treatment cycles compared to 5,483 during the previous year. This is an increase of 6% compared to the previous year. Table 5 provides an overview of the initiated cycles.

Table 5: **IVF treatments**

	IVF fresh	IVF thaw	Total
Women treated	2,524	1,342	**3,866**
Treatment cycle	3,558	2,233	**5,791**
Cycle with oocyte retrieval	3,139	-	**3,139**
Cycle with embryo transfer	2,289	2,022	**4,311**
Cycle with embryo storage	1,789	-	**1,789**

Fresh IVF transfer techniques included 200 surgical sperm aspirations and 1,826 intracytoplasmic sperm injection (ICSI) procedures, where a single sperm is directly injected into an egg and the fertilised egg is transferred to the uterus.

There were two gamete intrafallopian transfers (GIFT), which 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 and occurred in less than 0.1 per cent of treatment cycles in 2011 in Australia and New Zealand (Macaldowie *et al* 2013).

A total of 1,147 intrauterine insemination (IUI) treatment cycles were reported by seven licensees and one exempt practitioner. This is more than the previous year and represents a 3% increase in the number of IUI treatment cycles compared to the previous year (n=1,116).

The overall clinical pregnancy rate for IUI was 6% (74 ongoing pregnancies). Of the 74 ongoing pregnancies, 67 (91%) were singleton pregnancies and two were twin pregnancies, the remaining five pregnancies had no plurality reported. The partners' sperm were used for 77% of procedures. Donor sperm were used for 23% of procedures. Gonadotrophin was used for 49% of cycles, Clomid was used in 17% of cycles, and 35% were natural cycles.

IVF fertilisation treatment cycles involving the donation of oocytes, or embryos or the use of donated sperm, oocytes or embryos (recipient cycles) are shown in Table 6.

Table 6: **Number of cycles using donations**

Donated	Fresh	Thaw
Sperm	125	77
Oocyte	20	32
Embryos	3	19

There were 29 cycles where oocytes were donated and 3 cycles where embryos were donated. This year there was a total of 138 sperm donors (37 new donors).

Public fertility clinic referrals

This year 93 patients from King Edward Memorial Hospital Fertility Clinic were referred to Concept Fertility Clinic. A total of 135 treatment cycles were provided by Concept Fertility Centre, with 45 women having IVF with fresh embryo transfer and 25 having IVF with thawed embryo transfer.

Serious morbidity and mortality

Clinics are required to provide information regarding complications of ART treatment. There were 24 reported cases of serious morbidity associated with artificial fertilisation procedures. Nineteen cases were attributed to severe OHSS (of which, nine cases were reported to require hospitalisation for more than 48 hours). A further five women experienced serious morbidity following ART, which was not attributed to OHSS, but required hospitalisation for more than 48 hours. There were no reports of mortality in association with fertility treatment.

Counselling

A total of 1,915 couples or individuals received counselling, which represents a 10% decrease from the previous year (n=2,124). Most participants (81%) received a single counselling session and the majority of these sessions (76%) involved information counselling. Others having a single counselling session received support counselling (20%), therapeutic counselling (3%) and counselling for other reasons (2%). Of the 19% of participants who had more than one session, 32% had support counselling and 57% had information counselling. Counselling for donors and donor recipients accounted for 39% of all sessions. There were 759 donor counselling sessions representing a decrease of 22% from the previous year.

Embryo storage

The number of embryos in storage was reported as 20,323 as of 30 June 2014. The dispersal of embryos for this year is shown in Table 7.

Table 7: **Dispersal of stored embryos**

Embryo dispersal	Effect	n
Embryos in storage 30/06/13		18,455
Embryos created from IVF	+	5,977
Used in frozen embryo transfer treatments	-	2,832
Transferred between clinics in WA	NA	200
Transferred to clinics outside WA	-	77
Transferred from interstate	+	89
Embryo disposition	-	1,289
Embryos in storage 30/06/14		**20,323**

Assisted reproductive technology trends in WA

Treatment trends for both fresh and thawed IVF cycles show a 6% increase (figures 1 & 2). National statistics for 2011 show an 8% increase in ART treatment cycles (Macaldowie *et al* 2013).

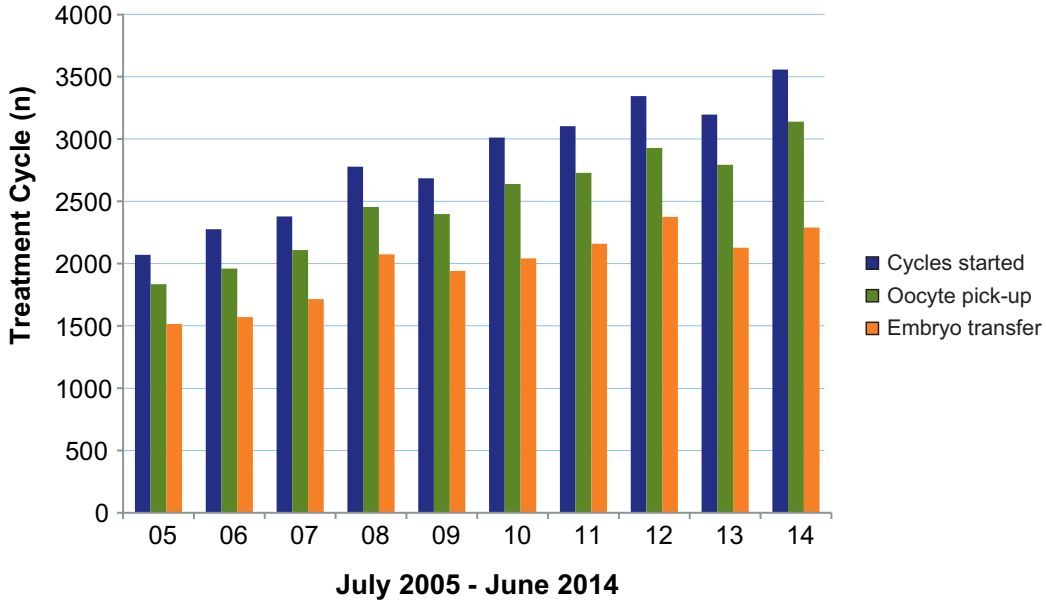

Figure 1: **Progression of fresh IVF cycles by year, 2005-2014**

The proportion of fresh to thaw IVF cycles has remained relatively unchanged (range 58-61%) and represented 61% of cycles this year. National statistics for 2011 show that 65% of ART cycles were fresh IVF cycles (Macaldowie *et al* 2013).

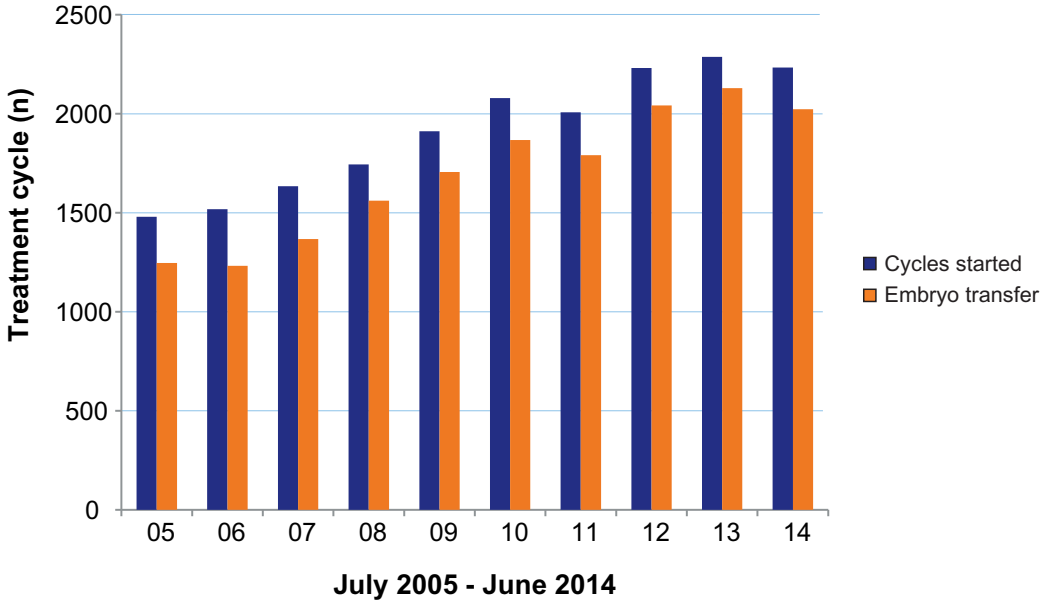

Figure 2: **Progression of thawed embryo cycles by year, 2005-2014**

Intracytoplasmic sperm injection procedures

The number of IVF procedures where ICSI was used is shown in figure 3. This procedure was used in 51% of fresh IVF cycles in WA this year. National statistics show that the use of ICSI has increased over the past decade. Data for Australia and New Zealand indicate that ICSI was used in 75% of fresh oocyte recipient cycles in 2011 (Macaldowie *et al* 2013).

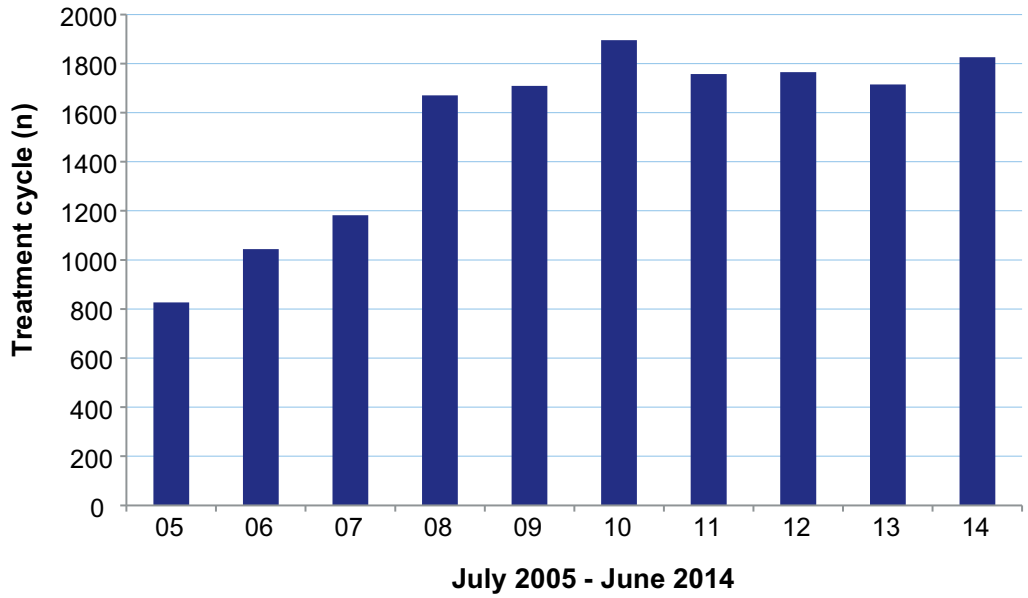

Figure 3: **Number of IVF cycles with ICSI by year, 2005-2014**

Number of sperm donors

The number of sperm donors has gradually increased over the past 10 years (Figure 4). Men in the 31-40 and 41-50 year age range represent the largest group of donors (35% and 34%, respectively).

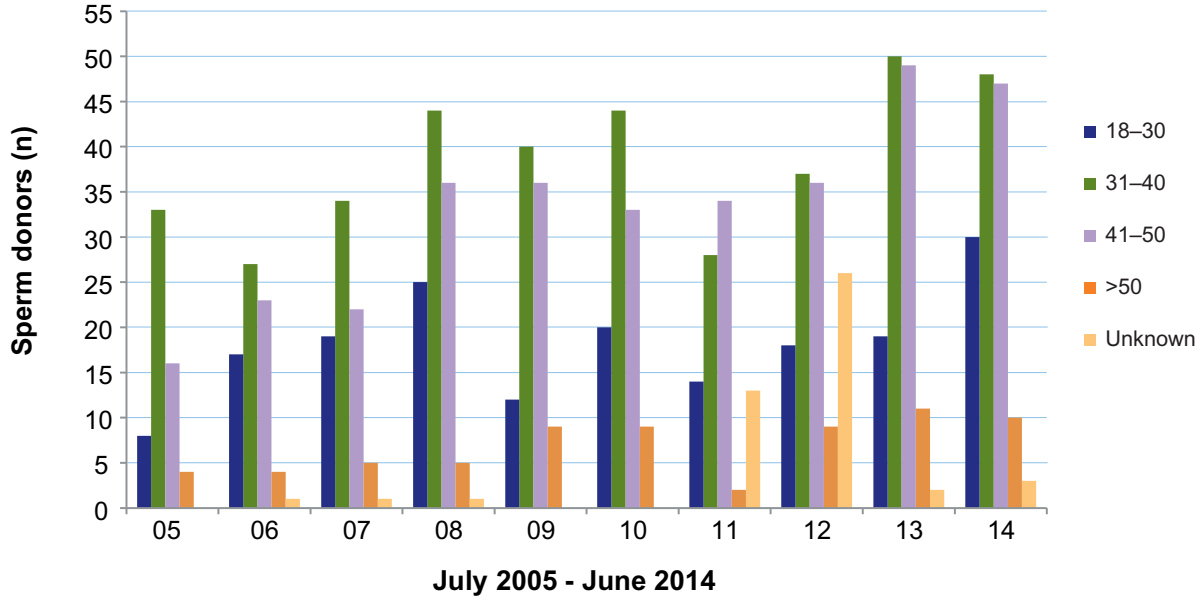

Figure 4: **Number of sperm donors by age group and year, 2005-2014**

Notes

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189 Royal Street
EAST PERTH WA 6004

RTC-012819 SEP'14