

Western Australian Reproductive Technology Council

Annual Report

1 July 2020 to 30 June 2021



Print: ISSN: 2205-8168. Electronic: ISSN: 2205-8176.

This report is available online at www.rtc.org.au

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Suggested citation

Western Australian Reproductive Technology Council. (2021). Western Australian Reproductive Technology Council Annual Report 2020–2021. Western Australian Reproductive Technology Council, Perth, Western Australia.

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Annual Report 1 July 2020 to 30 June 2021

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 2020 to 30 June 2021.

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, six clinics that provide fertility services in WA were issued with renewed practice and storage licences during the 2020–2021 financial year.

On 23 June 2021, amendments to the HRT Directions (HRT Directions 2021) and Surrogacy Regulations (Surrogacy Regulations 2021) were published in the Government Gazette. The amendments to the HRT Directions and Surrogacy Regulations give effect to some recommendations from the *Review of the Human Reproductive Technology Act 1991* and the *Surrogacy Act 2008* undertaken by Associate Professor Sonia Allan (Allan Review), pending wider regulatory reforms.

Council members reviewed a range of applications for approval under the HRT Act and the Surrogacy Act. Council approved 47 applications to extend embryo storage; and 68 applications for genetic testing of embryos.

The budget allocation to Council for this year was \$45,668 and the expenditure was \$29,392. 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 2020–2021 showed that 6,071 women underwent in vitro fertilisation (IVF) treatment, which is an increase of 25% from the previous year. Fertility clinics undertook 8,904 IVF treatment cycles this year, which is 22% more than the previous year.

A total of 624 intrauterine inseminations were undertaken, which represents an increase of 24% compared to the previous year.

A total of 1,792 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 2021 was 29,708.

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, specialising in philosophy in schools, professional ethics and health ethics. Prior to retirement he was 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 was a founding member of the Acute Clinical Ethics Service for the Child and Adolescent Health Service and is still actively involved. 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 was the Head of Department of the Diagnostic Genomics Laboratory, PathWest at Queen Elizabeth II Medical Centre for eight years 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.

Reproductive Technology Council members

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

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

Dr Andrew Harman (nominee of 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).

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

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

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

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

Appointment in progress (nominee of the Health Consumers' Council WA).

Dr Mo Harris (Executive Officer *ex officio*, Manager, Reproductive Technology Unit, Department of Health). (Until August 2020).

Reproductive Technology Council deputy members

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

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

Dr Andrew Lu AM (nominee of the Law Society of Western Australia).

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

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

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

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

Vacant (nominee of the UWA, School of Women's and Infants' Health).

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

Professor Alison Garton (nominee of the Minister for Health).

Ms Maxine Strike (Senior Policy Officer, Reproductive Technology Unit, Department of Health). (Until October 2020).

Preimplantation Genetic Diagnosis Committee

Terms of reference

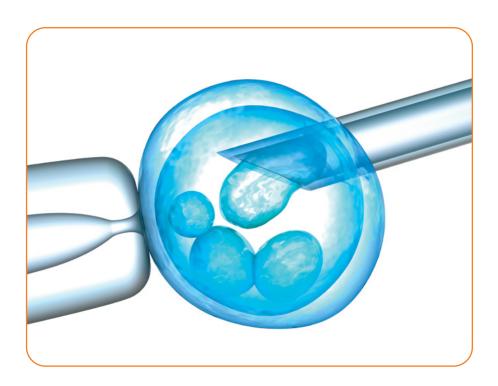
The committee's terms of reference are to:

- advise 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 Angela Cooney, Dr Kathy Sanders, Dr Sharron Townshend.



Operations of Council

Meetings

Council met on 12 occasions during the year, with attendances reaching a quorum at all meetings. The PGD Committee met on one occasion and considered all other requests for advice from Council out-of-session.

Memberships

Outgoing and in-coming members

Reverend Dr Joseph Parkinson

(nominee of the Minister for Health) retired from Council on 13 November 2020. Members thanked him for the 10 years of dedicated service to Council.

Dr Peter Burton

(nominee of the UWA, School of Women's and Infants' Health) retired from Council on 31 July 2020. Members thanked him for his 11 years of dedicated service to Council and Committees.

Kerry MacDonald

(nominee of the Health Consumers' Council) resigned from Council on 12 February 2021. Members thanked her for one year of valuable service to the Council.

Dr Andrew Lu AM

(nominee of the Law Society of Western Australia) was appointed on 22 December 2020.

Reproductive Technology Unit

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

Executive Officer, A/Manager, Dr Karen Pedersen

(Bachelor of Science (Hons), Doctor of Philosophy).

Senior Policy Officer, Dr Kate Brameld

(Bachelor of Science (Hons), Doctor of Philosophy).

Program Officer, Ms Laura Hodgson

(Bachelor of Arts).

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. On the advice of Council, six clinics that provide fertility services in WA were issued with renewed practice and storage licences during the 2020–2021 financial year. Licensing renewal activity included a review of clinic documentation and site visits to clinic premises by representatives of Council and staff from the Department of Health Reproductive Technology Unit.

One clinic (Fertility Great Southern) ceased operations on 31 March 2021 and its practice and storage licences were cancelled as of 1 April 2021.

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 s.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 two applications for recognition as an approved counsellor under the HRT Act this year. Under Part 5 of the HRT Directions 2021, reference to 'approved counsellors' has been replaced with 'counsellor'. The term 'counsellor' has been defined to mean a person who is eligible for full membership of the Australian and New Zealand Infertility Counsellors Association (ANZICA). This amendment ensures consistency between the Directions 2021 and the Surrogacy Regulations 2021.

There are no changes to the standards of counselling required in the HRT Directions 2021.

Applications to Council

Council is required to approve certain ART practices, including the storage of embryos beyond 10 years, diagnostic testing of embryos, surrogacy applications, innovative procedures, and research projects. Prior to publication of amendments to the HRT Directions on 23 June 2021, Council was also required to approve the storage of gametes beyond 15 years. Following the amendments to the Directions, applications to Council for storage of gametes beyond 15 years are no longer required.

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 44 applications for extension of the authorised embryo storage period compared to 42 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)	≤2	3-4	≥5	Total	

Length of storage extension (years)

Applications (n) 9 9 26 44

For the period 1 July 2020 to 22 June 2021, Council approved 21 applications for storage of gametes beyond the then authorised 15-year storage limit.

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 68 applications for PGT were approved. The genetic conditions that were approved for PGT are listed in Table 2.

Table 2: Genetic conditions/mutations approved for PGT

Condition

1q21.1 microdeletion Haemophilia A Angelman syndrome Huntington's disease Autosomal dominant polycystic Hyper IgE syndrome kidney disease Klinefelter syndrome Beta thalassaemia Lynch syndrome BRCA1 gene mutation Nemaline myopathy BRCA2 gene mutation Neurofibromatosis Chromosome inversions Osteogenesis imperfecta Cystic fibrosis Pendred syndrome Charcot-Marie-Tooth syndrome Renpenning syndrome Chromosomal duplication RBM10 gene mutation Congenital ichthyosis Severe congenital neutropenia Crigler Najjar syndrome Sickle cell anaemia Epidermolysis bullosa simplex Spondylometaphyseal dysplasia Facioscapulohumeral muscular **Translocations** dystrophy X-linked adrenoleukodystrophy Familial FLNA variant X-linked myotubular myopathy Fragile X syndrome

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 total number of surrogacy applications approved under the *Surrogacy Act 2008* (WA) to 30 June 2021 is 50.

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 received no applications for innovative procedures this year.

Research applications

Research projects undertaken by licensees, other than research on excess ART embryos requiring a National Health and Medical Research Council (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. Licensee's must submit progress reports of approved research projects with their annual data. Council received no research applications this year.

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 one formal complaint this year. The investigation has not yet concluded.

Finances

The budget allocation to Council was \$45,668. Council expenditure totalled \$29,392. The financial statement in Appendix 2 outlines the distribution of expenses.

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, Afrifa-Yamoah E, Russell A, **Roberts P**, et al. N-glycosylation profiling of Type 2 diabetes mellitus from baseline to follow-up: an observational study in a Ghanaian population. Biomarkers in Medicine. 2021;15(7):1-15. doi:10.2217/bmm-2020-0615.

Brauner E, Koch T, Doherty DA, Dickinson J, **Hart RJ**. The association between in utero exposure to maternal psychological stress and female reproductive function in adolescence: a prospective cohort study. Comprehensive Psychoneuroendocrinology. 2021 Feb;(5):100026. doi.10.1016/j.cpnec.2020.100026.

Brauner E, Koch T, Juul A, Doherty DA, **Hart RJ**, et al. Prenatal exposure to maternal stressful life events and earlier age at menarche: the Raine Study. Human Reproduction. 2021;36(7):1959-1969. doi:10.1093/humrep/deab039.

Berman YE, Doherty DA, Main KM, Frederiksen H, **Hart RJ**. The influence of prenatal exposure to phthalates on subsequent male growth and body composition in adolescence. Environmental Research. 2021 Apr;195:110313. doi:10.1016/j. envres.2020.110313.

Catford SR, Lewis S, Halliday J, Kennedy J, **Hart RJ**, et al. Health and fertility of ICSI-conceived young men: study protocol. Human Reproduction Open. 2020 Oct 03;4:hoaa042. doi:10.1093/hropen/hoaa042.

Glujovsky D, Pesce R, Sueldo C, Quinteiro Retamar AM, **Hart RJ**, et al. Endometrial preparation for women undergoing embryo transfer with frozen embryos or embryos derived from donor oocytes. Cochrane Database of Systematic Reviews. 2020;10: CD006359. doi: 10.1002/14651858.CD006359.pub3.

Hart RJ. There is a role for pre-conceptional treatment with CoQ10 – Argument – AGAINST. In: Homburg R, Balen AH, Casper RF, editors. 50 Big Debates in Reproductive Medicine. Cambridge University Press 2021.

Hart RJ, Walls M. In-vitro maturation of oocytes. In: Kovacs G, Fauser B, Legro R, editors. Polycystic ovary syndrome. 3rd Ed. Cambridge University Press (in press).

Koch T, Doherty DA, Dickinson J, Juul A, **Hart RJ**, et al. In utero exposure to maternal stressful life events and risk of polycystic ovary syndrome in the offspring: the Raine Study. Psychoneuroendocrinology. 2021 Mar;125:105104. doi:10.1016/j. psyneuen.2020.105104.

Norman R, **Hart RJ**. Human growth hormone use in poor ovarian response – caution and opportunities. Therapeutic Advances in Reproductive Health. 2021.15:1-9. doi:10.1177/2633494121999420.

Penova-Veselinovic B, Melton PE, Huang RC, Yovich JL, **Hart RJ**, et al. DNA methylation patterns within whole blood of adolescents born from assisted reproductive technology are not different from adolescents born from natural conception. Human Reproduction. 2021 Jun 18;36(7):2035-2049. doi: 10.1093/humrep/deab078.

Rozen G, Rogers P, Chander S, Anderson R, **Hart RJ**, et al. Clinical summary guide: Reproduction in women with previous abdominopelvic radiotherapy or total body irradiation. Human Reproduction Open. 2020 Oct 25(4):hoaa045. doi:10.1093/hropen/hoaa045.

Showell MG, Mackenzie-Proctor R, Jordan V, **Hart RJ**. Antioxidants for female subfertility Cochrane Database of Systematic Reviews 2020, Issue 8. Art. No. CD007807. doi:10.1002/14651858.CD007807.pub4.

Tay CT, **Hart RJ**, Hickey M, Moran LJ, Earnest A, et al. Updated adolescent diagnostic criteria for polycystic ovary syndrome: impact on prevalence and longitudinal body mass index trajectories from birth to adulthood. BMC Medicine. 2020 Dec;18:389. doi:10.1186/s12916-020-01861-x.

Vine D, Beilin L, Burrows S, Huang R, **Hart RJ**, et al. ApoB48-Lipoproteins are associated with cardiometabolic risk in adolescents with and without polycystic ovary syndrome. Journal of the Endocrine Society. 2020 Aug;4(8):1-12. doi:10.1210/jendso/bvaa061.

Ye'elah EB, Doherty DA, Main KM, Frederiksen H, **Hart RJ**, et al. Associations between prenatal exposure to phthalates and timing of menarche and growth and adiposity into adulthood: a twenty-years birth cohort study. International.Journal of Environonmental Research and Public Health. 2021;18(9):4725. doi:10.3390/ijerph18094725.

Presentations

Hart RJ. The early life influences on adult male reproduction. Plenary Presentation. European Society of Human Reproduction and Endocrinology, Paris virtual meeting 2021.

Hart RJ. Endocrine disrupting agents in pregnancy and their implications for fertility. The Royal Australian and New Zealand College of Obstetricians and Gynaecologists, Annual Scientific Meeting, Hobart virtual meeting 2021.

Hart RJ. Sub-specialty training in Reproductive Medicine and Infertility. The Royal Australian and New Zealand College of Obstetricians and Gynaecologists, Annual Scientific Meeting, Hobart virtual meeting 2021.

Developments in Reproductive Technology

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 currently permitted in Australia. The Mitochondrial Donation Law Reform (Maeve's Law) Bill was introduced into the Australian Parliament for debate on 24 March 2021 (Australian Government Department of Health 2021). On 24 June 2021, the Senate referred Maeve's Law to the Senate Community Affairs Legislation Committee for inquiry and report. The Committee is due to report on 18 August 2021. If passed, the law will allow mitochondrial donation to be introduced in Australia, through a staged approach and under strict regulatory conditions, to prevent transmission of severe mitochondrial disease.

IVF add-ons

IVF add-ons are procedures, techniques or medicines offered by IVF clinics which may be used in addition to standard IVF protocols with the hope that they will improve the chance of IVF success. A recent study conducted in Australia reported that 82% of women undertaking IVF in the last three years had used one or more IVF add-ons during treatment, despite most IVF add-ons not being supported by robust scientific evidence (Lenson et al, 2021). Of the 1,590 women surveyed, acupuncture was the most frequently used add-on (45%), while Chinese herbal medicine was also accessed by 26% of women.

Legislation

HRT Directions and Surrogacy Regulations

On 23 June 2021, amendments to the HRT Directions and Surrogacy Regulations were published in the Western Australian Government Gazette. The amendments to the Directions give effect to some recommendations from the Allan Review and include:

- changes to the process for reporting data to the Reproductive Technology Registers to provide for a more contemporaneous and responsive approach to reporting
- requirement for notification of serious adverse events to the CEO of Health to ensure these are brought to the attention of the CEO in a timely manner
- removal of the 15-year storage period limit for gametes and requirement for Council approval for further storage periods. Removal of this requirement recognises advances in scientific knowledge regarding long-term storage of gametes and changes in the social landscape with a view that long-term storage is a matter for personal and clinic consideration.

It is the responsibility of the licensee to ensure the proper and safe storage of gametes. Clinics are required to comply with the RTAC Code of Practice (RTAC 2017) and the NHMRC Guidelines (NHMRC 2017) as a condition of licensing under the HRT Act. The licensee is required to submit a gamete storage policy to Council, with reference to the NHMRC Guidelines noting that indefinite storage is not an option.

Donor conception register (SA)

In 2017, South Australia made amendments to the *Assisted Reproductive Treatment Act 1988* (SA) (ART Act) to mandate the establishment of a donor conception register (DCR) by November 2021 (Government of South Australia 2021). Consultation on the draft Bill to amend the ART Act was undertaken in May – June 2021. Proposed amendments include providing all donor-conceived people with the right to access identifying information about their donor (with retrospective effect); ensuring the DCR can operate retrospectively to include historical donor conception information; and ensuring all donor-conceived people have the option to have donor information included in their birth certificate.

Surrogacy legislation (NT)

The Northern Territory Government has commenced the development of surrogacy legislation (Northern Territory Government 2019). Currently, the Northern Territory is the only jurisdiction in Australia without surrogacy legislation.

Review of UK surrogacy law

Surrogacy legislation in the UK remains under review by the Law Commission of England and Wales and the Scottish Law Commission. It is anticipated that a draft bill will be available in Autumn 2022 (Law Commission 2019).

Storage of embryos (UK)

In February 2020 the UK government undertook consultation regarding possible changes to the *Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009*, to consider whether the current statutory storage period of 10 years remains fit for purpose (GOV.UK 2020). At present, the storage period may be extended for subsequent 10-yearly periods to a maximum of 55 years if premature fertility is demonstrated. The consultation will consider whether eggs, sperm and embryos should be stored for longer than 10 years for social and medical purposes.

Reproductive Technology Activity

Information on ART in WA is provided to the Department of Health by licensees and exempt practitioners, as set out in Schedule 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.



References

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Government of South Australia. yourSAy. Assisted Reproductive Treatment (Donor Conception Register) Amendment Bill 2021. https://yoursay.sa.gov.au/art-act-amendments [accessed 19 August 2021]

GOV.UK. Consultation document: gamete (egg, sperm) and embryo storage limits. 2020. www.gov.uk/government/consultations/egg-sperm-and-embryo-storage-limits. [accessed 19 August 2021].

Law Commission. Reforming the law: Surrogacy. 2019. www.lawcom.gov.uk/project/surrogacy. [accessed 19 August 2021].

Lensen S, Hammarberg K, Polyakov A, et al. How common is add-on use and how do patients decide whether to use them? A national survey of IVF patients. Human Reproduction 2021;36(7):1854-1861.

National Health Information Standards and Statistics Committee. Guidelines for the Disclosure of Secondary Use Health Information for Statistical Reporting, Research and Analysis. Canberra, ACT: Australian Institute of Health and Welfare. 2017.

National Health and Medical Research Council. Ethical guidelines on the use of assisted reproductive technology in clinical practice and research. Canberra: National Health and Medical Research Council. 2017.

Newman J, Paul RC, Chambers GM. Assisted Reproductive Technology in Australia and New Zealand, 2018. Sydney, NSW, National Perinatal Epidemiology and Statistics Unit. 2020.

Northern Territory Government. Northern Territory legislation for altruistic surrogacy. 2019. https://haveyoursay.nt.gov.au/altruisticsurrogacy [accessed 19 August 2021].

Reproductive Technology Accreditation Committee. Code of practice for assisted reproductive technology units. South Melbourne, Fertility Society of Australia. 2017.

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 (to 31 March 2021)

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

764 Canning Highway Applecross WA 6153

Genea Hollywood Fertility

190 Cambridge Street Wembley WA 6014

PIVET Medical Centre / ZEST IVF

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

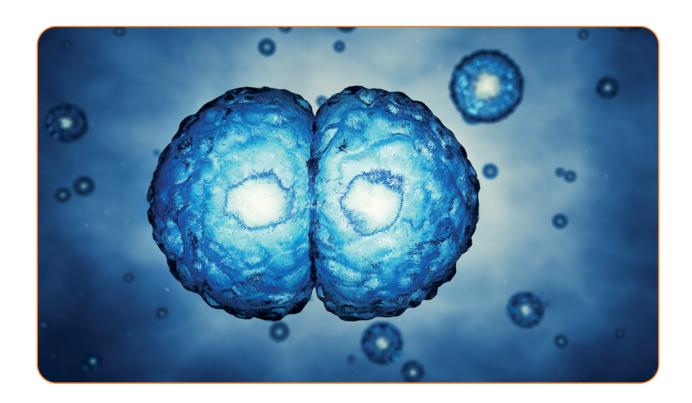
13/11 Wentworth Parade Success WA 6164

Appendix 2: Financial statement

The Department of Health funds the administration of the HRT Act, including the operations of Council. The 2020–2021 Council budget allocation was \$45,668 with expenditure totalling \$29,392 for the financial year. Table 3 shows the financial statement for the 2020–2021 annual report.

Table 3: Financial statement for the 2020–2021 annual report

Expenditure by category 2020–2021	Expenditure (\$)	Income (\$)
Food supplies and catering	1,441	
Conference fees	1,600	
Reproductive Technology Council sitting fees	22,280	
Other expenses:		
Stationery and printing, including annual report	264	
Information management	3,408	
Total	\$29,392	\$45,668



Appendix 3: Operations of licence holders

The aggregated data presented below provide information on the activities of licence holders under the HRT Act and carried out during the financial year 2020–2021. The data are provided together with those from previous years to show current activity and trends in assisted reproductive technology activity over the past 10 years.

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 6,071 women underwent assisted reproduction treatment in WA this year. There were 1,230 more women when compared to the previous year representing an increase of 25%. The number of treatment cycles in this financial year was 8,904 representing an increase of 22% compared to the previous year (n=7,307). Table 4 provides an overview of the initiated cycles.

Table 4: IVF treatments

	IVF fresh	IVF thaw	Total
Women treated	3,690	2,381	6,071
Treatment cycle	5,403	3,501	8,904
Cycle with oocyte retrieval	4,893	-	4,893
Cycle with embryo transfer	2,578	3,178	5,756
Cycle with embryo storage	2,485	-	2,485

Fresh IVF transfer techniques included 2,599 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 624 intrauterine insemination (IUI) treatment cycles were reported which represents a 24% increase compared to the previous year (n=505). The reported ongoing pregnancy rate for IUI was 16% (n=99). The partner's sperm was used in 59% of procedures and donor sperm was used in 41% of procedures.

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	334	288
Oocyte	11	58
Embryo	0	71

Public fertility clinic referrals

This year 49 patients from King Edward Memorial Hospital Fertility Clinic were referred to five fertility clinics for treatment. A total of 57 treatment cycles were provided, with 21 women having IVF with fresh embryo transfers, and 13 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) and two reported cases of severe pelvic infection. There were no reports of mortality in association with fertility treatment.

Counselling

Clinics reported a total of 1,792 individuals/couples received counselling. Most participants (64%) received a single counselling session and the majority of these sessions (68%) involved information counselling. Others having a single counselling session received support counselling (25%) and therapeutic counselling or counselling for other reasons (8%). Of the 36% of participants who had more than one session, 23% had support counselling and 59% had information counselling. Counselling for donors and donor recipients accounted for 55% of all sessions. There were 1,086 donor and recipient counselling sessions representing an increase of 12% from the previous year.

Embryo storage

The number of embryos in storage was reported as 29,708, as of 30 June 2021. The dispersal of embryos for this year is shown in Table 6.

Table 6: Dispersal of stored embryos

Embryo dispersal	n
Embryos in storage 30/06/2020	27,906*
Embryos created from IVF	7,453
Used in frozen embryo transfer treatments	3,920
Transferred within clinics in WA	671
Transferred to clinics outside WA	114
Transferred from interstate	105
Embryo disposition	1,722
Embryos in storage 30/06/2021	29,708

^{*}Figure revised from 2019–2020 Annual Report following correction to number of embryos in storage at 30 June 2020.

Assisted reproductive technology trends in WA

Overall, the number of IVF treatment cycles in WA increased by 22%, compared to the previous year (n=8,904 vs n=7,307). Data for Australia and New Zealand show a 2.2% increase in ART treatment cycles between 2017 and 2018 (Newman et al. 2020).

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%). Australian and New Zealand data for 2018 show that 57% of ART cycles were fresh IVF cycles where patients used their own eggs or embryos (Newman et al. 2020). Figure 1 shows the progression of fresh IVF cycles by year in WA.

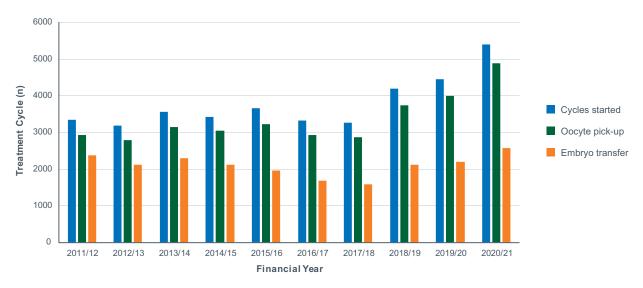


Figure 1: Progression of fresh IVF cycles by year, 2011–2021

There was a 21% increase in cycles started, 22% increase in oocyte pick-up and 17% increase in embryo transfer in comparison to the previous year.

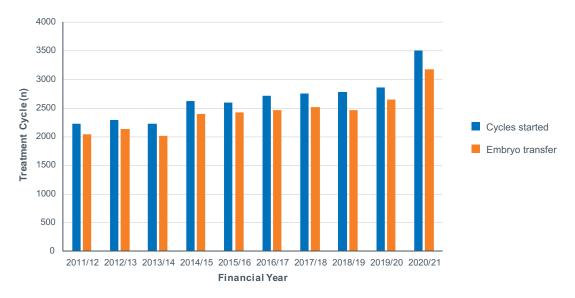


Figure 2: Progression of thawed embryo cycles by year, 2011-2021

Figure 2 shows the progression of thawed embryo cycles. The number of cycles started increased by 23% and embryo transfers by 20% in comparison to the previous year.

Intracytoplasmic sperm injection procedures

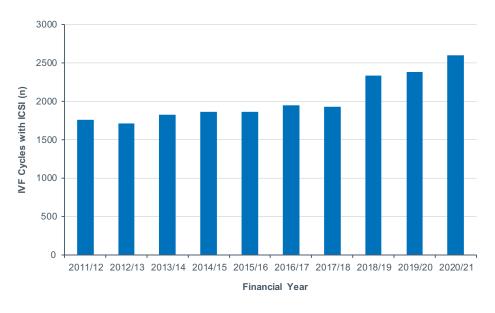


Figure 3: Number of IVF cycles with ICSI by year, 2011–2021

The number of IVF procedures where ICSI was used is shown in Figure 3. This procedure was used in 53% of fresh cycles where fertilisation was attempted in WA this year. Australia and New Zealand data for procedures in 2018, reported ICSI was used in 64% of autologous fresh cycles where fertilisation was attempted (Newman et al. 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 40 compared with 28 last year.



