Dear Dr Russell-Weisz

It is with pleasure that I submit the Reproductive Technology Council (Council) Annual Report for the financial year 2015 to 2016. This report sets out details of assisted reproductive technology (ART) practices in Western Australia (WA) and the activities of Council, as required by the Human Reproductive Technology Act 1991 (HRT Act). It is in a form suitable for submission to the Minister for Health and also, as is required, to be laid by the Minister before each House of Parliament.

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

This year Council provided submissions to the National Health and Medical Research Council (NHMRC), the House of Representatives Standing Committee on Social Policy and Legal Affairs Inquiry into Surrogacy and the review of the South Australia Assisted Reproductive Treatment Act 1988.

Council hosted a number of events including a consent workshop, presentations by invited speakers on the management of donor information, altruism and compensation for gametes and surrogacy, and the sociological meaning of donor conception.

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 2016
Executive summary

This annual report was prepared by the Reproductive Technology Council (Council) for the Chief Executive Officer (CEO), Department of Health, to comply with the requirements of Section 5(6) of the HRT Act. The CEO is required to submit the report to the Minister for Health, to be laid before Parliament. The annual report outlines the use of ART in WA, and the operation of Council for the financial year from 1 July 2015 to 30 June 2016.

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

This year Council was advised that reporting aggregated data with values of less than five may lead to the inadvertent identification of individuals, procedures or diagnosis (National Health Information Standards and Statistics Committee, 2015). Consequently Council will follow the national guidelines and numbers of less than five will not be reported.

Council members reviewed a range of applications for approval under the HRT Act and Surrogacy Act. Council approved 25 applications to extend embryo storage and 31 applications for genetic testing of embryos.

This year Council advised the Minister for Health on amendment to the terms of reference for the PGD Committee. These changes were approved as of 11 August 2015 and provide a specific function of the PGD Committee in the approval of PGD applications for translocations, cystic fibrosis and Huntington’s disease.

Council provided submissions to the National Health and Medical Research Council (NHMRC), the House of Representatives Standing Committee on Social Policy and Legal Affairs Inquiry into Surrogacy, and the review of the South Australia Assisted Reproductive Treatment Act 1988.

Council hosted a number of events including a consent workshop, presentations by invited speakers on the management of donor information, altruism and compensation for gametes and surrogacy, and the sociological meaning of donor conception.

The budget allocation to Council for this year was $62,935 and the expenditure was $60,208. 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 2015–2016 show that 4,092 women underwent in vitro fertilisation (IVF) treatment, which is a slight decrease from 4,099 the previous year. Fertility clinics undertook 6,256 IVF treatment cycles this year, which is 3% more than in the previous year.

A total of 1,080 intrauterine inseminations were undertaken, which represents an increase of 8% compared to the previous year.
There were nine reported cases of morbidity (complications), attributed to ovarian hyper stimulation syndrome and no reports of mortality (deaths) in association with fertility treatments.

A total of 2,389 couples or individuals received counselling, which represents a 14% increase from the previous year. Most counselling consisted of a single session and involved the provision of information.

The number of embryos reported in storage at 30 June 2016 was 23,026.

The effective operation of Council requires the significant and dedicated support of Council and committee members, and the ongoing financial and administrative support provided by the Department of Health. This support is essential to enable Council to meet the responsibilities set out in the HRT Act and the Surrogacy Act, and to ensure the effective regulation of these Acts.
Introduction

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

Council functions

The functions of Council are outlined in Section 14 of the HRT Act and include:

- the provision of advice to the Minister for Health on issues relating to reproductive technology, and the administration and enforcement of the HRT Act
- the provision of advice to the CEO of Health on matters relating to licensing, administration and enforcement of the HRT Act
- the review of the Directions and guidelines to govern ART practices and storage procedures undertaken by licensees, and thereby to regulate the proper conduct, including counselling provision, of any reproductive technology practice.
- the promotion of research, in accordance with the HRT Act, into the causes and prevention of all types of human infertility and the social and public health implications of reproductive technology
- the promotion of informed public debate on issues arising from reproductive technology, and communication and collaboration with similar bodies in Australia and overseas.

The Minister for Health determines Council membership and is required to ensure that Council comprises individuals with special knowledge, skills and experience in ART. Council has members who are consumer representatives and members with expertise in public health, ethics and law.
Membership of Council and Council committees

This section provides biographies of the Council Chair and Council committee Chairs, a list of Council membership for this year, and the terms of reference and membership of the various Council committees.

Council Chair and Council committee Chairs

Dr Brenda McGivern

Dr Brenda McGivern is Chair of the Council and specialises in torts and health law, having both practised and taught in those fields. She is the Deputy Dean of Law at the University of Western Australia, and continues to practise as a Consultant with Moray & Agnew Lawyers. In addition to her role with the Council, she also serves on the Clinical Ethics Service for Princess Margaret Hospital and King Edward Memorial Hospital.

Dr John Beilby

Dr John Beilby, BSc, PhD (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, Queen Elizabeth II Medical Centre and Adjunct Professor in the UWA School of Pathology and Laboratory Medicine. 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 was a member of Monash Medical Centre and Epworth Hospital’s Human Research Ethics Committee for over twenty years. He is currently a member of the Ethics Committees of both the Department of Health (WA) and the Western Australian Genetics Council.

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 School of Women’s and Infants’ Health, UWA. He is the lead clinician for the public fertility service of WA, and the Medical Director of Fertility Specialists of Western Australia. He is the holder of Australian NH&MRC grants to study the early life origins of impaired...
spermatogenesis and to study the long-term consequences of IVF treatment. He has over 100 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 a board member of the CREI sub-specialty committee, Chair of a Cancer Australia Working Party to study the management of menopausal symptoms for women with breast cancer and a member of the joint NHMRC and ESHRE PCOS Guideline development group.

Ms Iolanda Rodino

Ms Iolanda Rodino is Chair of the Counselling Committee. Ms Rodino graduated from the UWA in 1992. Ms Rodino practises as a clinical psychologist in Perth, WA and has extensive experience in the fields of infertility, pregnancy and post birth clinical services. Ms Rodino is a PhD candidate in the School of Anatomy, Physiology and Human Biology and School of Psychology, UWA. Her research interests include the areas of third party reproduction, Polycystic ovary syndrome (PCOS), disordered eating and the emotional impact of stress on fertility. She is Chair of the research sub-committee of the Australian New Zealand Infertility Counsellors Association.

Dr Joseph Parkinson

Dr Joseph Parkinson is Chair of the Licensing and Administration Committee Chair. Dr Parkinson holds a licence in moral theology from the Lateran University in Rome and a PhD in moral theology from the University of Notre Dame Australia. He is a Trustee of St John of God Healthcare, a Director of Catholic Health Australia, and an honorary Fellow of Australian Catholic University. He is also 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 Princess Margaret 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)

Dr Simon Clarke (nominee of the Royal Australian and New Zealand College of Obstetricians and Gynaecologists)

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

Dr Angela Cooney (nominee of the Australian Medical Association)

Ms Justine Garbellini (nominee of the Health Consumers’ Council WA)

Professor Roger Hart (nominee of the University of Western Australia, School of Women’s and Infants’ Health)

Ms Anne-Marie Loney (nominee of the Minister for Child Protection)

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 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 University of Western Australia, School of Women’s and Infants’ Health)

Reverend Brian Carey (nominee of the Minister for Health)

Dr Louise Farrell (nominee of the Australian Medical Association)

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

Dr Michele Hansen (nominee of the Minister for Health)

Ms Rachael Oakeley (nominee of the Department for Communities, Office of Women’s Interests)

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

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

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

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

Terms of reference

The committee’s terms of reference are to:

- establish standards for approval of counsellors as approved counsellors, as required by the Code of Practice or Directions of the HRT Act for counselling within licensed clinics, and for counselling services available in the community;
- recommend to Council those counsellors deemed suitable for Council approval or interim approval, and reconsider those referred back to the committee by Council for further information;
- monitor and review the work of any approved counsellor;
- convene training programs for counsellors if required;
- establish a process whereby counsellors may have approval withdrawn or may appeal a Council decision;
- report annually as required by Council for its annual report to the CEO of Health, including information on its own activities and information reported to it by Approved Counsellors;
- advise and assist Council on matters relating to consultation with relevant bodies in the community and the promotion of informed public debate in the community on issues relating to reproductive technology;
- advise Council on matters relating to access to information held on the IVF and Donor Registers;
- advise Council on psychosocial matters relating to reproductive technology as Council may request.

Membership

Ms Iolanda Rodino (Chair), Ms Justine Garbellini, Ms Anne-Marie Loney, Dr Elizabeth Webb, Dr Mo Harris (ex officio), Maxine Strike (deputy ex officio).
Embryo Storage Committee

Terms of reference

The committee’s terms of reference are to:

- make decisions on applications for extension of the periods of storage of embryos on a case by case basis, based on the criteria agreed to by Council, and to provide to the next meeting of Council details of all decisions made since the previous meeting;
- provide other advice or carry out other functions relating to the storage of embryos, as instructed by Council.

Membership

Reverend Brian Carey (Chair), Dr Michèle Hansen, Dr Andrew Harman, Ms Antonia Clissa, Dr Mo Harris (ex officio), Maxine Strike (deputy ex officio).

Licensing and Administration Advisory Committee

Terms of reference

The committee’s terms of reference are to:

- advise Council on matters relating to licensing under the HRT Act, including the suitability of applicants and conditions that should be imposed on any licence;
- advise Council generally as to the administration and enforcement of the HRT Act, particularly disciplinary matters;
- advise Council as to suitable standards to be set under the HRT Act, including clinical standards;
- advise Council on any other matters relating to licensing, administration and enforcement of the HRT Act.

Membership

Dr Joe Parkinson, (Chair), Dr Angela Cooney, Professor Roger Hart, Dr Mo Harris (ex officio) Mrs Maxine Strike (deputy ex officio).

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), Mrs Maxine Strike (deputy ex officio).

Scientific Advisory Committee

Terms of reference
The committee’s terms of reference are to:

- advise Council in relation to any project of research, embryo diagnostic procedure or innovative practice for which the specific approval of Council is (or may be) sought;
- advise Council in relation to review of the HRT Act, which is to be carried out as soon as practicable after the expiry of five years from its commencement, and any other matter as instructed by Council.

Membership
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), Mrs Maxine Strike (deputy ex officio).
Operations of Council

Meetings
Council met on 12 occasions during the year, with attendances reaching quorum at all meetings. The Counselling Committee met on four occasions. The PGD Committee met on two occasions, with the majority of applications for PGD considered out-of-session. The Embryo Storage Committee did not meet this year and most applications for extension of storage were considered out of session. The Scientific Advisory Committee met on two occasions, with additional business conducted out of session. The Licensing and Administration Advisory Committee met on two occasions.

Memberships

Outgoing and in-coming members

Professor Con Michael, Chair (nominee of the Minister for Health representing the Australian Medical Association) did not re-nominate when his term of office concluded 1 April 2016. Members of Council thanked Professor Michael for his leadership and commitment to Council since its inception.

Adjunct Associate Professor Jim Cummins (nominee of the Minister for Health) resigned as Council member and Chair of the Scientific Advisory Committee as of 20 December 2015. Members of Council thanked Associate Professor Cummins for many years of service to Council.

Dr Kathy Sanders (nominee of the Minister for Health) resigned as Council member and Chair of the PGD Committee as of 20 December 2015. However, Dr Sanders continues to serve as a member of the PGD Committee.

Dr Brenda McGivern, a serving member of Council, was appointed Chair of Council as of 2 April 2016.

Dr Angela Cooney was appointed member status as of 1 April 2016 (nominee of the Australian Medical Association).

Associate Professor Peter Roberts was appointed member status as of 20 December 2015 (nominee of the Minister for Health).

Professor Stephan Millett was appointed member of Council (nominee of the Minister for Health) as of 5 May 2016.

Dr John Beilby was appointed deputy member of Council (nominee of the Minister for Health), as of 20 December 2015 and subsequently appointed Chair of PGD Committee as of 16 February 2016.

Dr Louise Farrell was appointed deputy member of Council (nominee of the Australian Medical Association), as of 1 April 2016.
Reproductive Technology Unit

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

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

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

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 Fertility Society of Australia Reproductive Technology Accreditation Committee (RTAC) Code of Practice (RTAC 2014) and Certification Scheme (RTAC 2010). Each year all critical criteria and a third of good practice criteria and Quality Management Systems are audited. All standards are audited every three years. Fertility service providers must use a Joint Accreditation System – Australia and New Zealand (JAS-ANZ) accredited certification body for RTAC certification. Laboratories are also required to demonstrate compliance with the National Association of Testing Authority standards.

No new licences were issued this year and no licence renewals were due.

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 must ensure that minimum standards for practice, equipment, staff and facilities comply with those required for good medical practice. In addition, they must comply with any requirements established under the HRT Act.

An application for exemption must be made in the prescribed format and include evidence of registration as a medical practitioner and a written undertaking by the medical practitioner to comply with the Directions. Medical practitioners, who meet the requirements of the HRT Act, may provide artificial insemination procedures if they have a licence exemption. No new applications were received this year and two exemptions were revoked by the CEO at the request of the exempt practitioners. A list of exempt practitioners is available on the Council website www.rtc.org.au

Approved counsellors

Council received and approved one application this year for recognition as an approved counsellor under the HRT Act. A list of approved counsellors is available on the Council website www.rtc.org.au
Applications to Council

This year Council was advised that reporting aggregated data with values of less than five may lead to the inadvertent identification of individuals, procedures or diagnosis (National Health Information Standards and Statistics Committee, 2015). Consequently Council will follow the national guidelines and numbers of less than five will not be reported until aggregated data reach five when they will be included in cumulative totals.

Council is required to approve certain ART practices, including the storage of embryos beyond 10 years, the storage of gametes beyond 15 years, diagnostic testing of embryos, surrogacy applications, innovative procedures, and research projects. The following sections describe the activities for this year.

Embryo storage applications

Council approval is required for the storage of embryos beyond the authorised 10 year time limit. An extension may be granted under section 24(1a) of the HRT Act if Council considers there are special circumstances. Applications must be made by eligible participants (those for whom the embryos were created or donor recipients).

This year Council received and approved 25 applications for extension of the authorised embryo storage period, compared to 26 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

<table>
<thead>
<tr>
<th>Extension (years)</th>
<th>≤1</th>
<th>2–3</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Applications (n)</td>
<td>5</td>
<td>20</td>
<td>25</td>
</tr>
</tbody>
</table>

Storage of gametes beyond the authorised 15 year time limit also requires Council approval. This year Council received fewer than five 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. 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 31 applications for PGD were approved and of those 25 had PGS. The genetic conditions that were approved for PGD are listed in Table 2.

Table 2: Genetic conditions approved for PGD

<table>
<thead>
<tr>
<th>Condition</th>
<th>Condition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Achondroplasia</td>
<td>Multiple endocrine neoplasia type 1</td>
</tr>
<tr>
<td>Thalassaemia BPES</td>
<td>Oculocutaneous albinism type 1</td>
</tr>
<tr>
<td>Charcot-Marie-Tooth Disease</td>
<td>Polycystic Kidney Disease</td>
</tr>
<tr>
<td>LQTS syndrome</td>
<td>Translocations</td>
</tr>
<tr>
<td>Micro Y deletion</td>
<td>Type 1 Osteogenesis imperfecta</td>
</tr>
</tbody>
</table>

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 now 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 applications

The Surrogacy Act sets out the requirements for surrogacy arrangements and prescribes the processes. The Surrogacy Regulations 2009 outline the requirements for an application, including medical assessments, psychological assessment, counselling requirements and legal advice for surrogacy participants.

This year Council received fewer than five applications. National data for surrogacy cycles and births is reported in the Australian New Zealand Assisted Reproduction Database (ANZARD) report, (Macaldowie et al. 2015).

Innovative procedures

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

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

Associate Professor Natasha Nassar, Senior Research Fellow, Clinical and Population Perinatal Health Research, University of Sydney. Prenatal origins and health outcomes of male reproductive congenital anomalies diagnosed at birth and testicular cancer in adulthood. Approved 16 August 2015.

Dr Michelle Hansen, Telethon Institute for Child Health: Recent changes in IVF clinical practice: data linkage to investigate their impact on fetal growth, birth defects and cerebral palsy. Approved 17 December 2015.

National Health and Medical Research Council Licences

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

Complaints to Council

Council received no formal complaints this year.

Finances

The budget allocation to Council was $62,935 with expenditure totalling $60,208. 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.

This year Council advised the Minister for Heath on amendment to the terms of reference for the PGD Committee. These changes were approved as of 11 August 2015 and provide a specific function of the PGD Committee in the approval of PGD applications for translocations, cystic fibrosis and Huntington’s disease.

This year Council provided submissions to the National Health and Medical Research Council (NHMRC) review of ‘Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research’ (2007); the House of Representatives Standing Committee on Social Policy and Legal Affairs Inquiry into Surrogacy; and the review of the South Australia Assisted Reproductive Treatment Act 1988.

Council supported a Graduate and Post-graduate seminar attended by 40 people, held at the University Club of Western Australia 15 October 2015. Honours students, Masters students and PhD candidates in the field of reproductive biology gave presentations on their work.

Council hosted a workshop on 5 November 2015 held at the Department of Health with guest speaker Dr Brenda McGivern, Deputy Dean of Law, University of Western Australia. Dr McGivern discussed the principles of informed consent in the context of assisted reproduction. The workshop was attended by 21 participants, (Dr Brenda McGivern presentation).

Council hosted a special event on 16 February 2016 with invited speaker Dr Sonia Allen, Senior Lecturer, Macquarie Law School, Macquarie University, Sydney. Dr Allen’s presentation ‘Donor conception – systems for information release’ explored policies across Australian jurisdictions and examined legal and ethical issues of sharing donor information in different cultures. Dr Allen’s second presentation ‘A discussion concerning payment for gametes and surrogacy’ shed light on this complex, emotional and contested issue. A total of 51 participants attended the presentations.

Council hosted a special event on 6 April 2016 with guest speaker Professor Ken Daniels, who has undertaken influential work in the area of donor linkage and common themes that are beginning to emerge for donor conceived people in New Zealand. Professor Daniel’s presentation ‘The sociological meaning of donor conception’ shed light on the complex and emotional issues involved with donor conception and building families. The event attracted an audience of 34 people, (Prof Ken Daniels presentation).
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


Presentations


Harris M, November 2015. Risks and Regulation. IVF Nurses Professional Education Study Day, University Club of Western Australia.


Developments in reproductive technology

Gene editing technology

Gene editing technology such as CRISPR-Cas9 can modify genomes with more precision than previous techniques. This method can locate specific regions of DNA, cut out specified segments of DNA and replace them with new DNA segments. This technology has a wide range of potential applications in humans, from the development of tools to model diseases, non-reproductive therapies and potentially to repair faulty genes in eggs, sperm or embryos.

In the United Kingdom, the Human Fertilisation and Embryo Authority has approved research to manipulate the genes of human embryos, but does not allow the use of such embryos for reproductive purposes. While there is controversy surrounding the alteration of genes in a human embryo, the research does have the potential to provide important advances in scientific knowledge, the techniques are not sufficiently developed for reproductive purposes.

Developments in gene editing technology have provoked considerable discussion and debate. Recently, the Nuffield Council on Bioethics launched a genome editing project. This project aims to shed light on the impact and implications of genome editing in research, which will inform the development of ethical guidance, (Nuffield Council on Bioethics).

Commonwealth Surrogacy Inquiry

The House of Representatives Standing Committee on Social Policy and Legal Affairs commenced an inquiry into the regulatory and legislative aspects of international and domestic surrogacy arrangements. The report ‘Surrogacy Matters’ was released in April 2016 and recommended that commercial surrogacy should continue to be prohibited in Australia. The Committee supported altruistic surrogacy and the development of a national regulatory framework. The Committee also recommended the involvement of the Australian Law Reform Commission and the Council of Australian Governments to ensure a coordinated approach to surrogacy, (Surrogacy Matters 2016).

Legislative Amendments

Legislative amendments to Victorian legislation to enable all donor-conceived persons to apply for identifying information about their donor will come into force from March 2017. The changes are retrospective, so access will be regardless of when the donation was made or the consent of the donor. Donors will be able to register their contact preferences, including a contact veto. This recognises that these donors donated on the expectation that they could remain anonymous. Responsibility for managing the central and voluntary registers will be moved to the Victoria Assisted Reproductive Treatment Authority, (Victorian legislative amendments).
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 provides a service for donor-conceived adults and for parents of donor-conceived children to connect with genetic relatives. Access to identifying information can only be provided with the mutual consent of the genetically related people (matches) who must also have joined the Voluntary Register. All the people involved must also undergo mandatory counselling prior to the release of identifying information. Donor-conceived adults (≥18 years old), parents of donor-conceived children who are <18 years old and donors may join the Voluntary Register. Details of the Voluntary Register can be found on the Department of Health website, (Healthy WA).

Current registrations as of 30 June 2016 include 38 donor-conceived adults (DCA), 113 parents of donor-conceived children and 86 donors. Table 3 shows the number of Voluntary Register matches and the number ensuing contact.

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

<table>
<thead>
<tr>
<th>Matched</th>
<th>Contacted</th>
</tr>
</thead>
<tbody>
<tr>
<td>DCA and donor</td>
<td>&lt;5</td>
</tr>
<tr>
<td>Parent and donor</td>
<td>18</td>
</tr>
<tr>
<td>Half-siblings</td>
<td>15</td>
</tr>
</tbody>
</table>

The Voluntary Register is advertised by the Department of Health in the West Australian four times a year and periodically in other media to promote awareness of the service.
References


Appendix 1: Practice and Storage Licence holders

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

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

**Fertility North**  
Suite 30 level 2 Joondalup Private Hospital  
60 Shenton Avenue  
JOONDALUP WA 6027

**Fertility Specialists South**  
1st Floor 764 Canning Highway  
APPLECROSS WA 6153

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

**Hollywood Fertility Centre**  
Hollywood Private Hospital  
Monash Avenue  
NEDLANDS WA 6009

**Keogh Institute for Medical Research**  
1st Floor C Block  
QEII Medical Centre  
NEDLANDS WA 6009  
(Artificial insemination only)

**PIVET Medical Centre**  
Perth Day Surgery Centre  
166-168 Cambridge Street  
LEEDERVILLE WA 6007
Appendix 2: Financial statement

The Department of Health funds the administration of the HRT Act, including the operations of Council. The 2015–2016 Council budget allocation was $62,935 with expenditure totalling $60,208 for the financial year. Table 4 shows the financial statement for the 2015–2016 annual report.

Table 4: Financial statement for the 2015–2016 annual report

<table>
<thead>
<tr>
<th>Expenditure by category 2015–2016</th>
<th>Expenditure ($)</th>
<th>Income ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Training, registration, course fees, interstate travel</td>
<td>13,113</td>
<td></td>
</tr>
<tr>
<td>Food supplies and catering</td>
<td>3,106</td>
<td></td>
</tr>
<tr>
<td>Administration and clerical</td>
<td>3,331</td>
<td></td>
</tr>
<tr>
<td>Reproductive Technology Council sitting fees</td>
<td>18,812</td>
<td></td>
</tr>
<tr>
<td><strong>Other expenses:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stationery and printing, including annual report</td>
<td>2,099</td>
<td></td>
</tr>
<tr>
<td>RTC special event seminars</td>
<td>4,397</td>
<td></td>
</tr>
<tr>
<td>Website development</td>
<td>15,350</td>
<td></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>$60,208</strong></td>
<td><strong>$62,935</strong></td>
</tr>
</tbody>
</table>
Appendix 3: Operations of licence holders

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

The aggregated data, tables, graphs, analysis and interpretation of data presented in this appendix have been provided by the Purchasing and Systems Performance Division of the Department of Health. Data are presented on the activities of licence holders for this year and assisted reproductive technology trends for the past 10 years in WA. In some instances percentages do not add up to 100% due to rounding to whole numbers.

Assisted reproductive technologies in Western Australia

The most recent report from the Australian Institute of Health and Welfare, National Perinatal Epidemiology and Statistics Unit, estimated that in 2013 ART was used by 4.4% of women who gave birth in Australia, (Australian Institute of Health and Welfare, 2015).

The procedure of IVF involves the fertilisation of oocytes (eggs) in a laboratory and placing the embryo (fertilised egg) in the uterus. This procedure can be either a fresh cycle, where the embryo is not cryopreserved (frozen), or a thaw cycle where the embryo is thawed and transferred to the women’s uterus.

A total of 4,092 women underwent assisted reproduction treatment in WA this year. This number is essentially unchanged compared to the previous year (n=4,099). There were 6,256 treatment cycles compared to 6,050 during the previous year. This is an increase of three per cent. Table 5 provides an overview of the initiated cycles.

Table 5: IVF treatments

<table>
<thead>
<tr>
<th></th>
<th>IVF fresh</th>
<th>IVF thaw</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Women treated</td>
<td>2,576</td>
<td>1,516</td>
<td>4,092</td>
</tr>
<tr>
<td>Treatment cycle</td>
<td>3,662</td>
<td>2,594</td>
<td>6,256</td>
</tr>
<tr>
<td>Cycle with oocyte retrieval</td>
<td>3,218</td>
<td>-</td>
<td>3,218</td>
</tr>
<tr>
<td>Cycle with embryo transfer</td>
<td>1,956</td>
<td>2,420</td>
<td>4,376</td>
</tr>
<tr>
<td>Cycle with embryo storage</td>
<td>1,868</td>
<td>-</td>
<td>1,868</td>
</tr>
</tbody>
</table>
Fresh IVF transfer techniques included 192 surgical sperm aspirations and 1997 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 1,080 intrauterine insemination (IUI) treatment cycles were reported by eight licensees and one exempt practitioners. This represents an eight per cent rise in the number of IUI treatment cycles compared to the previous year (n=996). The reported ongoing pregnancy rate for IUI was 10% (112 ongoing pregnancies), of which 50 (45%) were singleton pregnancies, four (4%) were twin pregnancies, and the remaining 58 had no plurality reported. The partners’ sperm were used for 73% of procedures. Donor sperm were used for 27% of procedures. Gonadotrophin was used for 44% of cycles, Clomid was used in 28% of cycles, and 29% were natural cycles.

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

Table 6: Number of recipient cycles using donations

<table>
<thead>
<tr>
<th></th>
<th>Fresh IVF cycle</th>
<th>Thawed embryo cycle</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sperm</td>
<td>225</td>
<td>150</td>
</tr>
<tr>
<td>Oocyte</td>
<td>52</td>
<td>52</td>
</tr>
<tr>
<td>Embryo</td>
<td>&lt;5</td>
<td>31</td>
</tr>
</tbody>
</table>

In addition, there were 64 cycles where oocytes were donated and fewer than five fresh cycles where embryos were donated. This year there was a total of 164 sperm donors, of which 35 were new donors.

**Public fertility clinic referrals**

This year 45 patients from King Edward Memorial Hospital Fertility Clinic were referred to three fertility clinics for treatment. A total of 63 treatment cycles were provided, with 26 women having IVF with fresh embryo transfer and 10 women having IVF with thawed embryo transfer.
Serious morbidity and mortality

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

Counselling

A total of 2,278 couples or individuals received counselling, which represents a 13% increase from the previous year (n=2,014). Most participants (69%) received a single counselling session and the majority of these sessions (71%) involved information counselling. Others having a single counselling session received support counselling (22%), therapeutic counselling (2%) and counselling for other reasons (5%). Of the 31% of participants who had more than one session, 23% had support counselling and 56% had information counselling. Counselling for donors and donor recipients accounted for 47% of all sessions. There were 1,122 donor counselling sessions representing an increase of 24% from the previous year.

Embryo storage

The number of embryos in storage was reported as 23,026 as of 30 June 2016. The dispersal of embryos for this year is shown in Table 7.

Table 7: Dispersal of stored embryos

<table>
<thead>
<tr>
<th>Embryo dispersal</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>Embryos in storage 30/6/2015</td>
<td>21,278</td>
</tr>
<tr>
<td>Embryos created from IVF</td>
<td>6,940</td>
</tr>
<tr>
<td>Used in frozen embryo transfer treatments</td>
<td>3,346</td>
</tr>
<tr>
<td>Transferred between clinics in WA</td>
<td>154</td>
</tr>
<tr>
<td>Transferred to clinics outside WA</td>
<td>73</td>
</tr>
<tr>
<td>Transferred from interstate</td>
<td>64</td>
</tr>
<tr>
<td>Embryo disposition</td>
<td>1,837</td>
</tr>
<tr>
<td><strong>Embryos in storage 30/06/16</strong></td>
<td><strong>23,026</strong></td>
</tr>
</tbody>
</table>
Assisted reproductive technology trends in WA

Overall, the number of IVF treatment cycles in WA increased by three per cent compared to the previous year (n=6,256 vs n=6,050). National statistics show a 1.9% increase in ART treatment cycles in 2013 (Macaldowie et al. 2015).

Overall, in WA the proportion of fresh to thawed cycles this year was 59% of all cycles. This proportion has remained relatively stable over the years (range 57% – 61%). National statistics for 2013 show that 60.2% of ART cycles, where the patients used their own eggs or embryos, were fresh IVF cycles (Macaldowie et al 2015). Figure 1 shows the progression of fresh IVF cycles.

Figure 1: Progression of fresh IVF cycles by year, 2007–2016
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, 2007–2016

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 autologous 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 reported for procedures in 2013, ICSI was used in 68% of autologous fresh cycles where fertilisation was attempted. (Macaldowie et al 2015).

Figure 3: Number of IVF cycles with ICSI by year, 2007–2016
Number of sperm donors

The number of sperm donors has gradually increased over the past 10 years (Figure 4). As previously reported there was a total 164 sperm donors. Men in the 31–50 year age range represent the largest group of donors 72%.

Figure 4: Number of sperm donors by age group and year, 2007–2016