



Reproductive Technology Council

# Western Australian Reproductive Technology Council

## Annual Report 1 July 2018 to 30 June 2019



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Dr D J Russell-Weisz  
CHIEF EXECUTIVE OFFICER  
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 2018 to 2019. 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 including applications for embryo storage extension, gamete storage extension and genetic testing of embryos.

The Human Reproductive Technology and Surrogacy Legislation Amendment Bill 2018 was introduced into Parliament and subsequently referred to the Standing Committee on Legislation. Council provided a written submission to the Committee.

Council co-hosted a postgraduate student presentation evening where university students had the opportunity to showcase their work in assisted reproductive biology.

This year one clinic, the Keogh Institute for Medical Research requested revocation of their licence and ceased operation.

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

Dr Brenda McGivern  
Chair  
Reproductive Technology Council

September 2019

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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 assisted reproductive technology (ART) in Western Australia, and the operation of Council for the financial year from 1 July 2018 to 30 June 2019.

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 2008* (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. Council approved 40 applications to extend embryo storage, 46 applications for genetic testing of embryos and fewer than five surrogacy applications.

The Human Reproductive Technology and Surrogacy Legislation Amendment Bill 2018 was introduced into Parliament and subsequently referred to the Standing Committee on Legislation. Council provided a written submission to the Committee.

Council co-hosted an event where postgraduate university students had the opportunity to showcase their work in assisted reproductive biology.

This year one licensed clinic, the Keogh Institute for Medical Research requested revocation of their licence and ceased operation.

The budget allocation to Council for this year was \$64,350 and the expenditure was \$28,215. The financial statement, which outlines the distribution of expenses, is provided in this annual report.

Data collected from the annual reports submitted by WA licensees for 2018–2019 showed that 4,672 women underwent in vitro fertilisation (IVF) treatment, which is a increase of 19% from the previous year. Fertility clinics undertook 6,979 IVF treatment cycles this year, which is 16% more than the previous year.

A total of 685 intrauterine inseminations were undertaken, which represents a decrease of 13% compared to the previous year.

A total of 2,213 couples or individuals received counselling, which represents a slight 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 2019 was 26,692.

Council acknowledges the dedicated work of Council and committee members, and the ongoing financial and administrative support provided by the Department of Health.

## Introduction

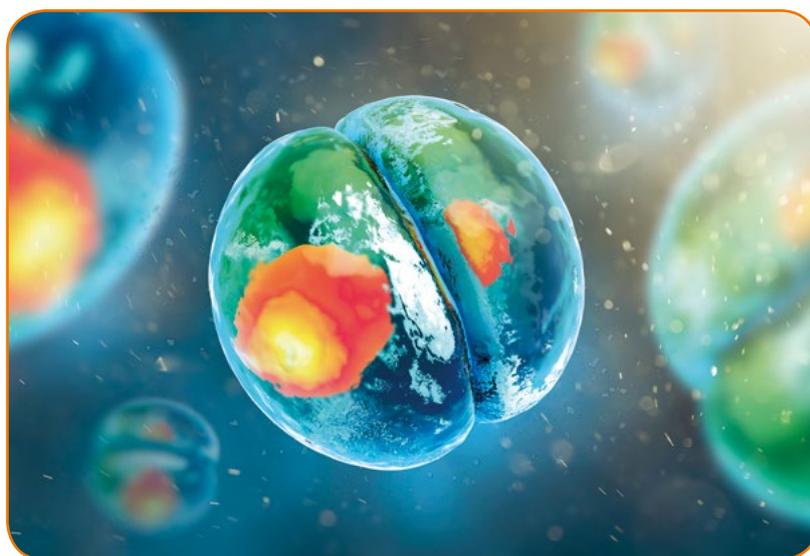
This annual report provides an account of the activities of Council for the past financial year. Council regulates ART practices in WA, as set out in the HRT Act and the Surrogacy Act. The report is structured around the legal requirements and major activities of Council and outlines the operation of 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 of 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

### Dr Brenda McGivern

Dr Brenda McGivern is Chair of the Council. With an academic and professional background in Law, she is the Deputy Executive Dean of the Faculty of Arts, Business, Law and Education at the University of Western Australia (UWA), and continues to practise as a Consultant with Moray & Agnew Lawyers. She specialises in health, torts and insurance law. In addition to her role with the Council, she also serves on the Clinical Ethics Service for the Child and Adolescent Health Service.

### Dr John Beilby

Dr John Beilby, Bachelor of Science, Doctor of Philosophy (UWA) is Chair of the Preimplantation Genetic Diagnosis Committee. He has a Fellowship of the Australasian Association of Clinical Biochemistry, is a Member of the Human Genetics Society of Australasia and a Founding Fellow of the Faculty of Science, the Royal College of Pathologists of Australasia. Dr Beilby is Head of Department of Diagnostic Genomics Laboratory, PathWest, Queen Elizabeth II Medical Centre and Adjunct Professor in the UWA School of Biomedical Science. Dr Beilby's research areas include studying genetic variants associated with ageing, cardiovascular disease, diabetes, and respiratory diseases.

### 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 Biotechnology Committee and a member of the Stem Cell Working Group. He is a past member of the Monash Medical Centre and Epworth Hospital's Human Research Ethics Committee, the Curtin University Human Research Ethics Committee and the Coroner's Ethics Committee.

### Professor Roger Hart

Professor Roger Hart is Chair of the Scientific Advisory Committee. Professor Hart is a fertility specialist who has a Certificate of Reproductive Endocrinology and Infertility (CREI) and is Professor of Reproductive Medicine and Deputy Head of the Division of Obstetrics and Gynecology, UWA. He is the lead clinician for the public fertility service of WA, and the Medical Director of Fertility Specialists of WA. He is the holder of Australian National Health and Medical Research Council (NHMRC) grants to study the

early life origins of impaired spermatogenesis and to study the long-term consequences of IVF treatment. He has over 150 publications in the field of reproductive medicine, is an associate editor of *Fertility and Sterility* and a member of the menstrual disorders and fertility sub-group of the Cochrane collaboration. He is Chair of the CREI sub-specialty committee and a member of the joint NHMRC and the European Society for Human Reproduction and Embryology Polycystic Ovary Syndrome (PCOS) Guideline development group.

### **Dr Iolanda Rodino**

Dr Iolanda Rodino is Chair of the Counselling Committee. She completed her Doctor of Philosophy at the University of Western Australia in 2019 and currently works as an approved infertility counsellor and clinical psychologist in private practice. Dr Rodino has worked in several fertility clinics in Perth and has extensive experience working in the fields of infertility, antenatal and postnatal counselling services. Her clinical specialisations focus on the psychological challenges for women seeking fertility treatment, particularly women with PCOS, and assisting couples contemplating third party reproduction. Dr Rodino has a strong interest in infertility research and serves as Chair of the Research Subcommittee for The Australian and New Zealand Infertility Counsellors Association. Dr Rodino has published in the areas of donor assisted conception, eating disorders in the context of women undergoing infertility treatment, obesity and preconception care.

### **Dr Joseph Parkinson**

Dr Joseph Parkinson is Chair of the Licensing and Administration Advisory Committee. Dr Parkinson holds a licence in moral theology from the Lateran University in Rome and a Doctor of Philosophy in moral theology from the University of Notre Dame Australia. He is a Trustee of St John of God Healthcare, and an Adjunct Associate Professor in the School of Philosophy and Theology at the University of Notre Dame Australia (Fremantle Campus). He is a member of several ethics committees, including the research ethics and clinical ethics committees for St John of God Healthcare and the Clinical Ethics Consultancy Service at Perth Children's Hospital. Since 2003, his substantive role has been Director the LJ Goody Bioethics Centre in Mount Hawthorn.



## Reproductive Technology Council Members

**Dr Brenda McGivern**, Chair (nominee of the Minister for Health, representing the Law Society of Western Australia).

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

**Dr Angela Cooney** (nominee of the Australian Medical Association).

**Dr Veronica Edwards** (nominee of the Minister for Child Protection).

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

**Professor Roger Hart** (nominee of the UWA, School of Women's and Infants' Health).

**Professor Stephan Millett** (nominee of the Minister for Health).

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

**Associate Professor Peter Roberts** (nominee of the Minister for Health).

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

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

## Reproductive Technology Council Deputy Members

**Dr John Beilby** (nominee of the Minister for Health).

**Dr Peter Burton** (nominee of the UWA, School of Women's and Infants' Health).

**Dr Megan Byrnes** (nominee of the Royal Australian and New Zealand College of Obstetricians and Gynaecologists).

**Reverend Brian Carey** (nominee of the Minister for Health).

**Dr Louise Farrell** (nominee of the Australian Medical Association).

**Dr Michèle Hansen** (nominee of the Minister for Health).

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

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

**Dr Iolanda Rodino** (nominee of the Health Consumers' Council WA).

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

**Ms Bridget Blackwell** (Senior Policy Officer, Reproductive Technology Unit, Department of Health).

**Mrs Maxine Strike** (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

Dr Iolanda Rodino (Chair), Dr Veronica Edwards, Ms Justine Garbellini, Dr Elizabeth Webb, Dr Mo Harris (*ex officio*), Ms Bridget Blackwell (Senior Policy Officer).

## 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 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), Ms Antonia Clissa, Dr Angela Cooney, Dr Andrew Harman, Dr Mo Harris (*ex officio*), Ms Bridget Blackwell (Senior Policy Officer).

## 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

Dr Joe Parkinson (Chair), Dr Angela Cooney, Professor Roger Hart, Associate Professor Peter Roberts, Dr Iolanda Rodino, Dr Mo Harris (*ex officio*) Ms Maxine Strike (Senior Policy Officer).

## Preimplantation Genetic Diagnosis Committee

### Terms of reference

The committee's terms of reference are to:

- advise the Council on a suitable framework for the approval of PGD under the HRT Act both generally and for specific cases;
- advise the Council on factors that it should consider when deciding whether to approve PGD;

- advise Council on standards for facilities, staffing and technical procedures;
- approve PGD applications for translocations, cystic fibrosis and Huntington’s disease;
- advise as to how the ongoing process of approval of PGD should be managed effectively by the Council;
- advise the Council on other relevant matters as requested by the Council.

## Membership

Dr John Beilby (Chair), Dr Peter Burton, Dr Kathy Sanders, Dr Sharron Townshend, Dr Mo Harris (*ex officio*), Ms Maxine Strike (Senior Policy Officer).

## 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

Professor Roger Hart (Chair), Dr Peter Burton, Dr Michèle Hansen, Dr Andrew Harman, Rev Dr Joe Parkinson, Associate Professor Peter Roberts, Dr Lucy Williams, Dr Mo Harris, (*ex officio*), Ms Maxine Strike (Senior Policy Officer).



# Operations of Council

## Meetings

Council met on 12 occasions during the year, with attendances reaching a quorum at all meetings. The Counselling Committee met on one occasion. The PGD Committee did not meet this year, instead considered all requests for advice from Council out of session. The Embryo Storage Committee did not meet this year, with most applications for extension of storage considered out of session. The Scientific Advisory Committee met on one occasion, additional requests for advice from Council considered out of session. The Licensing and Administration Advisory Committee did not meet this year with additional business conducted out of session.

## Memberships

### Outgoing and in-coming members

**Dr Simon Clarke** (nominee of the Royal Australian and New Zealand College of Obstetricians and Gynaecologists) completed his term on 19 March 2019. Members thanked him for his many years of dedicated service to Council.

**Dr Lucy Williams** (nominee of the Royal Australian and New Zealand College of Obstetricians and Gynaecologists) was appointed deputy member on 6 May 2008 and has since been appointed member on 11 June 2019.

**Dr Megan Byrnes** (nominee of the Royal Australian and New Zealand College of Obstetricians and Gynaecologists) was appointed deputy member on 16 May 2019.

## 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, Ms Maxine Strike** (Bachelor of Applied Science).

**Senior Policy Officer, Ms Bridget Blackwell** (Bachelor of Science, Master of Medical Science and Graduate Diploma of Education).

## 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. In addition, facilities are required to demonstrate compliance with the current versions of the Fertility Society of Australia Reproductive Technology Accreditation Committee (RTAC) Code of Practice and Certification Scheme. 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.

Accredited fertility clinics may be granted a licence by the CEO, following the advice of Council. No new licences were issued this year and no licence renewals were due.

This year one licensed clinic, the Keogh Institute for Medical Research requested revocation of their licence and ceased operation.

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.

Currently there are no exempt practitioners in WA.

### **Approved counsellors**

Council received two applications for recognition as an approved counsellor under the HRT Act this year. Council granted conditional approval with ongoing requirements for training and supervision. 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. Council reports in line with the National Health Information Standards and Statistics Committee Guidelines (2017) where values fewer than five are not reported. 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 approved 40 applications for extension of the authorised embryo storage period compared to 41 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**

Extension (years)	Length of storage extension (years)			Total
	≤2	3-4	≥5	
Applications (n)	19	8	13	40

Storage of gametes beyond the authorised 15 year time limit also requires Council approval. This year Council approved 17 applications.

## 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. PGS does not require specific Council approval when there are known risk factors for aneuploidy. However, PGS may also be indicated when there are other factors 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 or genetic counsellor. Council approval may be subject to the advice of the PGD 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 46 applications for PGD were approved. The genetic conditions that were approved for PGD are listed in Table 2.

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

<b>Condition</b>	
β Thalassaemia	Machado-Joseph disease
BRCA 2	Myotonic dystrophy type 1
Chromosome inversions	Neurofibromatosis
Cystic fibrosis	Pseudo achondroplasia
D-bifunctional protein deficiency	Retinitis pigmentosa
Duchenne Muscular Dystrophy	Rhizomelic chondrodysplasia punctata type 1
Fragile X syndrome	SDHB gene defect
Hereditary paraganglioma pheochromocytoma	Translocations
Huntington's disease	Von Hippel Lindau disease
Lethal multiple pterygium	X-linked lymphoproliferative disorder
Li-Fraumeni syndrome	

All diagnostic procedures for a fertilising egg or an embryo must have prior Council approval. Applications for cystic fibrosis, translocations and Huntington's disease may be approved by the PGD committee. 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 data**

This year Council approved fewer than five surrogacy applications. To date the total number of births following approved surrogacy arrangements in WA is 15. The total number of surrogacy applications approved by Council last reported in 2018 was 34. Aggregated data of five or more will be included in future cumulative totals.

Aggregated national data for surrogacy cycles and births are reported in the Australian New Zealand Assisted Reproduction Database (ANZARD) report (Fitzgerald et al. 2018).

### **Innovative procedures**

Innovative procedures must be approved by Council under Direction 9.4. New and innovative procedures are monitored through approval and annual reporting by clinics. Council approved two applications for innovative procedures this year. The applications were for the use of calcium ionophore activation of oocytes and in-vitro maturation of oocytes.

## **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. Council approved one research application this year. The application was entitled Microfluidic Sperm Sorting for In-Vitro Fertilisation Treatment.

## **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 a 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.

## **Finances**

The budget allocation to Council was \$64,350 with expenditure totalling \$28,215. The financial statement in Appendix 2 outlines the distribution of expenses.

## **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.

The Human Reproductive Technology and Surrogacy Legislation Amendment Bill 2018 (the Bill) was introduced into Parliament on 23 August 2018. The Bill was referred to the Standing Committee on Legislation (the Committee). Council provided a submission to the Committee.

Council co-hosted a postgraduate student seminar in collaboration with the Scientists in Reproductive Technology, a special interest group representing the scientific membership of the Fertility Society of Australia, on 29 May 2019. Postgraduate students from WA universities were given the opportunity to present their work in assisted reproductive biology and discuss their work with scientists and researchers from fertility clinics. The seminar was attended by 41 people.

## Publications and presentations

Council members are active in the field of ART. This section lists the publications and presentations of Council members. It demonstrates their level of activity, expertise and commitment to scientific endeavor, and social and ethical debates related to reproductive technology.

### Publications

Adua E, Memarian E, Russell A, **Roberts P**, et.al.. High throughput profiling of whole plasma N-glycans in type II diabetes mellitus patients and healthy individuals: A perspective from a Ghanaian population. *Archives of biochemistry and biophysics*. 2019 Jan 1;661:10-21.

Adua E, Anto EO, **Roberts P**, Kantanka OS, et.al.. The potential of N-glycosylation profiles as biomarkers for monitoring the progression of Type II diabetes mellitus towards diabetic kidney disease. *Journal of Diabetes & Metabolic Disorders*. 2018 Dec 31;17(2):233-46.

Anto EO, **Roberts P**, Turpin CA, Wang W. Oxidative Stress as a Key Signaling Pathway in Placental Angiogenesis Changes in Preeclampsia: Updates in Pathogenesis, Novel Biomarkers and Therapeutics. *Current Pharmacogenomics and Personalized Medicine (Formerly Current Pharmacogenomics)*. 2018 Dec 1;16(3):167-81.

Bilkey G, Burns BL, Coles EP, **Beilby J** et.al.. Genomic testing for human health and disease across the life cycle: applications and ethical, legal and social challenges. *Frontiers in public health*. 2019;7:40.

Bräuner EV, Hansen ÅM, Doherty DAA, **Hart R** et.al.. The association between in-utero exposure to stressful life events during pregnancy and male reproductive function in a cohort of 20 year-old offspring: The Raine Study. *Human Reproduction*. 2019 May 30;1-11.

Burns BL, Bilkey GA, Coles EP, **Beilby JP** et.al.. Healthcare system priorities for successful integration of genomics: an Australian focus. *Frontiers in public health*. 2019;7.

Chan YX, Knuiman MW, Divitini ML, **Beilby JP** et.al.. Lower Circulating Androgens Are Associated with Overall Cancer Risk and Prostate Cancer Risk in Men Aged 25–84 Years from the Busselton Health Study. *Hormones and Cancer*. 2018 Dec 1;9(6):391-8.

Costello MF, Misso ML, Balen A, **Hart R** et.al.. Evidence summaries and recommendations from the international evidence-based guideline for the assessment and management of polycystic ovary syndrome: assessment and treatment of infertility. *Human Reproduction Open*. 2019;1-24.

Costello MF, Garad RM, **Hart R**, Homer H et.al.. A Review of Second-and Third-line Infertility Treatments and Supporting Evidence in Women with Polycystic Ovary Syndrome. *Medical Sciences*. 2019 Jul;7(7):75.

- Deménais F, Margaritte-Jeannin P, Barnes KC, **Beilby J** et al.. Multiancestry association study identifies new asthma risk loci that colocalize with immune-cell enhancer marks. *Nature genetics*. 2018 Jan;50(1):42-53.
- Drake-Brockman L, Boisen B, Sanders K, **Burton P**. Effect of density gradient centrifugation and processing time on human sperm apoptosis. *Journal of Reproduction Biotechnology and Fertility*. 2018;7:38-46.
- Hansen M**, Greenop KR, Bourke J, **Hart RJ** et al.. Intellectual disability in children conceived using assisted reproductive technology. *Pediatrics*. 2018 Dec; 1;142(6):e20181269.
- Hart RJ**, Doherty DA, Mori TA, Adams LA et al.. Features of the metabolic syndrome in late adolescence are associated with impaired testicular function at 20 years of age. *Human Reproduction*. 2018 Dec 21;34(3):389-402.
- Hart RJ**. Optimizing the opportunity for female fertility preservation in a limited time-frame for patients with cancer using in vitro maturation and ovarian tissue cryopreservation. *Fertility and Sterility*. 2019 Feb 1;111(2):258-9.
- Hart R**. Generational Health Impact of PCOS on Women and Their Children. *Medical Sciences*. 2019 Mar;7(3):49.
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- Hart RJ.** In-vitro maturation of oocytes. Royal Australia and New Zealand College of Obstetricians and Gynaecologists Annual Scientific Meeting, Adelaide, Australia. 2018.
- Hart RJ.** Features of metabolic disorder in late adolescence are negatively associated with testicular function at 20 years of age; evidence from a birth cohort. ESHRE Barcelona, Spain. Clinical Prize Presentation. 2018.
- Hart RJ.** Female sexual dysfunction and fertility preservation options with rectal cancer. Royal Australian and New Zealand Colorectal Surgical Society Meeting, Fremantle, Australia. 2018.
- Hart RJ.** The generational impact of PCOS. Androgen Excess Society Meeting, New Orleans, USA. 2019.
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# Developments in reproductive technology

## Mitochondrial donation in Australia

The Australian Government published a response to the Senate Committee Community Affairs References Committee inquiry into the *'Science of Mitochondrial Donation and Related Matters Report'* in January 2019. Mitochondrial donation is a procedure performed in an IVF treatment that replaces the faulty mitochondria in an egg with healthy mitochondria from a donated egg. The technique is used to overcome serious mitochondrial disorders being passed from mother to child. This procedure is not permitted in Australia. The Government acknowledged the procedure is controversial and only a few treatments have been performed worldwide, therefore further community and expert consultations are required to inform future legislation (Australian Government 2019).

## Ethical review of genome editing

The Nuffield Council on Bioethics published a report on *'Genome Editing and Human Reproduction: Social and Ethical Issues'* in July 2018. Genome editing is a procedure that makes specific changes to the DNA in a cell. These changes when made as part of an ART alter the DNA of future generations. This procedure is at a very early stage of development and the scientific evidence is limited. The use of this procedure to prevent inherited disorders being passed from parents to children is currently prohibited in most countries. This report considered further broad societal debate regarding the desirability of such interventions and possible impact on the welfare of the future person was required (Nuffield Council on Bioethics 2018).

## Legislation

### HRT and Surrogacy Legislation Amendment Bill 2018

The Human Reproductive Technology and Surrogacy Legislation Amendment Bill 2018 (the Bill) was tabled in Parliament on 23 August 2018. The proposed amendments will enable male same-sex couples and single men access to surrogacy and clarify access to treatment for women with impending loss of fertility. The Bill was referred to the Standing Committee on Legislation for further deliberation. The report, tabled on 27 June 2019, agreed that the Acts are discriminatory and require amendments (WA Government 2019).

### Review of the HRT Act and Surrogacy Act

The report on the independent review of the Western Australian HRT Act and the Surrogacy Act (the Report) was tabled in Parliament on 21 March 2019. The recommendations are wide ranging and include reforms to develop responsible regulation that meets the needs of consumers, the formation of a new advisory body, access to donor identity for all donor conceived people and support services for those involved in donor conception (Allan 2019).

## **Inquiry into the Family Law System**

The Australian Law Reform Commission (ALRC) published a report on the review of the family law system in March 2019. The ALRC was tasked to consider existing reports relevant to the family law system including surrogacy, child protection and child support. The reviewers considered that the issues relating to surrogacy required a separate review (Australian Law Reform Commission 2019).

## **South Australia Surrogacy Law Review**

The South Australian Law reform published a report '*Surrogacy: A Legislative Framework*' in October 2018. The report supported the removal of discrimination against single people accessing surrogacy and supporting the rights of a child to know their surrogacy origins. The review recommended revising legislation to form a standalone act that works towards alignment of national surrogacy regulation (Plater et al. 2018).

## **Commonwealth Surrogacy Inquiry**

In November 2018, the Australian Government tabled a response to the '*Surrogacy Matters Report*' by the Standing Committee on Social Policy and Legal Affairs. The Government supported the continued ban on commercial surrogacy and the harmonisation of national surrogacy legislation (Australian Government 2018).

## **Independent Review of Assisted Reproductive Treatment – Victoria**

The final report on the review of Assisted Reproductive Treatment in Victoria was completed in May 2019. The wide community and industry consultation resulted in recommendations to redesign the regulatory system. These include the gradual harmonization of surrogacy legislation across jurisdictions, improved access to treatment and more affordable treatment (Gordon 2019).

## **Review of UK surrogacy laws**

The Law Commission of England and Wales and the Scottish Law Commission have released a joint consultation paper to consider reforms to improve the operation of surrogacy in the UK. Topics of the consultation include domestic and international surrogacy arrangements, eligibility for surrogacy and legal parentage (Law Commissions 2019).

## Reproductive Technology and Voluntary 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.

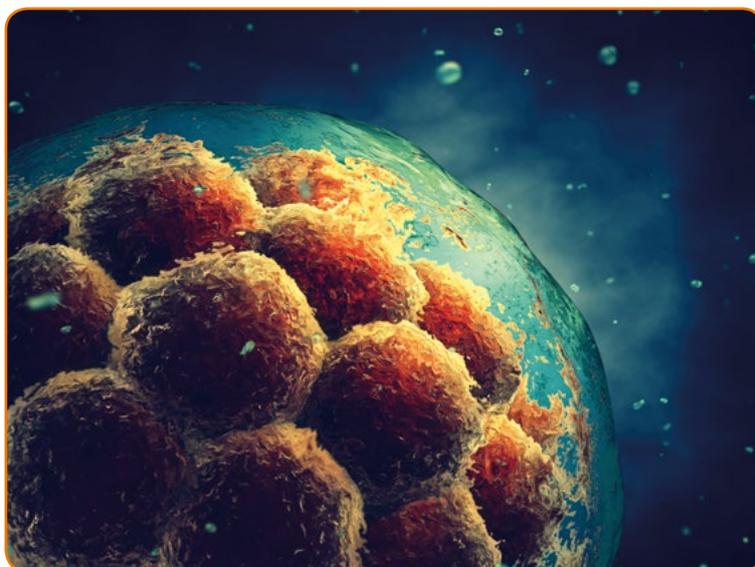
The Reproductive Technology Registers enable ongoing monitoring of practice and provide an important resource for epidemiological research. Appendix 3 provides summary data from the annual reports of the fertility clinics in WA.

The Voluntary Register (VR) provides a service for people to share information or meet people they are connected to as a result of donor conception treatment. Donor-conceived people 18 years or older, donors and parents of donor-conceived children under 18 years old are eligible to join the VR. Details of the VR can be found on the Department of Health website.

A match is when two people registered on the VR have the same donor code. Some people may have multiple matches when they are matched to more than person. Some people choose not to contact each other. There have been 81 identified matches. This year fewer than five matches proceeded to contact. The number of matches that have proceeded to contact last reported in 2018 was 30.

Since the inception of the VR 112 individuals have been matched to a donor related person and 51 have proceeded to contact.

As of 30 June 2019 there were 281 people registered on the VR.



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# Appendix 1: Practice and Storage Licence holders

## **Adora Fertility**

Craigie Day Surgery  
9 Perilya Road  
Craigie WA 6025

## **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 Highway  
Applecross WA 6153

## **Fertility Specialists of Western Australia**

Bethesda Hospital  
25 Queenslea Drive  
Claremont WA 6010

## **Genea Hollywood Fertility**

Level 2  
170 Cambridge Street  
Wembley WA 6014

## **PIVET Medical Centre / ZEST IVF**

Perth Day Surgery Centre  
166-168 Cambridge Street  
Leederville WA 6007

11 Wentworth Parade  
Success WA 6164

## Appendix 2: Financial statement

The Department of Health funds the administration of the HRT Act, including the operations of Council. The 2018–2019 Council budget allocation was \$64,350 with expenditure totaling \$28,215 for the financial year. Table 3 shows the financial statement for the 2018–2019 annual report.

Table 3: Financial statement for the 2018–2019 annual report

Expenditure by category 2018–2019	Expenditure (\$)	Income (\$)
Training, registration, course fees, interstate travel	5,848	
Food supplies and catering	2,642	
Administration and clerical	1,759	
Reproductive Technology Council sitting fees	16,179	
<b>Other expenses:</b>		
Stationery and printing, including annual report	1,196	
RTC special event seminars	543	
Information management	48	
<b>Total</b>	<b>\$28,215</b>	<b>\$64,350</b>

# 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 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 may not add up to 100% due to rounding to whole numbers.

## Assisted reproductive technologies in Western Australia

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, or a thaw cycle where the embryo is thawed and transferred to the women’s uterus.

A total of 4,672 women underwent assisted reproduction treatment in WA this year. There were 759 more women when compared to the previous year which showed an increase of 19%. The number of treatment cycles this year was 6,979 which is an increase of 16% compared to the previous year (n=6,024). Table 4 provides an overview of the initiated cycles.

Table 4: IVF treatments

	IVF fresh	IVF thaw	Total
Women treated	2,920	1,752	<b>4,672</b>
Treatment cycle	4,191	2,788	<b>6,979</b>
Cycle with oocyte retrieval	3,736	-	<b>3,736</b>
Cycle with embryo transfer	2,116	2,471	<b>4,587</b>
Cycle with embryo storage	1,977	-	<b>1,977</b>

Fresh IVF transfer techniques included 172 surgical sperm aspirations and 2,337 intracytoplasmic sperm injection (ICSI) procedures, where a single sperm is directly injected into an egg and the fertilised egg is transferred to the woman’s uterus.

A total of 685 intrauterine insemination (IUI) treatment cycles were reported by eight licensees. This represents a 13% reduction in the number of IUI treatment cycles compared to the previous year (n=783). The reported ongoing pregnancy rate for IUI was 15% (n=103). The partners' sperm were used for 69% of procedures and donor sperm were used for 31% of procedures. Gonadotrophin was used for 53% of cycles, Clomid was used in 22% of cycles, and 25% were natural cycles.

The number of IVF recipient cycles, where a woman received donor sperm, donor oocytes, or donor embryos is shown in Table 5.

**Table 5: Number of recipient cycles using donations**

	<b>Fresh IVF cycle</b>	<b>Thawed embryo cycle</b>
Sperm	225	232
Oocyte	35	58
Embryo	-	75

In addition there were 46 cycles where oocytes were donated.

### **Public fertility clinic referrals**

This year 66 patients from King Edward Memorial Hospital Fertility Clinic were referred to four fertility clinics for treatment. A total of 85 treatment cycles were provided, with 24 women having IVF with fresh embryo transfer and 32 having IVF with thawed embryo transfer.

### **Serious morbidity and mortality**

Clinics are required to provide information regarding complications of ART treatment. There were 10 reported cases of severe ovarian hyperstimulation syndrome (OHSS). There were no reports of mortality in association with fertility treatment.

### **Counselling**

A total of 2,213 couples or individuals received counselling, which represents a slight decrease from the previous year. Most participants (52%) received a single counselling session and the majority of these sessions (56%) involved information counselling. Others having a single counselling session received support counselling (28%), therapeutic counselling (9%) and counselling for other reasons (7%). Of the 48% of participants who had more than one session, 32% had support counselling and 51% had information counselling. Counselling for donors and donor recipients accounted for 48% of all sessions. There were 1,056 donor and recipient counselling sessions representing an increase of 4% from the previous year.

## Embryo storage

The number of embryos in storage was reported as 26,692, as of 30 June 2019. The dispersal of embryos for this year is shown in Table 6.

Table 6: **Dispersal of stored embryos**

<b>Embryo dispersal</b>	<b>n</b>
Embryos in storage 30/6/2018	25,694
Embryos created from IVF	6,003
Used in frozen embryo transfer treatments	3,169
Transferred between clinics in WA	316
Transferred to clinics outside WA	115
Transferred from interstate	69
Embryo disposition	1,790
<b>Embryos in storage 30/06/19</b>	<b>26,692</b>

## Assisted reproductive technology trends in WA

Overall, the number of IVF treatment cycles in WA increased by 16% compared to the previous year (n=6,979 vs n=6,024). National statistics show a 4% increase in ART treatment cycles in 2016 (Fitzgerald et al. 2018).

Overall, in WA the proportion of fresh to thawed cycles this year was 60% of all cycles. This proportion has remained relatively stable over the years (range 54%–61%). National statistics for 2016 show that 62% of ART cycles were fresh IVF cycles where the patients used their own eggs or embryos (Fitzgerald et al. 2018). Figure 1 shows the progression of fresh IVF cycle by year in WA.

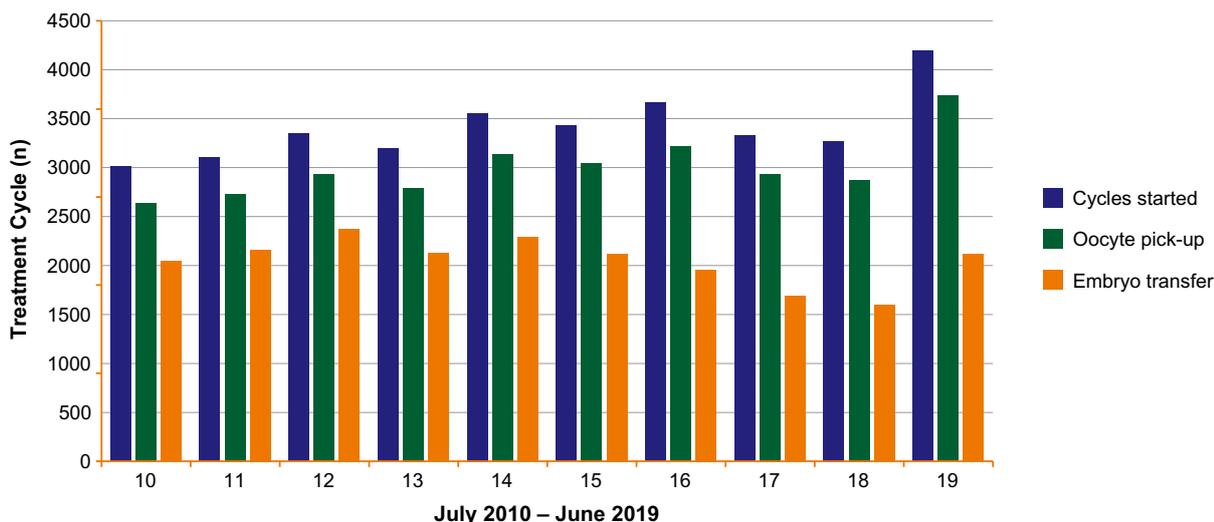


Figure 1: Progression of fresh IVF cycles by year, 2010–2019

Figure 2 shows the progression of thawed embryo cycles. The trend for thawed embryo transfer cycles is essentially unchanged.

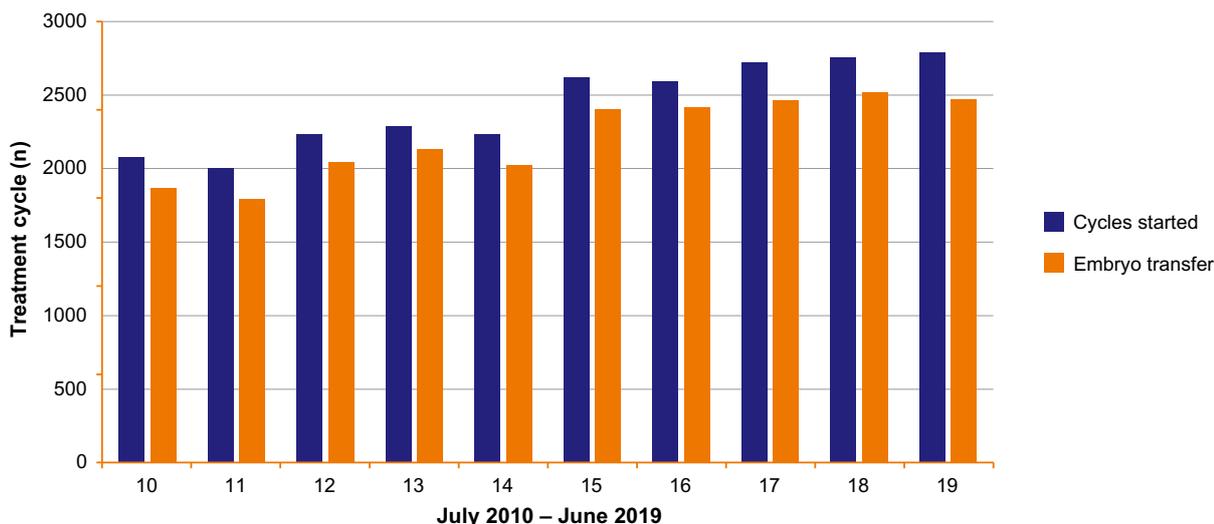


Figure 2: Progression of thawed embryo cycles by year, 2009–18

## Intracytoplasmic sperm injection procedures

The number of IVF procedures where ICSI was used is shown in Figure 3. This procedure was used in 62% of fresh cycles where fertilisation was attempted in WA this year. National statistics show that the use of ICSI has increased over the past decade. Australia and New Zealand data for procedures in 2016, reported ICSI was used in 69% of autologous fresh cycles where fertilisation was attempted (Fitzgerald et al. 2018).

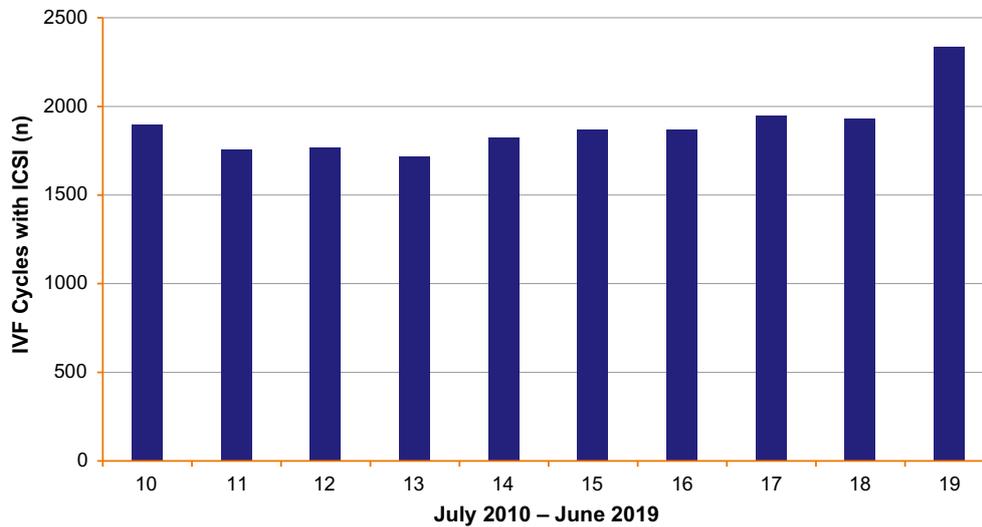


Figure 3: Number of IVF cycles with ICSI by year, 2010–2019

## Number of sperm donors

The number of new donors defined as donors whose samples became available for treatment in this financial year, was reported as 26 compared with 24 last year.







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