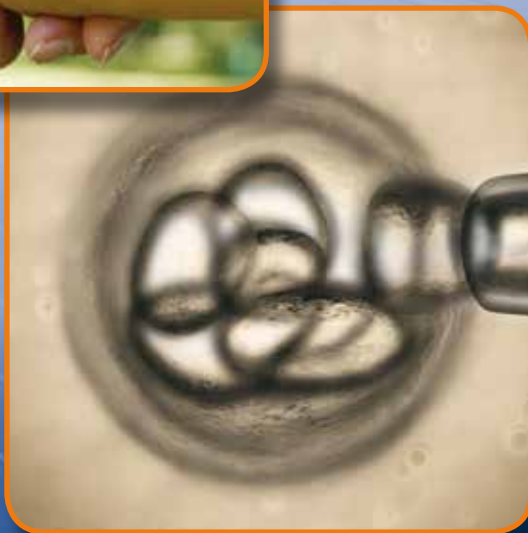




Reproductive Technology Council

# Western Australian Reproductive Technology Council

## Annual Report 1 July 2014 to 30 June 2015



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This report is available online at [www.rtc.org.au](http://www.rtc.org.au)

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Reproductive Technology Council

Dr D J Russell-Weisz  
DIRECTOR GENERAL  
Department of Health  
189 Royal Street  
East Perth WA 6004

Dear Dr Russell-Weisz

It is with pleasure that I submit the Reproductive Technology Council (Council) Annual Report for the financial year 2014 to 2015. 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.

On the recommendation of Council, renewed practice and storage licences were issued to seven fertility clinics that provide assisted reproductive technology services in WA.

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 and surrogacy arrangements.

Council also hosted two special events. The first guest speaker shed light on the experiences of people who seek to connect with their donor and donor-related siblings. The second guest speaker presented an insight into the complex and emotional experience of embryo donation.

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 2015

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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 2014 to 30 June 2015.

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.

Renewed practice and storage licences were issued to 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 26 applications to extend embryo storage and 32 applications for genetic testing of embryos. A total of three surrogacy applications were received and approved this year.

Council also hosted two special events. The first guest speaker shed light on the experiences of people who seek to connect with their donor and donor-related siblings. The second guest speaker presented an insight into the complex and emotional experience of embryo donation.

The budget allocation to Council for this year was \$62,935 and the expenditure was \$25,490. 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 2014-2015 show that 4,099 women underwent *in vitro* fertilisation (IVF) treatment, which is 6% more than in the previous year. Fertility clinics undertook 6,050 IVF treatment cycles this year, which is 4% more than in the previous year.

A total of 996 intrauterine inseminations were undertaken, which represents a decrease of 13% compared to the previous year.

There were nine reported cases of morbidity (complications), attributed to ovarian hyperstimulation syndrome and no reports of mortality (deaths) in association with fertility treatments.



A total of 2,014 couples or individuals received counselling, which represents a 5% increase 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 2015 was 21,278.

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 AO**

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 University of Western Australia (UWA) and Adjunct Professor of Medical Education, Faculty of Health Science, Curtin University. He is also a Fellow of the Royal Australian and New Zealand College of Obstetricians and Gynaecologists, a member of the Australian Health Practitioner Regulation Agency Management Committee, Chair of the Western Australian Board of the Medical Board of Australia. In 2001, Professor Michael was named an Officer of the Order of Australia and was awarded the Centenary Medal in 2001.

#### **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.

#### **Adjunct 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 a life member of 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 PhD 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.

## Dr Kathy Sanders

Dr Kathy Sanders is Chair of the Preimplantation Genetic Diagnosis (PGD) Advisory Committee. Dr 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. She is currently the Academic Coordinator of the Bachelor of Philosophy (Honours) program. Dr 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)

**Dr 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 Oakeley** (nominee of the Department for Communities, Office of Women's Interests)

**Associate Professor 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)

**Ms Diane Scarle** (nominee of the Minister for Child Protection)

**Mrs Maxine Strike** (Deputy Executive Officer, Senior Policy Officer, Reproductive Technology Unit, Department of Health)

**Mrs Sharmaine Ewan** (Deputy Executive Officer, Senior Policy Officer, Reproductive Technology Unit, 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*) Mrs Sharmaine Ewan (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*), Mrs Sharmaine Ewan (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*)

## Preimplantation Genetic Diagnosis 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 Kathy Sanders (Chair), Dr Peter Burton, Dr Sharron Townshend, Dr John Beilby, Dr Mo Harris (*ex officio*), Mrs Maxine Strike (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, Dr Kathy Sanders, Dr Mo Harris (*ex officio*), Mrs Maxine Strike (Deputy *ex officio*).





# Operations of Council

## Meetings

Council met on 11 occasions during the year, with attendances reaching quorum at all meetings. The Counselling Committee met on two occasions. The PGD Advisory Committee met on two occasions, with the majority of applications for PGD considered out-of-session. The Embryo Storage Committee did not meet this year and most applications for extension of storage were considered out of session. The Scientific Advisory Committee met on one occasion, with additional business conducted out of session. The Licensing and Administration Advisory Committee met on two occasions.

## Memberships

### Outgoing and in-coming members

**Ms Dianne Scarle** was appointed deputy member of Council (nominee of the Minister for Child Protection), 20 July 2014.

**Dr Ashleigh Murch** resigned from the PGD Committee, 5 March 2015.

**Dr John Beilby** was appointed to the PGD Committee, 17 March 2015.

## 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).

**Senior Policy Officer**, Mrs Maxine Strike (Bachelor of Applied Science).

**Senior Policy Officer**, Mrs Sharmaine Ewan (Registered Nurse, Advanced Diploma in Health Science & Management).

## 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. Seven clinics applied to renew their licence this year. The Executive Officer and / or a Deputy Executive Officer of Council visited all the fertility clinics as part of the licensing review process. Council members Dr Joe Parkinson, Associate Professor Peter Roberts, Ms Iolanda Rodino, and Dr Michele Hansen also visited a number of clinics to meet with 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 2014) and Certification Scheme (RTAC 2010). 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 (JAS-ANZ) accredited certification body for RTAC certification. Laboratories are 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 and on the Council website [www.rtc.org.au](http://www.rtc.org.au).

## **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. There were 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](http://www.rtc.org.au).

## **Approved counsellors**

Council has not received any applications this year for recognition as an approved counsellor under the HRT Act.

A list of approved counsellors is available on the Council website [www.rtc.org.au](http://www.rtc.org.au).

## **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 27 applications for extension of the authorised embryo storage period and approved 26 of the applications, compared to 21 applications that were approved 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) |           |          |          |          | Total     |
|------------------------|-------------------------------------|-----------|----------|----------|----------|-----------|
|                        | ≤1                                  | 2         | 3        | 4        | 5        |           |
| <b>Application (n)</b> | <b>1</b>                            | <b>15</b> | <b>7</b> | <b>0</b> | <b>3</b> | <b>26</b> |

Storage of gametes beyond the authorised 15 year time limit also requires Council approval. Council received 16 applications. Four applications were approved for an additional five years and 12 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 32 applications for preimplantation genetic testing were approved (20 for PGD; 11 for both PGD and PGS; 1 for PGS only). The genetic conditions that were approved for PGD are listed in Table 2.

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

| Condition                              |                                     |
|--|-------------------------------------|
| BRACA1                                 | Huntington's disease                |
| Brugada Syndrome                       | Li-Fraumeni syndrome                |
| β Thalassaemia                         | Multiple endocrine neoplasia type 1 |
| Cystic fibrosis                        | Translocations                      |
| Facioscapulohumeral muscular dystrophy | Turner's syndrome                   |
| Galactosaemia                          | Wiskott - Aldrich syndrome          |
| Gap junction protein, beta 2 gene      | X-linked ectodermal dysplasia       |

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 three surrogacy applications this year. Council received the first surrogacy application in 2010 and in total has approved 23 of the 24 applications received to-date. For the years 2010 to 2015 a cumulative total of 10 pregnancies and five births were reported.

### **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 there have been no applications to Council for research project approvals.

### **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 no formal complaints this year. However a complaint from the previous financial year was determined this year, after investigation by an authorised officer. No disciplinary action was required as the clinic has taken appropriate action in response to the incident.

### **Finances**

The budget allocation to Council was \$62,935, with expenditure totalling \$25,490. 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.

Council noted an increase in licence fees, which came into effect from January 2015. The fee for a three year Practice Licence increased to \$1000 and the fee for a three year Storage Licence increased to \$600.

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 continued its work on reviewing the information that is provided to the Department of Health by licensees.

Council hosted a special event on 3 December 2014 with guest speaker Ms Kate Bourne, Senior Community Education Officer, Victorian Assisted Reproductive Authority (VARTA). Ms Bourne's presentation 'The Etiquette of Donor Linking' explored the complex issues that need to be navigated when people seek to connect with their donor and donor-related siblings. The event attracted a multidisciplinary audience of 25 people.

Council hosted a special event on 30 April 2015 with guest speaker Dr Sonja Goedeke, who has undertaken seminal work in the area of embryo donation in New Zealand. Dr Goedeke's presentation 'Understandings and experiences of 'open' embryo donation in New Zealand' shed light on the complex and emotional journey. The event attracted an audience of 22 people. A video of the presentation is available at: [https://www.youtube.com/embed/\\_lupaC2NRhI?rel=0](https://www.youtube.com/embed/_lupaC2NRhI?rel=0)





## 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

- Abou-Setta AM, Peters LR, D'Angelo A, Sallam HN, **Hart RJ**, Al-Inany HG. (2014) Post-embryo transfer interventions for assisted reproduction technology cycles. *Cochrane library*. Issue 8 ID 861706092823342799 DOI: 10.1002/14651858.CD006567.pub3
- Chambers GM, Hoang VP, Lee E, **Hansen M**, Sullivan EA, Bower C and Chapman M. Hospital costs of multiple-birth and singleton-birth children during the first 5 years of life and the role of assisted reproductive technology. (2014) *JAMA Pediatrics*. 168: 1045-53.
- Doherty D, Newnham J, Bower C, **Hart R**. (2015) Implications of Polycystic Ovary Syndrome for Pregnancy and for the Health of the Offspring. *Obstetrics & Gynecology*. 125(6): 1397-406.
- Hansen M**, Bower C. (2014) Impact of assisted reproductive technologies on intrauterine growth and birth defects in singletons. *Seminars in Fetal and Neonatal Medicine*. 19: 228-233.
- Hart R**, Doherty D. (2015) The Potential Implications of a PCOS Diagnosis on a Woman's Long-term Health Using Data Linkage. *The Journal of Clinical Endocrinology & Metabolism*. 100(3):911-9. doi: 10.1210/jc.2014-3886.
- Liu Y, Chapple V, **Roberts P**, Ali J, Matson P. (2014) Time-lapse videography of human oocytes following intracytoplasmic sperm injection: events up to the first cleavage division. *Reproductive Biology*. 14: 249-256.
- Liu Y, Chapple V, **Roberts P**, Matson P. (2014) The prevalence, consequence and significance of reverse cleavage by human embryos viewed with the Embryoscope™ time lapse video system. *Fertility and Sterility*. 102: 1295–1300.
- Liu Y, Chapple V, Feenan K, **Roberts P**, Matson P. (2015) Time-lapse videography of human embryos: Using pronuclear fading rather than insemination in IVF and ICSI cycles removes inconsistencies in time to reach early cleavage milestones. *Reproductive Biology*. 15: 122-125.
- Liu Y, Copeland C, Chapple V, **Roberts P**, Feenan K, Matson P. (2015) The relationship between embryo quality assessed using routine embryology or time-lapse videography and serum progesterone concentration on the day of ovulatory trigger in in vitro fertilization cycles. *Asian Pacific Journal of Reproduction*. 4 (2): 140-146.
- Liu Y, Chapple V, Feenan K, **Roberts P**, Matson P. (2015) Clinical significance of intercellular contact at the 4-cell stage of human embryos, and the use of abnormal cleavage patterns to identify embryos with low implantation potential: a time-lapse study. *Fertility and Sterility*. 103 (6): 1485-1491.

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# Developments in reproductive technology

## Mitochondrial donation

Mitochondrial inheritable disorders are incurable disorders that are passed from mother to child and can result in progressive disability and death. Regulations regarding mitochondrial donation were approved by the United Kingdom Government (HFEA, 2015) to prevent the transmission of mitochondrial disease. The two proposed techniques that would be allowed under these Regulations are maternal spindle transfer and pronuclear transfer. The regulations also allow for children born from the procedure to have access to limited non-identifying information about their mitochondrial donor.

## Live birth after uterus transplantation

The Sahlgrenska University Hospital, Gothenburg, Sweden reported a live birth after a woman with congenital absence of the uterus underwent transplantation of the uterus from a living, 61-year-old woman. The woman was given immunosuppression and had a single embryo transfer after twelve months. Three episodes of mild rejection occurred, which were managed with steroid treatment. The baby was born by caesarean section at 31 weeks gestation (Brännström et al., 2015). A clinical trial of uterus transplantation in nine women reported two hysterectomies for thrombosis or infection, with remaining recipients maintaining viable grafts (Brännström et al., 2014).

## Legislation and regulation

A report of the review of the Western Australian Surrogacy Act 2008 (Department of Health, 2014) was published in November 2014. The report recommended the development of information resources for surrogacy in WA and also drew attention to the issues of the global commercial surrogacy market.

In August 2014 the Attorney General for Australia released the Family Law Council Report on Parentage and the Family Law Act (Family Law Council, 2013). The report included recommendations concerning surrogacy legislation within Australia and international commercial surrogacy arrangements. More recently, the House of Representatives Standing Committee on Social Policy and Legal Affairs held a Roundtable on Surrogacy to investigate the complexities of regulation of surrogacy, and issues faced by the increasing number of Australians who seek and use overseas surrogacy (House of Representatives, 2015).

The Victorian Government amended the Assisted Reproductive Treatment Act 2008 (Vic) which provides for donor-conceived persons to have greater access to non-identifying information about their donor and access to identifying information with consent of their donor (Victorian Assisted Reproduction Treatment Authority (VARTA, 2014)).



# 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. Appendices 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 ( $\geq 18$  years old), parents of donor-conceived children who are  $< 18$  years old, and donors may join the Voluntary Register.

Current registrations as of 30 June 2015 include 30 donor-conceived adults, 99 parents of donor-conceived children, and 76 donors. To-date, there have been 28 matches, with 14 ensuing contact (Table 3).

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

|                  | Matched   | Contacted |
|------------------|-----------|-----------|
| *DCA             | 3         | 2         |
| Parent and donor | 12        | 8         |
| Half-sibling     | 13        | 4         |
| <b>Total</b>     | <b>28</b> | <b>14</b> |

\*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.

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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 30 level 2 Joondalup Private Hospital  
60 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**

1st Floor C Block  
QEII Medical Centre  
NEDLANDS WA 6009  
(Artificial insemination only)

### **PIVET Medical Centre**

Perth Day Surgery 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 2014-2015 Council budget allocation was \$62,935 with expenditure totalling \$25,490 for the financial year. Council has a long record of remaining within the allocated budget and anticipates that the 2015-2016 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 2014-2015 annual report.

**Table 4: Financial statement for the 2014-2015 annual report**

| Expenditure by category 2014-2015                      | Expenditure (\$) | Income (\$)   |
|--|------------------|---------------|
| Training, registration, course fees, interstate travel | 4,756            |               |
| Food supplies and catering                             | 2,635            |               |
| Administration and clerical                            | 59               |               |
| Reproductive Technology Council sitting fees           | 15,194           |               |
| Other expenses:  |                  |               |
| Stationery and printing, including annual report       | 817              |               |
| RTC special event seminar                              | 2,029            |               |
| <b>Total</b>   | <b>25,490</b>    | <b>62,935</b> |



## Appendix 3: Operations of licence holders

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 clinic has a Storage Licence and a Practice Licence only for artificial insemination.

The aggregated data, tables, graphs, analysis and interpretation of data presented in this appendix have been provided by the Purchasing and Systems Performance 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 in WA. In some instances percentages do not add up to 100% due to rounding to whole numbers.

### Assisted reproductive technologies in Western Australia

The most recent report from the Australian Institute of Health and Welfare, National Perinatal Epidemiology and Statistics Unit, estimated that in 2012 ART was used by 4.0% of women who gave birth in Australia (Hilder et al., 2014).

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 4,099 women underwent assisted reproduction treatment in WA this year. This represents an increase of 6% (n=233) compared to the previous year. There were 6,050 treatment cycles compared to 5,791 during the previous year. This is an increase of 4%. Table 5 provides an overview of the initiated cycles.

**Table 5: IVF treatments**

|                             | IVF fresh | IVF thaw | Total |
|-----------------------------|-----------|----------|-------|
| Women treated               | 2,525     | 1,573    | 4,098 |
| Treatment cycle             | 3,429     | 2,621    | 6,050 |
| Cycle with oocyte retrieval | 3,048     | -        | 3,048 |
| Cycle with embryo transfer  | 2,122     | 2,404    | 4,526 |
| Cycle with embryo storage   | 1,725     | -        | 1,725 |

Fresh IVF transfer techniques included 136 surgical sperm aspirations and 1,867 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 was one gamete intrafallopian transfer (GIFT) treatment. GIFT is a procedure where mature oocytes and sperm are placed directly into the fallopian tubes to allow



fertilisation take place naturally. The use of this procedure has been in decline for several years and in 2012 was used for only seven treatment cycles in Australia and New Zealand (Macaldowie et al., 2014).

A total of 996 intrauterine insemination (IUI) treatment cycles were reported by eight licensees and two exempt practitioners. This is less than the previous year and represents a 13% decrease in the number of IUI treatment cycles compared to the previous year (n=1,147). The reported ongoing pregnancy rate for IUI was 6% (63 ongoing pregnancies), of which 42 (67%) were singleton pregnancies and 21 had no plurality reported. The partners' sperm were used for 78% of procedures. Donor sperm were used for 22% of procedures. Gonadotrophin was used for 51% of cycles, Clomid was used in 24% of cycles, and 25% were natural cycles.

The number of recipient cycles, where a woman receives donor sperm, oocytes or embryos is shown in Table 6.

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

|        | Fresh IVF cycle | Thawed embryo cycle |
|--------|-----------------|---------------------|
| Sperm  | 159             | 162                 |
| Oocyte | 20              | 45                  |
| Embryo | 12              | 28                  |

In addition, there were 28 cycles where oocytes were donated and 12 cycles where embryos were donated. This year there was a total of 185 sperm donors, of which 36 were new donors.

**Public fertility clinic referrals**

This year 14 patients from King Edward Memorial Hospital Fertility Clinic were referred to Concept Fertility Clinic. A total of 20 treatment cycles were provided by Concept Fertility Centre, with five women having IVF with fresh embryo transfer and five having IVF with thawed embryo transfer.

## Serious morbidity and mortality

Clinics are required to provide information regarding complications of ART treatment. There were nine reported cases of serious morbidity associated with artificial fertilisation procedures. All nine cases were attributed to severe ovarian hyper-stimulation syndrome (OHSS). Three of the nine cases were reported to require hospitalisation for more than 48 hours. There were no other reports of serious morbidity and there were no reports of mortality in association with fertility treatment.

## Counselling

A total of 2,014 couples or individuals received counselling, which represents a 5% increase from the previous year (n=1,915). Most participants (76%) received a single counselling session and the majority of these sessions (78%) involved information counselling. Others having a single counselling session received support counselling (17%), therapeutic counselling (4%) and counselling for other reasons (1%). Of the 24% of participants who had more than one session, 29% had support counselling and 52% had information counselling. Counselling for donors and donor recipients accounted for 43% of all sessions. There were 908 donor counselling sessions representing an increase of 20% from the previous year.

## Embryo storage

The number of embryos in storage was reported as 21,278 as of 30 June 2015. The dispersal of embryos for this year is shown in Table 7.

**Table 7: Dispersal of stored embryos**

| <b>Embryo Dispersal</b>                   | <b>n</b>      |
|---|---------------|
| Embryos in storage 30/6/2014              | 20,323        |
| Embryos created from IVF                  | 6,006         |
| Used in frozen embryo transfer treatments | 3,422         |
| Transferred between clinics in WA         | 223           |
| Transferred to clinics outside WA         | 87            |
| Transfer from interstate                  | 55            |
| Embryo disposition                        | 1,597         |
| <b>Embryos in storage 30/06/15</b>        | <b>21,278</b> |

## Assisted reproductive technology trends in WA

Overall, the number of treatment cycles in WA increased by 4% compared to the previous year (n=6,050 vs n=5,791). National statistics show a 5.8% increase in ART treatment cycles in 2012 (Macaldowie et al., 2014).

Figure 1 shows the progression of fresh IVF cycles. There were fewer fresh IVF cycles commenced this year in WA compared to last year. However, overall the progression of fresh IVF cycles to embryo transfer has remained relatively unchanged.

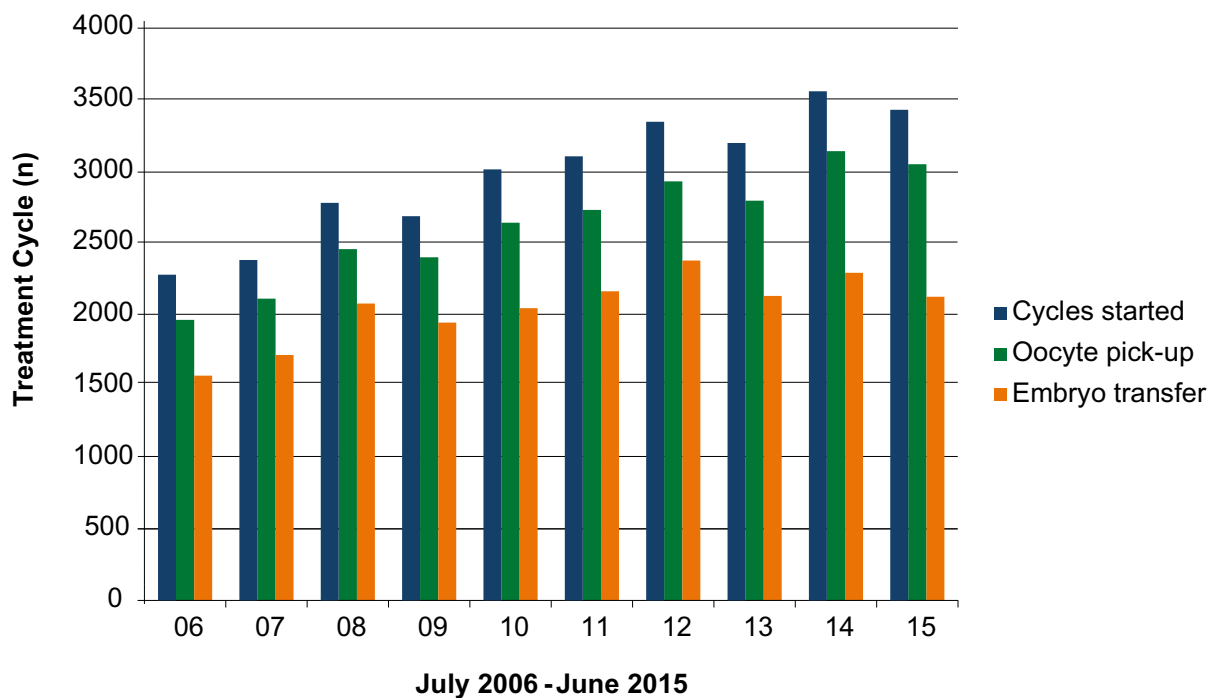
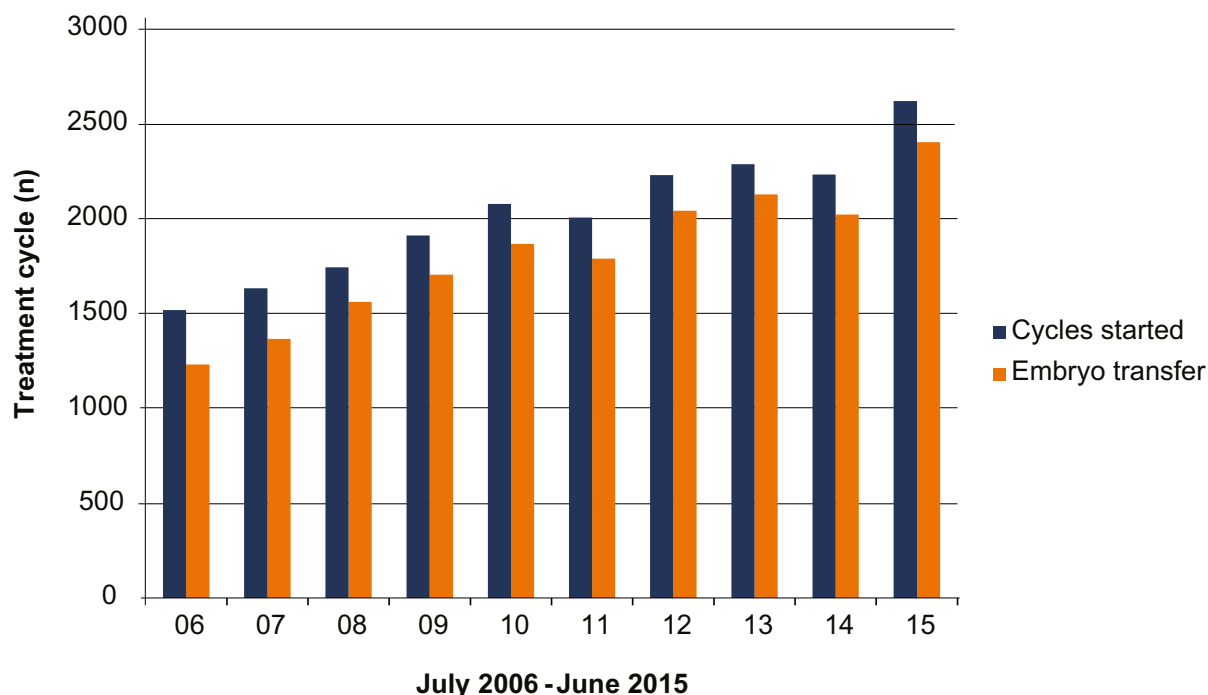


Figure 1: Progression of fresh IVF cycles by year, 2006-2015



Figure 2 shows the progression of thawed embryo cycles. There was a greater number of thawed embryo transfer cycles commenced this year.

Overall, in WA the proportion of fresh to thawed cycles, this year was 57% of all cycles. This proportion has remained relatively stable over the years (range 57% – 61%). National statistics for 2012 show that 63% of ART cycles, where the patients used their own eggs or embryos, were fresh IVF cycles (Macaldowie et al., 2014).



**Figure 2: Progression of thawed embryo cycles by year, 2006-2015**

### Intracytoplasmic sperm injection procedures

The number of IVF procedures where ICSI was used is shown in figure 3. This procedure was used in 54% of fresh IVF cycles in WA this year. National statistics show that the use of ICSI has increased over the past decade. Australia and New Zealand data report 65% of fresh oocyte recipient cycles used ICSI procedures in 2012 (Macaldowie et al., 2014).

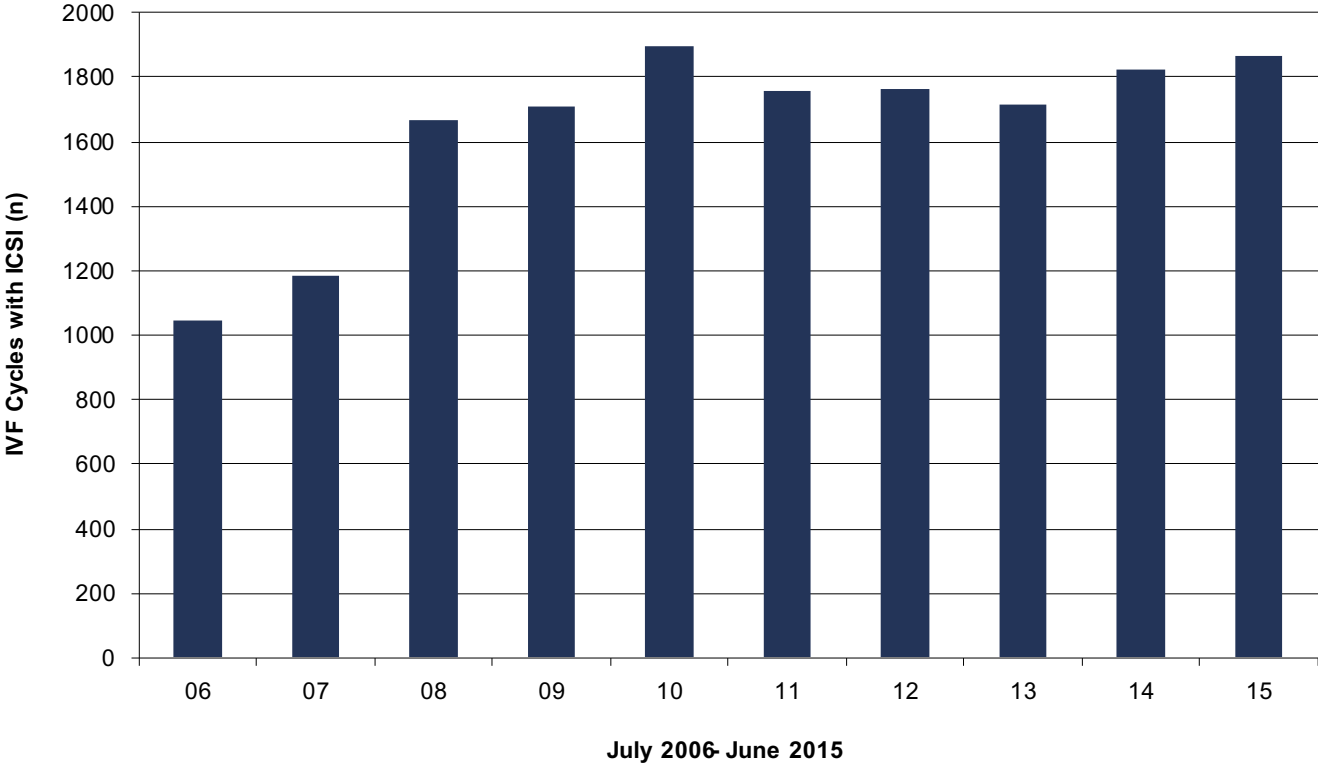
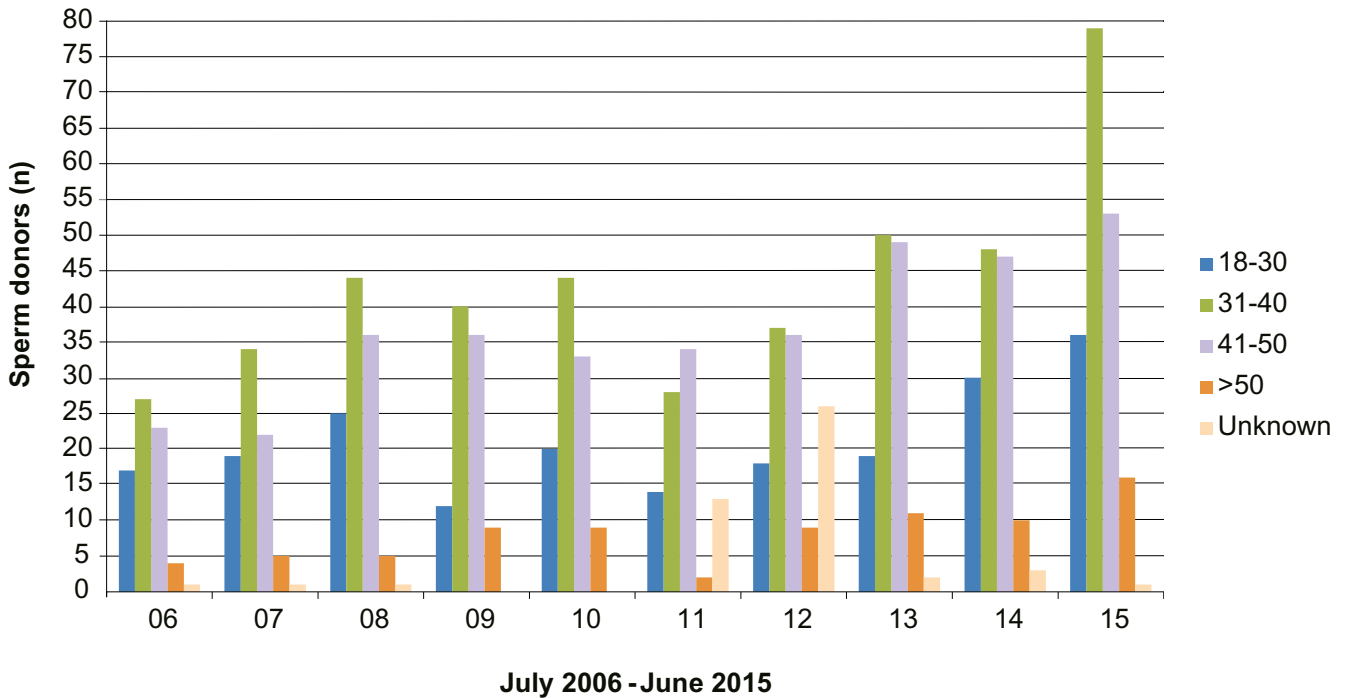


Figure 3: Number of IVF cycles with ICSI by year, 2006-2015



## Number of sperm donors

The number of sperm donors has gradually increased over the past 10 years (Figure 4). Men in the 31-40 year age range represent the largest group of donors (43%). The graph shows the majority of the new donors this year were in this age range.



**Figure 4: Number of sperm donors by age group and year, 2006-2015**



# Notes

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