

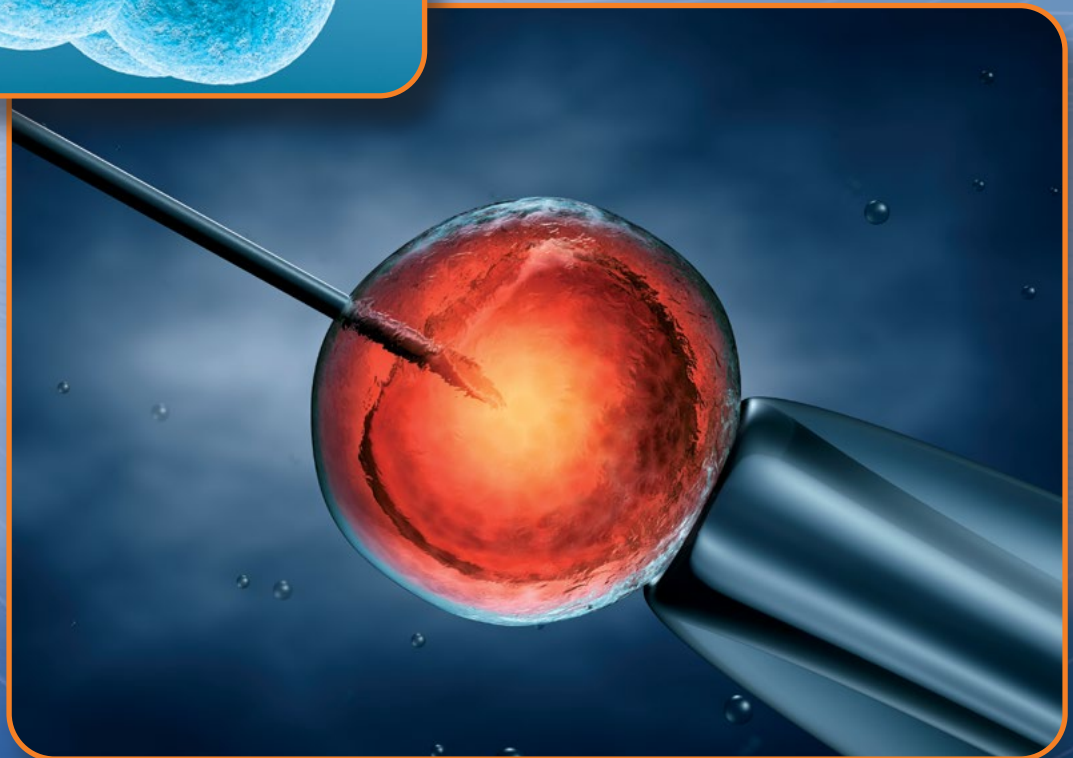
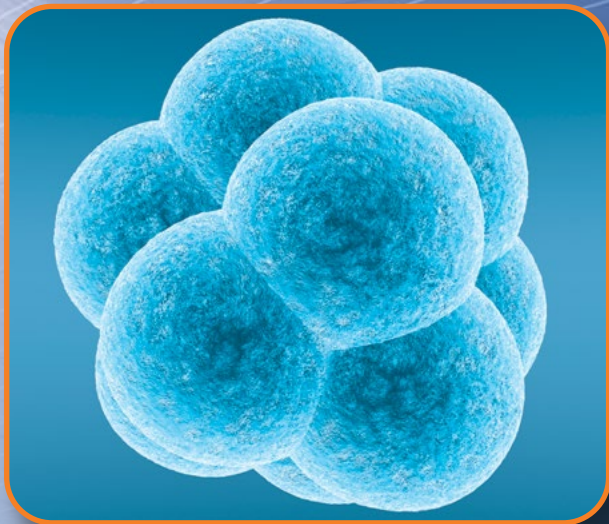


Reproductive Technology Council

Western Australian Reproductive Technology Council

Annual Report

1 July 2019 to 30 June 2020



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Annual Report

1 July 2019 to 30 June 2020

Western Australian Reproductive Technology Council

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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 *Human Reproductive Technology Act 1991* (HRT Act). The CEO is required to submit the report to the Minister for Health, to be laid before Parliament. The annual report outlines the use of assisted reproductive technology (ART) in Western Australia, and the operation of Council for the financial year from 1 July 2019 to 30 June 2020.

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. On the advice of Council, new practice and storage licences were issued to an existing fertility clinic as a company restructure resulted in a change of licensee.

Council provided advice to the CEO on proposed amendments to the HRT Act Directions 2004.

This year Council reviewed the Terms of Reference of its committees and agreed to discharge the following committees; the Counselling Committee; the Embryo Storage Committee; Licensing and Administration Advisory Committee; and Scientific Advisory Committee.

The Preimplantation Genetic Diagnosis (PGD) Committee was retained and its functions expanded. On the advice of Council, the Minister for Health approved an amendment to the Terms of Reference for the PGD Committee to allow additional PGD applications to be approved by the PGD Committee.

Council members reviewed a range of applications for approval under the HRT Act and the Surrogacy Act. Council approved 42 applications to extend embryo storage; and 52 applications for genetic testing of embryos.

The budget allocation to Council for this year was \$65,959 and the expenditure was \$23,567. 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 2019–2020 showed that 4,841 women underwent in vitro fertilisation (IVF) treatment, which is an increase of 4% from the previous year. Fertility clinics undertook 7,307 IVF treatment cycles this year, which is 5% more than the previous year.

A total of 505 intrauterine inseminations was undertaken, which represents a decrease of 26% compared to the previous year.

A total of 1,443 couples or individuals received counselling. Most counselling consisted of a single session and involved the provision of information.

The number of embryos reported in storage at 30 June 2020 was 27,791.

Council acknowledges the dedicated work of Council 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 and Surrogacy Act;
- the provision of advice to the CEO of Health on matters relating to licensing, administration and enforcement of the HRT Act and Surrogacy Act;
- the review of the Directions and guidelines governing ART practices and storage procedures undertaken by licensees, and thereby regulate the proper conduct 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

Council and Committee Chairs

Dr Stephan Millett

Dr Stephan Millett was appointed Chair of the Council on 5 May 2020. He is a moral philosopher and ethics consultant. Prior to retirement he was a Professor in the School of Occupational Therapy and Social Work at Curtin University and is an Adjunct Professor with the John Curtin Institute of Public Policy. Dr Millett was founding Director of the Centre for Applied Ethics and Philosophy, Chair of the Curtin University Human Research Ethics Committee, and taught ethics across the faculty of Health Sciences. His first career was in journalism and was editor of a Perth Sunday paper before teaching Journalism at Curtin University. While teaching Journalism he was awarded a Bachelor of Arts with Honours (First Class); and a PhD in Philosophy from Murdoch University. Dr Millett was the inaugural Director of Philosophical and Ethical Inquiry at Wesley College (Perth) and writer of the Western Australian Certificate of Education curriculum in Philosophy and Ethics, co-authoring four textbooks for that curriculum. He now specialises in teaching ethics, including professional ethics and health ethics. He serves on the Acute Clinical Ethics Service for the Child and Adolescent Health Service. He holds the Australian National Medal for service as a bushfire volunteer and is a life member of the Mount Helena Voluntary Bush Fire Brigade. He is married with two adult children.

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 and is a Member of the Human Genetics Society of Australasia. Dr Beilby was a Founding Fellow of the Faculty of Science, the Royal College of Pathologists of Australasia. He is Head of Department of the Diagnostic Genomics Laboratory, PathWest at 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.

Discharged committees

Reverend Brian Carey

The Reverend Brian Carey was 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.

The Embryo Storage Committee was discharged on 18 February 2020.

Professor Roger Hart

Professor Roger Hart was 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 more than 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.

The Scientific Advisory Committee was discharged on 21 January 2020.

Dr Joseph Parkinson

Dr Joseph Parkinson was 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 of the LJ Goody Bioethics Centre in Mount Hawthorn.

The Licensing and Administration Committee was discharged on 21 January 2020.

Dr Iolanda Rodino

Dr Iolanda Rodino was 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 is the Australian and New Zealand Infertility Counsellors Association (ANZICA) representative on the Fertility Society of Australia Board. She has a strong interest in infertility research and serves as Chair of the ANZICA Research Subcommittee. 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.

The Counselling Committee was discharged on 19 May 2020.

Reproductive Technology Council Members

Dr Stephan Millett Chair (nominee of the Minister for Health).

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).

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

Ms Kerry MacDonald (nominee of the Health Consumers' Council WA).

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).

Appointment in progress (nominee of the Law Society of Western Australia).

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).

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

Ms Renee Fox (nominee of the Health Consumers' Council WA).

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).

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

Appointment in progress (nominee of the Minister for Health).

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

Ms Maxine Strike (Senior Policy Officer, Reproductive Technology Unit, Department of Health).

Preimplantation Genetic Diagnosis Committee

Terms of reference

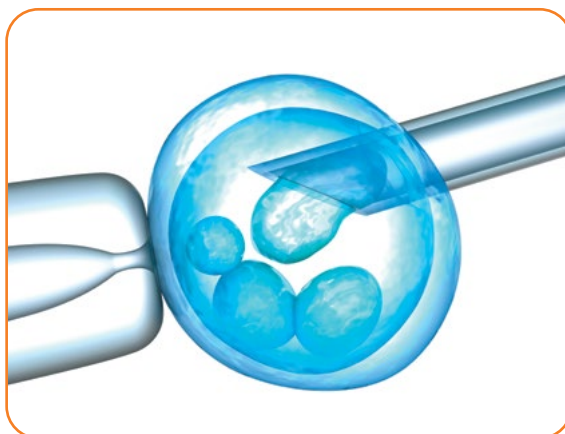
The committee's terms of reference are to:

- advise the Reproductive Technology Council (Council) on a suitable framework for the approval of PGD under the *Human Reproductive Technology Act 1991* (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 Beta-thalassemia; Cystic Fibrosis; D-Bifunctional Protein Deficiency; Duchenne Muscular Dystrophy; Fragile X; Huntington's Disease; Long QT Syndrome; Myotonic Dystrophy Type 1; Myotonic Dystrophy Type 2; Retinitis Pigmentosa; Spinal Muscular Atrophy and translocations.
- 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.

The Committee may consult with relevant experts in the preparation of this advice for 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).



Terms of Reference of Discharged Committees

Council acknowledges and thanks members of the discharged committees for their commitment and service.

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).

The Counselling Committee was discharged on 19 May 2020.

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).

The Embryo Storage Committee was discharged on 18 February 2020.

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).

The Licensing and Administration Committee was discharged on 21 January 2020.

Scientific Advisory Committee

Terms of reference

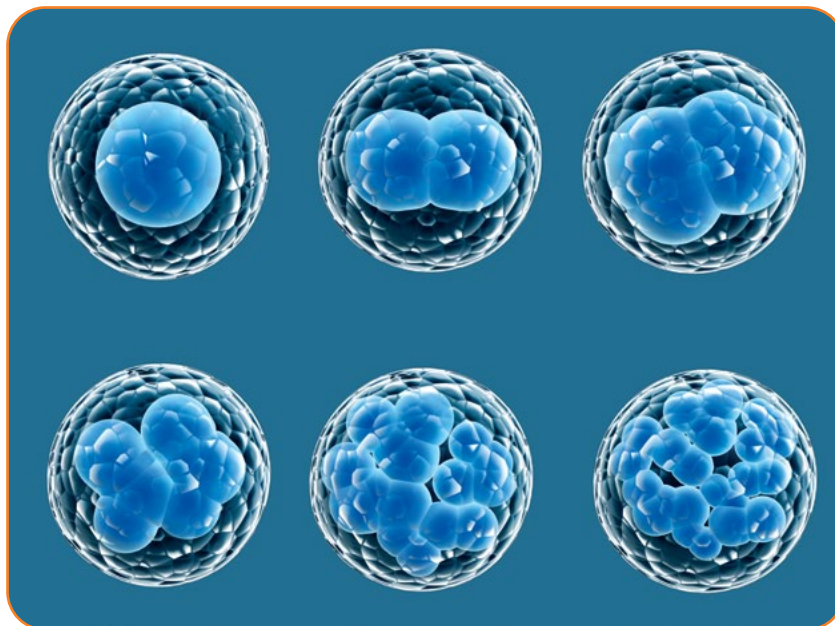
The committee's terms of reference are to:

- 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).

The Scientific Advisory Committee was discharged on 21 January 2020.



Operations of Council

Meetings

Council met on 10 occasions during the year, with attendances reaching a quorum at all meetings. Business for two months was conducted out of session due to COVID-19 related physical distancing requirements. The Counselling Committee met on two occasions. The PGD Committee met on one occasion and considered all other requests for advice from Council out-of-session. The Embryo Storage Committee met on one occasion, with most applications for extension of storage considered out-of-session. The Scientific Advisory Committee met on one occasion, with additional requests for advice from Council considered out-of-session. The Licensing and Administration Advisory Committee met on one occasion this year and additional business was conducted out of session.

Council reviewed the function of all committees and agreed to discharge the Counselling Committee on 19 May 2020; Embryo Storage Committee on 18 February 2020; Licensing & Administration Advisory Committee on 21 January 2020; and Scientific Advisory Committee on 21 January 2020. Committee membership predominantly included members of Council and members decided committee business could be addressed at Council meetings. The PGD Committee was retained.

Memberships

Outgoing and in-coming members

Dr Brenda McGivern, Chair (nominee of the Law Society of Western Australia) resigned from Council on 17 December 2019. Members thanked her for the 14 years of dedicated service to Council as member, including three years as Chair.

Ms Justine Garbellini (nominee of the Health Consumers' Council WA) completed her term on 1 January 2020. Members thanked her for the nine years of dedicated service to Council.

Reverend Brian Carey (nominee of the Minister for Health) retired from Council activity from 17 December 2019. Members thanked him for the 13 years of dedicated service to Council.

Ms Iolanda Rodino (nominee of the Health Consumers' Council WA) completed her term on 2 December 2019. Members thanked her for the six years of dedicated service to Council.

Dr Stephan Millett (nominee of the Minister for Health) was appointed Chair of Council on 5 May 2020.

Ms Renee Fox (nominee of the Health Consumers' Council WA) was appointed deputy member on 26 February 2020.

Ms Kerry MacDonald (nominee of the Health Consumers' Council WA) was appointed member on 26 February 2020.

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, 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, on the advice of Council. This year new practice and storage licences were issued to an existing fertility clinic as a company restructure resulted in a change of licensee.

Details of practice and storage licence holders are listed in Appendix 1 and on the Council website www.rtc.org.au.

Exempt practitioners

A medical practitioner who is an exempt practitioner (under section 28 of the Act) 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 no applications for recognition as an approved counsellor under the HRT Act this year. A list of approved counsellors is available on the Council website 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 42 applications for extension of the authorised embryo storage period compared to 40 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)	20	8	14	42

Storage of gametes beyond the authorised 15 year storage limit also requires Council approval. This year Council approved 21 applications.

Preimplantation genetic testing

Council approves applications for preimplantation genetic testing (PGT) of embryos. PGT for monogenic/single gene disorders and for structural rearrangements in chromosomes can be used where there is a known risk for serious genetic conditions.

PGT for aneuploidy (PGT-A) tests the developing embryo for either extra or missing chromosomes. This can be a common cause of pregnancy loss. PGT-A does not require specific Council approval when there are known risk factors for aneuploidy. However, PGT-A may also be indicated when there are other factors, and these are considered by Council on a case by case basis.

Each application for PGT 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 52 applications for PGT were approved. The genetic conditions that were approved for PGT are listed in Table 2.

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

Condition	
BCAP 31 gene variant	Neurofibromatosis
Chromosome inversions	Pseudoachondroplasia
Chromosome insertions	Ornithine transcarbomylase deficiency
Cystic fibrosis	Ocular albinism
Fragile X syndrome	Pfeiffer syndrome
Frontal lobe dementia	Polycystic kidney disease
Gene deletions	Spinal muscular atrophy
Gene duplications	TBC1D24 gene defect
Huntington's disease	Translocations
Hypertrophic cardiomyopathy	Velo-cardio-facial syndrome
Incontinentia pigmenti	WWOX syndrome
Haemolytic disease of the newborn	X-linked gammaglobulinaemia
Lynch Syndrome	X-linked myotubular myopathy
Motor neurone disease	X-linked ocular albinism
Myotonic dystrophy	X-linked retinoschisis

All diagnostic procedures for a fertilising egg or an embryo must have prior Council approval. PGT applications for conditions that may be approved by the PGD Committee are listed in the PGD Committee Terms of Reference. 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

The number of surrogacy applications approved under the *Surrogacy Act 2008* (WA) to 30 June 2020 is 43. The number of births following an approved surrogacy arrangement, last reported in 2019 was 15. 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 (Newman et al. 2019).

Innovative procedures

Innovative procedures must be approved by Council under Direction 9.4. New and innovative procedures are monitored through the approval process and annual reporting by clinics. Council approved one application for an innovative procedure this year. The application involved intrauterine instillation of autologous platelet rich plasma to treat recurrent implantation failure and poor endometrial thickness, within frozen embryo transfer cycles.

Research applications

Research projects undertaken by licensees, other than research on excess embryos requiring a NHMRC licence, must receive Council approval. General approval by Council 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.

Licencees must submit progress reports of approved research projects with their annual data. Council approved one research application this year. The application related to the use of intra-ovarian injection of autologous platelet rich plasma.

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 \$65,959. Council expenditure totalled \$23,567. 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.

Council provided advice to the CEO on proposed amendments to the HRT Act Directions 2004.

This year Council advised the Minister for Health on an amendment to the terms of reference for the PGD Committee. Council recommended the number of PGT applications for conditions requiring approval by the PGD Committee be increased from three to twelve. This change was approved as of 21 June 2020.

PGT applications approved by the PGD Committee are usually processed within five working days. All other PGT applications are considered by Council at its monthly meeting. The PGD Committee may now approve PGT applications for the following conditions; Beta-thalassemia; Cystic Fibrosis; D-Bifunctional Protein Deficiency; Duchenne Muscular Dystrophy; Fragile X; Huntington's Disease; Long QT Syndrome; Myotonic Dystrophy type 1; Myotonic Dystrophy type 2; Retinitis Pigmentosa; Spinal Muscular Atrophy; and chromosome translocations.



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 endeavour, and social and ethical debates related to reproductive technology.

Publications

- Adua E, Memarian E, Russell A, **Roberts P**, et al. Utilization of N-glycosylation profiles as risk stratification biomarkers for suboptimal health status and metabolic syndrome in a Ghanaian population. *Biomarkers in Medicine*. 2019 Oct;13(15):1273-87. doi: 10.2217/bmm-2019-0005.
- Anto EO, **Roberts P**, Coall DA, Adua E, et al. Suboptimal health pregnant women are associated with increased oxidative stress and unbalanced pro-and antiangiogenic growth mediators: a cross-sectional study in a Ghanaian population. *Free Radical Research*. 2020 Jan 2;54(1):27-42. doi: 10.2217/bmm-2019-0005. doi: 10.1007/s13167-019-00183-0.
- Anto EO, **Roberts P**, Coall D, Turpin CA, et al. Integration of suboptimal health status evaluation as a criterion for prediction of preeclampsia is strongly recommended for healthcare management in pregnancy: a prospective cohort study in a Ghanaian population. *European Association for Predictive Preventative Medicine Journal*. 2019 Sep 15;10(3):211-26. doi: 10.1007/s13167-019-00183-0.
- Anto EO, Owiredu WK, Adua E, **Roberts P**, et al. Prevalence and lifestyle-related risk factors of obesity and unrecognized hypertension among bus drivers in Ghana. *Heliyon*. 2020 Jan 1;6(1):e03147. doi: 10.1016/j.heliyon.2019.e03147.
- Bräuner EV, Hickey M, Hansen ÅM, **Hart R**, et al. In-utero exposure to maternal stressful life events and risk of cryptorchidism: The Raine Study. *Frontiers in Endocrinology*. 2019;10:530. doi: 10.3389/fendo.2019.00530.
- Balogh R, Leonard H, Bourke J, **Hansen M**, et al. Data linkage: Canadian and Australian perspectives on a valuable methodology for intellectual and developmental disability research. *Intellectual and Developmental Disabilities*. 2019 Oct;57(5):439-62. doi: 10.1352/1934-9556-57.5.439.
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Developments in Reproductive Technology

COVID-19 Pandemic Response

In response to the COVID-19 pandemic the Federal Government required elective surgical procedures to be reduced or cancelled to preserve resources in the event that demand for hospital care exceeded the current capacity. Assisted reproduction treatments were considered elective procedures. The Fertility Society of Australia (FSA) COVID-19 Response Committee released advice on fertility treatments to clinics and patients. The restrictions on elective procedures were eased progressively from the 21 April 2020 with ongoing monitoring (FSA 2020).

Mitochondrial donation in Australia

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 Australian Government response to the Senate Community Affairs Reference Committee *Inquiry into the science of mitochondrial donation and related matters* (Commonwealth of Australia 2019), recommended the NHMRC determine the views of the broader Australian community on the possible introduction of mitochondrial donation into clinical practice. The NHMRC released two reports on 5 June 2020. The *Mitochondrial Donation Community Consultation Report* and the *Expert Statement*. A consensus was not reached on whether further research should be undertaken prior to the introduction of mitochondrial donation in Australia (NHMRC 2020).

Endometrial Scratching

Endometrial scratching is performed to improve the chance of an IVF pregnancy by inducing the release of growth factors that may make the womb more receptive to an embryo. A multicenter randomized controlled trial to evaluate the effectiveness of the procedure involved 1,044 women under 37 years of age having their first cycle of IVF. Women were randomised equally to endometrial scratch, or no scratch, with the primary outcome of the study being a live birth. Results showed no statistical difference in the live birth rate between the intervention group (38.6%) and the control group (37.1%). Secondary outcomes of the trial assessed clinical pregnancy rate, embryo implantation rate and obstetric complications and again showed no statistical difference (Metwally 2020).

Special International Rapporteur for Children – surrogacy focus

The Special Rapporteur presented a report to the Human Rights Council on the sale and exploitation of children. The report identified a growing demand for surrogacy in states with emerging economies by more wealthy intended parents as an area for concern for the rights and protection of the child and surrogate mothers. The report's recommendations included: the core principles of the best interests of the child be included in legislation; the implementation of the prohibition of the sale of children as it relates to surrogacy; and the establishment of registers of genetic and gestational records of surrogacy-born children that are accessible by surrogacy-born people (United Nations Special Rapporteur 2019).

Legislation

Surrogacy Act 2019 (SA)

The South Australian *Surrogacy Act 2019* received assent on 7 November 2019 and comes into effect from 1 September 2020. The new legislation provides single people with access to surrogacy. Surrogate mothers will be required to provide a criminal history report provided by South Australia Police or the Australian Crime Commission to the intended parent/s within 12 months of the arrangement. The minimum age for the surrogate mother and each intending parent was raised to 25 years (*Surrogacy Act 2019 (SA)*).

Assisted Reproductive Treatment Amendment Bill 2020 (Vic)

A Bill to amend the *Assisted Reproductive Treatment Act 2008 (Vic)* to remove requirements for criminal records checks and child protection order checks before a treatment procedure received royal assent on 10 June 2020 (*Assisted Reproductive Treatment Amendment Bill 2020 (Vic)*).

Review of UK Surrogacy Law

Public consultation on reforms to UK surrogacy law was undertaken by the Law Commission from 6 June to 11 October 2019. Provisional proposals aim to better support the child, surrogates and intended parents. A key proposal is that in many cases intended parents will be the legal parents of the child from the moment of birth (*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. 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 Department of Health Voluntary Register established in 2002 to enable information sharing between donor related people was decommissioned on 20 March 2020.

A new support service for information sharing and identity disclosure in donor conception is now provided by [Jigsaw DNA Connect](#).



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United Nations Special Rapporteur. Report of the Special Rapporteur on the sale and sexual exploitation of children, including child prostitution, child pornography and other child sexual abuse material. General Assembly Seventy- fourth session. Item 68(a). New York: United Nations; 2019. <https://undocs.org/A/74/162> [accessed 22/7/2020].

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 of Western Australia

Bethesda Hospital
25 Queenslea Drive
Claremont WA 6010

Fertility Specialists of Western Australia-Applecross

1st Floor
764 Canning Highway
Applecross WA 6153

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 2019–2020 Council budget allocation was \$65,959 with expenditure totaling \$23,567 for the financial year. Table 3 shows the financial statement for the 2019–2020 annual report.

Table 3: Financial statement for the 2019–2020 annual report

Expenditure by category 2019–2020	Expenditure (\$)	Income (\$)
Food supplies and catering	2,001	
Administration and clerical	1,804	
Reproductive Technology Council sitting fees	16,021	
Other expenses:		
Stationery and printing, including annual report	381	
Information management	3,360	
Total	\$23,567	\$65,959

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 Reproductive Technology Unit 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 a frozen embryo is thawed and transferred to the women's uterus.

A total of 4,841 women underwent assisted reproduction treatment in WA this year. There were 167 more women when compared to the previous year representing an increase of 4%. The number of treatment cycles this year was 7,307 representing an increase of 5% compared to the previous year (n=6,979). Table 4 provides an overview of the initiated cycles.

Table 4: **IVF treatments**

	IVF fresh	IVF thaw	Total
Women treated	3,011	1,830	4,841
Treatment cycle	4,451	2,856	7,307
Cycle with oocyte retrieval	3,997	-	3,997
Cycle with embryo transfer	2,200	2,651	4,851
Cycle with embryo storage	2,027	-	2,027

Fresh IVF transfer techniques included 196 surgical sperm aspirations and 2,385 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 505 intrauterine insemination (IUI) treatment cycles were reported by eight licensees which represents a 26% decrease compared to the previous year (n=685). The reported ongoing pregnancy rate for IUI was 13% (n=64). The partner’s sperm was used in 68% of procedures and donor sperm was used in 32% of procedures. Gonadotrophin was used in 44% of cycles, Clomid was used in 30% of cycles, and 26% 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

	Fresh IVF cycle	Thawed embryo cycle
Sperm	288	271
Oocyte	40	65
Embryo	-	55

In addition there were 21 cycles where oocytes were donated.

Public fertility clinic referrals

This year 47 patients from King Edward Memorial Hospital Fertility Clinic were referred to four fertility clinics for treatment. A total of 48 treatment cycles were provided, with 13 women having IVF with fresh embryo transfers, and 16 having IVF with thawed embryo transfers.

Serious morbidity and mortality

Clinics are required to provide information regarding complications of ART treatment. There were 13 reported cases of severe ovarian hyperstimulation syndrome (OHSS). There were no reports of mortality in association with fertility treatment.

Counselling

Clinics reported a total of 1,443 individuals/couples received counselling*. Most participants (69%) received a single counselling session and the majority of these sessions (64%) involved information counselling. Others having a single counselling session received support counselling (26%), therapeutic counselling (3%) and counselling for other reasons (7%). Of the 31% of participants who had more than one session, 39% had support counselling and 40% had information counselling. Counselling for donors and donor recipients accounted for 48% of all sessions. There were 971 donor and recipient counselling sessions representing a decrease of 8% from the previous year.

*Reporting of individuals/couples receiving counselling in this annual cycle identified that comparative data from the clinics in previous years had been overestimated.

Embryo storage

The number of embryos in storage was reported as 27,791, as of 30 June 2020. The dispersal of embryos for this year is shown in Table 6.

Table 6: **Dispersal of stored embryos**

Embryo dispersal	n
Embryos in storage 30/6/2019	26,692
Embryos created from IVF	6,344
Used in frozen embryo transfer treatments	3,283
Transferred between clinics in WA	320
Transferred to clinics outside WA	61
Transferred from interstate	59
Embryo disposition	1,960
Embryos in storage 30/06/2020	27,791

Assisted reproductive technology trends in WA

Overall, the number of IVF treatment cycles in WA increased by 5%, compared to the previous year (n=7,307 vs n=6,979). National statistics show a 1.0% increase in ART treatment cycles in 2017 (Newman et al. 2019).

In WA this year 61% of all IVF cycles were fresh cycles, and 39% were thawed cycles. This proportion has remained relatively stable over the years (range 54%–61%). National statistics for 2017 show that 62% of ART cycles were fresh IVF cycles where patients used their own eggs or embryos (Newman et al. 2019). Figure 1 shows the progression of fresh IVF cycles by year in WA.

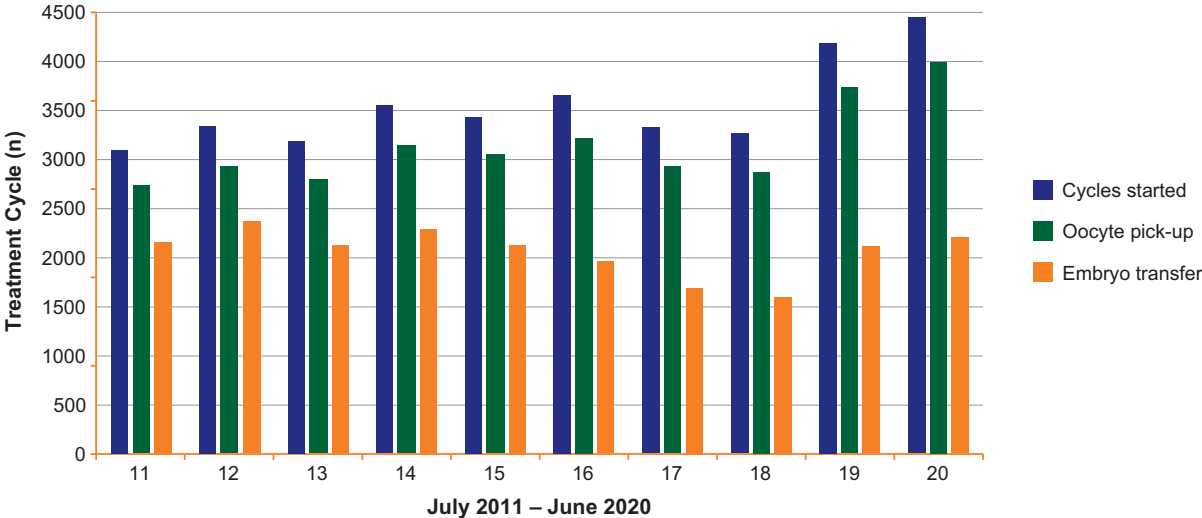


Figure 1: Progression of fresh IVF cycles by year, 2011–2020

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

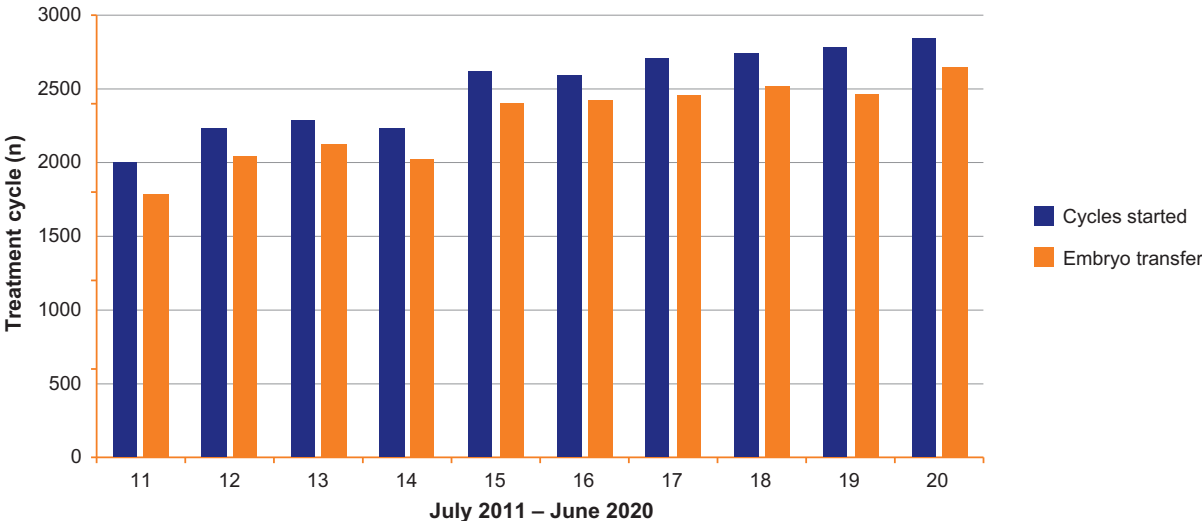


Figure 2: Progression of thawed embryo cycles by year, 2011–2020

Intracytoplasmic sperm injection procedures

The number of IVF procedures where ICSI was used is shown in Figure 3. This procedure was used in 60% 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 2017, reported ICSI was used in 67% of autologous fresh cycles where fertilisation was attempted (Newman et al. 2019).

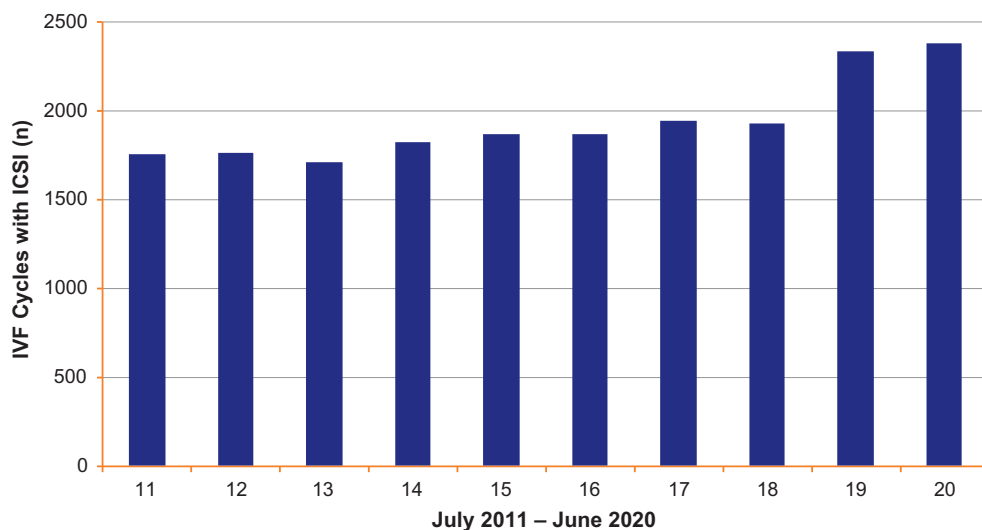


Figure 3: **Number of IVF cycles with ICSI by year, 2011–2020**

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 28 compared with 26 last year.



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