Government of **Western Australia**
Department of **Health**

Ministerial Expert Panel on Assisted Reproductive Technology and Surrogacy

Final report

Acknowledgement of Country and People

WA Health acknowledges the Aboriginal people of the many traditional lands and language groups of Western Australia. It acknowledges the wisdom of Aboriginal Elders both past and present and pays respect to Aboriginal communities of today.

Contents

Hon Amber-Jade Sanderson MLA
Minister for Health; Mental Health
5th Floor, Dumas House
2 Havelock Street
West Perth WA 6005

Dear Minister Sanderson

On behalf of the members of the Ministerial Expert Panel (MEP) on Assisted Reproductive Technology (ART) and Surrogacy Legislation, I present to you the panel's report, with its recommendations relating to the development of new legislation for ART and surrogacy in Western Australia.

I would like to thank you for the opportunity for myself and on behalf of the other members of the MEP to contribute to the development of proposed new ART and surrogacy legislation for the state.

WA was one of the first jurisdictions in the world to pass legislation regulating ART, via the *Human Reproductive Technology Act 1991* (HRT Act). The *Surrogacy Act 2008* (Surrogacy Act) followed 17 years later. In the 32 years since the HRT Act was passed, much has changed both in terms of medical and scientific advancements in ART, as well as societal and ethical attitudes to creating and supporting families. The number of people accessing ART and seeking surrogacy continues to increase. As the Labor Government recognised, WA's current regulation should be updated to reflect these changes over the past 30 plus years. Central to all of this remains the best interests of any person born as a result of ART and surrogacy.

In 2018, the WA Government commissioned the independent *Review of the Western Australian Human Reproductive Technology Act 1991 and the Surrogacy Act 2008* undertaken by Associate Professor Sonia Allan (Allan Review). The Allan Review, which was completed in 2019, outlined 122 recommendations, of which 67 recommendations related to the HRT Act and 55 related to the Surrogacy Act.

The government response to the Allan Review was tabled in Parliament on 18 August 2021 and was accompanied by a commitment to the development of new ART and surrogacy legislation in WA. While the majority of the Allan Review recommendations were supported, several were identified by government as requiring further consideration in order to identify the implications for developing proposed legislation.

The MEP convened in May 2022 and was given the task to provide advice to the government and undertake targeted consultation with those with lived experience and other key stakeholders, for those areas identified as requiring further deliberation in the Allan Review and the government response.

To assist in this targeted consultation, a Public Discussion Paper was produced and made available on the MEP webpage on the WA Department of Health (the department) website. This was emailed to key stakeholder and advocacy groups, as well as those people and organisations who had previously made submissions to the Allan Review. General feedback was requested with an email and postal address provided to accept submissions. Forty-two responses were received, and a summary of the themes is provided in this report.

A survey was also developed specifically addressing donor conception matters. It was recognised that this practice has become controversial in recent years with donor-conceived persons, their parent(s) and some donors keen to end the secrecy surrounding donor conception. A themed summary of the 268 responses to the survey is provided in this report.

The MEP held a forum on 19 July with 36 attendees representing researchers and WA licensed ART providers to better understand how changes to legislation may impact ART research and the ART industry.

Alongside these targeted consultations the MEP held multiple sessions from June to December 2022 to examine specific topics related to the breadth of matters covered under the umbrella of ART, including surrogacy. Consideration was given to the approaches to regulation that would be applied. Subject matter experts were invited to these sessions to speak to the issues specific to their fields, and people with 'lived experience' of navigating the existing legislation were included to discuss what they sought in future legislation.

Feedback received from the submissions and speakers invited to the MEP sessions raised several key themes. First was the continuing requirement for proposed legislation to ensure that the best interests of the person who may be born as a result of ART are central to any decision involving an ART procedure.

As anticipated, equity of access to ART, including surrogacy, was also a key theme from submissions although the cost of ART services was only raised in 3 submissions. Access to surrogacy for same-sex couples and single men is required so that WA complies with Commonwealth discrimination legislation. Feedback also highlighted areas where access to particular ART practices is currently prohibited in WA but not in other Australian states and territories, such as the posthumous use of gametes, reciprocal in vitro fertilisation (IVF) for women who are couples, and certain preimplantation genetic testing of embryos, such as human leukocyte antigen typing for tissue type matching.

Another key theme was the right for people who are donor-conceived to access information about their genetic and birth heritage. WA ceased anonymous gamete and embryo donation for any child conceived on or after 1 December 2004. Persons conceived after this date may now apply to access identifying information about their donors when they attain 16 years of age.

People who were donor-conceived before this date however, highlighted their request to have access to identifying information about their donor parent(s), and for support services to help with matching between parties to donor conception. A number of measures are proposed for future legislation that will facilitate disclosure of the identity of the donor from the time a child's birth is registered, and work with the Registry of Birth, Deaths and Marriages is continuing to explore how this could be managed. Data verifying a donor's identity in order to match them to a donor-conceived person using the department's Reproductive Technology Registers (RT Registers) has improved, but there are no data held by the department for donors or donor-conceived persons born before 1993 when legislation first required this information be recorded. Fertility clinics may hold clinical records that pre-date the legislation.

Supported by Associate Professor Allan, and highlighted by licensed ART providers, those with lived experience and other stakeholders, was the need for proposed legislation to have clear streamlined processes where regulation was required. It was strongly recommended that approval processes for a purpose that was considered necessary historically but is no longer relevant, be removed. Formal approval for surrogacy, extension of storage limits for gametes and embryos, and preimplantation genetic testing for some conditions, creates extra burden for licensed ART providers – often with little to no added benefit – and forces delays for participants at a time when infertility can make treatment timeframes critical.

Another key theme included calls for further clarity and streamlined processes for surrogacy. Ensuring a straightforward alturistic surrogacy process, that keeps the best interests of the child as paramount, would be expected to make surrogacy more accessible in WA and discourage people from engaging in overseas surrogacy where there is a risk of commercialisation of the process.

Separately, there is a need for WA to enact nationally consistent legislation regarding research involving excess ART embryos and embryos formed by means other than fertilisation under a National Health and Medical Research Council (NHMRC) licence, and prohibition of human cloning for reproductive purposes and other prohibited practices, as discussed in recommendation 8.

The MEP is grateful to those people who provided their views, suggestions and submissions, all of which were very helpful and have informed the panel's recommendations for proposed ART and surrogacy legislation in WA.

I would like to thank Associate Professor Sonia Allan for her considered and detailed review which formed the basis for the MEP's targeted consultation. Professor Allan presented to the MEP and provided useful reflections on her recommendations that assisted the panel to focus on key areas that were identified for further consideration.

Sincere thanks to my fellow MEP members for their dedication and valuable contributions to the development of the recommendations that are the basis of this report. Our sessions together were enlightening, enjoyable and at times lively. Your expertise helped produce clear and insightful recommendations for proposed ART and surrogacy legislation.

Thank you finally to the secretariat team at the department for supporting the MEP by organising the sessions, speakers, resource information, consultation documents, and for assisting me in keeping the panel to task to develop the recommendations and produce this report.

I hope you find this report and its recommendations helpful. I wish the government every success in passing new legislation in WA for ART and surrogacy and to permit research involving excess ART embryos and embryos formed by means other than fertilisation under a NHMRC licence. The changes recommended will benefit Western Australians through extending access and eligibility to create or expand their families using ART.

Yours sincerely

Professor Roger Hart

Chair of the Ministerial Expert Panel on Assisted Reproductive Technology and Surrogacy Legislation

Ministerial Expert Panel members

Professor Roger Hart – Chair

Professor Roger Hart is an internationally recognised expert in the treatment of infertility and research regarding assisted reproductive technology. He is Professor of Reproductive Medicine at The University of Western Australia, Medical Director at Fertility Specialists of WA, National Medical Director of City Fertility, and Head of Reproductive Medicine Service at King Edward Memorial Hospital.

Dr Louise Farrell OAM – Deputy Chair

Dr Louise Farrell OAM is a Consultant Obstetrician and Gynaecologist and recent previous Head of Colposcopy Services at King Edward Memorial Hospital.
Dr Farrell is a former Vice-President of the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG), Chair of the WA Branch of the RANZCOG and previous Clinical Director (Obstetrics and Gynaecology) at St John of God Hospital Subiaco.

Dr Angela Cooney – Member

Dr Angela Cooney is a General Practitioner with expertise in reproductive health, women's health and working with LGBTQI+ clients. Dr Cooney is the former Medical Director of Family Planning WA (now Sexual Health Quarters) and is a current sessional medical practitioner with Sexual Health Quarters.

Dr Ian Hammond AM – Member

Dr Ian Hammond AM is a retired Consultant Gynaecologic Oncologist and former Clinical Professor in the School of Women's and Infants Health at The University of Western Australia. He is a previous Director of the WA Cancer and Palliative Care Network and previous Chair and Member of National Cervical Screening Program Committees and Expert Advisory Groups.

Martin Kavanagh – Member

Mr Martin (Marty) Kavanagh is a Barrister and Solicitor with extensive experience in family law and family violence orders with a particular interest in surrogacy, LGBTQI+ legal issues, State Administrative Tribunal, Guardianship and Administration, Hague Convention (Child Abduction) matters, and international family law (particularly Ireland, USA, England and Wales).

Rachel Oakeley – Member

Ms Rachel Oakeley is a Barrister with a special interest in family law, infertility law and surrogacy matters. Her experience in family law includes complex property, parenting, adoption, child protection, child support and international cases. She is a registered arbitrator and nationally accredited mediator chairing family law mediations and providing advocacy services to instructors from family law practices.

Fiona Seaward SC – Member

Ms Fiona Seaward is the Acting Deputy State Solicitor – Public and General Litigation at the State Solicitor's Office. Ms Seaward provides legal advice to government and practices as counsel in a broad range of matters, with a particular emphasis on public law and constitutional law. Ms Seaward is a former Commissioner of the Law Reform Commission of Western Australia.

Hon Dr Sally Talbot MLC – Member

The Hon Dr Sally Talbot MLC is the Member for South West Region. Dr Talbot is the current Chair of the Standing Committee on Legislation. She is a former Chair, Deputy Chair and Member of various Parliamentary Committees including the Select Committee into Public Obstetric Services and the Joint Select Committee on End of Life Choices.

Recommendations

Ministerial Expert Panel recommendations

The following list of recommendations was developed by the Ministerial Expert Panel (MEP) on Assisted Reproductive Technology and Surrogacy Legislation. The basis for the development of the MEP's recommendations was the request by the Minister for Health to undertake a targeted analysis of the recommendations from *The Review of the Western Australian Human Reproductive Technology Act 1991 and the Surrogacy Act 2008* by Associate Professor Sonia Allan (Allan Review)[1,2], in 2019, and the government response to the Allan Review.[3]

Part A: Proposed legislation for regulation of ART practice

Ministerial Expert Panel recommendation 1:

That the *Human Reproductive Technology Act 1991* (HRT Act), the *Surrogacy Act 2008* (Surrogacy Act) and the *Artificial Conception Act 1985* (AC Act) be repealed and replaced with a single Act combining the treatment and practice of ART and surrogacy. The title of the proposed legislation should be the Assisted Reproductive Technology and Surrogacy (ARTS) Act.

Ministerial Expert Panel recommendation 2:

That a second, separate Act is required to regulate research involving excess ART embryos and embryos formed by means other than fertilisation under a NHMRC licence in WA, and the continued prohibition of human cloning for reproduction and other prohibited practices.

Ministerial Expert Panel recommendation 3:

That proposed legislation:

a) regulate the WA ART industry and reflect the changing context of medical, ethical, social and commercial challenges, to protect the best interests of persons born as a result of ART, individuals and their partners (if any) accessing ART, and those donating reproductive material or capabilities

b) outline the roles and responsibilities of regulators and licensed ART providers, including reporting requirements

c) establish an advisory and review board for specific ART matters.

1 Sonia Allan, *The Review of the Western Australian Human Reproductive Technology Act 1991 and the Surrogacy Act 2008* (Report: Part 1) (2019).

2 Sonia Allan, *The Review of the Western Australian Human Reproductive Technology Act 1991 and the Surrogacy Act 2008* (Report: Part 2) (2019).

3 Government of Western Australia: Response to the recommendations from *The Review of the Western Australian Human Reproductive Technology Act 1991 and the Surrogacy Act 2008*, Parliament of Western Australia (August 2021).

Ministerial Expert Panel recommendation 4:

That proposed legislation includes objectives to inform the intent and purpose of the legislation. The following objectives be adopted in the proposed legislation to:

a) regulate the use of ART by licensed ART providers to deliver best clinical practice and decision-making that meet industry standards and safety and quality outcomes defined by the regulator

b) regulate collection of participant and treatment data, and access to information about ART treatments and procedures carried out under the Act

c) provide for the keeping of the Reproductive Technology Registers (RT Registers), and any other data collections related to the Act

d) enable participant information relating to donor conception and surrogacy to be recorded for the purpose of sharing this with persons entitled to access the information under the legislation

e) facilitate research into the incidence, causes and prevention of infertility, and the impact of treatments on the health outcomes of ART participants

f) establish the ART Advisory and Review Board (AARB) to provide advice and support governance and oversight of ART in WA.

Ministerial Expert Panel recommendation 5:

That proposed legislation contain principles developed by the MEP to guide the interpretation and administration of the Act and how activities to be regulated by the Act are conducted. Principles to be included in the proposed legislation:

a) the best interests (including health, safety, welfare and rights) of persons to be born as a result of ART are paramount

b) the health, safety and wellbeing, including physical, emotional and mental health, of persons accessing ART, their partner (if any), donors and surrogates must be protected

c) all persons accessing ART must provide informed consent prior to a treatment or procedure being performed

d) persons accessing ART must not be unlawfully discriminated against on grounds which include but are not limited to their sexual orientation, relationship status, gender identity, disability, race or religion

e) trade in the reproductive capabilities of persons and the exploitation of people including children for commercial ends raise health and ethical concerns

f) persons born as the result of the use of donated gametes have a right to information about their genetic heritage and biological parents

g) the provision of ART must be transparent and open to scrutiny, while ensuring the protection of the privacy of all persons and their partner (if any) involved in ART, and persons born, to the degree that is protected by law

h) licensed ART providers must provide safe, person-centred services and foster continuous improvement in the safety and quality of treatment procedures they provide

i) the provision of ART must be underpinned by policies that support effective and efficient practices that minimise interventions not supported by evidence of successful clinical outcomes.

Ministerial Expert Panel recommendation 6:

That the sections of the proposed legislation which address eligibility criteria and other associated matters involving access to ART and surrogacy be made effective as soon as possible after commencement of the proposed legislation.

That there be a minimum 6-month period between commencement of the ARTS Act and implementation of the proposed legislation for other aspects of the legislation.

Ministerial Expert Panel recommendation 7:

That proposed legislation be reviewed 3 years after the date the Act (or review provision) comes into operation and every 5 years thereafter.

Part B: Legislation for research involving excess ART embryos and prohibition of human cloning for reproduction

Ministerial Expert Panel recommendation 8:

That there be a single piece of WA legislation to align with the 2 Commonwealth Acts, namely the *Research Involving Human Embryos Act 2002* (Cth) (RIHE Act) and the *Prohibition of Human Cloning for Reproduction Act 2002* (Cth) (PHCR Act). This legislation would be separate to the proposed legislation addressing ART treatment and practice in WA.

Legislation regulating research involving excess ART embryos and embryos formed by means other than fertilisation under a NHMRC licence in WA, and prohibition of human cloning for reproduction and other prohibited practices, would commence at the same time as the proposed legislation for ART practice.

Ministerial Expert Panel recommendation 9:

That proposed legislation regarding research involving excess ART embryos and embryos formed by means other than fertilisation under a NHMRC licence should be constructed in a manner that allows for flexibility, responsiveness, and regular review in anticipation of further advances in science, medicine and emerging technologies in ART treatment and practice.

Part C: Access to ART

Ministerial Expert Panel recommendation 10:

That proposed legislation enable access to ART, including surrogacy and reciprocal IVF for any person and partner (if any) who meets the following eligibility criteria:

a) the person and partner (if any) are unlikely to conceive other than by an ART procedure

b) the person and partner (if any) are unlikely to be able to carry a pregnancy to term or give birth to a healthy child without an ART procedure

c) the person and partner (if any) is at risk of transmitting a genetic condition or genetic disease to a child born as a result of a pregnancy conceived other than by an ART procedure, including a genetic abnormality or genetic disease when the person or their partner (if any) is the carrier

d) where the treating clinician has assessed the person and believes that ART is appropriate having regard to all current and future physical, psychological and social circumstances.

Ministerial Expert Panel recommendation 11:

That proposed legislation use gender-inclusive language and refer to 'person' and 'they/them' instead of 'woman/man' and 'he/she', and use anatomical language where this is appropriate.

Ministerial Expert Panel recommendation 12:

That proposed legislation exclusively use the term partner in reference to members of a couple who are seeking access to ART, with the term defined in the legislation as either:

a) the person's legal spouse irrespective of gender (other than a spouse from whom the person has separated)

b) the person's de facto partner irrespective of gender, who has lived with the first person on a genuine domestic basis for a minimum of 3 months

c) a person not currently married or living in a de facto relationship, but where there is an established relationship.

Ministerial Expert Panel recommendation 13:

That proposed legislation will require:

a) implications counselling for the donor and recipient(s) by an Australian and New Zealand Infertility Counsellors Association (ANZICA) eligible counsellor (or overseas equivalent) prior to the donor and recipient(s) providing written valid consent to proceed

b) the gamete and medical screening period run concurrently with the implications counselling for known donors and recipients

c) at any stage during the period for gamete screening or implications counselling, any party to the ART arrangement may choose not to proceed with the process.

Ministerial Expert Panel recommendation 14:

That proposed legislation maintains the existing worldwide five-family limit for using donor gametes or embryos from the same donor to create or extend a family, with penalties or conditions on a licence introduced for exceeding the limit. In circumstances where exceptions are sought, these should be considered by the AARB. Exceptions will not be considered unless there are extraordinary circumstances that will affect the wellbeing of the child(ren). No exception will be considered unless donor information is available.

Ministerial Expert Panel recommendation 15:

That licensed ART providers in WA be permitted to request or conduct genetic testing of embryos as follows:

a) testing for monogenic and single gene disorders and testing for structural chromosomal rearrangements using a list of approved conditions for which genetic testing can be conducted without the need for further approval

b) genetic testing for aneuploidy when genetic testing for monogenic and single gene disorders or genetic testing for structural chromosomal rearrangements is requested by a treating ART clinician

c) other use of genetic testing for aneuploidy will be at the discretion of the treating ART clinician who can use testing when they deem it clinically appropriate

d) genetic testing of embryos for non-medical reasons (including sex-selection for family balancing) is prohibited

e) use of genetic testing should align with the NHMRC Ethical Guidelines on the use of ART.

For conditions not included on the list of approved conditions, licensed ART providers must apply to the AARB for the condition to be added to the list. In making its decision, the AARB can refer the application to a gene review panel who will advise the AARB.

All patients receiving genetic testing for monogenic and single gene disorders, and genetic testing for structural chromosomal rearrangements will need to receive counselling from a clinical geneticist and/or genetic counsellor prior to testing being performed.

Ministerial Expert Panel recommendation 16:

That proposed legislation permits genetic testing for the purpose of tissue typing an embryo (human leukocyte antigen (HLA) typing) for subsequent stem cell therapy for a parent, sibling or other relative who requires tissue or organ donation due to illness. Use of genetic testing for HLA tissue typing should align with the NHMRC Ethical Guidelines on the use of ART.

Genetic testing of embryos for the purpose of supporting approved mitochondrial donation techniques for the treatment of mitochondrial disease will be permitted, following any introduction of mitochondrial donation in WA.

All applications for genetic testing of embryos for the purpose of tissue typing or to support mitochondrial donation techniques must be approved by the AARB. In making its decision the AARB can seek the advice of a gene review panel.

Ministerial Expert Panel recommendation 17:

That proposed legislation be drafted in a manner allowing flexibility in response to emerging scientific and medical evidence, advances in technology and clinical practice relating to genetic testing of embryos.

Ministerial Expert Panel recommendation 18:

That proposed legislation permits reciprocal IVF. Reciprocal IVF enables one person to contribute their oocyte (egg) in order to create an embryo that will be carried to term by their partner.

The partner's oocyte(s) used in reciprocal IVF will not be considered as donor material in the proposed ART legislation.

Consent for embryo creation for the purpose of reciprocal IVF must include written direction regarding the use, on-donation or removal from storage of the embryos, including in the event of the death of either partner or separation of the partners.

Ministerial Expert Panel recommendation 19:

That proposed legislation continues to permit the collection of gametes and reproductive tissue from a person who is deceased, and also permit collection from a person who is near death (dying) and unable to provide consent. This is to preserve the option for intended future reproductive purposes by the person's surviving partner. Collection must be consistent with the elements outlined in s 22 of the *Human Tissue and Transplant Act 1982* (HTT Act) being met and alignment with the NHMRC Ethical Guidelines for the use of ART using the following criteria:

a) the dying person left clearly expressed oral or written directions consenting to the collection (retrieval) of their gametes or reproductive tissue in the event they are near death or following their death, or there is some evidence that the person would have supported the collection of their gametes or tissue for use by their partner

b) where the deceased person left no instructions, the designated officer shall consider any information that supports the intention of the deceased person to have a child following their death, or determine there is no evidence that the deceased person would have objected to the use of their gametes, reproductive tissue or embryos by their surviving partner

c) if a person expressly objected to the collection of their gametes or reproductive tissue, then collection is prohibited

d) the person was an adult at the time of their death

e) the request for collection has come from the partner of the person who is near death, unless the partner is temporarily incapacitated, then the senior available next of kin may make this request on the surviving partner's behalf

f) the gametes or reproductive tissue collected are only for use by the partner, using a surrogate if required, for the purposes of bearing a child(ren) who will be cared for by the partner.

Ministerial Expert Panel recommendation 20:

That proposed legislation permits the posthumous use of:

- embryos created from the gametes of a person who subsequently dies
- gametes and reproductive tissue collected prior to, or after a person's death.

Use is subject to meeting the below criteria:

a) the best interests of the person(s) to be born will be a primary consideration for any posthumous use of gametes, reproductive tissue or embryos

b) the deceased person left clearly expressed oral or written directions consenting to the use of their gametes, reproductive tissue or embryos following their death, or there is some evidence that the deceased person would have supported the posthumous use of their gametes, reproductive tissue or embryos by their surviving partner. If a person has expressly objected to the posthumous use of their stored gametes, reproductive tissue or embryos, use to achieve pregnancy is prohibited

c) where the deceased person left no instructions, the AARB shall consider any information that supports the intention of the deceased person to have a child following their death, or determine there is no evidence that the deceased person would have objected to the use of their gametes, reproductive tissue or embryos by their surviving partner

d) the deceased was an adult at the time of their death

e) the request to use the gametes, reproductive tissue or embryos will only be by the person's surviving partner, including use of a surrogate, for the purposes of bearing a child(ren) who will be cared for by the surviving partner

f) the surviving partner has undergone appropriate implications counselling and has been provided with sufficient information to facilitate an accurate understanding of the potential social, psychological and health implications for the person who may be born

g) sufficient assessment has been made that the surviving partner's grief and related emotions have been addressed to ensure their effective decision-making

h) use will require approval by the proposed AARB and will align with the requirements of the NHMRC Ethical Guidelines on the use of ART, unless otherwise specified in the proposed legislation.

The MEP recommends that the collection, storage and use of all reproductive material to be used for intended reproductive purposes is regulated under the proposed ART legislation. This would include posthumous collection of gametes and reproductive tissue. The MEP notes this will require amendment to the HTT Act.

Ministerial Expert Panel recommendation 21:

Where a child is born as the result of the posthumous use of a deceased partner's gametes or an embryo created with such gametes in an artificial conception procedure, that provision in the *Births, Deaths and Marriages Registration Act 1998* be made to enable the deceased person to be listed on the child's birth certificate as a parent of that child.

Ministerial Expert Panel recommendation 22:

That, consistent with the principles for the proposed legislation outlined in recommendation 5, prerequisites for a valid surrogacy arrangement include:

a) the intended parent(s), and the surrogate and partner (if any) are all 18 years of age or older

b) the intended parent(s) be ordinarily resident in WA at the time an application for parentage is made and the Family Court have the discretion to dispense with the residency requirements

c) the intended parent(s) and the surrogate receive separate legal advice from separate lawyers, not in the same practice

d) the parties' intentions and agreement be documented and executed in a written agreement

e) in determining eligibility, the treating ART clinician should have regard to medical and psychosocial suitability of all participants and undertake an appropriate risk assessment regarding these factors

f) the intended parent(s) and the surrogate must undertake implications counselling at the following times as a minimum:

- separate implications counselling prior to ART treatment
- joint implications counselling prior to ART treatment

g) known donors receive joint implications counselling with the intended parent(s) prior to donation, and separate implications counselling as required for any gamete or embryo donation

h) unknown donors will have advice/consent provided/obtained at the time of donation and are therefore not required to undertake counselling or provide consent to the use of their gametes/embryos in a surrogacy arrangement.

Ministerial Expert Panel recommendation 23:

That the proposed legislation include provision for licensed ART providers to seek advice from the AARB in relation to concerns the licensed ART provider may have about a potential surrogacy arrangement.

Ministerial Expert Panel recommendation 24:

That surrogacy arrangements remain unenforceable except for the current exceptions for agreed reimbursement of expenses detailed in the surrogacy arrangement and the Family Court's discretion to dispense with the consent of the surrogate.

Ministerial Expert Panel recommendation 25:

That the parentage of a person already born via an overseas surrogacy arrangement where that child has been granted citizenship by descent, has their parentage recognised by operation of law and reflected on their WA birth certificate.

That parentage can include the person who provided their gametes and their partner (if any).

This arrangement should only apply to persons born via an overseas surrogacy arrangement prior to the commencement and up to 2 years after the commencement of the new legislation.

Ministerial Expert Panel recommendation 26:

That surrogates continue to be eligible for reimbursement for actual incurred costs due to the surrogacy arrangement. Reimbursement be expanded to include reasonable travel, accommodation and childcare expenses, with particulars detailed in ART regulations. Penalties to remain where a surrogate has received money for reward or other material benefit due to the surrogacy arrangement.

Ministerial Expert Panel recommendation 27:

That proposed legislation permits licensed ART providers in WA to advertise for, and recruit, potential altruistic surrogates. Prospective intended parents and surrogates continue to be allowed to advertise their willingness to enter an altruistic surrogacy arrangement. Formal introduction through a licensed ART provider should be permitted, as should introduction of parties via informal channels, so long as the process remains altruistic and not for reward.

Part D: Regulation

Ministerial Expert Panel recommendation 28:

That proposed legislation establishes a framework for regulating and governing ART in WA. The regulatory system will:

a) set the parameters for access and eligibility to ART

b) address safety and quality in delivery of services providing ART, including reporting of adverse events

c) establish the requirements for licensing and monitoring of licensed ART providers in WA

d) establish the requirements for reporting of data and information by licensed ART providers for the RT Registers

e) allow flexibility to address regulatory stewardship and risk-based regulation

f) allow the CEO to investigate and respond to complaints related to ART

g) establish an ART Advisory and Review Board to support the Minister for Health and the CEO with their responsibilities to administer the legislation.

Under proposed legislation:

a) licensing functions will remain with the CEO, who will have the ability to delegate some responsibilities to appropriate officers within the department

b) the CEO will retain powers to investigate a breach of the legislation or participant complaints

c) the CEO will retain powers to impose conditions on licensing of WA ART providers, and may impose penalties for non-compliance and determine disciplinary action with the ability for the licensed ART provider to seek review in the State Administrative Tribunal

d) ART clinical practitioners in WA must be registered with the Australian Health Practitioner Regulation Agency (AHPRA) or be eligible for membership of their relevant professional body

e) licensing of ART providers will require that they comply with:

- relevant WA and Commonwealth legislation
- applicable standards and guidelines as defined in regulations and directions under proposed legislation, including relevant standards set by national regulators, industry codes of practice, national ethical guidelines for ART, and standards developed by the WA regulator

f) the Minister for Health and CEO may issue directives from time to time, as required.

Ministerial Expert Panel recommendation 29:

That proposed legislation establishes a WA ART Advisory and Review Board (AARB) that will:

a) provide information on its own initiative or upon request to the Minister for Health and/or CEO regarding regulation and governance of ART in WA

b) provide advice on its own initiative or upon request to the Minister for Health and/or CEO regarding trends and issues relating to the medical, social, scientific, legal and ethical/moral issues arising from ART

c) provide guidance (but not legal advice) where requested, to licensed ART providers for matters relating to a potential surrogacy arrangement, noting that under proposed legislation the AARB does not approve surrogacy arrangements and decision-making lies with the clinician(s)

d) provide guidance (but not legal advice) where licensed ART providers seek further assistance or where a clinician has concerns regarding issues beyond the eligibility criteria

e) approve applications for:

- genetic testing of embryos for conditions outside of the list of approved conditions for genetic testing
- addition of a condition to the list of approved conditions for genetic testing
- genetic testing of an embryo for tissue typing or to support mitochondrial donation techniques
- use of posthumously collected gametes or reproductive tissue for intended reproductive purposes where conditions of use are met
- posthumous use of previously stored gametes, reproductive tissue or embryos for intended reproductive purposes in the absence of written consent from a now deceased person for such posthumous use
- exceptions to the five-family limit.

For matters where approval decisions are made by the AARB, there will be a review process enabling AARB decisions to be referred to the State Administrative Tribunal.

The AARB will have the capacity to seek further specialist input for specific matters, as required. For matters relating to genetic testing of embryos, the AARB will be supported by a gene review panel that will function as an ad-hoc committee to inform the AARB on applications and matters related to genetic testing.

Ministerial Expert Panel recommendation 30:

That the Minister for Health appoint membership of the AARB for terms of 3 years with the option of one additional term. The AARB to comprise 8 members, including the Chair, being:

a) 2 suitably qualified specialist medical practitioners, at least one with significant experience in ART such as RANZCOG certification in reproductive endocrinology and infertility (CREI) or similar

b) a legal practitioner with extensive experience in family law, infertility law and surrogacy matters

c) a representative from the WA State Solicitor's Office

d) a person who has accessed ART or a person born of ART

e) an ethicist with experience in medical and social ethics

f) a counsellor eligible for full membership of the Australian and New Zealand Infertility Counsellors Association (ANZICA)

g) a WA ART regulator from the department (ex officio member).

Membership terms and operational matters for the AARB will comply with directives and instructions and policies for WA Government boards and committees.

Ministerial Expert Panel recommendation 31:

That proposed legislation allows the time for storage of gametes and embryos to be determined by a written agreement between the licensed ART provider and the person or persons for whom the gametes or embryos will be stored.

Under WA licensing requirements:

a) the storage of gametes and embryos by licensed ART providers will align with the NHMRC Ethical Guidelines on the use of ART

b) storage of gametes and embryos must be with the valid, written consent of the parties

c) consent for storage must capture decisions regarding the management and plan for:
   - embryos no longer needed by a person or persons for their own reproductive purposes
   - disputes between members of a couple for whom an embryo is stored
   - stored gametes or embryos in the event of the death of a gamete provider, including that gametes or embryos should not be stored beyond the death of the gamete provider unless there is valid, written consent for the posthumous use of the gametes or embryos by the surviving partner
   - the removal of gametes and embryos from storage.

d) licensed ART providers will be required to have clear policies relating to storage of gametes and embryos that comply with requirements of the legislation and align with the NHMRC Ethical Guidelines on the use of ART

e) should ownership of the licensed ART provider transfer to another entity, the original contract for storage must be upheld until an alternative contract is in place

f) at the end of the storage period specified in the consent form, if the person(s) responsible for the stored gametes or embryos cannot be contacted to provide further direction and consent, a licensed ART provider may after a further 2 year period (in which further attempts to contact the person(s) are made) remove the gametes or embryos from storage in accordance with the provider's policy.

Ministerial Expert Panel recommendation 32:

That proposed legislation requires licensed ART providers to ensure compliance with all regulatory requirements before accepting imported donor gametes and embryos into WA. Licensed ART providers must confirm that:

a) the gametes and/or embryos will be used only in an ART procedure, or for approved research

b) the donation is altruistic and complies with State and Commonwealth legislation which prohibits commercial trade in human gametes and embryos

c) there is compliance with the five-family limit

d) all information required for submission to the RT Registers is available as would be required had the gametes and/or embryos been donated in WA

e) the donor has received counselling to a standard equivalent to counselling provided to donors in WA

f) the donor has given informed consent prior to the donation being made.

Before exporting donated gametes and/or embryos from WA, the licensed ART provider must obtain confirmation in writing from the receiving fertility provider that:

a) information required for the RT Registers about the ART treatment(s) using the exported gametes and/or embryos will be provided to the exporting ART provider for submission to the RT Registers

b) identifying information about the recipient(s) of the gametes and/or embryos to be exported, will be provided to the exporting ART provider in order that the required information may be submitted to the RT Registers

c) the recipient(s) consent will be recorded, and the recipient(s) will be advised that their identifying information will be submitted to the RT Registers.

AARB approval is required in exceptional circumstances where the above criteria are not met. The decision of the AARB will reflect the legislative principles. Exceptions will not be considered unless there are extraordinary circumstances that will affect the wellbeing of the child(ren). Penalties will apply if licensed ART providers do not comply with all regulatory requirements.

Ministerial Expert Panel recommendation 33:

That proposed legislation will outline the conditions of licensing and registration requiring that:

a) licensed ART providers do not engage in false or misleading advertising or practices in relation to treatments or practices that may be considered experimental, do not have a sound evidence-base, or are not supported by research to improve birth outcomes

b) all participants in an ART treatment procedure must provide informed consent prior to the treatment procedure being performed and must receive appropriate written information including the rationale for any treatments offered to the person undergoing ART or to the gametes/embryos that will be used in the person's treatment

c) licensed ART providers do not provide treatments that are of unknown efficacy unless it is part of a clinical trial where ethics approval and informed consent has been granted

d) licensed ART providers do not provide treatments that are unnecessary or motivated by interests that are non-therapeutic.

If the regulator has concerns about the practice of a licensed ART provider, the CEO may commission an investigation which may involve experts within or outside of WA.

Part E: Data collection and registers

Ministerial Expert Panel recommendation 34:

That proposed legislation be drafted with flexible, but clearly defined provisions around the collection, access and use of reproductive technology data. The ability to link with other datasets, including but not limited to the WA Midwives Notification System (MNS), should be enabled. Licensed ART providers should ensure that all birth outcomes are shared with the department for inclusion on the RT Registers.

Opportunities for collecting and linking data about ART participants and children born of ART should be identified to meet the following important objectives:

a) to monitor health outcomes, including long-term health outcomes, for ART participants and persons born of ART

b) for safety, quality and assurance purposes including monitoring and compliance undertaken by the department as a regulator of ART, including the monitoring of adverse events

c) for approved research purposes.

A statutory duty will remain to record information between parties to donor conception or surrogacy to enable future matching.

Ministerial Expert Panel recommendation 35:

That proposed legislation should enable donor-conceived persons to have access to identifying information about their donor(s) when they reach 16 years of age regardless of when they were born, subject to a contact preference system and availability of records. Until the donor-conceived child has reached 16 years of age, their parent(s) should be able to access identifying information about their donor(s). To support this, the MEP recommends a broad public education and information campaign.

Ministerial Expert Panel recommendation 36:

That proposed legislation requires licensed ART providers to notify all donors whose gametes are used following commencement of the legislation, of any births resulting from their donation and provide information about the sex assigned at birth and year of birth.

Ministerial Expert Panel recommendation 37:

That proposed legislation requires licensed ART providers to keep all existing records about ART, including historical records that predate the HRT Act. Penalties should be introduced should a licensed ART provider intentionally destroy any records, particularly those relating to donor conception.

Ministerial Expert Panel recommendation 38:

That the Donor Conception Information Service (DCIS) should be expanded to support donor-conceived persons 16 years of age and over to obtain identifying information about their donor(s), regardless of when they were conceived, where information is available.

That donors will have access to identifying information regarding their donor-conceived offspring, only with the consent of that person, and where information is held. Donor-conceived persons would be supported by the service to lodge a contact preference should a donor request information about them. The DCIS should offer appropriate intermediary support and counselling when successful matching of parties has occurred. All parties to a donation should be encouraged to lodge their contact details and contact preferences with the DCIS. This will facilitate information sharing between parties, and where contact is desired by the parties and information is available, the DCIS will facilitate contact that is informed by the preferences lodged by all parties.

Ministerial Expert Panel recommendation 39:

That resources be provided to the DCIS to deliver services and introduce a public information campaign to advise all parties to donation of the proposed changes to the legislation.

Ministerial Expert Panel recommendation 40:

That the department works with the Registry of Births, Deaths and Marriages (BDM) to adapt the birth registration form to enable the recording of donor conception or surrogacy. That legislation should enable BDM to verify the details of children born from donor conception or surrogacy once the birth registration form is submitted by the parents recording the use of donor conception or surrogacy.

Ministerial Expert Panel recommendation 41:

That the *Births, Deaths and Marriages Registration Act 1998* should be amended, and the department should work with BDM, to permit addendums to be added to birth certificates for all future children born from donor conception or surrogacy once they reach 16 years of age, in the event a donor-conceived person contacts BDM for a copy of their birth certificate. Licensed ART providers should advise recipient(s) or intended parents of this approach at the time of treatment to ensure they understand that information may be disclosed to their child from 16 years of age.

The proposed legislation should expressly recognise that donor-conceived persons, and people born via surrogacy, have the right to request replacement birth certificates that reflect accurate information about both their biological and legal parentage from 16 years of age. This should be retrospective where accurate information is held and would not confer any legal obligations on the donor.

Part F: Other matters

Ministerial Expert Panel recommendation 42:

That the Minister for Health consider a request to the Commonwealth Government to explore ways to expand the Medicare Benefits Schedule (MBS) to include IVF in surrogacy arrangements. Medicare rebates should be accessible for anyone who meets the eligibility criteria for ART.

Ministerial Expert Panel recommendation 43:

That the Minister for Health and/or the CEO of the department explore further options for promoting the advantages and benefits of using a licensed ART provider when persons access donated reproductive material or services.

Ministerial Expert Panel recommendation 44:

That the Minister for Health and/or the CEO of the department explore options for increasing provision for ART services in WA, including expansion of resources for public ART treatment, and opportunities to support travel and accommodation to access ART.

Ministerial Expert Panel recommendation 45:

That proposed ART legislation allows for the provision of 'delegated practitioners', that are clinicians who can undertake some limited ART procedures in regional WA with the support, approval and supervision of a licensed ART provider, with the list of delegated practitioners expanded to include registered nurses and midwives.

Ministerial Expert Panel recommendation 46:

That the Minister for Health and/or the CEO of the department explore options to:

- provide information to Aboriginal people about fertility preservation through gender specific education campaigns aimed at protecting fertility and identifying potential infertility
- expand access to ART services for Aboriginal people
- require licensed ART providers to report the number of Aboriginal clients treated
- monitor licensed ART providers to ensure delivery of culturally safe care.

Executive summary

Purpose

The purpose of this executive summary is to provide an overview of the background and scope of the work of the Ministerial Expert Panel (MEP) on Assisted Reproductive Technology (ART) and Surrogacy Legislation. The MEP's recommendations address the specific matters identified by the Government of Western Australia (the Government) as requiring further consideration to inform the development of proposed new legislation in this area.

Background

In 2018, Associate Professor Sonia Allan was appointed by the Government to undertake an independent review of the existing legislative framework. *The Review of the Western Australian Human Reproductive Technology Act 1991 and the Surrogacy Act 2008* (Allan Review) was published in 2019 and made 122 recommendations.[4,5] In August 2021, the Government tabled its response to the Allan Review in Parliament.[6]

The Allan Review highlighted the changes since ART was first practiced in WA. Given the significant advances in science, medicine and technology, and changing societal attitudes over the past 30 years, it is imperative that the legislative and regulatory framework for ART in WA, including surrogacy, reflects contemporary standards, practice and attitudes, and is fit for purpose to best serve the needs of Western Australians.

In August 2021, the Labor Government announced it would introduce new legislation into Parliament for ART and surrogacy in WA. While the government response to the Allan Review supported many recommendations, there were a limited number of areas that the Government identified where further consideration and/or consultation was required to inform the development of proposed new legislation. Subsequently, the Minister for Health established the MEP to undertake a further targeted consultation, review new research and evaluate the impact of trends in WA and other jurisdictions, in order to make additional recommendations that would support the development of modern legislation.

The MEP, chaired by Professor Roger Hart, included people with expertise from clinical, legal, ethics and research backgrounds. Brief profiles of members of the MEP are outlined on page vi.

Scope

In establishing the MEP and setting its Terms of Reference (refer to Appendix 2), the Government recognised the extensive consultation undertaken by Associate Professor Allan during her review – including significant and broad consultation with people who have accessed or intend to access ART, licensed ART providers, and other members of the WA community.

The deliberations and targeted consultations undertaken by the MEP were to build on the work previously undertaken by Associate Professor Allan and supplement those areas identified by the Government as requiring further consideration and/or consultation. The MEP's task was to take the recommendations made in the Allan Review and supported by the Government, together with the findings from subsequent targeted consultation, including those with lived experience, and consider how new legislation could be implemented safely and appropriately in WA.

4 Sonia Allan, *The Review of the Western Australian Human Reproductive Technology Act 1991 and the Surrogacy Act 2008* (Report: Part 1) (2019).

5 Sonia Allan, *The Review of the Western Australian Human Reproductive Technology Act 1991 and the Surrogacy Act 2008* (Report: Part 2) (2019).

6 Government of Western Australia: Response to the recommendations from *The Review of the Western Australian Human Reproductive Technology Act 1991 and the Surrogacy Act 2008*, Parliament of Western Australia (August 2021).

As stated in the MEP's Terms of Reference, the role of the panel was to develop and endorse policy positions and recommendations on specific elements for new ART and surrogacy legislation, for consideration by the Government in developing instructions for drafting proposed legislation. The MEP's role did not extend to drafting the legislation itself or focusing on the detail of implementation.

Ministerial Expert Panel process and consultation

The MEP commenced work in June 2022 with a detailed review of current relevant literature, the findings of the Allan Review and the government response to the review. Additional updated research findings, evidence and information regarding trends in other jurisdictions informed subsequent panel discussion and deliberation. Structured panel meetings (sessions) were held from June to December 2022. The sessions focused on specific topics where further clarity was sought by the Government and included consideration of information and evidence from selected experts and key stakeholder groups.

The MEP undertook several consultation activities from June to November 2022, as detailed in the consultation section of this report. This included the development of a Public Discussion Paper,[7] an online Donor Conception Survey,[8] a forum for ART industry and researchers, and specific meetings with topic experts, those with lived experience and other key stakeholders.

These consultation activities were an opportunity for the MEP to hear responses to the questions for consideration in the Public Discussion Paper and online survey. These focused on the key issues where the MEP was seeking to further understand the views and opinions of relevant stakeholder groups. In all consultation activities the MEP listened carefully and respectfully to the range of perspectives that were presented, evaluating competing views that were expressed and seeking further corroborating information where this existed.

In reaching the conclusions and formulating their recommendations, the MEP considered the findings from the consultation activities, the recommendations in the Allan Review, the government response to the review, legislative reviews in other Australian jurisdictions, and information in reports from other Australian states and territories, and national and international ART regulatory agencies.

Throughout their deliberations, the MEP carefully considered the range of views and significant volume of information available to it. Where there were different perspectives to evaluate and resolve, the MEP referred to its Guiding Principles (included in the Terms of Reference noted in Appendix 2) that emphasise:

- the paramountcy of the best interests (including health, welfare and rights) of the person born as a result of ART, including surrogacy
- the health and wellbeing of those accessing ART, donors and surrogates
- principles of non-discrimination
- values of non-commercialisation of human reproductive material or human reproductive capabilities
- ensuring no exploitation of participants engaged in ART, including surrogacy.

Next steps

The recommendations of the MEP will be considered by the Government and inform the development of legislative and operational reforms for ART, including surrogacy, and research involving excess ART embryos and embryos formed by means other than fertilisation under a National Health and Medical Research Council (NHMRC) licence in WA. It is estimated that Western Australians access surrogacy in other jurisdictions and overseas in greater numbers than Australians living in other states or territories. It is expected that the proposed legislation will address this issue, for reasons explained in the section on surrogacy commencing on page 40.

7 Ministerial Expert Panel on Assisted Reproductive Technology and Surrogacy Legislation, Public Discussion Paper, Department of Health, Western Australia (2022).

8 Ministerial Expert Panel on Assisted Reproductive Technology and Surrogacy Legislation, Donor Conception Survey, Department of Health, Western Australia (2022).

Introduction

Purpose of the report

This final report presents the MEP's expert advice and policy recommendations to the Government to inform the development and implementation of legislative and operational reforms for ART, including surrogacy in WA, and permit research involving excess ART embryos and embryos formed by means other than fertilisation under a NHMRC licence in WA.

The MEP, which was established following the government response to the recommendations from the Allan Review, undertook further research and evaluation of contemporary ART practices in WA and other jurisdictions (refer to Appendix 3), and targeted consultation regarding selected key topics. This report and the MEP's recommendations to the Minister for Health are to assist with establishing a framework for development of ART legislative and operational reforms in WA that:

- reflects contemporary societal views and technological advancements in ART
- enables more Western Australians to start or expand their family using ART under laws that are inclusive and safe.

The MEP, through the lens of their expertise, integrated the recommendations from the Allan Review and the government response to the Allan Review, the views and experiences outlined by WA stakeholders and people with lived experience in targeted consultation activities, and the knowledge, insights and experience of relevant experts and industry groups, to produce this report.

It is the intention of the MEP that the recommendations will be of value to the Minister for Health in the first instance, and useful for the Government in fulfilling the commitment to introduce new, contemporary legislation for ART, including surrogacy to Parliament as a matter of priority.

For many people, the ability to form a family is bound closely with their sense of identity and values. Being unable to access ART, if that is the only way people can conceive or carry a healthy child, may be a source of significant distress and the current legislation is an impediment for Western Australians who require ART to create or expand their families, particularly those who are currently ineligible due to their sexual orientation, relationship status or gender. For people who are donor-conceived, a lack of knowledge of their biological heritage may impact their sense of personhood and an intention of the proposed legislation is to expand the options for greater information sharing.

In 1978, the first child in the world was born as a result of an IVF pregnancy. Today, the most recent national report on *Assisted reproductive technology in Australia and New Zealand 2020* indicates that 5 per cent of all Australian births involve some form of ART treatment.[9] In WA, knowledge and understanding of ART, including the health, psychological and social impact upon the individuals, donors and families, has deepened over the last few decades.

ART and surrogacy in WA are regulated through dedicated legislation, namely the HRT Act[10] and the Surrogacy Act[11]. The HRT Act is 32 years old and the Surrogacy Act is 15 years old. Since the enactment of the initial legislation much has changed in the field of ART. The past 30 years have seen major advances in science, technology and reproductive medicine, as well as changes in health regulation and the ART industry itself.

9 Newman JE, Paul RC, Chambers GM. *Assisted reproductive technology in Australia and New Zealand 2020*. Sydney: National Perinatal Epidemiology and Statistics Unit, the University of New South Wales (2022).

10 *Human Reproductive Technology Act 1991* (WA). Hereafter, HRT Act.

11 *Surrogacy Act 2008* (WA). Hereafter, Surrogacy Act.

In this interval, societal views regarding the ethical, social and legal issues considered in earlier legislation have also changed. Other legislation also regulates matters relevant to the practice of ART in WA and some recommendations in this report relate to these Acts.

Allan Review

In 2018, the WA Government initiated an independent review of the HRT Act and the Surrogacy Act. The review, undertaken by Associate Professor Sonia Allan, was completed in 2019 and recommended multiple areas where WA's existing legislation for ART and surrogacy could be modernised and streamlined so that the process of accessing ART treatment is made simpler for participants and licensed providers, and to facilitate expanded access to ART including altruistic surrogacy in WA. The Allan Review Report (published in 2 parts)[12,13] and the 122 recommendations it contains are available at: ww2.health.wa.gov.au/Review.

On 18 August 2021, the Government tabled its detailed response to the Allan Review in Parliament,[14] signaling the Government's commitment to develop new, contemporary legislation for ART and surrogacy that is fit for purpose and best serves the needs of Western Australians.

In keeping with objectives for social justice and equity, and provision of safe, high quality and accessible health services, new legislation should be inclusive and safe for participants and protect the best interests of any person(s) conceived with the assistance of ART. New legislation should reflect society's current views regarding family formation, as well as technological advances in ART, to enable more Western Australians to start or expand their family.

While the Government supported many of the Allan Review recommendations, both recommended that in several areas additional consideration or consultation should be undertaken to inform the development of proposed legislation. A targeted consultation process allows stakeholders and the public, including those with lived experiences, to further inform the Government prior to proposed legislation being drafted. It ensures that the intended legislative and regulatory framework is consistent with best practice and community expectations.

The MEP was appointed by the Minister for Health in May 2022, to give further consideration to the issues raised in the Allan Review, and undertake further targeted consultation. The MEP contains health, legal, ethics and research expertise (refer to page vi). The role of the MEP was to build on the extensive consultation already undertaken with WA stakeholders as part of the Allan Review.[15]

The Ministerial Expert Panel's role, scope and process

Consistent with its Terms of Reference (refer to Appendix 2), the MEP provides this advice to the Government to assist in the development and implementation of proposed legislation for ART and surrogacy in WA.

A role of the MEP was to consider the Allan Review recommendations and the Government's response to the review and develop policy position statements that support proposed legislation that better enables Western Australians to start or expand their families with help from ART and surrogacy.

12 Sonia Allan, *The Review of the Western Australian Human Reproductive Technology Act 1991 and the Surrogacy Act 2008* (Report: Part 1) (2019). Hereafter, Allan Review Part 1.

13 Sonia Allan, *The Review of the Western Australian Human Reproductive Technology Act 1991 and the Surrogacy Act 2008* (Report: Part 2) (2019). Hereafter, Allan Review Part 2.

14 Government of Western Australia: Response to the recommendations from *The Review of the Western Australian Human Reproductive Technology Act 1991 and the Surrogacy Act 2008*, Parliament of Western Australia (August 2021). Hereafter, Government Response to the Allan Review.

15 Allan Review Part 1, pp 10–15.

The MEP's focus was on the specific elements of ART and surrogacy identified by the Government where further consideration was required. To inform this, the MEP sought additional expert advice and undertook a targeted consultation with people with lived experience and key stakeholders as outlined in the targeted consultation section in this report. The consultations focused on key areas including:

- improving access to IVF and surrogacy for Western Australians
- ongoing compliance with other regulatory requirements in Australia
- expanding the co-regulatory model for ART regulation in WA
- establishing a new advisory/review board for ART in WA
- the role of licensing in regulating for safety and quality of ART services
- collection, storage and use of data for monitoring clinical practice(s), research and other purposes defined in proposed legislation
- access to information by donor-conceived persons, and other participants in donor conception
- expanding the recording and use of data relating to ART by the Registry of Births, Deaths and Marriages (BDM)
- consent(s) for gamete and embryo storage and use
- requirements for import and export of gametes and embryos (including for own use and donor material)
- conditions regulating transfer of gametes/embryos into and out of the state for treatments/use not permitted under WA legislation
- posthumous collection of gametes, from a person following their death, or where informed consent cannot be given
- conditions for approval for posthumous use of gametes and/or embryos from the deceased person by their partner
- genetic testing of embryos to prevent serious genetic disease, and to create human leukocyte antigen (HLA) tissue matched offspring for treatment of a relative
- modernising and streamlining the requirements for altruistic surrogacy arrangements in WA, with compliance by licensed ART providers to ensure all conditions for an intended surrogacy arrangement have been met, and outlining consequences for non-compliance including penalties
- implications for Western Australians accessing international and/or commercial surrogacy
- consideration of the development of legislation to regulate prohibited practices and any Western Australian research involving excess ART embryos and embryos formed by means other than fertilisation under a NHMRC licence in WA.

The MEP commenced work in June 2022. From June to December 2022, a series of structured panel meetings (sessions) were held that focused on the topics for which further information was sought by government. In addition, from June to November 2022 the MEP undertook several consultation activities that included the development of a Public Discussion Paper[16] which was released for public consultation, an online consultation survey relating to donor conception[17], a forum for ART industry and researchers, and specific meetings with those with lived experiences, topic experts and key stakeholders.

The consultation activities were an opportunity for the MEP to receive information and hear responses to the issues where the panel was seeking to further understand the views and opinions of relevant stakeholder groups.

16 Ministerial Expert Panel on Assisted Reproductive Technology and Surrogacy Legislation, Public Discussion Paper, Department of Health, Western Australia (2022).

17 Ministerial Expert Panel on Assisted Reproductive Technology and Surrogacy Legislation, Donor Conception Survey, Department of Health, Western Australia (2022).

Targeted consultation

ART Industry and Research Forum

A forum for ART industry practitioners and researchers was held on 19 July 2022 and attended by 36 participants, including representatives from WA licensed ART providers. The forum focused on access and eligibility to ART, contemporary models for regulation based on the best interests of persons born as a result of ART and the health and wellbeing of ART participants, and challenges in existing legislation for researchers and future potential opportunities under a new legislative framework.

The forum summary informed MEP consideration and deliberation on specific matters.

Public Discussion Paper to engage stakeholders

A Public Discussion Paper was made available on the MEP's webpage on the Department of Health website, with links emailed to 287 key stakeholders and advocacy groups, including those individuals and organisations who had previously made submissions to the Allan Review. General feedback to the discussion paper was requested with an email and postal address provided to accept submissions. The period for submissions was open for 5 weeks from July to September 2022. Forty-two responses were received: 19 from members of the public and 23 from professionals or organisations. A summary of the themes from the submissions is provided in this report (refer to Appendix 4).

Donor Conception Survey

A survey was developed specifically seeking feedback from stakeholders and those with lived experiences regarding donor conception matters. The survey sought to capture community feedback on the specific Allan Review recommendations regarding donor conception and the right for people who are donor-conceived to access information about their birth and genetic heritage. The survey was open for 5 weeks from July to September 2022 and 268 responses were received. A summary of the responses is provided in this report (refer to Appendix 5).

WA context for delivery of ART services

WA is a geographically large state covering 2.5 million square kilometers of the Australian mainland. The state's population of approximately 2.7 million[18] is heavily concentrated with some 80 per cent residing in the Perth metropolitan region and surrounds.[19] While most of the population live in the Greater Perth area, there are significant populations residing in regional areas, and people living in remote or very remote locations. The MEP recognises that many of these people are Aboriginal, and that there are cultural and economic barriers that further limit access. WA is also a culturally and linguistically diverse state with migrants and refugees accounting for approximately 24 per cent of its population.[20]

At the time of writing, all licensed ART providers based in WA were located within the Perth metropolitan area. Fertility services for WA residents are predominantly delivered in the private health sector. There is limited provision of public ART services in WA, which are delivered through the Reproductive Medicine Service at King Edward Memorial Hospital (KEMH). This service is funded to offer a limited number of IVF treatments following referral to a private licensed ART provider. The MEP notes there are different models of service in the private sector, some of which offer predominantly Medicare rebatable services.

18 Australian Bureau of Statistics. National, state and territory population, March 2022.

19 Australian Bureau of Statistics: Snapshot of Western Australia, 2021.

20 WA Department of Local Government, Sport and Cultural Industries, Office of Multicultural Interests. Western Australians from culturally and linguistically diverse backgrounds: a profile. The report mainly uses 2016 population and housing Census data from the Australian Bureau of Statistics.

In addition, a recent shift has seen movement in WA away from individually owned and operated licensed ART providers to an increasingly corporate model involving acquisition of local clinics by national and international companies providing fertility services. All companies providing licensed ART services in WA must comply with State legislation and local regulatory requirements and be licensed by the department.

Western Australia's Sustainable Health Review (2019) guides the 'direction of the WA health system to deliver patient first, innovative and financially sustainable care'.[21] The proposed ART and surrogacy legislation will need to be consistent with the stated objectives of the *Sustainable Health Review* to deliver safe, high-quality health care to all participants.

ART activity in WA

ART activity in WA has significantly increased since the introduction of the HRT Act in the early 1990s. Annual report data from the Western Australian Reproductive Technology Council (RTC) shows trends in ART activity in WA (refer to Appendix 6). Current information from the RTC Annual Report 2021–2022[22] is provided below.

Information from the RTC Annual Report 2021–2022:

- 5,833 women in WA underwent IVF – down 4 per cent on the previous year
- 8,462 treatments cycles were undertaken by licensed ART providers – down 5 per cent on the previous year (both the number of fresh and frozen embryo transfers are recorded)
- 656 intra uterine inseminations (IUI) were undertaken – using partner's sperm (71 per cent) or donor sperm (29 per cent), in these procedures
- 673 IVF recipient cycles involving sperm donation, 101 IVF recipient cycles involving oocyte donation, and 71 IVF recipient cycles involving embryo donation
- 2,183 persons undergoing ART (couples or individuals) received counselling (usually one session, and involving provision of information)
- 83 applications for preimplantation genetic testing (PGT) of embryos
- 39 public patients (seen at the KEMH clinic) were referred to 5 private licensed ART providers in Perth, and had a total of 53 treatment cycles
- 26 reported cases of severe ovarian hyperstimulation syndrome (OHSS)
- 0 mortality associated with fertility treatment.

Aggregate data from 2008 to 2022 for surrogacy applications shows that 59 surrogacy applications were approved by the RTC during this 14-year period, resulting in 24 births. According to some estimates, for every child born in WA through a locally approved surrogacy arrangement, there may be up to 26 children born of overseas surrogacy arrangements. It is estimated that Western Australians access surrogacy in other jurisdictions and overseas in greater numbers than Australians living in other states or territories (refer to Appendix 6). It is expected that the proposed legislation will address this issue, for reasons explained in the section on surrogacy beginning on page 40.

21 Sustainable Health Review: Final Report to the Western Australian Government, Department of Health, Western Australia (2019).

22 Western Australian Reproductive Technology Council. Western Australian Reproductive Technology Council Annual Report 2021–2022, Western Australian Reproductive Technology Council, Perth, Western Australia (2022).

Language and key terms

The MEP acknowledges the importance of using language both in proposed legislation and in this report that is culturally appropriate and respectful of the diversity of WA people. Various terms have been used in Australia and internationally in relation to ART and the report reflects contemporary application of these terms. The approach adopted by the MEP is to use gender-inclusive language and words and definitions that are consistent with inclusivity and respect for the diversity of the community. It is intended that proposed legislation will follow this approach.

As indicated in part A of the report, it is proposed that new ART legislation use gender-inclusive language, replacing 'woman/man' with 'person', and 'he/him' and 'she/her' with 'they/them' where this is possible. Anatomical terms will also be used where best suited to reflect modern ART practice.

The focus on women in existing legislation is not inclusive of men and people who are non-binary, intersex and transgender. It is intended that a change in the emphasis on women accessing ART and less restrictive language will also reduce the stigma of infertility being perceived as a women's issue and recognise the diversity of ways that families form.

Below are some key terms frequently used in this report. A glossary of terms is also available (refer to Appendix 1).

Key terms

Assisted Reproductive Technology

Assisted reproductive technology (ART) is a group of procedures that involve the in vitro (outside of body) handling of human oocytes (eggs) and sperm or embryos for the purposes of establishing a pregnancy. It includes a range of ART treatments and procedures, including IVF, embryo transfer (ET), gamete intra-fallopian transfer (GIFT), artificial insemination (AI), all manipulative procedures involving gametes and embryos (including storage and screening), and treatment to induce ovulation or spermatogenesis when used in conjunction with the above methods.

For the purpose of this report and the proposed legislation, the term ART includes surrogacy which is considered a form of ART.

Donor

A person who donates human reproductive material (eggs, sperm, embryos or gonadal tissue) for the purposes of an ART procedure, and/or their reproductive capabilities in a surrogacy arrangement. These procedures are undertaken with a licensed ART provider with the intention of the person not to be a parent of a child born as a consequence of the procedure. Donors can be:

- **Known donor** – this is where the donor has specified a recipient for their gametes or embryos. They could be a friend or family member of the recipient of the donation noting that some known donors may wish to have some involvement in the child's life but with no intention of being a parent of the child.
- **Unknown donor** – this is where the donor has not specified a recipient for their gametes or embryos and has altruistically donated via a licensed ART provider.

Licensed ART provider

An organisation or entity licensed by the WA Department of Health to deliver ART services in WA. This includes the storage of gametes and embryos and the practice of a range of ART treatments and procedures. Licensed ART providers are responsible for ensuring all employees or contracted staff undertaking ART treatments and procedures on behalf of their organisation are appropriately trained and registered by the Australian Health Practitioner Regulation Agency (AHPRA) or eligible for membership of their professional organisation if the profession is not registered by AHPRA.

Parent

The MEP has considered whether the term 'parent' should or can be defined. It has concluded that the term parent should be broad and inclusive.

In this regard, the MEP recognises and notes the following:

a) the High Court of Australia in *Masson v Parsons* [2019] HCA 21, noted that:

   1. Whilst the Family Law Act does not contain a definition of parent, there is no basis to suggest that term parent should mean anything other than its natural and ordinary meaning (except when and if a provision of the Family Law Act provides otherwise)
   2. Whether a person is a parent is a question of fact and degree to be determined according to the ordinary, contemporary Australian understanding of the term parent and the relevant circumstances of the specific case at hand
   3. This does not mean that the only persons who, by law, have parental responsibilities are persons who are parents according to ordinary meaning of parent (or who are otherwise defined in the Family Law Act as parents). Further, it does not mean that the only persons who may seek parenting orders are parents according to ordinary meaning of parent (or those who are otherwise defined in the Family Law Act as parents)[23]

b) the term parent may have different meanings in different factual situations

c) the social concepts of a parent and a family have changed over time, and will vary for different people

d) there is a distinction between a person who donates their reproductive material (eggs, sperm, embryos or gonadal tissue) via a licensed ART provider and who has no intention of being involved in the care and welfare of the child or having parental responsibility for the child, and a person who provides their reproductive material with the intention of being involved in the care and welfare of the child and having parental responsibility.

For these reasons, the MEP recommends that a broad and inclusive approach to the concept of who is a parent is applied.

Partner

A proposed definition of partner is included in recommendation 12:

a) the person's legal spouse irrespective of gender (other than a spouse from whom the person has separated)

b) the person's de facto partner irrespective of gender, who has lived with the first person on a genuine domestic basis for a minimum of 3 months

c) a person not currently married or living in a de facto relationship, but where there is an established relationship.

Surrogacy arrangement

An arrangement whereby a person (surrogate) agrees to carry a child on behalf of another person and their partner (if any), with the intention:

a) that a child born as a result of the pregnancy has parenting responsibilities and legal parentage transferred to the intended parent(s) (whether by court order, adoption, agreement or otherwise)

b) of transferring custody or guardianship for a child born as a result of the pregnancy to the intended parent(s).

23 High Court of Australia, Masson v Parsons [2019] HCA 21, 19 June 2019, S6/2019.

Structure to report parts A to F (recommendations)

Parts A to F of the report contain the MEP's recommendations for proposed legislation relating to ART in WA. In reaching its conclusions and formulating the recommendations, the MEP considered the recommendations in the Allan Review, the government response to the Allan Review, the findings from the targeted consultation activities, legislative reviews in other Australian jurisdictions, research and information in published reports, and from national and international ART regulatory agencies.

Throughout their deliberations, the MEP carefully considered the range of views and significant volume of information available to it. Where there were different perspectives to evaluate and resolve, the MEP referred to the Guiding Principles in its Terms of Reference set out by the Minister for Health (refer to Appendix 2).

Part A: Proposed legislation for regulation of ART practice

Structure of proposed ART legislation in WA

The Allan Review recommends that existing WA legislation, namely the HRT Act and the Surrogacy Act and subsidiary instruments (regulations and directions), be revised and/or repealed to create a modern legislative framework for the regulation of ART and surrogacy in WA that sets the parameters for ART eligibility, access and practice.[24]

These recommendations were supported by the Government in its response noting that further work would be required to inform the drafting of new legislation. This project provides an opportunity to deliver a modern regulatory framework that is responsive and streamlined while protecting the best interests of any person(s) who might be born as a result of ART, the health and wellbeing of ART participants, and the public.

The MEP supports repeal of the HRT Act and Surrogacy Act; and for new ART legislation to be inclusive, remove barriers to access, and meet contemporary standards for ART practice and regulation.

In considering the structure of proposed ART legislation, the MEP recommends that legislation for ART and surrogacy in WA be consolidated in a single piece of legislation instead of continuing to have 2 separate Acts. This reflects that while there are specific considerations relating to surrogacy, it is intrinsically linked to, and comes under the umbrella of ART, together with IVF and donor treatments.

It is recommended that the title of the proposed Act should be the Assisted Reproductive Technology and Surrogacy Act (ARTS Act).

Amendments to WA legislation

The MEP recognises that new ART legislation will impact on and require amendments to other existing WA legislation.

While not specifically addressed in the Allan Review, the MEP recommends that the *Artificial Conception Act 1985* (AC Act)[25] be repealed, and any remaining relevant provisions be included in the proposed legislation.

24 Allan Review Part 1, Recommendations 1 to 13.

25 *Artificial Conception Act 1985* (WA).

The AC Act is a short 7 section Act that relates to 'the status of persons conceived by artificial means' and consequential rules/assumptions regarding parentage. Without repeal of the AC Act many of the recommendations in this report could not be implemented, particularly principle 1 that the best interests of persons born as a result of ART are paramount (see recommendation 5). The MEP's concerns regarding the AC Act include:

- the effect of ss 6 and 7(2) of the AC Act is that any man in WA (other than the husband/partner of a woman undergoing an artificial fertilisation procedure) whose sperm is used in an artificial conception procedure, is deemed not to be the father of any child born regardless of the intention of that man or woman
- by contrast, s 6A provides that 2 women in a same-sex relationship shall be conclusively presumed to be the parents of any child born via an artificial conception procedure. The parentage presumption in favour of the children of same-sex female couples and the parentage presumption against the children of same-sex male couples is illogical, discriminatory, and contrary to the principles outlined in recommendation 5
- the AC Act is outdated regarding language and the recognition of same-sex marriage
- the AC Act's provisions fail to address surrogacy applications for parentage and do not permit appropriate parentage for reciprocal IVF (see recommendation 18).

Repealing the HRT Act, Surrogacy Act and AC Act and replacing with a single piece of legislation in WA addressing ART treatment and practice, including surrogacy, will ensure consistency in the application of the principles relating to ART and establish a cohesive framework for the subsequent operation of the proposed legislation.

When considering who is a parent in proposed legislation, the MEP reflected that persons seeking to conceive a child who do not access a licensed ART provider (e.g. those who use unregulated sperm suppliers) will not be covered by the proposed ART legislation, and any determination regarding who is a parent in these cases will be made by the Family Court of WA. This is further considered in the surrogacy and supply of gametes outside of licensed ART providers sections of this report.

Consideration should also be given to any necessary consequential amendments of other legislation, including but not limited to the following Acts:

- *Administration Act 1903*
- *Acts Amendment (Prohibition of Human Cloning and Other Practices) Act 2004*
- *Births, Deaths, and Marriages Registration Act 1998*
- *Criminal Code Act 1913*
- *Family Court Act 1997*
- *Family Provision Act 1972*
- *Guardianship and Administration Act 1990*
- *Health (Miscellaneous Provisions) Act 1911*
- *Health Services Act 2016*
- *Human Tissue and Transplant Act 1982*
- *Interpretation Act 1984*
- *Private Hospitals and Health Services Act 1927*
- *Public Health Act 2016.*

Ministerial Expert Panel recommendation 1:

That the *Human Reproductive Technology Act 1991* (HRT Act), the *Surrogacy Act 2008* (Surrogacy Act) and the *Artificial Conception Act 1985* (AC Act) be repealed and replaced with a single Act combining the treatment and practice of ART and surrogacy. The title of the proposed legislation should be the Assisted Reproductive Technology and Surrogacy (ARTS) Act.

Policy intent for recommendation 1: A single ARTS Act incorporating ART treatment and practice and surrogacy would recognise the intrinsic link between surrogacy and wider ART procedures and establish a cohesive and focused framework for subsequent regulation. Repeal of the AC Act is recommended to ensure alignment regarding who is considered a parent in proposed legislation, and to broaden the rules relating to parentage to be more inclusive and respectful of currently accepted family configurations.

There will be necessary consequential amendments to other WA Acts following the drafting of new ART and surrogacy legislation.

The MEP acknowledges that repealing the existing HRT Act will necessitate addressing elements included in this Act that cover prohibition of human cloning for reproduction and other prohibited practices, and research involving excess ART embryos and embryos formed by means other than fertilisation under a NHMRC licence in WA. It is recommended that these matters be addressed in a second, separate Act. Further details regarding the proposed legislation for research using excess ART embryos and embryos formed by means other than fertilisation under a NHMRC licence in WA and prohibited practices is specifically addressed in part B of this report.

Ministerial Expert Panel recommendation 2:

That a second, separate Act is required to regulate research involving excess ART embryos and embryos formed by means other than fertilisation under a NHMRC licence in WA, and the continued prohibition of human cloning for reproduction and other prohibited practices.

Policy intent for recommendation 2: A separate Act for research involving excess ART embryos and embryos formed by means other than fertilisation under a NHMRC licence in WA, and prohibition of human cloning for reproduction would:

- support WA's commitment at the national level to enact uniform legislation for these matters
- would align WA with other states and territories.

Objectives of proposed ARTS Act

Proposed ART legislation in WA should continue to regulate the ART industry and reflect the changing context of medical, ethical, social and commercial challenges, to protect the best interests of persons born as a result of ART, persons accessing ART, and those donating reproductive material or capabilities.

The MEP recommends that the proposed ARTS Act contain objectives to inform the intent and purpose of the legislation. These can be included in the preamble or purpose section of the Act and can be used to facilitate understanding of the legislation as a whole and assist with interpretation.

Further details regarding the policy intent and proposed regulatory framework for ART in WA are included in parts C, D and E of the report.

Ministerial Expert Panel recommendation 3:

That proposed legislation:

a) regulate the WA ART industry and reflect the changing context of medical, ethical, social and commercial challenges, to protect the best interests of persons born as a result of ART, individuals and their partners (if any) accessing ART, and those donating reproductive material or capabilities

b) outline the roles and responsibilities of regulators and licensed ART providers, including reporting requirements

c) establish an advisory and review board for specific ART matters.

Policy intent for recommendation 3: To ensure there is greater clarity regarding roles and responsibilities of parties to the legislation, including:

- the Chief Executive Officer (CEO) of the department with responsibilities for licensing ART providers, and managing collection and use of data
- the proposed new ART Advisory and Review Board (AARB) with responsibilities for approving a limited number of specified ART activities
- licensed ART providers, who have responsibilities in delivering ART and reporting to the department.

The legislative framework will regulate activities and specific prohibitions, eligibility and requirements for access to ART treatment, appeal processes, reporting of procedures and outcomes of treatment, and management and intended use of data collected.

Ministerial Expert Panel recommendation 4:

That proposed legislation includes objectives to inform the intent and purpose of the legislation. The following objectives be adopted in the proposed legislation to:

a) regulate the use of ART by licensed ART providers to deliver best clinical practice and decision-making that meet industry standards and safety and quality outcomes defined by the regulator

b) regulate collection of participant and treatment data, and access to information about ART treatments and procedures carried out under the Act

c) provide for the keeping of the Reproductive Technology Registers (RT Registers), and any other data collections related to the Act

d) enable participant information relating to donor conception and surrogacy to be recorded for the purpose of sharing this with persons entitled to access the information under the legislation

e) facilitate research into the incidence, causes and prevention of infertility, and the impact of treatments on the health outcomes of ART participants

f) establish the ART Advisory and Review Board (AARB) to provide advice and support governance and oversight of ART in WA.

Policy intent for recommendation 4: The objectives provide a framework for activities regulated under the ARTS Act.

Principles for proposed ART legislation

The proposed legislation for ART should contain the following principles to provide a statement of intent for inclusion in the legislation and to help guide the actions of providers and regulators carrying out activities and functions under the ARTS Act. The recommended principles reinforce the overarching values for proposed legislation that emphasise the paramountcy of the best interests (including health, welfare and rights) of any person to be born as a result of ART, the health, safety and wellbeing of those accessing ART, donors and surrogates, the principles of non-discrimination, the values of non-commercialisation of human reproductive material or human reproductive capabilities, and ensuring no exploitation of participants engaged in ART.

Ministerial Expert Panel recommendation 5:

That proposed legislation contain principles developed by the MEP to guide the interpretation and administration of the Act and how activities to be regulated by the Act are conducted. Principles to be included in the proposed legislation:

a) the best interests (including health, safety, welfare and rights) of persons to be born or born as a result of ART are paramount

b) the health, safety and wellbeing, including physical, emotional and mental health, of persons accessing ART, their partner (if any), donors and surrogates must be protected

c) all persons accessing ART must provide informed consent prior to a treatment or procedure being performed

d) persons accessing ART must not be unlawfully discriminated against on grounds which include but are not limited to their sexual orientation, relationship status, gender identity, disability, race or religion

e) trade in the reproductive capabilities of persons and the exploitation of people including children for commercial ends raise health and ethical concerns

f) persons born as the result of the use of donated gametes have a right to information about their genetic heritage and biological parents

g) the provision of ART must be transparent and open to scrutiny, while ensuring the protection of the privacy of all persons and their partner (if any) involved in ART, and persons born, to the degree that is protected by law

h) licensed ART providers must provide safe, person-centred services and foster continuous improvement in the safety and quality of treatment procedures they provide

i) the provision of ART must be underpinned by policies that support effective and efficient practices that minimise interventions not supported by evidence of successful clinical outcomes.

Policy intent for recommendation 5: The proposed ARTS Act should contain principles to provide a statement of the intent of the legislation, and to help guide the actions of providers and regulators carrying out their activities and functions.

Commencement and review for proposed ART legislation

The MEP is acutely aware that WA has failed to amend its ART and surrogacy legislation to ensure consistency with the *Sex Discrimination Act 1984* (Cth) and alignment with the principles of the *Equal Opportunity Act 1984* (WA). For this reason, the MEP recommends that the sections of the proposed legislation which amend eligibility criteria and other associated matters involving access to ART and surrogacy be implemented as soon as possible after passage of the proposed legislation.

The MEP recognises that many elements of the proposed legislation will require licensed ART providers to educate staff and make the necessary changes to their policies, documentation, risk management systems and other processes, in order to make operational the proposed licensing approach and framework. The MEP recommends that, apart from the sections of the proposed legislation which amend eligibility criteria and other associated matters involving access to ART and surrogacy, the new legislation be implemented a minimum of 6 months after the commencement of the Act. This will ensure a safe, smooth and effective transition to the new licensing approach and framework. During this time the department will need to provide stewardship of the process including support for licensed ART providers in the form of education and guidance.

The MEP supports inclusion of a provision for regular review to ensure ART legislation remains contemporary and operates in a manner that is responsive to changes in science, technology, medical practice and societal views. It is important that the regulatory approach remains flexible and in line with best practice. The MEP recommends that new legislation be initially reviewed 3 years from the date of enactment and every 5 years thereafter.

Ministerial Expert Panel recommendation 6:

That the sections of the proposed legislation which address eligibility criteria and other associated matters involving access to ART and surrogacy be made effective as soon as possible after commencement of the proposed legislation.

That there be a minimum 6-month period between commencement of the ARTS Act and implementation of the proposed legislation for other aspects of the legislation.

Policy intent for recommendation 6: To ensure there is sufficient time to inform licensed ART providers and people intending to use ART services, and to develop a licensing framework and protocols to ensure the legislation is translated safely, effectively and appropriately for WA. However, changes to eligibility criteria and other associated matters involving access to ART and surrogacy should apply as soon as possible. Other parts of proposed legislation will require a longer period of time to ensure data collection, a framework for licensing of fertility providers and integration of consequent amendments with other Acts.

Ministerial Expert Panel recommendation 7:

That proposed legislation be reviewed 3 years after the date the Act (or review provision) comes into operation and every 5 years thereafter.

Policy intent for recommendation 7: To ensure that the legislation remains contemporary and in line with science, technology, medical practices and societal views.

Part B: Legislation for research involving excess ART embryos and prohibition of human cloning for reproduction

National framework for regulation

In Australia, legislation at the Commonwealth level establishes a national regulatory framework to:

1. prohibit certain unacceptable practices including human cloning for reproduction
2. regulate uses of human embryos, including excess embryos created through ART and embryos created through processes other than fertilisation, subject to a licensing system.

The national framework for regulation was established through agreement in April 2002 by the then Council of Australian Governments (COAG) to develop nationally consistent legislation to regulate human embryo research and ban human cloning and other unacceptable practices.

The Commonwealth's *Research Involving Human Embryos Act 2002* (RIHE Act)[26] and the *Prohibition of Human Cloning Act 2002* were passed by the Australian Parliament in December 2002. The Commonwealth legislation was developed in response to community concerns, including ethical concerns, about scientific developments in relation to human reproduction and the use of human embryos.

Following an independent review of the operation of the Acts (Lockhart Review) in 2006, the Commonwealth legislation was amended to expand the range of research activities involving embryos that may be licensed under the legislation, and the *Prohibition of Human Cloning Act 2002* was renamed the *Prohibition of Human Cloning for Reproduction Act 2002* (PHCR Act).[27] The amended legislation recognised scientific developments enabling the creation of embryos via means other than fertilisation of a human egg by human sperm (such as somatic cell nuclear transfer (SCNT)) and the need to capture permitted use, and prohibitions on use, of such embryos under the national regulatory framework.

The RIHE Act requires that research on certain human embryos may only be conducted under a licence issued by the NHMRC Embryo Research Licensing Committee.[28] The NHMRC Licensing Committee must be satisfied that the research proposal has been assessed and approved by a Human Research Ethics Committee acting in accordance with the NHMRC *National Statement on Ethical Conduct in Human Research 2007*[29] and the NHMRC *Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research 2017* (NHMRC Ethical Guidelines on use of ART).[30]

26 *Research Involving Human Embryos Act 2002* (Cth).

27 *Prohibition of Human Cloning for Reproduction Act 2002* (Cth).

28 NHMRC Embryo Research Licensing Committee.

29 NHMRC National Statement on Ethical Conduct in Human Research 2007 (updated 2018).

30 NHMRC Ethical Guidelines on the use of Assisted Reproductive Technology in Clinical Practice and Research (2017), hereafter NHMRC Ethical Guidelines on the use of ART (2017).

Existing WA legislation

In 2004, the HRT Act was amended to incorporate a new part 4A (prohibited practices) and part 4B (regulation of certain uses involving excess ART embryos) that mirrored the original Commonwealth Acts. The WA and Commonwealth legislation remained consistent until amendments to the Commonwealth Acts in 2006.

In 2007, the WA Government sought to amend the HRT Act to include the amendments made to the Commonwealth Acts, so that WA legislation would remain consistent with the Commonwealth legislation. The *Human Reproductive Technology Amendment Bill 2007* (the Bill)[31] was intended to achieve this corresponding legislation. The Bill contained 3 significant provisions relating to NHMRC licensing of research. These included strict regulation relating to:

- the donation for research of embryos created for ART treatment which were excess to the needs of the people for whom they were created
- the creation of embryos by means other than fertilisation of a human egg by human sperm and the use of those embryos for research and not for reproductive purposes
- retaining the ban on human cloning for reproductive purposes and other prohibited practices.

The Bill was defeated in Parliament in 2008. Debate on the Bill in the Upper House included discussion of induced pluripotent stem cells being generated from skin cells. Opponents to the Bill (which was the subject of a conscience vote) indicated there was no ongoing justification for the amendments, on the basis that these skin-based stem cells were likely to have the same qualities as human embryonic stem cells. Members at the time asserted that research on human embryos could continue if the Bill was defeated.[32] This assumption proved to be wrong and the status of the HRT Act as a 'corresponding state law' was revoked on 12 June 2007. Since that time, the NHMRC Licensing Committee has not been able to grant a licence for embryo research under the HRT Act and research on human embryos that would require an NHMRC licence has not been permitted in WA.

The Allan Review noted that:

- as a result of the defeat of the 2007 Bill, WA legislation is now inconsistent with the Commonwealth and with all other states and the Australian Capital Territory
- because WA legislation is inconsistent to that of the Commonwealth, there is legal uncertainty regarding the authority of the NHMRC to licence and monitor research on excess ART embryos in WA. In particular:
  - under the HRT Act the licensing scheme for research on excess ART embryos in WA relies on the Commonwealth agreeing to undertake the licensing function, through the NHMRC Licensing Committee
- as the declaration of the HRT Act as a corresponding state law was revoked in June 2007 following amendments to the Commonwealth Acts in 2006, the relevant section of the RIHE Act (section 43) does not apply. There is no authority for the WA law to confer powers on Commonwealth officers and the NHMRC Licensing Committee. The Licensing Committee cannot grant a licence for embryo research under the HRT Act
- there is also no authority for the Chair of the NHMRC Licensing Committee to appoint officers to inspect and monitor embryo research in WA
- the consequence of this is that currently no embryo research in WA can be licensed under the HRT Act, including that which was previously permitted under the 2004 amendments to the Act.[33]

31 *Human Reproductive Technology Amendment Bill 2007* (WA).

32 Parliament of Western Australia, Parliamentary Debate Hansard, 6 May 2008, Human Reproductive Technology Amendment Bill 2007 [Second Reading].

33 Allan Review Part 1, p 260.

The Allan Review further noted that:

- the defeat of the 2007 Bill has not only prevented embryonic stem cell research, it has also stopped all research on human embryos in WA that would require a NHMRC licence including research involving new and emerging technologies
- the WA Chief Scientist had expressed concern regarding the status of embryo research in WA and called for Parliament to reconsider legislation to allow the cloning of human embryos for medical research, to help find cures for life-threatening diseases
- there is concern that WA scientists may consider relocating away from WA to access greater opportunities and fear that WA has fallen behind the international research community.[34]

The *Mitochondrial Donation Law Reform (Maeve's Law) Bill 2021*[35] was passed by the Australian Parliament in March 2022 and amends relevant Commonwealth Acts including the PHCR Act and RIHE Act and associated regulations to make mitochondrial donation legal for research, training and human reproductive purposes. The overall aim is for persons at risk of passing on mitochondrial disease to have reproductive options for biological children without the increased risk of their child having mitochondrial disease.

The intended approach for the introduction of mitochondrial donation in Australia involves a 2 staged approach with licences for initial stages one to 3 (pre-clinical and clinical trial research, training and activity) being issued, administered and regulated by the NHMRC Embryo Research Licensing Committee. The MEP notes that inability to be licensed under the NHMRC licensing scheme precludes WA centres from potentially participating in this activity.

Proposed legislation

These matters continue to require inclusion in the legislative framework for ART in WA to ensure ongoing regulation and oversight.

Consistent with the Allan Review recommendation and government response, the MEP recommends that WA should enact uniform legislation to the Commonwealth RIHE Act and the PHCR Act. This facilitates adoption in WA of a uniform Australian approach to banning human cloning for reproduction and other unacceptable practices (prohibitions) and allowing certain uses of excess ART embryos and embryos formed by means other than fertilisation under strict regulation and licence.

To address prohibited practices and research involving excess ART embryos and embryos formed by means other than fertilisation under a NHMRC licence in proposed legislation, the MEP recommends that a second, separate piece of legislation be created that accompanies the proposed primary ARTS Act.

In drafting proposed legislation, consideration should be given to the most effective way to provide robust statutory regulation while recognising the rapid pace with which science, medicine and technology can develop and the significant improvements to health and wellbeing which such developments may bring.

34 Allan Review Part 1, p 260.

35 *Mitochondrial Donation Law Reform (Maeve's Law) Bill 2021* (Cth).

Ministerial Expert Panel recommendation 8:

That there be a single piece of WA legislation to align with the 2 Commonwealth Acts, namely the *Research Involving Human Embryos Act 2002* (Cth) (RIHE Act) and the *Prohibition of Human Cloning for Reproduction Act 2002* (Cth) (PHCR Act). This legislation would be separate to the proposed legislation addressing ART treatment and practice in WA.

Legislation regulating research involving excess ART embryos and embryos formed by means other than fertilisation under a NHMRC licence in WA, and prohibition of human cloning for reproduction and other prohibited practices, would commence at the same time as the proposed legislation for ART practice.

Policy intent for recommendation 8: Proposed legislation aligning with the relevant Commonwealth legislation will enable research involving excess ART embryos and embryos formed by means other than fertilisation under the NHMRC licensing and approvals framework in WA, and enable alignment with the nationally consistent approach for prohibition of human cloning for reproduction and other prohibited practices.

Ministerial Expert Panel recommendation 9:

That proposed legislation regarding research involving excess ART embryos and embryos formed by means other than fertilisation under a NHMRC licence should be constructed in a manner that allows for flexibility, responsiveness, and regular review in anticipation of further advances in science, medicine and emerging technologies in ART treatment and practice.

Policy intent for recommendation 9: To ensure WA residents are not disadvantaged by restrictive legislation that prevents their participation in and access to nationally approved, evidence-based ART treatments and practices, and that WA researchers are not prevented from participating in approved research activity under the national framework.

Part C: Access to ART

Eligibility criteria

The Allan Review highlighted that amendments to the HRT Act and Surrogacy Act are required as a matter of priority to remove provisions in the existing legislation that prevent access to ART or surrogacy on the basis of sex, relationship status, gender identity, intersex status, or sexual orientation.[36] The government response to the review supported this action.[37]

New legislation for ART in WA should be consistent with the *Sex Discrimination Act 1984* (Cth)[38] and align with the principles of the *Equal Opportunity Act 1984* (WA)[39].

The MEP supports this approach and recommends that under new legislation eligibility for ART treatment and procedures, including surrogacy and reciprocal IVF, is expanded to everyone (regardless of sex, relationship status, gender identity, intersex status or sexual orientation) who meet the following eligibility criteria:

a) the person and partner (if any) are unlikely to conceive other than by an ART procedure

b) the person and partner (if any) are unlikely to be able to carry a pregnancy to term or give birth to a healthy child without an ART procedure

c) the person and partner (if any) is at risk of transmitting a genetic condition to a child born as a result of a pregnancy conceived other than by an ART procedure, including a genetic condition for which the person or their partner (if any) is the carrier

d) where the treating clinician has assessed the person and believes that ART is appropriate having regard to all current and future physical, psychological and social circumstances.

This recommendation would remove discriminatory barriers to access and outdated provisions from the legislation. The proposed criteria would expand ART access to single men, same-sex partnerships, transgender, non-binary and intersex people, and allow them to access ART procedures under the same criteria as single women and opposite sex couples.

The MEP recommends that reciprocal IVF be included in the eligibility criteria (refer to recommendation 18) permitting one person in a partnership to contribute their oocyte (egg) in order to create an embryo that will be carried to term by their partner. This is further detailed in the reciprocal IVF section in part C of this report.

The MEP further recommends that the proposed ART legislation use gender-inclusive language, replacing 'woman/man' with 'person', and 'he/him' and 'she/her' with 'they/them' where this is possible. Anatomical terms will also be used where best suited and would better reflect modern ART practice.

36 Allan Review Part 2, Recommendations 1 to 6.

37 Government Response to the Allan Review.

38 *Sex Discrimination Act 1984* (Cth).

39 *Equal Opportunity Act 1984* (WA).

Ministerial Expert Panel recommendation 10:

That proposed legislation enable access to ART, including surrogacy and reciprocal IVF, for any person and partner (if any) who meets the following eligibility criteria:

a) the person and partner (if any) are unlikely to conceive other than by an ART procedure

b) the person and partner (if any) are unlikely to be able to carry a pregnancy to term or give birth to a healthy child without an ART procedure

c) the person and partner (if any) is at risk of transmitting a genetic condition or genetic disease to a child born as a result of a pregnancy conceived other than by an ART procedure, including a genetic abnormality or genetic disease when the person or their partner (if any) is the carrier

d) where the treating clinician has assessed the person and believes that ART is appropriate having regard to all current and future physical, psychological and social circumstances.

Policy intent for recommendation 10: To ensure that ART procedures are available to persons who require ART intervention in order to become a parent or expand their family including single persons (irrespective of gender) and partners (irrespective of gender) who intend to conceive and raise a child together. This includes reciprocal IVF which will permit one person to contribute their oocyte (egg) in order to create an embryo that will be carried to term by their partner (refer to Ministerial Expert Panel recommendation 18).

Ministerial Expert Panel recommendation 11:

That proposed legislation use gender-inclusive language and refer to 'person' and 'they/them' instead of 'woman/man' and 'he/she', and use anatomical language where this is appropriate.

Policy intent for recommendation 11: To promote inclusivity of people in same-sex relationships and avoid transgender, non-binary or intersex participants being inadvertently excluded from ART procedures due to restrictive language in new legislation.

Age

Section 23 of the HRT Act states that IVF cannot be carried out where the reason for infertility is due to the participant's age.[40] The eligibility criteria for proposed legislation should exclude any reference to age to ensure that discrimination on the grounds of age is avoided. The exception would be in relation to participants in a surrogacy arrangement who would be required to have attained the age of 18 years. This is further detailed in the surrogacy section in part C of this report.

The NHMRC Ethical Guidelines on the use of ART state that there must be no unlawful or unreasonable discrimination on the basis of age. However, the guidelines also state that:

40 HRT Act s 23.

> where the choice of an individual or a couple is in conflict with current clinical evidence and practice, is likely to have an adverse effect on the person who would be born, or has demonstrable adverse social impacts (e.g. the transfer of multiple embryos at the one time), then it is appropriate that these factors are taken into account in decision-making regarding the procedure. There are circumstances where it is reasonable for a clinician to delay treatment or decline to treat an individual or couple.[41]

The MEP supports the principle that provision of treatment should be a clinical decision and may involve a multidisciplinary team. The decision to treat a person, and the treatment(s) offered must be consistent with the expectations of good medical practice and appropriate evidence-based standards of clinical care. Under proposed legislation, provision of fertility treatment would continue to require licensed ART providers to support decision-making by clinicians with a framework and tools to enable effective care. As part of its licensing provisions, licensed ART providers should have appropriate clinical policies and treatment guidelines that are evidence-based and clinically safe for participants and the child to be born. Evidence that staff are aware of these guidelines and that they are being followed to ensure patient safety will be part of the licensing review.

In line with the intended principles for new legislation, the paramount consideration is the best interests of the person to be born. The MEP notes that this extends to considering circumstances relating to the risks of genetic 'damage' associated with older gametes and obstetric and medical risk to the person carrying a pregnancy, as well as the capacity of prospective participants to be available to effectively parent a child.

Where it is reasonable for a clinician to delay or decline to offer treatment to a person and their partner (if any), the basis for such a decision should be explained. Clinicians are not compelled to offer treatment.

Licensed ART providers providing ART treatments and services must have relevant written patient information available evaluating the success rates for treatments being offered by that clinic. This will enable persons seeking or accessing treatment to realistically understand the likely outcome of treatment based on the clinic's information for a matched cohort.

Licensed ART provider staff must consider and record the rationale for offering a service to a person or persons who they believe are likely to have a low or very low success rate of treatment.

Definition of partner

The HRT Act and the Surrogacy Act both use the terms spouse and de facto partner in reference to circumstances where members of a couple are seeking to access ART treatment. Neither term is defined in the Acts, or regulations or directions under the Acts.

To assist with clarity of interpretation and application of the Act, it is recommended that the proposed ART legislation exclusively use the term partner, with no assumption made about whether a person has a partner (as captured in the phrase 'partner (if any)' used in this report). The MEP recommends that the proposed legislation should define partner in the following terms as either:

a) the person's legal spouse irrespective of gender (other than a spouse from whom the person has separated)

b) the person's de facto partner irrespective of gender, who has lived with the first person on a genuine domestic basis for a minimum of 3 months

c) a person not currently married or living in a de facto relationship, but where there is an established relationship.

For the posthumous use of gametes or embryos, the proposed AARB would have the authority to approve use for couples who were in a de facto partnership for less than 3 months where there is sufficient evidence that the deceased wanted to have children with the surviving partner. The role and function of the AARB is further outlined in part D of this report.

41 NHMRC Ethical guidelines on the use of ART (2017), Part B, 3.7 p 26.

Ministerial Expert Panel recommendation 12:

That proposed legislation exclusively use the term partner in reference to members of a couple who are seeking access to ART, with the term defined in the legislation as either:

a) the person's legal spouse irrespective of gender (other than a spouse from whom the person has separated)

b) the person's de facto partner irrespective of gender, who has lived with the first person on a genuine domestic basis for a minimum of 3 months

c) a person not currently married or living in a de facto relationship, but where there is an established relationship.

Policy intent for recommendation 12: To clarify the definition of partner in the Act, and to acknowledge the range of relationships now either recognised in Australian law, or where there is proof of a committed relationship that has been of an ongoing duration.

Consent

Provision of informed consent by a person capable of making the decision is crucial to the delivery of appropriate, person-centred ART treatment and care. This is recognised by the inclusion of informed consent as a principle for proposed ART legislation in WA.

MEP deliberations emphasised that participants, including a person's partner (if any), involved in an ART treatment or procedure must provide informed consent prior to the treatment or procedure being carried out. The MEP acknowledges the parties potentially involved in ART include the person undergoing the ART treatment or procedure, the person's partner (if any), the donor(s) and surrogate. In recognition of the principle of bodily autonomy, the MEP's view is that consent of a surrogate's partner should not be required. However, the NHMRC Ethical Guidelines on the use of ART recommend that if the surrogate has a partner, counselling should address the benefits of open discussion regarding the potential impact of the decision on the partner, the couple's relationship and/or the family unit.[42] The MEP endorses this recommendation.

Information to support informed consent should be tailored to the specific ART treatment or procedure, and the person's involvement in the process. In considering capacity for decision-making, the MEP notes that:

- it is presumed that an adult is able to make decisions unless there is evidence to the contrary
- there are existing legal presumptions in WA about a person's capacity for decision-making (*Guardianship and Administration Act 1990* and *Mental Health Act 2014,* refer to Appendix 7)
- for a decision to be valid it must be:
    1. made by a person with capacity
    2. specific to the ART treatment or procedure
    3. properly informed
    4. voluntary
    5. current.

42 NHMRC Ethical Guidelines on the use of ART (2017), 8.10.3, p 67.

Capacity of a person to provide informed consent will be determined by the treating ART clinician. Under proposed legislation, licensing provisions should mandate that licensed ART providers have policies requiring valid informed consent to be obtained prior to a treatment or procedure being performed, and that there is a written record documenting a person's consent that is appropriately stored and maintained.

Where a person has provided gametes for use by their partner in an ART treatment or procedure, consent must capture the decision of both partners regarding management of the gametes, and any embryos created using the gametes, in the event of separation of the partners or the death of one of the partners.

Requirements relating to consent are also included in sections of this report discussing specific ART treatments, procedures and processes. The Fertility Society of Australia and New Zealand's Reproductive Technology Accreditation Committee (RTAC) Code of Practice outlines the requirements for consent, which is included at Appendix 8.

Donor conception

The MEP considered a range of matters related to donor conception. Recommendations regarding streamlining the current process for known donation and retaining the limit on number of families created using donor gametes from a single donor are included in this section of the report. For discussion on access to identifying information relating to donor conception, please refer to part E of the report.

Implications counselling for donors and donation recipients

Under current legislation, donors and recipients are required to undertake implications counselling. The MEP recommends that this requirement continue under proposed legislation. Consistent with existing HRT legislation, an appropriately qualified counsellor will be a person who is eligible for full membership of the Australian and New Zealand Infertility Counsellors Association (ANZICA) (or overseas equivalent).[43]

The MEP's view is that implications counselling is required prior to the donor and recipient providing written valid consent to proceed. Implications counselling must ensure, amongst other things, that the donor and recipient are advised that the donor's identifying information will be accessible by the recipient parent(s) from the registration of the child's birth, and by the donor-conceived person from the time they have reached 16 years of age.

The NHMRC Ethical Guidelines on the use of ART recommend where a potential donor has a partner, that licensed ART providers should encourage the potential donor to include their partner in the discussions about their donation, acknowledging the benefits of open disclosure and the potential impact of the decision on the partner, the couple's relationship and/or the family unit.[44]

Gamete screening in known donation

For known donation, best medical practice requires gamete and medical screening for management of infection risk and screening for a number of genetic disorders. This process generally takes 3 months. The MEP recommends that this screening period runs concurrently with the implications counselling for donors and recipients. The MEP notes that in the case of unknown donors, screening will have already been completed.

43 Human Reproductive Technology Directions 2021 (WA), p 37.

44 NHMRC Ethical Guidelines on the use of ART (2017), 4.2.5, p 33.

Decision not to proceed

At any stage during the period when screening of gamete(s) or implications counselling is being undertaken, any party to the ART arrangement may choose not to proceed with the process and may withdraw their consent to ongoing participation or use of their gametes. However, once an embryo has been created the donor cannot withdraw consent for use of the embryo. For example, an intended surrogate whose own egg has been donated to create the embryo may decide not to proceed as the surrogate, but the determination about the future use of the embryo(s) created rests with the person(s) for whom the embryo(s) were created.

Ministerial Expert Panel recommendation 13:

That proposed legislation will require:

a) implications counselling for the donor and recipient(s) by an Australian and New Zealand Infertility Counsellors Association (ANZICA) eligible counsellor (or overseas equivalent) prior to the donor and recipient(s) providing written valid consent to proceed

b) the gamete and medical screening period run concurrently with the implications counselling for known donors and recipients

c) at any stage during the period for gamete screening or implications counselling, any party to the ART arrangement may choose not to proceed with the process.

Policy intent for recommendation 13: The MEP's view is that donors and recipient(s) should continue to undertake implications counselling by an appropriately qualified counsellor (eligible for ANZICA registration) to ensure the donor and recipient(s) have a full understanding of the ramifications of donation.

Enabling gamete and medical screening to occur concurrently with implications counselling can streamline the process for known donation and avoid unnecessary delays for ART treatment, providing all mandatory requirements have been met.

Five-family limit

The MEP recommends that proposed legislation retain the requirement for a limit on the use of donated gametes. Under the proposed legislation the limit on use of donated gametes will remain as being a total of 5 families worldwide, excluding the donor's own family(s). Donors will have the right to determine a lower limit than 5 families in the terms of their consent to use of their donation.

The existing Human Reproductive Technology Directions 2021 limit the use of donor reproductive material to 5 families worldwide, excluding the donor's own family.[45] The MEP received considerable feedback regarding donor family limits. Feedback strongly supported the retention or reduction of the five-family limit in order to limit the overall number of donor siblings. This reflects concerns from donor-conceived persons and recipients about consanguinity between donor siblings, and the distress some donor-conceived persons feel when they discover they have many siblings. Others argued for an increase to the family limit to ensure an adequate supply of donor gametes.

The MEP felt that the current five-family limit still represents the most appropriate number given the population of WA (2.7 million) in comparison with Victoria (6.5 million)[46], where the limit is 10 families. Victorian legislation

45 Human Reproductive Technology Directions 2021 (WA), p 32.

46 Australian Bureau of Statistics. National, state and territory population, March 2022.

has specific penalties for licensed ART providers who breach this limit.[47] The MEP supports the five-family limit for the proposed WA legislation, recognising the challenge this presents to licensed ART providers who utilise international gamete banks. The MEP has considered the issues that this raises for WA licensed ART providers but considers that the five-family limit is consistent with the principle that the best interests of the person(s) to be born are paramount.

The MEP recognises there will be some circumstances where a person may seek an exception to the five-family limit and recommends exceptions should be referred to the AARB. For example, a situation may arise where a request is made to permit family expansion involving the importation of gametes from an Australian state or territory that has a family limit that exceeds the five-family limit of WA. The MEP's recommendation is that exceptions will not be considered unless there are extraordinary circumstances that will affect the wellbeing of the child(ren). Further, no exception to import gametes will be considered unless donor information required for the RT Registers is available.

Ministerial Expert Panel recommendation 14:

That proposed legislation maintains the existing worldwide five-family limit for using donor gametes or embryos from the same donor to create or extend a family, with penalties or conditions on a licence introduced for exceeding the limit. In circumstances where exceptions are sought, these should be considered by the AARB. Exceptions will not be considered unless there are extraordinary circumstances that will affect the wellbeing of the child(ren). No exception will be considered unless donor information is available.

Policy intent for recommendation 14: Limiting the use of donor gametes or embryos to up to 5 families worldwide (excluding the donor's own family) supports recommendations from donor-conceived advocates that family limits are kept low to ensure smaller numbers of donor siblings, and less risk of consanguinity. This aligns WA (population 2.7 million) with Victoria (population 6.5 million) where legislation prohibits using donated gametes to produce more than 10 families.

Genetic testing of embryos

Genetic testing of embryos can be used to screen embryos at the preimplantation stage (prior to embryo transfer and potential pregnancy) for specific known single gene disorders or chromosomal abnormalities. Genetic testing enables chromosomally healthy embryos or those unaffected by a specific serious genetic disorder to be selected for use in an IVF cycle, increasing the chance of a successful pregnancy and helping reduce the risk of passing on a known serious inherited genetic condition.

Types of genetic testing used in preimplantation screening of embryos are:

- testing for aneuploidy. Involves testing embryos for the correct number of chromosomes (testing for missing or additional chromosomes)
- testing for single gene defects/disorders (also called monogenic). Used to screen embryos for serious genetic diseases or conditions where a single gene is known to be the cause of the disease or condition
- testing for chromosomal structural rearrangements. Used to identify abnormalities in the chromosome structure (translocations, inversions or microdeletions) that are known to cause genetic disorders, or which can increase risk of an unsuccessful pregnancy.

47 Assisted Reproductive Treatment Act 2008 (Vic), s 29, p 23.

In addition, genetic testing of embryos can be used together with human leukocyte antigen (HLA) typing (a technology that enables tissue type matching) to create a child with a tissue type that matches an existing sibling or close family member with a particular disease or disorder that may respond to stem cell therapy. Preimplantation genetic testing of embryos to determine tissue type compatibility may be considered when no suitable donor is available for a person requiring a stem cell transplant, when the requirement is non-urgent.

Genetic testing of embryos may also be used to support mitochondrial donation – an IVF-based ART technique that can aid in avoiding transmission of mitochondrial disease. Mitochondrial donation is an emerging technology in reproductive medicine that is being introduced in Australia under a restricted and staged process involving clinical trials.[48] It is currently not available in WA.

Access to genetic testing of embryos under current WA legislation

Under the current HRT Act, preimplantation genetic testing is permitted to test embryos to identify genetic diseases or disorders that will affect the child, however all diagnostic procedures carried out on an embryo must have the prior approval of the RTC before testing can be conducted. Currently in WA, unless the parents are eligible for IVF, genetic testing of embryos for the purpose of tissue type matching is not permitted.

The Allan Review highlighted several criticisms of the current approval process in WA for genetic testing of embryos including that the process delays treatment and adds additional stress for patients. Given that ART participants seeking genetic testing must have genetic counselling and a medical consultation, the RTC approval process seems bureaucratic and unnecessary. The review noted that no other jurisdiction in Australia requires approval for preimplantation genetic testing from a regulator or government body (except for non-medical sex selection) and concluded that:

> It is unsatisfactory to require RTC approval for PGD [preimplantation genetic diagnosis] when the patients have already undertaken significant steps to determine its use, and the RTC approval process adds little if anything to the process.[49]

The Allan Review recommended repealing provisions in the HRT Act that require approval of the RTC for genetic testing of embryos subject to ART providers adhering to the NHMRC Ethical Guidelines on the use of ART regarding use of genetic testing. The review also recommended that WA make provision in its legislation to permit use of genetic testing on embryos for the purpose of tissue typing an embryo for subsequent stem cell therapy for a relative, subject to meeting the requirements of the NHMRC Ethical Guidelines on the use of ART. Both recommendations were supported in principle by the Government.

The NHMRC Ethical Guidelines on the use of ART state that preimplantation genetic testing of embryos may only be used to:

- select against genetic conditions, diseases or abnormalities that would severely limit the quality of life of the person who would be born
- increase the likelihood of a live birth
- select an embryo with compatible tissue for subsequent stem cell therapy intended for a parent, sibling or other relative.[50]

While the guidelines do not list the genetic conditions, diseases or abnormalities for which use of genetic testing of embryos is ethically acceptable they give criteria (refer to Appendix 9) to be considered by clinicians when making this decision. The guidelines state that where a clinician/clinic are unsure whether the use of genetic testing in a particular situation is consistent with the guidelines, they should seek advice from an independent body.

48 Australian Government, Department of Health and Aged Care – Mitochondrial donation.

49 Allan Review Part 1, p 250.

50 NHMRC Ethical Guidelines on the use of ART (2017), p 76.

Criteria for the use of genetic testing for the purposes of tissue typing an embryo for subsequent stem cell therapy in the NHMRC Ethical Guidelines are:

- testing may only be used to select an embryo with compatible tissue for subsequent stem cell therapy for the planned treatment of an intended parent, sibling or other relative
- clinicians must seek advice from an independent body before undertaking preimplantation genetic testing to select an embryo with compatible tissue for subsequent stem cell therapy. The independent body should be satisfied that:
  - there is no evidence to suggest that the person who would be born would not be a welcomed, respected member of the family unit
  - the use of preimplantation genetic testing will not significantly affect the welfare and interests of the person who would be born
  - the medical condition of the intended parent, sibling or other relative to be treated is serious and stem cell treatment is the medically recommended management of the condition.[51]

Ministerial Expert Panel recommendation for proposed ART legislation

Submissions received as part of the targeted consultation process strongly supported streamlining access to genetic testing of embryos in WA under a process that maintains alignment with NHMRC Ethical Guidelines on the use of ART and other appropriate safeguards. Submissions further supported access to genetic testing of embryos in WA for the purposes of tissue typing and to assist with mitochondrial donation techniques should this become available in WA in the future.

The MEP recommends that under proposed ART legislation, genetic testing of embryos be permitted in WA according to the following framework and criteria:

1. Genetic testing of embryos would be permitted to:
   - test an embryo for the presence of a serious genetic disease, condition or abnormality that would severely limit the quality of life of the person who would be born, or is likely to cause pregnancy failure or significant developmental defects (testing for monogenic and single gene disorders and genetic testing for structural chromosomal arrangements)
   - increase the likelihood of a live birth (testing for aneuploidy)
   - select an embryo with compatible tissue type for subsequent stem cell therapy intended for a parent, sibling or other relative
   - support use of mitochondrial donation techniques under approved processes for mitochondrial donation (if available in the future).
2. Licensed ART providers will be permitted to conduct genetic testing of embryos for monogenic and single gene disorders and genetic testing for structural chromosomal arrangements using a list of approved conditions for which licensed ART providers can perform testing without the need for further approval.

   The MEP recommends that WA adopts the UK Human Fertilisation and Embryology Authority (HFEA) list of authorised conditions for genetic testing for monogenic or single gene disorders[52] together with the conditions included in the Australian Mackenzie's Mission reproductive genetic carrier screening.[53] In both instances, conditions and genes included for testing/screening are assessed by a committee comprised of relevant experts against defined criteria that include that the condition has to have a serious impact on a person's quality of life and/or be life-limiting.

51 NHMRC Ethical Guidelines on the use of ART (2017), p 75.

52 Human Fertilisation and Embryology Authority, Approved PGT-M and PTT conditions (UK).

53 Mackenzie's Mission Gene & Condition List.

3. For genetic conditions not included on the list, licensed ART providers will need to apply to the proposed AARB to have the condition included on the list. In making its decision, the AARB can refer the application to a gene review panel for specialist input and advice. Approval for addition of a condition to the list will require sufficient evidence demonstrating that the gene is associated with a serious genetic disease, condition or abnormality.
4. Licensed ART providers will be permitted to conduct genetic testing of embryos for aneuploidy when genetic testing of embryos for single gene defects/disorders or structural chromosomal rearrangements is requested by a treating ART clinician. Other use of genetic testing for aneuploidy will be at the discretion of the treating ART clinician who can test when they deem it clinically appropriate.
5. Genetic testing of embryos for non-medical reasons (including gender selection for the purposes of selecting a preferred sex or for family balancing) is prohibited.
6. All applications for genetic testing of embryos for the purposes of tissue typing or mitochondrial donation (if available) will need to be reviewed by the proposed AARB on a case-by-case basis. This is consistent with the role and function of the AARB in the proposed legislation (refer to part D of this report) and the NHMRC Ethical Guidelines on the use of ART.
7. In line with the proposed principles for proposed ART legislation, the AARB would prioritise the best interests of any person(s) born.
8. Consistent with existing WA legislation and the NHMRC Ethical Guidelines on the use of ART, under proposed legislation all patients receiving genetic testing of embryos for monogenic and single gene disorders and genetic testing for structural chromosomal rearrangements will receive counselling from a clinical geneticist and/or genetic counsellor prior to testing being performed.

The MEP further recommends that proposed ART legislation be drafted in a manner allowing flexibility in response to emerging scientific/medical evidence and advances in technology and clinical practice relating to genetic testing of embryos.

Ministerial Expert Panel recommendation 15:

That licensed ART providers in WA be permitted to request or conduct genetic testing of embryos as follows:

a) testing for monogenic and single gene disorders and testing for structural chromosomal rearrangements using a list of approved conditions for which genetic testing can be conducted without the need for further approval

b) genetic testing for aneuploidy when genetic testing for monogenic and single gene disorders or genetic testing for structural chromosomal rearrangements is requested by a treating ART clinician

c) other use of genetic testing for aneuploidy will be at the discretion of the treating ART clinician who can use testing when they deem it clinically appropriate

d) genetic testing of embryos for non-medical reasons (including sex-selection for family balancing) is prohibited

e) use of genetic testing should align with the NHMRC Ethical Guidelines on the use of ART.

For conditions not included on the list of approved conditions, licensed ART providers must apply to the AARB for the condition to be added to the list. In making its decision, the AARB can refer the application to a gene review panel who will advise the AARB.

All patients receiving genetic testing for monogenic and single gene disorders, and genetic testing for structural chromosomal rearrangements, will need to receive counselling from a clinical geneticist and/or genetic counsellor prior to testing being performed.

Policy intent for recommendation 15: To permit access to genetic testing of embryos under a more streamlined process, while retaining appropriate oversight and consideration of circumstances where testing is requested outside of the list of approved conditions.

Ministerial Expert Panel recommendation 16:

That proposed legislation permits genetic testing for the purpose of tissue typing an embryo (human leukocyte antigen (HLA) typing) for subsequent stem cell therapy for a parent, sibling or other relative who requires tissue or organ donation due to illness. Use of genetic testing for HLA tissue typing should align with the NHMRC Ethical Guidelines on the use of ART.

Genetic testing of embryos for the purpose of supporting approved mitochondrial donation techniques for the treatment of mitochondrial disease will be permitted, following any introduction of mitochondrial donation in WA.

All applications for genetic testing of embryos for the purpose of tissue typing or to support mitochondrial donation techniques must be approved by the AARB. In making its decision, the AARB can seek the advice of a gene review panel.

Policy intent for recommendation 16: To permit access to genetic testing of embryos to support tissue typing for subsequent stem cell therapy of a relative requiring tissue or organ donation due to illness, and access to genetic testing of embryos to support mitochondrial donation for approved treatment of mitochondrial disease in the future.

Ministerial Expert Panel recommendation 17:

That proposed legislation be drafted in a manner allowing flexibility in response to emerging scientific and medical evidence, advances in technology and clinical practice relating to genetic testing of embryos.

Policy intent for recommendation 17: To allow flexibility in response to emerging scientific/medical evidence, advances in reproductive medicine and health technology, and potential changes in community opinion.

Reciprocal IVF

Reciprocal IVF allows one person in a partnership to contribute their oocyte (egg) in order to create an embryo that will be carried to term by their partner. One partner undergoes ovarian stimulation and egg retrieval. Using sperm from a known or unknown donor, the embryo is created through IVF and is implanted in the second partner who carries the pregnancy to term.

This allows both members of the partnership to contribute to the creation of the child (one is the biological parent and the other is the birth parent).

Reciprocal IVF is currently restricted in WA as the HRT Act stipulates that IVF can only be accessed due to infertility or other medical reasons.[54] Reciprocal IVF is currently practiced in all other Australian states and territories.

The Allan Review did not reach a conclusion on reciprocal IVF. In her recommendation on this matter, Associate Professor Allan stated:

> Further consultation and consideration be had with members of the LGBTQI community, ART clinicians, counsellors, people born as a result of ART, legal and ethics experts and other interested parties, on issues related to egg sharing or use of an embryo formed with one partner's ova by the other female partner in a same-sex relationship.[55]

Feedback received during the Allan Review consultation stated that the existing legislation is restrictive by Australian standards and forces people to travel interstate to access this treatment.

Feedback received by the MEP as part of the targeted consultation further supported permitting reciprocal IVF in WA. Support for reciprocal IVF was received in submissions from WA ART providers, people who have sought or intend to seek reciprocal IVF and other stakeholders.

The MEP recommends that proposed ART legislation permits reciprocal IVF. People seeking access to reciprocal IVF will need to meet the definition of 'partner' under the proposed ARTS Act.

Proposed ART legislation should make it clear that oocytes (eggs) used in reciprocal IVF are not donor material. The MEP notes that repeal of the AC Act (as recommended in part A of the report) provides opportunity to address current provisions in the AC Act that state:

> Where –
>
> a) a woman becomes pregnant in consequence of an artificial fertilisation procedure
>
> b) the ovum used for the purposes of the procedure was taken from some other woman, then for the purposes of the law of the state, the woman from whom the ovum was taken is not the mother of any child born as a result of the pregnancy. [56]

Ministerial Expert Panel recommendation 18:

That proposed legislation permits reciprocal IVF. Reciprocal IVF enables one person to contribute their oocyte (egg) in order to create an embryo that will be carried to term by their partner.

The partner's oocyte(s) used in reciprocal IVF will not be considered as donor material in the proposed ART legislation.

Consent for embryo creation for the purpose of reciprocal IVF must include written direction regarding the use, on-donation or removal from storage of the embryos including in the event of the death of either partner or separation of the partners.

54 HRT Act, s 23.

55 Allan Review Part 1, p 280.

56 Artificial Conception Act 1985 (WA), s 7.

Policy intent for recommendation 18: To permit access to ART treatments that will allow for reciprocal IVF. Partners seeking access to reciprocal IVF will need to meet the definition of 'partner' under the proposed legislation to ensure alignment with the policy intent for access to ART treatments in WA. The proposed legislation will make it clear that oocytes used in reciprocal IVF are not considered donor materials to ensure the oocyte (egg) provider is, for the purposes of the law of the state, a parent.

Posthumous collection and use of gametes and embryos in WA

Background

In Australia, laws regarding posthumous collection, storage and use of gametes and/or embryos vary between states and territories.

In WA, posthumous collection of human tissue, including reproductive tissue, is governed by the *Human Tissue and Transplant Act 1982* (HTT Act). Under s 22 of the HTT Act, a designated officer for a hospital can authorise the collection of gametes/reproductive tissue from a recently deceased person where there was consent (or no reason to believe that the person objected during their lifetime) to the gametes/reproductive tissue being collected, and the senior available next of kin consents to the collection.[57] The MEP notes that this represents a departure from the NHMRC Ethical Guidelines for the use of ART (which suggest limiting consent provision to a person's partner) (refer to Appendix 10) but notes that there are circumstances in which a clinician may feel it is appropriate to depart from these guidelines.[58]

However, while posthumous collection of gametes/reproductive tissue may currently be possible in WA, the Human Reproductive Technology Directions 2021[59] prohibit the use of gametes in an artificial fertilisation procedure after the death of the gamete provider. This prohibits use of gametes collected and stored prior to a person's death, as well as gametes (or gametes derived from reproductive tissue) collected from a now deceased person. WA is the only jurisdiction in Australia that prohibits the posthumous use of gametes.[60]

Although the HRT Act provides that "in the event of the death of one member of a couple in whom the rights [of a human egg undergoing fertilisation or a human embryo] are vested, those rights vest solely in the survivor"[61], the definition of artificial fertilisation procedure in the HRT Act leads to a prohibition on the use of embryos posthumously due to Direction 8.7[62].

The Allan Review made several recommendations relating to the posthumous use of gametes and embryos in WA. The review recommended that new ART legislation in WA include provision for posthumous use of gametes (collected prior to or after death) and embryos in ART subject to meeting strict criteria, including that:

57 *Human Tissue and Transplant Act 1982* s 22.

58 For example, where a person's partner is temporarily incapacitated, clinicians may not feel it necessary to follow the guideline about obtaining consent only from a person's partner.

59 See Direction 8.7 ("*8.7 No posthumous use of gametes: Any person to whom the licence applies must not knowingly use or authorise the use of gametes in an artificial fertilisation procedure after the death of the gamete provider.") and note: the prohibition does not appear in the HRT Act.

60 Allan Review, Part 1, p 228.

61 HRT Act s 26.

62 See Direction 8.7 ("*8.7 No posthumous use of gametes: Any person to whom the licence applies must not knowingly use or authorise the use of gametes in an artificial fertilisation procedure after the death of the gamete provider.") and note: the prohibition does not appear in the HRT Act.

> retrieval of gametes from a person who is unconscious and near death, or after their death may only occur when the requirements of s 22 of the *Human Tissue and Transplant Act* (WA) have been met, and only for the purpose of use by the surviving spouse or partner of the person, or a surrogate, for the purposes of bearing a child(ren) who will be cared for by the surviving spouse or partner.[63]

The government response to the Allan Review identified these, and other matters relating to posthumous use, as matters requiring further consideration.[64]

The collection and subsequent use of gametes from a person who is near death (dying) or deceased and/or the posthumous use of stored gametes and embryos for reproductive purposes are addressed in the NHMRC Ethical Guidelines on the use of ART.[65]

Collection of gametes from a person who is near death or deceased

The MEP supports that WA legislation permit the collection of gametes or reproductive tissue from a person who is:

a) near death (dying) and unable to provide consent, or

b) deceased

to preserve the option for future reproductive purposes by the person's surviving partner.

NHMRC Guideline requirement for court authority

It is settled law in WA that gametes can be collected from a deceased person without the need for a Court Order.[66] The MEP heard evidence that despite the Supreme Court decision of Justice Edelman in 2013[67], which confirms that a court order is not necessary, medical practitioners are frequently reluctant to proceed with the retrieval in absence of a court order being sought. Confusion as to the need for a court order is understandable – see NHMRC Ethical Guidelines for the use of ART (2017) section 8.21, page 80, "…court authority is required before a clinician may facilitate the collection of gametes from a person who is deceased or is dying and lacks the capacity to provide valid consent…" The MEP suggests that WA health services and clinicians are given clear information about the WA Supreme Court decision relating to posthumous collection of gametes/reproductive tissue, noting in that there is no requirement for individual court orders at the point of collection.

Clinicians, including hospital designated officers, and licensed ART providers undertaking posthumous collection should be supported with an education campaign, so they are aware of the specific requirements relating to posthumous collection in the current HTT Act and additional provisions around collection and storage for posthumous use which it is recommended be included in proposed ART legislation.

The MEP notes that this represents a departure from the NHMRC Ethical Guidelines on the use of ART (which suggest that a court order is required for collection) but has formed the view that the WA Supreme Court decision captures another situation in which clinicians may feel it is appropriate to depart from the guidelines.

63 Allan Review Part 1, Recommendations 48 to 54.

64 Government Response to the Allan Review, p11.

65 NHMRC Ethical guidelines on the use of ART, s 8 pp 79–82.

66 Edelman J. RE Section 22 of the *Human Tissue and Transplant Act 1982* (WA); Ex Parte C [2013] WASC 3.

67 *Ibid.*

Storage of collected gametes

Proposed legislation will also need to consider the storage of reproductive material collected from a person who is near death (dying) or deceased. If the person stored their reproductive material prior to their death (including where embryos were created using their gametes), then their wishes for the posthumous use of their reproductive material should be defined and recorded in their written consent at the point of storage. For material collected from a person who is near death (dying) or deceased, decision-making for the material would fall to the surviving partner only and require a valid consent for storage.

The MEP notes the operation of the existing HTT Act which may permit posthumous collection of reproductive tissue from a person who is recently deceased[68]; but which under Part II of the Act (Donations of tissue by living persons) excludes any reference to human eggs, sperm, embryos, or fetal tissue. The consequence flowing from this is that reproductive tissue that may be used in intended future ART by the surviving partner of a person who is near death (dying) cannot be collected.

> Currently, where s 22 of the HTT Act operates in relation to gametes the MEP acknowledges that this is likely to predominantly relate to the collection of sperm and, given the cyclical nature of mature eggs release, less likely to apply to collection of eggs (ova). It is the MEP's view that it would be unacceptable to extend a person's life to induce a cycle to make available egg(s) for collection. Where s 22 operates in relation to reproductive tissue (for example, ovarian tissue which might later be used to generate mature eggs), a clinical decision will be made to facilitate appropriate removal and storage of the tissue for future reproductive use.

Options for future legislation

The MEP's intent is that proposed legislation continues to permit the collection of gametes and reproductive tissue from a person who is deceased and will also permit collection from a person who is near death (dying) and unable to provide consent. This is to preserve the option for intended future reproductive purposes by the person's surviving partner.

The MEP recommends that the proposed ART legislation incorporates the current legislative regime in s 22 of the HTT Act insofar as it relates to reproductive tissue. Alternatively, the Government may wish to exclude reproductive tissue from s 22 of the HTT Act and move those legislative provisions to the proposed ART legislation.

68 HTT Act Part III, s 22.

Ministerial Expert Panel recommendation 19:

That proposed legislation continues to permit the collection of gametes and reproductive tissue from a person who is deceased, and also permit collection from a person who is near death (dying) and unable to provide consent. This is to preserve the option for intended future reproductive purposes by the person's surviving partner. Collection must be consistent with the elements outlined in s 22 of the *Human Tissue and Transplant Act 1982* (HTT Act) being met and alignment with the NHMRC Ethical Guidelines for the use of ART using the following criteria:

a) the dying person left clearly expressed oral or written directions consenting to the collection (retrieval) of their gametes or reproductive tissue in the event they are near death or following their death, or there is some evidence that the person would have supported the collection of their gametes or tissue for use by their partner

b) where the deceased person left no instructions, the designated officer shall consider any information that supports the intention of the deceased person to have a child following their death, or determine there is no evidence that the deceased person would have objected to the use of their gametes, reproductive tissue or embryos by their surviving partner

c) if a person expressly objected to the collection of their gametes or reproductive tissue, then collection is prohibited

d) the person was an adult at the time of their death

e) the request for collection has come from the partner of the person who is near death, unless the partner is temporarily incapacitated, then the senior available next of kin may make this request on the surviving partner's behalf

f) the gametes or reproductive tissue collected are only for use by the partner, using a surrogate if required, for the purposes of bearing a child(ren) who will be cared for by the partner.

Policy intent for recommendation 19: To permit collection of gametes and reproductive tissue under a clearly defined framework that recognises the significant ethical implications of permitting collection of reproductive material from a person who is deceased or near death (dying). The wishes of the person who is deceased or near death where these are known must be respected.

Posthumous use of gametes, reproductive tissue and embryos in WA

Gametes, reproductive tissue and embryos stored prior to death

The MEP recommends that under proposed ART legislation, posthumous use of gametes, reproductive tissue or embryos that were stored prior to a person's death be permitted in WA subject to the deceased person leaving express, written consent for their use in the event of their death. Use would only be by the deceased person's surviving partner, or using a surrogate, for the purpose of bearing a child(ren) that will be cared for by the surviving partner. Use will require approval of the proposed AARB.

If a person has expressly objected to the posthumous use of their stored gametes, reproductive tissue or embryos, then use of the gametes, tissue or embryos to achieve pregnancy will be prohibited.

Following commencement of the proposed legislation, the AARB may consider approval of posthumous use of gametes or embryos where express written consent for posthumous use was not given at the time of storage, if that written consent was given prior to the introduction of the new legislation which expressly permits posthumous use.

Gametes and reproductive tissue collected and stored after death

The MEP recommends that proposed legislation permit the posthumous use of gametes or reproductive tissue collected from a person who is now deceased and where there is compliance with the conditions for collection outlined above. Use would only be by the deceased person's surviving partner, or using a surrogate, for the purpose of bearing a child(ren) that will be cared for by the surviving partner. Use will require approval of the proposed AARB.

ART Advisory and Review Board approval for posthumous use

The MEP recommends that the AARB may approve an application for posthumous use of gametes, reproductive tissue or embryos by the surviving partner where the below conditions are met:

- the best interests of the person(s) to be born will be a primary consideration for any posthumous use of gametes, reproductive tissue or embryos
- the deceased person left clearly expressed oral or written directions consenting to the use of their gametes, reproductive tissue or embryos following their death, or there is some evidence that the deceased person would have supported the posthumous use of their gametes, reproductive tissue or embryos by their surviving partner. If a person has expressly objected to the posthumous use of their stored gametes, reproductive tissue or embryos, use to achieve pregnancy is prohibited
- where the deceased person left no instructions, the AARB shall consider any information that supports the intention of the deceased person to have a child following their death, or determine there is no evidence that the deceased person would have objected to the use of their gametes, reproductive tissue or embryos by their surviving partner
- the deceased was an adult at the time of their death
- the request to use the gametes, reproductive tissue or embryos will only be by the person's surviving partner, including use of a surrogate, for the purposes of bearing a child(ren) who will be cared for by the surviving partner
- the surviving partner has undergone appropriate implications counselling and has been provided with sufficient information to facilitate an accurate understanding of the potential social, psychological and health implications for the person who may be born
- sufficient assessment has been made that the surviving partner's grief and related emotions have been addressed to ensure their effective decision-making
- use will require approval by the proposed AARB and should align with the requirements of the NHMRC Ethical Guidelines on the use of ART, unless otherwise specified in the proposed legislation.

Ministerial Expert Panel recommendation 20:

That proposed legislation permits the posthumous use of:

- embryos created from the gametes of a person who subsequently dies
- gametes and reproductive tissue collected prior to, or after a person's death.

Use is subject to meeting the below criteria:

a) the best interests of the person(s) to be born will be a primary consideration for any posthumous use of gametes, reproductive tissue or embryos

b) the deceased person left clearly expressed oral or written directions consenting to the use of their gametes, reproductive tissue or embryos following their death, or there is some evidence that the deceased person would have supported the posthumous use of their gametes, reproductive tissue or embryos by their surviving partner. If a person has expressly objected to the posthumous use of their stored gametes, reproductive tissue or embryos, use to achieve pregnancy is prohibited

c) where the deceased person left no instructions, the AARB shall consider any information that supports the intention of the deceased person to have a child following their death, or determine there is no evidence that the deceased person would have objected to the use of their gametes, reproductive tissue or embryos by their surviving partner

d) the deceased was an adult at the time of their death

e) the request to use the gametes, reproductive tissue or embryos will only be by the person's surviving partner, including use of a surrogate, for the purposes of bearing a child(ren) who will be cared for by the surviving partner

f) the surviving partner has undergone appropriate implications counselling and has been provided with sufficient information to facilitate an accurate understanding of the potential social, psychological and health implications for the person who may be born

g) sufficient assessment has been made that the surviving partner's grief and related emotions have been addressed to ensure their effective decision-making

h) use will require approval by the proposed AARB and will align with the requirements of the NHMRC Ethical Guidelines on the use of ART, unless otherwise specified in the proposed legislation.

The MEP recommends that the collection, storage and use of all reproductive material to be used for intended reproductive purposes is regulated under the proposed ART legislation. This would include posthumous collection of gametes and reproductive tissue. The MEP notes this will require amendment to the HTT Act.

Policy intent for recommendation 20: To permit posthumous use of gametes, reproductive tissue and embryos under a clearly defined consent framework and approvals process that recognises the significant ethical implications of permitting posthumous use to conceive a child, and which respects the intent of the (now deceased) individual to allow posthumous use.

Persons in post-coma unresponsiveness or a minimally responsive state

In considering the posthumous collection and use of gametes, reproductive tissue and embryos, the MEP's attention was drawn to other situations where a person may seek to use gametes or reproductive tissue from their partner who is unable to provide informed consent for the purposes of reproduction due to, for example, being in a state of post-coma unresponsiveness (PCU) or in a minimally responsive state (MRS).

The MEP recognises that there are highly complex and sensitive ethical issues associated with such situations. Further, the MEP notes that these situations were not considered in the Allan Review beyond the situation of a person who is "unconscious and near death" or any of the responses and discussion papers relating to the Allan Review, and that no other jurisdiction has legislated or regulated such situations. Consequently, the MEP has determined that it is beyond the scope of the panel's mandate to make specific recommendations about how questions relating to such situations might be answered.

The MEP wishes to draw attention to the specific guidance provided by the NHMRC *Ethical Guidelines for the Care of People in Post-Coma Unresponsiveness (Vegetative State) or a Minimally Responsive State (2008)* (NHMRC Ethical Guidelines for Care of People in PCU or MRS) which provide an ethical framework to guide decisions in the best interests of persons in PCU or MRS.

The NHMRC Ethical Guidelines for Care of People in PCU or MRS highlight that:

> People in PCU or MRS are highly vulnerable because of their total dependence on others. They are owed a particular duty of care to promote their interests and protect them from exploitation, abuse and neglect. That duty is likely to extend over a long period of time.[69]

Principles underpinning the NHMRC Ethical Guidelines for Care of People in PCU or MRS include that decisions about the care of people in PCU or MRS should:

> a) demonstrate respect for all aspects of human dignity, including the worth, welfare, rights, beliefs, perceptions, customs and cultural heritage of all involved
>
> b) respect, where these are ascertainable, the values, beliefs and previous wishes of the person in PCU or MRS
>
> c) respect the basic rights of people in PCU or MRS, including their rights to be treated with respect, to security, to self-determination and rights to privacy and confidentiality (refer to Appendix 11 for full details).[70]

The MEP makes 2 final observations about this issue. First, should the WA Government decide to explore the possibilities of regulating requests seeking collection of gametes or reproductive tissue from a person in PCU or MRS for intended reproductive purposes, the NHMRC Ethical Guidelines for Care of People in PCU or MRS provide a useful starting point, along with the principles outlined in this report by the MEP for proposed ART legislation, especially the paramountcy of the best interests of the person to be born as a result of ART. Second, the MEP suggests that should such possibilities be developed, the AARB, with its capacity to seek input from relevant experts as required, would be ideally placed to be the body to which such matters are referred for consideration, advice and/or determination.

69 NHMRC Ethical Guidelines for the Care of People in Post-Coma Unresponsiveness (Vegetative State) or a Minimally Responsive State (2008), p 8.

70 NHMRC Ethical Guidelines for the Care of People in Post-Coma Unresponsiveness (Vegetative State) or a Minimally Responsive State (2008), p 9.

Inclusion of deceased person's name on child's birth certificate

Consistent with the Allan Review,[71] the MEP supports that in cases in which a child has been born as the result of posthumous use of a deceased partner's gametes or an embryo made with such gametes, that provision be made in the *Births, Deaths and Marriages Registration Act 1998* to enable the deceased to be listed on the child's birth certificate as a parent of that child.[72]

The MEP notes the need to make provisions for the name of the deceased person on a birth certificate of a child as part of the repeal of the *Artificial Conception Act 1985* and for potential consequential amendments to other WA legislation including the *Administration Act 1903* and *Family Provision Act 1972*.

Ministerial Expert Panel recommendation 21:

Where a child is born as the result of the posthumous use of a deceased partner's gametes or an embryo created with such gametes in an artificial conception procedure, that provision in the *Births, Deaths and Marriages Registration Act 1998* be made to enable the deceased person to be listed on the child's birth certificate as a parent of that child.

Policy intent for recommendation 21: To recognise the child's genetic heritage and the relationship status of the deceased person to the child born.

Surrogacy

A valid surrogacy arrangement in WA achieves 2 distinct outcomes:

a) a child is born to intended parent(s) who cannot otherwise have children

b) the child has its intended parent(s) recognised in law by the Family Court and named on the child's WA birth certificate.

Access to surrogacy in WA

Between 2008 and 2022 only 24 children were born via approved altruistic (not for profit) surrogacy arrangements in WA, approximately one birth per year. Factors influencing such a low birth rate include:

- the original surrogacy legislation was broadly designed to meet the needs of infertile heterosexual couples and has not been amended since 2008
- significantly, groups in society such as single men, people in same-sex relationships and transgender people have been legislatively excluded from access to altruistic surrogacy
- the nuclear family enshrined in the Surrogacy Act no longer represents the modern understanding of family and social units
- varying eligibility and regulatory requirements relating to altruistic surrogacy between Australian states and territories, and perceived and actual limits on advertising for surrogates in WA, have made it very difficult for many Western Australian families to locate a suitable surrogate
- the application process has been over-regulated, is cumbersome and has lengthy delays built into the system.

71 Allan Review Part 1, Recommendation 53.

72 *Births, Deaths and Marriages Registration Act 1998* (WA).

Commercial surrogacy

Commercial (for profit) surrogacy is prohibited throughout Australia. The government response to the Allan Review reaffirmed that under proposed ART legislation, commercial surrogacy will remain prohibited in WA. This aligns with the NHMRC Ethical Guidelines on the use of ART, which state that:

> Commercial surrogacy is ethically unacceptable because it raises concerns about the commodification and exploitation of the surrogate, the intended parent(s) and any person born as a result of the surrogacy arrangement… Clinics and clinicians must not practice, promote or recommend commercial surrogacy, nor enter into contractual arrangements with commercial surrogacy providers.[73]

An inclusive light touch surrogacy model

The Allan Review recommended that the application process for surrogacy be simplified, to make the assessment procedure less bureaucratic and burdensome.[74] The MEP is supportive of this approach.

Significant proposed changes include:

- eligibility criteria for access to altruistic surrogacy in WA should be expanded to all people who are unlikely to conceive or give birth without an ART procedure regardless of their sex, relationship status, gender identity, intersex status, or sexual orientation. This is to ensure equity of access and consistency with the *Sex Discrimination Act 1984* (Cth)[75] and alignment with the principles of the *Equal Opportunity Act 1984* (WA)[76]
- the current requirement for a clinical psychologist's assessment should be removed to align WA with the approach of all other Australian jurisdictions
- the removal of the RTC approval process in its entirety. Under the existing legislation, the RTC is required to approve surrogacy arrangements. This approval process adds further delays and processes for participants and ART providers to follow. The MEP could identify no benefit associated with these delays and processes
- before fertility treatment is provided, the licensed ART provider must be satisfied that all legislative prerequisites have been met, as is currently the case in other Australian jurisdictions.

The MEP is of the view that, in making an order for the transfer of parentage, the requirement that a surrogacy arrangement must be detailed in a valid written agreement should continue.

Prerequisites for surrogacy arrangements

Counselling and legal advice

Consistent with the principle of the best interests of the child and to ensure the safety and non-exploitation of participants in a surrogacy arrangement (intended parent(s), the surrogate, and known donors of gametes or embryos), it is proposed that all surrogacy arrangements in WA meet essential prerequisites including:

- legal advice, including the drafting of a written agreement, signed by the intended parent(s) and the surrogate. This written agreement is necessary to provide assurance to the parties to the surrogacy arrangement, the legal practitioner, the licensed ART provider, and the Family Court
- medical and psychosocial review by the treating clinicians and implications counselling by the ANZICA eligible counsellor to be overseen by the licensed ART provider.

73 NHMRC Ethical Guidelines on the use of ART (2017), p 65.

74 Allan Review Part 2, p xviii.

75 *Sex Discrimination Act 1984* (Cth).

76 *Equal Opportunity Act 1984* (WA).

Residency requirements

The Surrogacy Act requires that intended parent(s) must reside in WA with no stipulation that the surrogate reside in WA.[77] The MEP notes that an unintended consequence of a strict residency requirement is that many Western Australians who temporarily live or work outside the state may not be granted a parentage order. The MEP recommends that intended parent(s) be ordinarily resident in WA at the time an application for parentage is made. In any case, the MEP recommends that the Family Court have the discretion to dispense with the residency requirements.

Further safeguards, unenforceability and counselling

Concerns regarding an intended parent or surrogacy arrangement

The MEP recommends that a licensed ART provider who has concerns regarding a proposed surrogacy arrangement may submit these concerns to the AARB for review and advice.

Unenforceability

The Surrogacy Act stipulates that surrogacy arrangements remain unenforceable so that the final decision regarding parentage is based on the best interests of the child as determined by the Family Court. There are 2 exceptions:

a) reimbursement of expenses is enforceable

b) the Family Court has the discretion to dispense with the consent of the surrogate.[78]

The MEP's view is that these exceptions be retained in the proposed legislation.

Donor Counselling

The Surrogacy Act also requires all donors (including unknown altruistic donors) to undertake counselling and provide consent to a surrogacy arrangement. This prevents intended parents from accessing donor gametes or embryos for use in a surrogacy arrangement. The MEP recommends that this is removed in proposed ART legislation, with unknown donors being advised that their gametes or embryos may be used in a surrogacy arrangement at the time of donation.

The MEP supports the continuation in WA of both gestational and traditional surrogacy.

Steps in a surrogacy arrangement under proposed legislation are outlined in Appendix 12.

77 Surrogacy Act, s 19.

78 Surrogacy Act, s 21 (2)(d).

Ministerial Expert Panel recommendation 22:

That consistent with the principles for the proposed legislation outlined in recommendation 5, prerequisites for a valid surrogacy arrangement include:

a) the intended parent(s), and the surrogate and partner (if any) are all 18 years of age or older

b) the intended parent(s) be ordinarily resident in WA at the time an application for parentage is made and the Family Court have the discretion to dispense with the residency requirements

c) the intended parent(s) and the surrogate receive separate legal advice from separate lawyers, not in the same practice

d) the parties' intentions and agreement be documented and executed in a written agreement

e) in determining eligibility, the treating ART clinician should have regard to medical and psychosocial suitability of all participants and undertake an appropriate risk assessment regarding these factors

f) the intended parent(s) and the surrogate must undertake implications counselling at the following times as a minimum:

- separate implications counselling prior to ART treatment
- joint implications counselling prior to ART treatment

g) known donors receive joint implications counselling with the intended parent(s) prior to donation, and separate implications counselling as required for any gamete or embryo donation

h) unknown donors will have advice/consent provided/obtained at the time of donation and are therefore not required to undertake counselling or provide consent to the use of their gametes/ embryos in a surrogacy arrangement.

Policy intent for recommendation 22: In order to streamline the surrogacy process and to make the process less burdensome for participants and licensed ART providers, the MEP recommends that a number of current prerequisites to a surrogacy arrangement be removed including the requirement for approval from a regulatory body, mandatory clinical psychologist assessment (this remains an option if deemed by the treating ART clinician to be clinically appropriate), and the requirement for a surrogate to have previously given birth to a live child.

The prerequisites listed above are consistent with the principles of the proposed legislation.

Ministerial Expert Panel recommendation 23:

That the proposed legislation include provision for licensed ART providers to seek advice from the AARB in relation to concerns the licensed ART provider may have about a potential surrogacy arrangement.

Ministerial Expert Panel recommendation 24:

That surrogacy arrangements remain unenforceable except for the current exceptions for agreed reimbursement of expenses detailed in the surrogacy arrangement and the Family Court's discretion to dispense with the consent of the surrogate.

Legal parentage and overseas surrogacy

Legislating for and expanding access to altruistic surrogacy in WA establishes an effective framework to guard against the risks of:

- exploitation of women and children
- treatment of children as commodities
- financial coercion of the surrogate and intended parent(s).

The MEP received considerable feedback from people with lived experience and other stakeholders including licensed ART providers regarding surrogacy, with most asking for processes to be significantly streamlined. Feedback suggested that intended parent(s) would prefer to access surrogacy in WA but were compelled to go interstate or overseas due to either ineligibility or the onerous processes in WA.

The MEP recognises that the historic limitation of access to surrogacy in WA has previously presented many Western Australians with stark choices:

- stay with a complex, lengthy, burdensome, and expensive system which was unlikely to result in a child being born
- not have children, despite the powerful desire to do so
- travel overseas and engage in overseas surrogacy arrangements, the majority of which are commercial arrangements.

All children should be equal

Western Australian children and their 'parents.'

Due to the illegality of overseas surrogacy arrangements, it is extremely difficult to source accurate figures about how many children have been born overseas. However, estimates suggest that in WA since 2008 about 400 children have been born overseas. Many of these children are born to same-sex male couples. Under WA law, these children do not have their intended parents recognised. The people who these children consider to be their parents, whose DNA the children often share, and who love and care for them every day are not legally their parents. In broad terms under WA law, the legal mother of these children is the surrogate, and the legal father is the surrogate's husband/partner.

The lack of legal recognition of parentage is due to the AC Act which presumes that any man in WA (other than the husband/partner of the intended mother), who provides his gametes is presumed not to be the father of any child subsequently born. The lack of recognised legal parentage has caused many difficulties for such children and their parents with government authorities, schools and hospitals. In many cases it has also meant that such children's inheritance rights are compromised.

Citizenship by descent

Commonwealth legislation allows for parents engaging in commercial surrogacy overseas to apply for citizenship by descent for the child if there is a genetic relationship with at least one of the parents. Where the genetic relationship is proven the child is granted an Australian passport and may live in Australia. Where there is no genetic relationship, they must apply for a long-term visa. These parents are not eligible to apply for legal parentage in Australia but can apply for parenting orders and may be allocated parental responsibility by the Family Court. Some overseas jurisdictions list the intended parents on the birth certificate, but others do not. In cases of commercial surrogacy involving same-sex male couples, the overseas birth certificate cannot be used as a basis to have either parent named in a WA birth certificate.

Extra-territorial criminal sanctions

The MEP is of the view that improving and expanding access to altruistic surrogacy in WA will reduce the demand for international commercial surrogacy. In NSW, Queensland and the ACT there are extra-territorial provisions prohibiting Australians from engaging in international commercial surrogacy. The Allan Review noted that these provisions have never been used as they are deemed not to be in the best interest of the child.[79] Extra-territorial provisions are not recommended by the MEP for inclusion in proposed legislation for WA.

Legal recognition of parentage for Western Australian children

In line with the principle that all children have the right to have their parentage recognised, and to reflect the reality that altruistic surrogacy has not previously been available to single men, people in same-sex relationships and transgender people, the MEP recommends:

- recognition for children already born who have been granted citizenship by descent
- such recognition to extend to those born overseas and granted citizenship by descent up to 2 years after commencement of the proposed legislation.

This recognition will by operation of law permit and authorise BDM to issue a birth certificate recognising the biological parent and their partner at the time of birth as the legal parents of the child.

Thereafter, the MEP recommends that the parents of children born via overseas commercial surrogacy arrangements be required to apply to the Family Court for parentage.

Ministerial Expert Panel recommendation 25:

That the parentage of a person already born via an overseas surrogacy arrangement where that child has been granted citizenship by descent, has their parentage recognised by operation of law and reflected on their WA birth certificate.

That parentage can include the person who provided their gametes and their partner (if any).

This arrangement should only apply to persons born via an overseas surrogacy arrangement prior to the commencement and up to 2 years after the commencement of the new legislation.

Policy intent for recommendation 25: It is in the best interests of a child(ren) born through ART to have certainty regarding who are considered their parents and that this is reflected on their WA birth certificate for any future requirement. This is consistent with Article 8 of the United Nations Convention on the Rights of the Child which guarantees the right of the child to preserve his or her identity, including nationality, name and family relations as recognised by law without unlawful interference.

79 Allan Review Part 2, p 173.

Reimbursement of costs in a surrogacy arrangement

It is the MEP's view that proposed legislation should continue to stipulate that all surrogacy arrangements are altruistic, with clear penalties to intended parent(s) who provide a surrogate with material benefit or advantage as a result of a surrogacy arrangement.

The provisions for surrogates to be reimbursed for the prescribed costs actually incurred by them as a direct consequence of entering into the surrogacy arrangement should be expanded to reflect modern practice. These should be detailed in ART legislation and include:

- any reasonable medical expenses incurred by the surrogate that are not recoverable under Medicare, health insurance or another scheme, including costs incurred prior to conception, during pregnancy and birth, and costs related to any child born from the surrogacy arrangement
- any reasonable counselling and legal expenses associated with the surrogacy arrangement incurred by the surrogate
- any reasonable out-of-pocket costs directly associated with the surrogacy arrangement incurred by the surrogate including, but not limited to, travel, accommodation and childcare costs
- cost of reimbursing the surrogate for earnings actually lost as a direct result of taking unpaid leave for 4 months during which the birth occurred or was expected to, or for longer should the surrogate be unable to work on medical grounds as a result of the surrogacy arrangement
- cost of reimbursing the surrogate's partner for earnings actually lost as a direct result of taking leave for up to 6 weeks during the pregnancy or following birth or miscarriage of the baby
- health, life or disability insurance, or additional premium to existing policies, to cover the period prior to conception, the pregnancy, the birth and post-natal recovery.

An obligation under a surrogacy arrangement to pay or reimburse reasonable expenses would remain enforceable, even if the surrogate chooses to keep the child born from the surrogacy arrangement.

Ministerial Expert Panel recommendation 26:

That surrogates continue to be eligible for reimbursement for actual incurred costs due to the surrogacy arrangement. Reimbursement be expanded to include reasonable travel, accommodation and childcare expenses, with particulars detailed in ART regulations. Penalties to remain where a surrogate has received money for reward or other material benefit due to the surrogacy arrangement.

Policy intent for recommendation 26: The expansion of criteria for permitted reimbursements to surrogacy arrangements is to align WA with other Australian jurisdictions and provide greater clarity to participants and legal practitioners.

Advertising and brokerage for surrogacy

Currently in WA, prospective intended parents can advertise their desire for a surrogate, and prospective surrogates can advertise their willingness to enter a surrogacy arrangement. It is proposed by the MEP that this continue in any proposed ART legislation.

Licensed ART providers are currently able to introduce prospective surrogates who have approached their clinics to prospective intended parents but cannot advertise or broker such a service.

The MEP proposes that advertising and brokerage for surrogates be permitted for licensed ART providers. Advertising would be limited to informing people that they may approach the clinic to express their interest in volunteering to act as an altruistic surrogate. No parties, including the clinics and the prospective participants, must charge a fee for any aspect of advertising or brokerage, as this would commercialise the process. Penalties should remain for doing so.

This approach was supported by the Allan Review.[80] Allowing clinics to advertise for altruistic surrogates would be consistent with the clinics' current ability to advertise for gamete and embryo donors. This may also help increase community awareness of WA surrogacy laws. This avenue would allow prospective surrogates to express their interest directly to a clinic.

This is proposed as it is recognised that many prospective intended parents struggle to find a surrogate. The difficulty in finding someone in WA is a major factor in intended parents looking to other jurisdictions for surrogates, including overseas where many surrogacy arrangements are commercial. A principle of the proposed legislation is that there be no commercialisation of reproductive capabilities. It is recommended that consideration be given to expanding opportunities for matching between intended parents and surrogates in WA. The intention is to support access to surrogacy arrangements in WA, where this can be better regulated and where there is less chance for exploitation, as well as increased transparency around the birth, biological origins and legal status of any child born.

Promoting altruistic surrogacy is already permitted in WA, however licensed ART providers have not exercised opportunities to connect surrogates and intended parents. The Allan Review found most participants were not aware that advertising for altruistic surrogacy arrangements is permitted in WA.[81] The MEP believes there is a strong case for promoting these opportunities through education and public awareness campaigns.

Informal brokerage or advertising by intended parents or surrogates through informal channels, such as social media should also continue to be permitted in proposed legislation.

Ministerial Expert Panel recommendation 27:

That proposed legislation permits licensed ART providers in WA to advertise for, and recruit, potential altruistic surrogates. Prospective intended parents and surrogates continue to be allowed to advertise their willingness to enter an altruistic surrogacy arrangement. Formal introduction through a licensed ART provider should be permitted, as should introduction of parties via informal channels, so long as the process remains altruistic and not for reward.

Policy intent for recommendation 27: Advertising is already permitted in WA, but knowledge of this remains low amongst potential participants and other stakeholders. The inability to find a surrogate is a major factor in people seeking surrogacy overseas. Allowing licensed ART providers to recruit altruistic surrogates could help reduce this. Intended parent(s) and surrogates should be permitted to advertise their willingness to enter an altruistic surrogacy arrangement through informal channels.

80 Allan Review Part 2, p 145.

81 Allan Review Part 2, p 144.

Part D: Regulation

The current HRT Act establishes the legal framework governing access to, and delivery of, safe ART practices by licensed ART providers in WA. These entities are licensed to undertake ART treatments and procedures and store gametes and embryos. In addition to licensing, the HRT Act requires the maintenance of registers of ART treatments/procedures, permits investigation of complaints and outlines disciplinary action and appeals when the legislation is not followed. Some of these responsibilities are currently carried out by the RTC which is appointed by the Minister for Health, and some by the department. In WA, licensed ART providers are also required to be separately licensed by the department's Licensing and Regulatory Accreditation Unit (LARU) for activities undertaken within a private hospital setting.

In addition to the requirements of the HRT Act and Surrogacy Act, licensed ART providers in WA must comply with industry codes of practice in order to be licensed. The current key industry codes of practice are the Fertility Society of Australia and New Zealand's Reproductive Technology Accreditation Committee (RTAC) *Code of Practice*[82] and the NHMRC Ethical Guidelines on the use of ART.

The Allan Review highlighted that the current regulatory system in WA, while having served a significant purpose in the early years of ART, is no longer effective or required. The review noted the need to adopt a regulatory structure that better responds to risk while removing duplication, redundancy and unnecessary regulatory burden. The review recommended the adoption of a co-regulatory approach – intended to reduce the burden for individuals and licensed ART providers without compromising safe clinical practice.[83]

The Government supported in principle the Allan Review recommendations relating to the WA regulatory system for ART, noting that further work would be required to inform new legislation and develop the proposed co-regulatory model. The government response identified this as an opportunity to develop "...a modern regulatory framework, which will be responsive and help to simplify the way ART is regulated [in WA], while protecting the welfare of participants, children who might be born and the public."[84] The MEP notes that this approach is consistent with the recommended principles set out in recommendation 5.

Contemporary model for regulation of ART in WA

The MEP supports the proposition that while proposed legislation in WA should reduce unnecessary regulatory burden and duplication for licensed ART providers, formal regulation remains essential both to ensure the provision of high-quality, safe and appropriate ART services for participants and to protect the bests interests of persons born as a result of ART.

The recommendations of the MEP are intended to support a regulatory framework that reflects contemporary approaches to managing safety and quality in healthcare; best-practice in risk-based regulation and regulatory stewardship; and the need to be flexible and responsive to advances in science, technology and clinical practice in reproductive medicine, as well as national approaches to regulation of ART.

The MEP notes that while there is currently limited provision of ART services in the public sector in WA any changes to the regulatory model will need to ensure there is a consistent framework applied to both public and private sectors.

82 Fertility Society of Australia and New Zealand, Reproductive Technology Accreditation Committee – Code of practice for assisted reproductive technology units (October 2021).

83 Allan Review Part 1, pp 82-85.

84 Government Response to the Allan Review, p 4.

The MEP recommends that proposed ART legislation:

- establishes the framework for regulating and governing ART in WA including setting the parameters for access and eligibility for ART and the requirements for who can provide ART treatments and services
- addresses safety and quality in service delivery for ART including adverse event reporting
- establishes the requirements for the licensing and monitoring of licensed ART providers in WA, including that:
  - licensing functions remain with the CEO of the Department of Health, who will have the ability to delegate some responsibilities to appropriate officers within the department
  - the CEO retain powers to impose conditions on licensing of WA ART providers, and impose penalties for non-compliance and determine disciplinary action
  - licensing of ART providers require that they comply with relevant WA and Commonwealth legislation and applicable standards and guidelines including relevant standards set by national regulators, national industry codes of practice, national ethical guidelines for ART, and standards developed by the WA regulator
  - provides for a licensed ART provider to seek review of the following decisions of the CEO:
    - the decision to grant or withhold a licence
    - the imposition of a condition(s) on a licence
    - the decision to suspend or cancel a licence
    - the imposition of penalties for non-compliance with the legislation and other requirements
- establish the requirements for reporting of data and information by licensed ART providers for the RT Registers
- establish the AARB to support the Minister for Health and the CEO with their responsibilities to administer the legislation.

Under the proposed approach, the requirement for licensed ART providers in WA to comply with the RTAC Code of Practice and align with the NHMRC Ethical Guidelines on the use of ART, as the current national industry code of practice and national ethical guidelines for ART respectively, will be maintained.

Development of clinical governance and compliance standards for ART providers by the WA regulator can support robust clinical governance processes and ongoing improvements in safety and quality. The MEP notes this provides opportunity to align with requirements contained in WA health sector regulations and National Safety and Quality Health Service Standards. The development of any WA clinical governance and compliance standards should be undertaken in collaboration with appropriate stakeholders including RTAC, the WA ART industry, and professional groups and patient representatives.

The Allan Review found "that provision should be made, and information clearly communicated, regarding rights of review or appeal of decisions regarding matters governed by the HRT Act and associated legislation".[85] The MEP notes that as per the NHMRC Ethical Guidelines on the use of ART there is no obligation for licensed ART providers to provide treatment, providing there is no unlawful or unreasonable discrimination.[86]

The MEP also notes that the department as the WA regulator receives complaints from participants regarding the treatment or service(s) provided by a licensed ART provider. Complaints may relate to safety and/or quality of clinical care or about the facility, reports of actual or potential adverse health outcomes and other matters. Complaints will continue to be investigated by officers of the department, and the CEO will determine whether there is a corrective action required, including conditions on the licence of a licensed ART provider. The CEO may also cause a referral to AHPRA.

85 Allan Review Part 1, p 82.

86 NHMRC Ethical Guidelines on the use of ART (2017) s 3.7, p 26.

Participants may also refer concerns and complaints to the Health and Disability Services Complaints Office (HaDSCO).[87]

Ministerial Expert Panel recommendation 28:

That proposed legislation establishes a framework for regulating and governing ART in WA. The regulatory system will:

a) set the parameters for access and eligibility to ART

b) address safety and quality in delivery of services providing ART, including reporting of adverse events

c) establish the requirements for licensing and monitoring of licensed ART providers in WA

d) establish the requirements for reporting of data and information by licensed ART providers for the RT Registers

e) allow flexibility to address regulatory stewardship and risk-based regulation

f) allow the CEO to investigate and respond to complaints related to ART

g) establish an ART Advisory and Review Board to support the Minister for Health and the CEO with their responsibilities to administer the legislation.

Under proposed legislation:

a) licensing functions will remain with the CEO, who will have the ability to delegate some responsibilities to appropriate officers within the department

b) the CEO will retain powers to investigate a breach of the legislation or participant complaints

c) the CEO will retain powers to impose conditions on licensing of WA ART providers, and may impose penalties for non-compliance and determine disciplinary action with the ability for the licensed ART provider to seek review in the State Administrative Tribunal

d) ART clinical practitioners in WA must be registered with the Australian Health Practitioner Regulation Agency (AHPRA) or be eligible for membership of their relevant professional body

e) licensing of ART providers will require that they comply with:
   - relevant WA and Commonwealth legislation
   - applicable standards and guidelines as defined in regulations and directions under proposed legislation, including relevant standards set by national regulators, industry codes of practice, national ethical guidelines for ART, and standards developed by the WA regulator

f) the Minister for Health and CEO may issue directives from time to time, as required.

Policy intent for recommendation 28: To provide a robust framework for the regulation and governance of ART in WA that is contemporary, responsive and reflects best practice in regulatory stewardship and risk-based regulation to protect ART participants, persons born of ART, providers and the wider WA public.

87 Government of Western Australia, Health and Disability Services Complaints Office.

Proposed ART Advisory and Review Board

The Allan Review recommended that the current RTC and its committees be abolished, and a new body be established whose role is to:

- provide the Minister/CEO of the department with information regarding any research that may inform regulation and governance of ART
- advise the Minister/CEO of the department regarding medical, social, scientific, ethical, legal, and moral issues arising from ART and any necessary directives/conditions of registration needed to clarify acceptable practice in WA.[88]

Separately from establishing a new ART advisory body, the Allan Review highlighted the lack of a formal appeals process for participants who may be denied specific ART treatments and recommended that right of review concerning government decision making is set out in the legislation and/or relevant department communications and be clearly communicated to the public and clinics.

Consistent with recommendations from the Allan Review,[89] a revision of the RTC committee structure was completed in 2020 with discharge of 4 of the 5 RTC committees. The Preimplantation Genetic Diagnosis (PGD) Committee remains and supports the RTC with requirements in existing legislation relating to genetic testing of embryos.

Under proposed legislation, genetic testing of embryos will be permitted through a more streamlined process that retains appropriate governance and oversight, including consideration of circumstances where testing is requested outside of the list of approved conditions. This is discussed in the genetic testing of embryos section in part C of the report. Approval of the AARB will be required for some specific aspects involving genetic testing of embryos including tissue typing and addition of conditions to the approved conditions list.

Functions of proposed ART Advisory and Review Board

Under proposed legislation, it is recommended that aspects of the regulation of licensed ART providers will remain with the department. However, it is the view of the MEP that an independent AARB for ART will be best placed to make formal decisions on some potentially contentious or innovative ART procedures and practices. The proposed AARB could also function to review and provide advice to licensed ART providers for specific matters for which guidance is sought to assist provider decision-making. There would be a limited range of queries that can be considered by the AARB and the legislation should specifically outline what these are.

The MEP recommends that proposed ART legislation establish the AARB which will replace some of the approval functions of the existing RTC and provide licensed ART providers with the option of a review process enabling AARB decisions to be referred to the State Administrative Tribunal (SAT). The AARB would report to the Minister for Health.

The proposed functions of the AARB and comparison with the functions of the existing RTC are shown in Appendix 13. Several approval functions currently performed by the RTC including approvals for embryo storage, all preimplantation genetic testing of embryos and surrogacy arrangements would be dispensed with because it is deemed that under the proposed regulatory framework, and in-line with contemporary practice, there is no longer a need for approval by a separate body. Responsibility for ensuring compliance with WA legislation and regulatory system will rest with licensed ART providers, with oversight by the department under the licensing regime.

88 Allan Review Part 1, Recommendation 5.

89 Allan Review Part 1, Recommendation 8.

This would meet the requirements of the NHMRC Ethical Guidelines on the use of ART where review is recommended by an independent body for several specific ART matters. The NHMRC recommends that an independent body provide advice before:

- the collection and storage of gonadal tissue or gametes for a child or young person for fertility preservation
- some preimplantation genetic testing, including tissue typing
- the posthumous use of gametes or embryos
- an ART provider introduces an innovative practice, or a proposed change to routine clinical practice.[90]

It will remain a function of the AARB to provide advice to the Minister for Health and the CEO of the department, as CEO under the ARTS Act, with information relating to the regulation and governance of ART; and matters regarding social, scientific, ethical, legal, and moral issues arising from ART to clarify acceptable activity and support best practice in the provision of ART services in WA. The MEP recommends that a licensed ART provider who has concerns regarding a proposed surrogacy arrangement may submit these concerns to the AARB for review and advice.

Decisions made by the AARB can be reviewed by the SAT.

90 NHMRC Ethical Guidelines on the use of ART (2017).

Ministerial Expert Panel recommendation 29:

That proposed legislation establishes a WA ART Advisory and Review Board (AARB) that will:

a) provide information on its own initiative or upon request to the Minister for Health and/or CEO regarding regulation and governance of ART in WA

b) provide advice on its own initiative or upon request to the Minister for Health and/or CEO regarding trends and issues relating to the medical, social, scientific, legal and ethical/moral issues arising from ART

c) provide guidance (but not legal advice) where requested, to licensed ART providers for matters relating to a potential surrogacy arrangement, noting that under proposed legislation the AARB does not approve surrogacy arrangements and decision-making lies with the clinician(s)

d) provide guidance (but not legal advice) where licensed ART providers seek further assistance or where a clinician has concerns regarding issues beyond the eligibility criteria

e) approve applications for:

- genetic testing of embryos for conditions outside of the list of approved conditions for genetic testing
- addition of a condition to the list of approved conditions for genetic testing
- genetic testing of an embryo for tissue typing or to support mitochondrial donation techniques
- use of posthumously collected gametes or reproductive tissue for intended reproductive purposes where conditions of use are met
- posthumous use of previously stored gametes, reproductive tissue or embryos for intended reproductive purposes in the absence of written consent from a now deceased person for such posthumous use
- exceptions to the five-family limit.

For matters where approval decisions are made by the AARB, there will be a review process enabling AARB decisions to be referred to the State Administrative Tribunal.

The AARB will have the capacity to seek further specialist input for specific matters, as required. For matters relating to genetic testing of embryos, the AARB will be supported by a gene review panel that will function as an ad-hoc committee to inform the AARB on applications and matters related to genetic testing.

Policy intent for recommendation 29: To establish a contemporary ART Advisory and Review Board to support the Minister for Health and CEO with their responsibilities under the legislation; and support the provision of safe, high-quality and accessible ART treatment and procedures to persons in WA.

Composition of proposed ART Advisory and Review Board

Members of the proposed AARB would be appointed by the Minister for Health. To best serve its role and responsibilities, the MEP recommends that the proposed ART AARB be comprised of 8 members with relevant backgrounds and expertise, as detailed below. A quorum for required for decision making would be 5 members, including the Chair. As a government board, the AARB will need to comply with all relevant instructions and policies relating to State Government boards and committees.

Ministerial Expert Panel recommendation 30:

That the Minister for Health appoint membership of the AARB for terms of 3 years with the option of one additional term. The AARB to comprise 8 members, including the Chair, being:

a) 2 suitably qualified specialist medical practitioners, at least one with significant experience in ART such as RANZCOG certification in reproductive endocrinology and infertility (CREI) or similar

b) a legal practitioner with extensive experience in family law, infertility law and surrogacy matters

c) a representative from the WA State Solicitor's Office

d) a person who has accessed ART or a person born of ART

e) an ethicist with experience in medical and social ethics

f) a counsellor eligible for full membership of the Australian and New Zealand Infertility Counsellors Association (ANZICA)

g) a WA ART regulator from the WA Department of Health (ex officio member).

Membership terms and operational matters for the AARB will comply with directives and instructions and policies for WA Government boards and committees.

Policy intent for recommendation 30: To ensure appropriate representation on the AARB to support its role and function in providing advice relating to ART and in making decisions for those ART matters where the board will provide approval such as genetic testing for embryos and posthumous use of gametes and embryos.

Storage of gametes and embryos

Historically, embryos were accorded a special status when compared to other human biological material because they can lead to a new human life. There are complex ethical issues associated with their storage and removal from storage when they are no longer required by the person(s) for whom they had been created. To safeguard the viability of human embryos and the wellbeing of the child which may be born, the HRT Act limited storage of embryos to 10 years, with extensions possible via RTC approval.[91]

Since the HRT Act came into force there have been significant improvements in cryo-storage, with studies finding no negative impacts on live birth outcomes or child development. Current concerns with storage limits are mostly focused on social, ethical and legal issues.

The NHMRC Ethical Guidelines on the use of ART permit a person and their partner (if any) to decide upon the storage period based upon their circumstances. When consenting to storage, people must also decide what will happen to their gametes and/or embryos if either or both of them separate, die, become unable to vary or withdraw consent, or fail to give instructions about what is to happen when the storage period expires.[92]

Currently, in WA once embryos are created their future use rests with the person and their partner (if any) for whom they were created. Clause 5.11.1 of the NHMRC Ethical Guidelines on the use of ART state that:

91 HRT Act, s 24.

92 NHMRC Ethical Guidelines on the use of ART (2017) ss 7.3-7.6, pp 56-57.

Clinics must maintain clear procedures for the transfer of responsibility for gametes and the resulting embryos at each stage.

- When the gamete donor has not specified a recipient for their gametes (unknown donation), the clinic has responsibility for decision-making about the allocation, storage and discard of the gametes, subject to any directions or limitations expressed in the consent of the donor. Once allocated, the responsibility for decision-making is transferred to the recipient (see paragraph 6.2).
- When the gamete donor has specified a recipient for their gametes (known donation), and consent for treatment has been given by the recipient, the recipient has responsibility for decision-making about the use, storage and discard of the gametes or resulting embryos, subject to any directions or limitations expressed in the consent of the donor (see paragraph 6.2).
- The clinic is responsible for maintaining the appropriate storage of donated gametes (see Chapter 7).[93]

In WA, a gamete donor cannot revoke their consent for use of the embryos. However, the donor can withdraw consent for the use of their unused stored gametes.

Ministerial Expert Panel recommendation 31:

That proposed legislation allows the time for storage of gametes and embryos to be determined by a written agreement between the licensed ART provider and the person or persons for whom the gametes or embryos will be stored.

Under WA licensing requirements:

a) the storage of gametes and embryos by licensed ART providers will align with the NHMRC Ethical Guidelines on the use of ART

b) storage of gametes and embryos must be with the valid, written consent of the parties

c) consent for storage must capture decisions regarding the management and plan for:
   - embryos no longer needed by a person or persons for their own reproductive purposes
   - disputes between members of a couple for whom an embryo is stored
   - stored gametes or embryos in the event of the death of a gamete provider, including that gametes or embryos should not be stored beyond the death of the gamete provider unless there is valid, written consent for the posthumous use of the gametes or embryos by the surviving partner
   - the removal of gametes and embryos from storage

d) licensed ART providers will be required to have clear policies relating to storage of gametes and embryos that comply with requirements of the legislation and align with the NHMRC Ethical Guidelines on the use of ART

e) should ownership of the licensed ART provider transfer to another entity, the original contract for storage must be upheld until an alternative contract is in place

f) at the end of the storage period specified in the consent form, if the person(s) responsible for the stored gametes or embryos cannot be contacted to provide further direction and consent, a licensed ART provider may after a further 2 year period (in which further attempts to contact the person(s) are made) remove the gametes or embryos from storage in accordance with the provider's policy.

93 NHMRC Ethical Guidelines on the use of ART (2017) s 5.11, p 48.

Policy intent for recommendation 31: To establish a contemporary framework relating to the storage of gametes and embryos by licensed ART providers that provides clear instruction on the requirement for documented consent to arrangements for storage, and the management of the stored gametes or embryos including when no longer required by the person and partner (if any) for their own reproductive purposes, as well as separation of the persons, and in instances of dispute or death.

Import and export of gametes and embryos where donor material has been used

Current situation

The Human Reproductive Technology Directions 2021 permit licensed ART providers to import donor gametes and embryos from outside WA for approved use under the criteria below:

- compliance with the prohibition of commercial trade of gametes and embryos
- the donor has provided informed consent, including that donor-conceived children will have a right to identifying information about the donor from 16 years of age
- counselling provided to the donor is of an equivalent standard to counselling provided to donors in WA
- identifying information for both donor and recipient must be available for submission to the RT Registers
- compliance with the world-wide five-family limit (including families outside WA) for each donor.[94]

If all requirements are met, the licensed ART provider may accept transfer of the donor gametes or embryos. It is the responsibility of the ART provider to demonstrate due diligence that the import meets all legal requirements.

Applications to the RTC to import donor gametes and embryos into WA must be submitted by the licensed ART provider if:

- there is a request to waive the five-family limit
- there is a request to waive the requirement to have available all necessary information for the RT Registers.

Approval for the export of donated gametes or embryos from WA requires the interstate or overseas ART provider to commit to submitting to the WA licensed ART provider:

- identifying information about the recipient
- details of any child born from the donation
- evidence that prior to obtaining a recipient's consent to a procedure, the recipient understands that their identifying information will be submitted to the WA RT Registers.

All exports currently require RTC approval.

94 Human Reproductive Technology Directions 2021 (WA), Part 6, pp 17-18.

Proposed legislation

The MEP recommends that responsibility for ensuring the regulatory compliance regarding import and export of donor gametes and embryos falls to licensed ART providers, with the existing criteria being maintained:

- compliance with the prohibition of commercial trade of gamete and embryos
- the donor has provided informed consent, including that donor-conceived children will have a right to their identifying information about the donor from 16 years of age
- counselling provided to the donor is of an equivalent standard to counselling provided to donors in WA
- all information required for the RT Registers, had the donation occurred in WA, is available for submission
- compliance with the world-wide five-family limit (including families outside WA) for each donor.

This is to ensure that the principles around consent and the prohibition of commercial trade of gametes and embryos are clearly articulated in the proposed legislation; and to ensure that the rights of donor-conceived persons to access information about their genetic heritage are protected and enhanced.

In circumstances where exceptions occur, these may be considered by the AARB. Exceptions will not be considered unless there are extraordinary circumstances that will affect the wellbeing of the child(ren) or there are existing embryos. No exception to import gametes will be considered unless donor information required for the RT Registers is available.

Penalties may be applied to ensure that the five-family limit is maintained, and that information required for the RT Registers is recorded. Penalties should not apply where the AARB has given approval to waive the five-family limit. A strong stewardship and monitoring function by the department as regulator should also be maintained.

In considering the export of all embryos (both to be donated or for the person(s) own use) licensed ART providers must not facilitate the export from WA of an embryo for a use that would not be permitted under the proposed legislation. The onus is on the licensed ART provider to ensure that the receiving fertility service is able to comply with WA legislation. It is recommended that penalties apply where the licensed ART provider does not demonstrate due diligence to ensure the receiving clinic can comply.

Ministerial Expert Panel recommendation 32:

That proposed legislation requires licensed ART providers to ensure compliance with all regulatory requirements before accepting imported donor gametes and embryos into WA. Licensed ART providers must confirm that:

a) the gametes and/or embryos will be used only in an ART procedure, or for approved research

b) the donation is altruistic and complies with State and Commonwealth legislation which prohibits commercial trade in human gametes and embryos

c) there is compliance with the five-family limit

d) all information required for submission to the RT Registers is available as would be required had the gametes and/or embryos been donated in WA

e) the donor has received counselling to a standard equivalent to counselling provided to donors in WA

f) the donor has given informed consent prior to the donation being made.

Before exporting donated gametes and/or embryos from WA, the licensed ART provider must obtain confirmation in writing from the receiving fertility provider that:

a) information required for the RT Registers about the ART treatment(s) using the exported gametes and/or embryos will be provided to the exporting ART provider for submission to the RT Registers

b) identifying information about the recipient(s) of the gametes and/or embryos to be exported, will be provided to the exporting ART provider in order that the required information may be submitted to the RT Registers

c) the recipient(s) consent will be recorded, and the recipient(s) will be advised that their identifying information will be submitted to the RT Registers.

AARB approval is required in exceptional circumstances where the above criteria are not met. The decision of the AARB will reflect the legislative principles. Exceptions will not be considered unless there are extraordinary circumstances that will affect the wellbeing of the child(ren). Penalties will apply if licensed ART providers do not comply with all regulatory requirements.

Policy intent for recommendation 32: It is intended that the current criteria for the import and export of gametes and embryos are preserved in proposed legislation to maintain the principles of consent and prohibition of commercial trade of gametes and embryos, and to ensure donor-conceived persons have the right to information about their genetic heritage.

Research, innovative procedures and emerging technology

It is important that licensed ART providers be encouraged to engage in research, separate to research involving embryos requiring a NHMRC licence. Such research is intended to support advances in reproductive medicine, science, technology and psychosocial care, and improve outcomes for Western Australians undergoing ART.

All research must be undertaken within an appropriate framework that includes ethics approval from a relevant body, informed patient consent, and appropriate regulatory oversight.

Innovative procedures intended to improve patient outcomes are also recognised as offering opportunities to support advances in ART treatment and practices. It is essential that these are conducted under a strict safety and quality framework, with oversight via the licensing of ART providers. The MEP notes the importance of activities involving innovative procedures being conducted with ethics approval, informed patient consent, strong regulatory oversight, and demonstrated evidence of benefit to ART participants.

The MEP supports the need for ongoing consideration regarding the benefits of undertaking treatments or practices that have a sound evidence base and improve outcomes.

Ministerial Expert Panel recommendation 33:

That proposed legislation outlines the conditions of licensing and registration requiring that:

a) licensed ART providers do not engage in false or misleading advertising or practices in relation to treatments or practices that may be considered experimental, do not have a sound evidence-base, or are not supported by research to improve birth outcomes

b) all participants in an ART treatment procedure must provide informed consent prior to the treatment procedure being performed, and must receive appropriate written information including the rationale for any treatments offered to the person undergoing ART or to the gametes/embryos that will be used in the person's treatment

c) licensed ART providers do not provide treatments that are of unknown efficacy unless it is part of a clinical trial where ethics approval and informed consent has been granted

d) licensed ART providers do not provide treatments that are unnecessary or motivated by interests that are non-therapeutic.

If the regulator has concerns about the practice of a licensed ART provider, the CEO may commission an investigation which may involve experts within or outside of WA.

Policy intent for recommendation 33: The MEP notes the value and importance of research and activities involving innovative procedures that are intended to improve ART treatments and outcomes, and potentially for persons born of ART. These activities must be conducted with ethics approval, informed patient consent, strong regulatory oversight, and consideration of, or demonstrated evidence of benefit to ART participants.

Part E: Data collection and registers

Reproductive Technology Registers

The Department of Health has held statutory Reproductive Technology Registers (RT Registers) since 1993. Surrogacy arrangements were recorded from the commencement of the Surrogacy Act. The RT Registers include details of the ART treatment(s), the person receiving the treatment, their partner (if any) and where the treatment involves donor conception or surrogacy the details of the donor or surrogate. From 2004, birth outcome data have also been held, but importantly no identifying information about the child.

The current RT Registers hold information across 5 data tables:

- **Table 1:** Treatment data as specified for the Australia and New Zealand Assisted Reproduction Database (ANZARD)
- **Table 2:** Treatment data in addition to those specified for ANZARD
- **Table 3:** Identifying information about ART participants, surrogates, partners and donors described in treatment data supplied in Tables 1 and 2
- **Table 4:** Non-identifying donor information
- **Table 5:** Outcome information of exported donated material.

All ART providers in Australia and New Zealand are required to provide ANZARD with treatment data as part of their accreditation by the Fertility Society of Australia and New Zealand. These data must also be shared with the RT Registers as part of the current WA Human Reproductive Technology Directions 2021.[95]

The Allan Review highlighted concerns with the accuracy of RT Registers, and work has been undertaken since 2019 to verify and streamline the data held by the department.

The Allan Review recommended that consideration be given to establishing a donor conception register to be held at BDM for the purpose of recording genealogical information accurately in relation to donor conception and surrogacy. This is further addressed in the BDM section below.

Feedback during the MEP's targeted consultation highlighted the need for RT Register data to be able to link with health and other datasets to allow for better analysis of long-term outcomes for persons born via ART, as well as for approved information sharing and research purposes. For example, current provisions in the *Health (Miscellaneous Provisions) Act 1911* do not permit Midwives Notification System (MNS) data to be linked with the RT Registers.[96]

Opportunities for collecting and linking data about ART participants and persons born of ART should be identified to meet the following important objectives:

- to monitor health outcomes, including long-term health outcomes, for ART participants and persons born of ART
- for safety, quality and assurance purposes including monitoring and compliance undertaken by the department as a regulator of ART, including the monitoring of adverse events
- for approved research purposes.

The MEP is of the view that a statutory duty should remain to record information between parties to donor conception or surrogacy to enable future matching.

95 Human Reproductive Technology Directions 2021 (WA), 2.4.

96 *Health (Miscellaneous Provisions) Act 1911* (WA).

Much of the wording of the current HRT Act hinders efficient data processes, which in turn impacts on the department's capacity to regulate effectively. This also impacts on the quality of data that can be shared with participants (such as those with rights to donor conception information), licensed ART providers, and researchers where disclosure is approved. Proposed legislation should use measured language to ensure that data processes are flexible enough to work effectively, while ensuring data are disclosed only in approved circumstances. This includes defining broader legal purposes in proposed legislation to provide a clear and exhaustive list of who can access data.

While the RT Registers record birth outcomes from ART treatments, future regulation would benefit from highly accurate data in this area. The MEP recommends that proposed legislation require ART providers to record birth outcomes from all pregnancies relating to ART treatments and share these with the department.

Ministerial Expert Panel Recommendation 34:

That proposed legislation be drafted with flexible, but clearly defined provisions around the collection, access and use of reproductive technology data. The ability to link with other datasets, including but not limited to the Midwives Notification System (MNS), should be enabled. Licensed ART providers should ensure that all birth outcomes are shared with the department for inclusion on the RT Registers.

Opportunities for collecting and linking data about ART participants and children born of ART should be identified to meet the following important objectives:

a) to monitor health outcomes, including long-term health outcomes, for ART participants and persons born of ART

b) for safety, quality and assurance purposes including monitoring and compliance undertaken by the department as a regulator of ART, including the monitoring of adverse events

c) for approved research purposes.

A statutory duty will remain to record information between parties to donor conception or surrogacy to enable future matching.

Policy intent for recommendation 34: The drafting of proposed legislation presents an opportunity to create clear instructions regarding what data licensed ART providers must provide to the department, and the subsequent permissible use of these data, what agencies the data can be shared with, and which parties can access certain data. Roadblocks, such as the current inability to link with the MNS, should be resolved to enable data linkage to be as effective as possible, for the benefit of all parties involved in ART.

Access to donor identifying information

The Allan Review made a series of recommendations about access to information relating to donor conception including that proposed ART legislation in WA should make provision for a central donor register, birth certificate addendums, options for voluntary registration on the central register, and removal of donor anonymity with the inclusion of the option for contact preferences for donors.

The government response supported the recommendations in principle. In its response the Government noted that:

- information about a person's biological heritage should be protected in perpetuity and that all donor-conceived persons should have access to identifying information about their donor regardless of the year they were born
- further consultation is required regarding processes for the release and management of identifying information, taking into consideration issues of confidentiality and privacy for all participants.[97]

In the early days of ART, the anonymity of all parties to the donor process was encouraged by medical providers due to perceptions of stigma about infertility. As a result, many people were unaware that they were conceived using donor sperm (the main form of gamete donation at the time). Some did not discover they were donor conceived until adulthood and many may still be unaware. In recent decades, there has been a shift towards recognising the interests of donor-conceived persons. This is evident through universal rights for access to donor-identifying information being granted in Switzerland in 2001[98], Victoria, Australia in 2017[99] and Germany in 2018.[100] This means that access to identifying information may be provided regardless of whether donor anonymity was required or guaranteed at the time of donation.

Currently in WA, a person conceived on or after 1 December 2004 from donated gametes or embryos can access identifying information about their donor from 16 years of age. For people conceived prior to this date the information is released only with the consent of the donor where the information is available and can be verified by the treating fertility clinic. People who were donor conceived before the RT Registers were developed cannot access their donor's identifying information from these registers. It may be possible to discover this information if they approach the ART provider who undertook the treatment. However, records of artificial insemination were not systematically kept, and many records may no longer be available as medical practices have closed or changed management, and records have been destroyed.

The MEP recognises the importance for donor-conceived persons to access information about their donors. This can support people who are donor conceived with their sense of self-identity and alleviate concerns about consanguineous relationships. Encouraging transparency and permitting access to information would also promote openness regarding a person's conception and about infertility, and over time is likely to lessen discrimination toward people requiring donor gametes (or embryos) to create or expand their families, and encourage donation of gametes and embryos.

During its targeted consultation the MEP received considerable feedback from recipients and donor-conceived persons about the importance of transparency and allowing donor-conceived persons to have access to information about their genetic and birth heritage, and to be supported to make contact with donors and siblings, with consent from all parties.

Some donor-conceived persons, and donors, are now identifying their donor relatives through commercial DNA and genealogical services. This means that donors may not be able to maintain their anonymity and donor-conceived persons may be approached by a donor without knowing of their donor-conceived status, or without having consented to contact. These situations of unregulated contact are likely to increase as such technology becomes cheaper and more effective, and databases grow. Proposed legislation seeks to offer opportunities for making identifying information available and supporting positive contact between donor-conceived persons and donors. However, it is important to note that the right to privacy for donors may have been agreed at the time of donation.

97 Government Response to the Allan Review, p 7.

98 Federal Act on Medically Assisted Procreation of 18 December 1998 – FF 1996 III, 197 (LPMA).

99 *Infertility (Medical Procedures) Act 1984* (Vic) (Repealed); *Infertility Treatment Act 1995* (Vic) (Repealed); *Infertility Treatment Regulations 1997* (Repealed); *Assisted Reproductive Treatment Act 2008* (Vic).

100 Act to Regulate the Right to Know One's Heritage in Cases of Heterological Use of Sperm], July 17, 2017, Bundesgesetzblatt [BGBl.] [Federal Law Gazette] I at 2513, BGBl website.

The MEP recommends that proposed legislation enables donor-conceived persons, or their parents until the child reaches 16 years of age, to access identifying information about their donor regardless of when they were born, subject to a donor's contact preference. This would retrospectively remove a donor's anonymity prior to 1 December 2004, where information is held about a donor conception procedure. It is noted that the potential to retrieve information may be limited by the incompleteness or inaccuracy of information held by the RT Registers or licensed ART providers.

The MEP recommends that options must be given to donors who do not wish to have contact with persons conceived using their donation. Contact preferences, including contact vetoes, will be available. For example, a donor would be able to request 'no contact' or specify the type and timing of any contact. If a donor-conceived person and their donor agree to contact or information sharing, the MEP recommends that appropriate counselling be encouraged.

To promote wider transparency around donor conception, it is the MEP's view that licensed ART providers should notify future donors when a child has been born using their donation and be provided with non-identifying information (i.e. the child's sex and year of birth). In historical cases, where information is requested and available, this information should be released to the donor subject to any recorded contact preference on the part of the donor-conceived person. The MEP recommends that penalties be introduced should a licensed ART provider destroy any records, particularly those relating to donor conception, including historical records that predate the HRT Act.

Appendix 14 outlines the current and proposed access to information by parties to donor conception occurring in WA.

Ministerial Expert Panel recommendation 35:

That proposed legislation should enable donor-conceived persons to have access to identifying information about their donor(s) when they reach 16 years of age regardless of when they were born, subject to a contact preference system and availability of records. Until the donor-conceived child has reached 16 years of age, their parent(s) should be able to access identifying information about their donor(s). To support this, the MEP recommends a broad public education and information campaign.

Policy intent for recommendation 35: To ensure that donor-conceived persons conceived before 1 December 2004 have an opportunity to request and, where available, receive information about their genetic and birth heritage. While the consent of the donor to release their identifying information to the donor-conceived person or recipient would not be required in proposed legislation, a contact preference system would permit donors to record their contact preference, including the option for no contact at all.

Ministerial Expert Panel recommendation 36:

That proposed legislation requires licensed ART providers to notify all donors whose gametes are used following commencement of the legislation, of any births resulting from their donation and provide information about the sex assigned at birth and year of birth.

Policy intent for recommendation 36: Some ART providers already notify donors of any births resulting from their donation, however making this a requirement will allow donors to actively know how many donor-conceived person(s) have resulted from their donation, to make the donor conception process more transparent.

Ministerial Expert Panel recommendation 37:

That proposed legislation requires licensed ART providers to keep all existing records about ART, including historical records that predate the HRT Act. Penalties should be introduced should a licensed ART provider intentionally destroy any records, particularly those relating to donor conception.

Policy intent for recommendation 37: While the department does not hold any data regarding donor conception prior to 1993, support should still be available to donor-conceived persons born before this date, including liaising with licensed ART providers at the time to access the data available. There is evidence in Australia of donor conception records being destroyed by ART providers in the past and this should be strongly discouraged via penalties.

Donor Conception Information Service

The Allan Review makes it clear that the secrecy and anonymity which have historically been part of the practice of ART and surrogacy have caused significant harm and distress for donor-conceived offspring, recipients and donors. With moral, religious and socio-cultural attitudes changing significantly in recent decades, the MEP agrees with Allan that proposed legislation should address information-sharing in the spirit of openness, honesty, equity and non-discrimination.[101] The following discussion and recommendations of the MEP reflect this approach.

In 2002, the department established what was known as a Voluntary Register following a policy decision to enable parties to donor conception to register their consent and contact details, that could potentially match donor-conceived persons, donors, recipients, and donor siblings who joined the Voluntary Register. In 2019 this activity was transferred to an independent agency. From 2023, the service will be delivered by a health service provider under a memorandum of understanding (MOU) with the department and will be known as the Donor Conception Information Service (DCIS).

In addition, the DCIS will also support donor-conceived persons conceived on or after 1 December 2004, who have a statutory right to identifying information about their donor. The intention is that the DCIS will serve as the 'trusted agency' recommended by the Allan Review. The DCIS will offer appropriate counselling and other intermediary support when linkage is made at the request of a donor-conceived person. The MEP notes that the DCIS will be responsible for holding and maintaining records of the contact preferences of all parties to ART and surrogacy arrangements and persons born of ART.

The MEP supports expanding options for information sharing between donor-conceived persons, donors and other parties. After the commencement of the proposed legislation recipients may request identifying information about their child's donor once the birth is registered. Donors will be informed by the licensed ART provider of the year of birth and sex assigned at birth of offspring born using their donation after commencement of the legislation.

101 Allan Review Part 1, p 126.

Sharing of information between other parties (donor-conceived persons, donors, recipients and siblings) who have provided their consent will also be facilitated by the DCIS. When information is shared, implications counselling will be encouraged, and intermediary support offered to facilitate contact between parties with consent. The DCIS will continue to record the consent and contact preference for matching other relatives, such as donor siblings, or when a donor requests identifying information about donor offspring.

At the request of donor-conceived offspring, the DCIS would approach their donor if they donated prior to 1 December 2004 to advise them that a request for information has been lodged by their donor offspring. The DCIS will offer the donor the option to lodge a contact preference (including no contact) and implications counselling. Reasonable effort will be made to locate the donor, but if the donor cannot be found, or if they are deceased, their identifying information will be released to the donor-conceived person 4 months after the request was made.

Where a donor requests identifying information about their adult donor offspring, the DCIS will seek information from the RT Registers (where these exist – post 1993) and contact the clinic where the donation was made. Where accurate information can be found about the donor-conceived person's identity, the DCIS will approach the donor-conceived person to record their contact preferences and, unless consent is vetoed, seek their consent to their information being released. The RT Registers do not currently hold identifying information about donor-conceived persons, but this will be required prospectively in proposed legislation.

When a donor-conceived person seeks information about a donor sibling (where the same donor was used in their conception) and both parties have joined the DCIS, then matching will be facilitated by the DCIS. Information is not currently recorded about the birth of donor-conceived persons so proposed legislation will require identifying information to be recorded in the RT Registers. This will enable the option to match donor siblings in the future.

Currently connections between donor siblings (and where the person has not reached 16 years of age then the recipient(s) of donor siblings) is via a consent process between the parties seeking to be matched, and potentially to make a connection. Identifying the donor is via a donor code which may identify other recipient(s), depending on when the donation was made and when the gametes were used. The MEP recommends that this approach continues.

Ministerial Expert Panel recommendation 38:

That the Donor Conception Information Service (DCIS) should be expanded to support donor-conceived persons 16 years of age and over to obtain identifying information about their donor(s), regardless of when they were conceived, where information is available.

That donors will have access to identifying information regarding their donor-conceived offspring, only with the consent of that person, and where information is held. Donor-conceived persons would be supported by the service to lodge a contact preference should a donor request information about them. The DCIS should offer appropriate intermediary support and counselling when successful matching of parties has occurred. All parties to a donation should be encouraged to lodge their contact details and contact preferences with the DCIS. This will facilitate information sharing between parties, and where contact is desired by the parties and information is available, the DCIS will facilitate contact that is informed by the preferences lodged by all parties.

Policy intent for recommendation 38: Donor-conceived persons will be supported to access information about their donor(s) with the removal of anonymity of donors, to be applied retrospectively and facilitated in proposed legislation. Donor siblings continue to seek opportunities for contact with other offspring conceived using the same donor and the DCIS will continue to support this and encourage all parties to lodge contact preferences when contact is made by any party. A public information campaign will give parents who have not informed their children of their donor conception with the opportunity to do so. The knowledge will potentially prepare adult donor-conceived offspring, prior to notification by the DCIS regarding requests for their identifying information, or for a request for contact by their donor, or other donor siblings.

Ministerial Expert Panel recommendation 39:

That resources be provided to the DCIS to deliver services and introduce a public information campaign to advise all parties to donation of the changes to the legislation.

The Registry of Births, Deaths and Marriages

Donor conception and surrogacy, and the recording of parentage, impacts on services undertaken by BDM, which is managed by the Department of Justice. To enable openness and future disclosure (should a donor-conceived person choose this) the MEP recommends that BDM be supported to add a question to the birth registration form asking parents if their child was conceived via donor conception or born via surrogacy. This would not appear on the child's birth certificate. Once disclosed BDM would link with the RT Registers and/or the licensed ART provider to verify the details.

The MEP recommends that there is an addendum to the birth certificate notifying the donor-conceived person, once they have reached 16 years of age, that more information about their conception is held on the birth register (indicating that they are donor conceived or born via surrogacy). This approach is used in Victoria. Upon contacting BDM, the person would be referred to the DCIS for disclosure and support. The addendum would not be visible on the birth certificate of the donor-conceived child.

Some donor-conceived persons have highlighted the importance of their birth certificate recording their accurate biological parentage alongside legal parentage. The MEP recommends that BDM be supported to issue replacement birth certificates at the request of a donor-conceived person, a person born via surrogacy, or the legal parent(s) until the person reaches 16 years of age, that contains factual information about their genetic and birth heritage. This would not confer any responsibilities on the donor, they would continue to not be the parent of the child. Victoria allows donor-conceived-people to add their donor to their birth certificate.[102] In NSW replacement birth certificates can currently be requested by adoptees, with information showing both their birth parents and their legal parents.[103]

102 Births, deaths and marriages Victoria – Add a parent to a birth certificate.

103 NSW Government, Service NSW – Apply for adoption information and/or an integrated birth certificate.

Ministerial Expert Panel recommendation 40:

That the department works with the Registry of Births, Deaths and Marriages (BDM) to adapt the birth registration form to enable the recording of donor conception or surrogacy. That legislation should enable BDM to verify the details of children born from donor conception or surrogacy once the birth registration form is submitted by the parents recording the use of donor conception or surrogacy.

Policy intent for recommendation 40: Information regarding donor conception and birth via surrogacy should be recorded with BDM by the parents at the time of the child's birth registration.

To ensure accurate information is captured via BDM, reciprocal information sharing with the RT Registers and/or a licensed ART provider should be permitted. BDM should be enabled to verify identifying information about children born from donor conception or surrogacy, as well details of the donor or surrogate, via the RT Registers and/or licensed ART providers.

Ministerial Expert Panel recommendation 41:

That the *Births, Deaths and Marriages Registration Act 1998* should be amended, and the department should work with BDM, to permit addendums to be added to birth certificates for all future children born from donor conception or surrogacy once they reach 16 years of age, in the event a donor-conceived person contacts BDM for a copy of their birth certificate. Licensed ART providers should advise recipient(s) or intended parents of this approach at the time of treatment to ensure they understand that information may be disclosed to their child from 16 years of age.

The proposed legislation should expressly recognise that donor-conceived persons, and people born via surrogacy, have the right to request replacement birth certificates that reflect accurate information about both their biological and legal parentage from 16 years of age. This should be retrospective where accurate information is held and would not confer any legal obligations on the donor.

Policy intent for recommendation 41: Recognising the rights of donor-conceived persons to information about their birth and genetic heritage, this recommendation provides donor-conceived persons with an opportunity to learn about their donor conception or birth following a surrogacy arrangement when they contact BDM from 16 years of age. Parent(s) will need to be informed of this approach early on to encourage them to be more open and transparent when discussing with their child the circumstances of their conception and birth.

Options for replacement birth certificates would allow donor-conceived persons and people born via surrogacy to accurately reflect their conception and/or birth via surrogacy on their birth certificate, should they choose to do so.

Part F: Other matters

This section of the report explores other matters that were raised during the MEP's consultation and deliberations. This includes Medicare funding for IVF in a surrogacy arrangement, the supply of gametes outside of licensed ART providers and expanding access to ART services.

Medicare funding of IVF in a surrogacy arrangement

Medicare currently provides rebates for participants who need to access IVF but does not cover IVF when used in a surrogacy arrangement, particularly if the need for the surrogacy is not due to medical infertility. The Allan Review recommended that the WA Minister for Health approach the Commonwealth with a view to allowing IVF for surrogacy to be added to the Medicare Benefits Schedule (MBS). Allan noted this would reduce the costs and support altruistic surrogacy arrangements in WA, which may also serve to support people in choosing not to travel to other jurisdictions to engage in commercial surrogacy[104]. The MEP supports this view and recommends that conversations be held with the Commonwealth.

ART reviews in other states have also drawn similar conclusions. Helping Victorians create families with assisted reproductive treatment – Final Report of the Independent Review of Assisted Reproductive Treatment by Mr Michael Gorton AM highlighted the potential inequality in treating IVF for surrogacy as different from other IVF.[105] Surrogacy may be the only way some cohorts of people can have a family, including single men, same-sex male couples and some transgender people. This could exacerbate inequity and access to ART with one approach to IVF attracting an MBS item while the other does not. A similar conclusion was also reached by the ACT Government in Assisted Reproductive Technology: Regulation and Access – ACT Government Response, with the government committing to "advocate to the Commonwealth Government to expand the eligibility criteria for accessing Medicare rebates to include people accessing ART treatment due to 'social infertility".[106]

The MEP notes conversations across Australia regarding affordability and accessibility to ART, and how cost (and distance) can act as barriers to accessing ART. The Minister for Health and the CEO for the department should have consideration of this for WA.

Ministerial Expert Panel recommendation 42:

That the WA Minister for Health consider a request to the Commonwealth Government to explore ways to expand the Medicare Benefits Schedule (MBS) to include IVF in surrogacy arrangements. Medicare rebates should be accessible for anyone who meets the eligibility criteria for ART.

Policy intent for recommendation 42: To combat inequities that arise by treating some cohorts who access ART differently from others and ensure that certain cohorts accessing ART are not being discriminated against.

104 Allan Review Part 2, Recommendation 54, p 197.

105 Helping Victorians create families with assisted reproductive treatment – Final Report of the Independent Review of Assisted Reproductive Treatment, May 2019, Mr. Michael Gorton AM.

106 Assisted Reproductive Technology: Regulation and Access – ACT Government Response (ACT) August 2022.

Supply of gametes outside of licensed ART providers

Unregulated or informal gamete supply refers to the practice of arranging sperm supply for the purpose of conceiving a baby, using artificial insemination practices or coital conception, outside of a licensed ART provider (sperm exclusively, as egg retrieval requires medical intervention). The current HRT Act does not include information on this matter, however the MEP recognises that unregulated sperm supply is increasingly occurring worldwide. While some unregulated sperm supply is focused and limited (such as between friends and family) the MEP is concerned about the increase in more organised forums for unregulated sperm supply, including via social media groups that match sperm recipient(s) with sperm suppliers.

While proposed ART legislation cannot regulate sperm supply outside of a licensed ART provider, the MEP suggests that this should be strongly discouraged due to a number of reasons as highlighted below.

For the person conceived from unregulated sperm supply:

- sperm is unscreened and may potentially result in a preventable inherited condition
- limited or no information recording the history of the sperm supplier that can be accessed by the person conceived
- limited options for seeking contact at a point in the future with the sperm supplier or other persons conceived using the same sperm supplier where no official records exist
- potentially being the subject of a custody/parenting dispute
- the possibility that many siblings may be created which could cause distress and potentially increase the risk of consanguinity.

For the sperm recipient(s):

- contracting an infectious disease
- having a child with an inherited genetic condition that may be life limiting or cause pain and suffering
- no control over the number of siblings born using the same sperm supplier, with an increased risk of consanguinity between siblings particularly in small communities
- issues regarding legal parentage/rights to access with the child – the *Artificial Conception Act 1985* does not offer protection in these circumstances[107]
- sperm recipient(s) may be coerced or forced to have intercourse, experience other physical or emotional abuse, or exploitation.

For the unregulated sperm supplier:

- issues regarding legal parentage exposing them to financial demands/risks
- passing on or contracting an infectious disease
- emotional or financial abuse from the sperm recipient(s).

Accessing gamete donation via a licensed ART provider, by contrast, offers recipient(s) legal clarity regarding parentage, opportunities for medical review, counselling and other support, and access to altruistically donated gametes that have been medically and genetically screened and have the appropriate consent recorded.

Regulated sperm donation supports the principle that people have a right to information about their genetic heritage and biological parents. Gamete donation via a licensed ART provider offers access to donor information currently for persons conceived on or after 1 December 2004, with recommendation 35 of this report recommending expanding access to persons conceived before this date.

107 *Artificial Conception Act 1985* (WA).

The MEP recognises that much unregulated sperm supply in WA may be due to costs associated with attending a licensed ART provider for donor conception services; the perceived 'user-unfriendliness' of the current legislation, regulation and practices; overly bureaucratic and lengthy procedures; and the clinical environment where conception occurs. Some people prefer to have the opportunity to meet a sperm supplier before making a choice to use their sperm and find that the anonymity of donors when accessing regulated donor sperm through a licensed ART provider is unappealing.

While information detailing the risk of unregulated sperm supply is already available on the department and Healthy WA websites, the MEP recommends that the Minister for Health and/or the CEO of the department explore further options for promoting the advantages and benefits of using a licensed ART provider. Risks associated with unregulated sperm supply need to be highlighted.

Ministerial Expert Panel recommendation 43:

That the Minister for Health and/or the CEO of the department explore further options for promoting the advantages and benefits of using a licensed ART provider when persons access donated reproductive material or services.

Policy intent for recommendation 43: Although recognising the challenges of regulating sperm supply outside of licensed ART providers in any proposed ART legislation, it is important that the department promote the benefits of using a licensed ART provider and advise of the risks of unregulated sperm supply.

Expanding access to ART services

As mentioned in the introduction to this report, all licensed ART providers in WA are currently located within the Perth metropolitan area and ART services are predominantly delivered in the private health sector. While a small amount of State Government funding is available for ART services in the public health system, the eligibility criteria for accessing this funding are strict.

The MEP recognises that financial and geographical barriers to accessing ART are a factor in exacerbating inequity, perhaps even encouraging members of the public to use unregulated sperm donation and surrogacy services both in other Australian jurisdictions, and internationally.

The MEP recommends that the Minister for Health and/or the CEO of the department explore options for increasing access to ART services in WA, including funding for public IVF treatment and providing resources to support access to licensed ART providers.

Ministerial Expert Panel recommendation 44:

That the Minister for Health and/or the CEO of the department explore options for increasing provision for ART services in WA, including expansion of resources for public ART treatment, and opportunities to support travel and accommodation to access ART.

Policy intent for recommendation 44: The Minister for Health and/or the CEO of the department should consider ways to expand access to ART services in WA, recognising the financial and geographical barriers to ART.

The MEP notes that there are provisions in the current HRT Act that facilitate medical practitioners acting as 'exempt practitioners' to undertake a limited number of treatments, but that currently there are no approved exempt practitioners. The MEP recommends that provision be incorporated in proposed legislation to permit medical practitioners to deliver services with support, approval and supervision of a licensed ART provider as a 'delegated practitioner'.

Delegated practitioners would be required to comply with all policies, guidelines and standards (including record keeping) pertaining to the overseeing licensed ART provider, who would in turn, ensure all reporting of data to the RT Registers was complete. The intention of this measure is to expand access to ART services for people living outside the Perth metropolitan area. Further, the MEP recommends that the list of delegated practitioners be expanded to include registered nurses and midwives.

Ministerial Expert Panel recommendation 45:

That proposed ART legislation allows for the provision of 'delegated practitioners', that are clinicians who can undertake some limited ART procedures in regional WA with the support, approval and supervision of a licensed ART provider, with the list of delegated practitioners expanded to include registered nurses and midwives.

Policy intent for recommendation 45: Recognising the geographical barriers to ART this measure could improve access to fertility services through the formation of partnerships with licensed ART providers and regional health services or medical practitioners who may be able to provide limited clinical services.

During the targeted consultation, MEP members met with health professionals, including a number of Aboriginal health professionals who spoke about issues for their families and communities. The MEP considered whether proposed legislation should establish a precedent by including an acknowledgement of the values, beliefs and needs of Aboriginal people, their important spiritual and cultural contributions to WA – and pay respect to past, present and emerging traditional elders and custodians of these lands. Feedback to the MEP highlighted that access for Aboriginal people to fertility services in WA is very limited and that there are significant barriers with few options to overcome these. The attendees emphasised that it is imperative that the sensitive matter of assessment and treatment for infertility be delivered in a way that is culturally safe for Aboriginal clients.

The stakeholders pointed out that for Aboriginal men there is shame about not being able to have a child, and the potential of a diagnosis of infertility can impact young men's willingness to seek assessment and treatment, with a reluctance to discuss their concerns with others, including their GP. They also stressed the need for gender specific fertility education for Aboriginal communities to address this and other barriers to seeking information about infertility and/or treatment options. Culturally safe and targeted education campaigns about how to preserve and protect fertility and how to recognise potential infertility remain important and should be expanded.

The MEP recommends that the Minister for Health and/or the CEO for the department explore options to improve access to ART services for Aboriginal people. These could include:

- setting aside a percentage of the annual public funding for IVF treatment for Aboriginal clients to support their attendance at the King Edward Memorial Hospital Reproductive Medicine Service
- funding assistance to meet some of the costs associated with care as clients from rural and remote areas face significant travel and accommodation expenses that further restrict access options
- access to a cultural support worker to assist clients to navigate their IVF journey and facilitate culturally safe care.

The MEP recommends that licensed ART providers be encouraged to develop culturally safe services and report how many Aboriginal people they treat annually.

Ministerial Expert Panel recommendation 46:

That the Minister for Health and/or the CEO of the department explore options to:

- provide information to Aboriginal people about fertility preservation through gender specific education campaigns aimed at protecting fertility and identifying potential infertility
- expand access to ART services for Aboriginal people
- require licensed ART providers to report the number of Aboriginal clients treated
- monitor licensed ART providers to ensure delivery of culturally safe care.

Policy intent for recommendation 46: To address health inequity, there is a need to explore options to provide gender specific education programs for Aboriginal people regarding factors that can be addressed to prevent future infertility, options for treating infertility, and consider ways to increase access to ART services for Aboriginal people. Culturally safe care will be enhanced by requiring licensed ART providers to provide cultural support workers and report annually on delivery of ART services to Aboriginal people.

Appendices

Appendix 1: Glossary and abbreviations

Accreditation

RTAC provides accreditation to a person or group of people to conduct assisted reproductive technology. It is an offence in Australian Commonwealth law to create or use human embryos in any way without RTAC accreditation.

Allan Review

A review of the WA *Human Reproductive Technology Act 1991* (HRT Act) and the *Surrogacy Act 2008* (Surrogacy Act) undertaken by independent reviewer Associate Professor Sonia Allan which makes 122 recommendations. The report is the most comprehensive review of WA's surrogacy and HRT regulations since the original legislation was enacted. Part 1 of the review focuses on the HRT Act and part 2 on the Surrogacy Act.

Australia and New Zealand Assisted Reproduction Database (ANZARD)

A clinical outcome registry comprising information on all ART treatment cycles undertaken in Australian and New Zealand fertility clinics. The information in the registry is used to monitor perinatal outcomes and assess the effectiveness of ART. The ANZARD collection began in 2004 as a collaborative venture between the National Perinatal Epidemiology and Statistics Unit (NPESU) at the University of New South Wales, the Fertility Society of Australia and New Zealand (FSANZ) and ART providers across Australian and New Zealand (website).

Assisted reproductive technology (ART)

A group of procedures that involve the in vitro (outside of body) handling of human oocytes (eggs) and sperm or embryos for the purposes of establishing a pregnancy. It includes a range of ART treatments and procedures, including in vitro fertilisation (IVF), embryo transfer (ET), gamete intra-fallopian transfer (GIFT), artificial insemination (AI), all manipulative procedures involving gametes and embryos (including storage and screening), and treatment to induce ovulation or spermatogenesis when used in conjunction with the above methods.

For the purpose of this report and the proposed legislation, the term ART includes surrogacy which is considered a form of ART.

ART with donor

ART may involve the use of donated gametes, spermatozoa (sperm) and/or oocytes (eggs) or donated embryos. The use of donor gametes or embryos may occur when there are difficulties conceiving due to infertility, when a person carries a disease or genetic abnormality, or when single people or people in a same-sex couple access ART to have children.

Chief Executive Officer (CEO) of Health

The HRT Act refers to the Chief Executive Officer (CEO) of Health. The CEO of Health is the Director General (DG) of the Western Australian Department of Health.

Cloning

An umbrella term traditionally used to describe different processes for duplicating biological material. Human reproductive cloning is banned in Australia under the *Prohibition of Human Cloning for Reproduction Act 2002*. Human reproductive cloning aims to recreate an existing living or dead person by creating a cloned embryo and placing it in a person's uterus to attempt to achieve pregnancy. Therapeutic cloning, also known as somatic cell nuclear transfer (SCNT) is permitted in Australia under a licence issued by the NHMRC Embryo Research Licensing Committee. The aim of SCNT is to create a cloned embryo to derive an embryonic stem cell line that could be used for research.

Conception

The process of becoming pregnant involving fertilisation or implantation or both.

Commonwealth legislation

Legislation relating to human embryo research exists at the Federal (Commonwealth) level and includes the *Prohibition of Human Cloning for Reproduction Act 2002*, the *Research Involving Human Embryos Act 2002*, the *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006* and the *Research Involving Human Embryos Regulations 2017*.

Data linkage

A technique for connecting separately recorded information that is thought to relate to the same person, family, place or event. When permitted by relevant legislation, linking of data occurs in WA to support approved research, review health outcomes of targeted cohorts or populations, develop policies, and plan and evaluate health services. This provides a more complete picture of the health of people in WA.

Donor

A person who donates human reproductive material (eggs, sperm, embryos or gonadal tissue) for the purposes of an ART procedure, and/or their reproductive capabilities in a surrogacy arrangement. These procedures are undertaken with a licensed ART provider with the intention of the person not to be a parent of a child born as a consequence of the procedure. Donors can be:

- **Known donor:** where the donor has specified a recipient for their gametes or embryos. They could be a friend or family member of the recipient of the donation noting that some known donors may wish to have some involvement in the child's life but with no intention of being a parent of the child.
- **Unknown donor:** this is where the donor has not specified a recipient for their gametes or embryos and has altruistically donated via a licensed ART provider.

Donor conception

Means conception of a child by an ART procedure using human reproductive material provided by a donor.

Donor-conceived person

A person born via donor conception.

Donor insemination

Treatment that involves inserting a donor's concentrated semen through the cervix ('neck' of the uterus) into the uterus (womb) close to the time of ovulation, with the intention of achieving a pregnancy.

Embryo

Once the sperm has fertilised the egg it is called an embryo.

A human embryo is defined as 'a discrete entity that has arisen from either:

1. the first mitotic division when fertilisation of a human oocyte by a human sperm is complete
2. any other process that initiates organised development of a biological entity with a human nuclear genome or altered human nuclear genome that has the potential to develop up to, or beyond, the stage at which the primitive streak appears; and has not yet reached 8 weeks of development since the first mitotic division.'[108]

108 *Research Involving Human Embryos Act 2002* s 7. Hereafter RIHE Act.

Embryonic stem cells

Cells derived from the early embryo. They have the potential to develop into all cell types in the body. In Australia, human embryonic stem cells can be derived from human embryos that are excess to the needs of patients undergoing ART and have been donated to a particular research project by the people for whom they were created. They are not derived from eggs fertilised in a person's body. Embryonic stem cells can also be derived from embryos created by somatic cell nuclear transfer (see Cloning).

Excess ART embryo

An excess ART embryo is a human embryo that:

1. was created by ART, for use in the ART treatment of a person
2. is excess to the needs of:
   (i) the person for whom it was created
   (ii) their partner (if any) at the time that the embryo was created.

For the purposes of paragraph (2), 'a human embryo is excess to the needs of the persons mentioned in that paragraph at a particular time if:

a) each such person has given written authority for the use of the embryo for a purpose other than a purpose relating to the ART treatment of the person concerned, and the authority is in force at the time
b) each such person has determined in writing that the embryo is excess to their needs, and the determination is in force at that time.'[109]

Fertility Society of Australia and New Zealand (FSANZ)

The peak body representing scientists, doctors, researchers, nurses, ART participants and counsellors in reproductive medicine in Australia and New Zealand. It includes the Reproductive Technology Accreditation Committee (RTAC) (website).

Gamete

A word that describes reproductive cells i.e. the spermatozoa (sperm) and oocytes (eggs).

Gamete provider

A person who provides human reproductive material (eggs, sperm, embryos or gonadal tissue) for the purposes of an ART procedure, undertaken by a licensed ART provider, with the intention of being a parent of a child born as a consequence of the procedure.

Gonadal tissue

Tissue from ovaries or testes.

Human Reproductive Technology Act 1991 (HRT Act)

An Act to establish the Western Australian Reproductive Technology Council, to require the compilation of a Code relating to the practice of, the procedures used in, and the ethics governing, human reproductive technology; to make provision with respect to the use of that technology in relation to artificially assisted human conception and for the regulation of certain research; and for related purposes (website).

Human Reproductive Technology Directions 2021 (Directions)

Issued by the CEO of Health to set the standards of practice under the *Human Reproductive Technology Act 1991* on the advice of the Western Australian Reproductive Technology Council (website).

109 RIHE Act s 9.

Human Tissue and Transplant Act 1982

An Act to make provision for and in relation to the removal of human tissues for transplantation, for therapeutic purposes, or medical or scientific purposes, or for post-mortem examinations. This Act permits the posthumous retrieval of gametes under specified circumstances.

Identifying and non-identifying information

Data which identifies a person's name, date of birth, place of birth, occupation and post code. Non-identifying information can include health history, and other characteristics such as hair and eye colour.

Informed consent

For consent to be informed:

- the person giving consent must be considered to have the capacity to provide consent
- the decision to consent to the treatment or procedure must be made without undue pressure
- all relevant requirements regarding the provision of information and counselling requirements must be satisfied
- the consent must be specific and is effective only in relation to the treatment or procedure for which information has been given.

Intended parent

This report uses 'intended parent', particularly in relation to surrogacy in preference to the terms arranged parent and commissioning parent.

Intra-uterine insemination (IUI)

Treatment that involves inserting concentrated semen through the cervix ('neck' of the uterus) into the uterus (womb) close to the time of ovulation with the intention of causing fertilisation of the egg resulting in conception.

IVF (in vitro fertilisation)

The medical procedure by which an egg (oocyte or ovum) is fertilised with sperm in a test tube or outside the body, or where a sperm is injected into an egg, in a specialised laboratory. The fertilised egg (embryo) is grown in a protected environment for some days before being transferred into the uterus or frozen for future fertility treatment.

LGBTI+

Lesbian, gay, bisexual, trans and gender diverse, and intersex. This acronym describes the lesbian, gay, bisexual, trans and gender diverse and intersex individuals and communities. The + symbol is used to represent any additional identities that may fall under this banner.

Licensed ART provider

An organisation or entity licensed by the WA Department of Health to deliver ART services in WA. This includes the storage of gametes and embryos and the practice of a range of ART treatments and procedures. Licensed ART providers are responsible for ensuring all employees or contracted staff undertaking ART treatments and procedures on behalf of their organisation are appropriately trained and registered by the Australian Health Practitioner Regulation Agency (AHPRA) or eligible for membership of their professional organisation if the profession is not registered by AHPRA.

Licensing and Accreditation Regulatory Unit (LARU)

Responsible for the licensing and monitoring of private hospitals in WA. LARU is within the Patient Safety and Clinical Quality Directorate, Clinical Excellence Division, WA Department of Health.

Mitochondrial donation

Mitochondrial donation is a form of ART that may help a person whose mitochondrial disease is caused by mutations in their mitochondrial DNA to avoid passing that mutation to their children. It involves taking the nuclear DNA from the intended parents and placing it in a donated egg which has had its own nuclear DNA removed. The reconstructed embryo has nuclear DNA from the parents and healthy mitochondrial DNA from the egg donor. It is transferred to the uterus of the intended gestational carrier to attempt to achieve pregnancy.

National Health and Medical Research Council (NHMRC)

An independent statutory agency within the portfolio of the Australian Government Minister for Health and Ageing, operating under the *National Health and Medical Research Council Act 1992* (NHMRC Act). As the government's lead agency for funding health and medical research, the NHMRC invests in the creation of new knowledge about the origins, prevention and treatment of disease and the promotion of health and wellbeing. Through clinical, public health and environmental health guidelines and other pathways, the NHMRC supports the translation of research into health practice and policy. The NHMRC publishes the *Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research* (ART Guidelines) (website).

Oocyte

A mature egg usually produced from one ovary each month.

Parent

The MEP has considered whether the term 'parent' should or can be defined. It has concluded that the term 'parent' should be broad and inclusive. In this regard, the MEP recognises and notes the following:

a) The High Court of Australia in Masson v Parsons [2019] HCA 21, noted that:
   1. Whilst the Family Law Act does not contain a definition of 'parent', there is no basis to suggest that term parent should mean anything other than its natural and ordinary meaning (except when and if a provision of the Family Law Act provides otherwise)
   2. Whether a person is a parent is a question of fact and degree to be determined according to the ordinary, contemporary Australian understanding of the term and the relevant circumstances of the specific case at hand
   3. This does not mean that the only persons who, by law, have parental responsibilities are persons who are parents according to ordinary meaning of parent (or who are otherwise defined in the Family Law Act as parents). Further, it does not mean that the only persons who may seek parenting orders are parents according to ordinary meaning of parent (or those who are otherwise defined in the Family Law Act as parents)[110]

b) the term parent may have different meanings in different factual situations

c) the social concepts of a parent and a family have changed over time, and will vary for different people

d) there is a distinction between a person who donates their reproductive material (eggs, sperm, embryos or gonadal tissue) via a licensed ART provider and who has no intention of being involved in the care and welfare of the child or having parental responsibility for the child, and a person who provides their reproductive material with the intention of being involved in the care and welfare of the child and having parental responsibility.

For these reasons, the MEP recommends that a broad and inclusive approach to the concept of who is a parent is applied.

110 High Court of Australia, Masson v Parsons [2019] HCA 21, 19 June 2019, S6/2019.

Partner

A proposed definition of partner is included in recommendation 12:

a) the person's legal spouse irrespective of gender (other than a spouse from whom the person has separated)

b) the person's de facto partner irrespective of gender, who has lived with the first person on a genuine domestic basis for a minimum of 3 months

c) a person not currently married or living in a de facto relationship, but where there is an established relationship.

Practice licence

A licence granted by the CEO of the Department of Health to a person or group of persons to carry out any artificial fertilisation procedure, not being a storage procedure, and any approved project of fertility research.

Preimplantation Genetic Testing

Procedures used prior to embryo transfer to detect serious genetic conditions, diseases or abnormalities, which the gamete provider(s) are known to be at risk, to carry or to be predisposed. Can also be used to test embryos for unspecified and multiple genetic or chromosomal abnormalities where the gamete provider(s) are not known to have any genetic condition, disease or abnormality, or who do not carry a known causative abnormality. Testing may be undertaken to improve live birth rates (by improving pregnancy rates from embryo transfer and reducing incidence of miscarriage) and may be suitable in cases of advanced maternal age and repeated implantation failure. In rare circumstances it is used to select an embryo with compatible tissue for subsequent stem cell therapy for a parent, sibling or other relative.

Reciprocal IVF

Allows one person in a partnership to contribute their oocyte (egg) in order to create an embryo that will be carried to term by their partner. One partner undergoes ovarian stimulation and egg retrieval. Using sperm from a known or unknown donor, the embryo is created through IVF and is implanted in the second partner who carries the pregnancy to term.

Reproductive Technology Accreditation Committee (RTAC)

A professional group of the Board of the FSANZ. It is responsible for setting standards for the performance of ART through an audited Code of Practice and the accreditation of ART providers within Australia (website).

Reproductive Technology Registers (RT Registers)

Multiple registers kept by the WA Department of Health containing information specified in the HRT Directions and other legislation. In operation since 1993-94, these include information about licensed clinics and storage facilities, individual's treatment cycle data, identifying information about participants, partners and donors, non-identifying data about donors, and birth outcomes for treatments in other jurisdictions using donated material exported from WA. The purpose of keeping the RT Registers is to ensure the safety and quality of ART services in WA by monitoring its outcomes and for maintaining information about donation, genetic parentage and donor conception.

Semen

The ejaculated fluid comprising sperm and other secretions of the sex glands.

Spermatozoa (sperm)

The reproductive cell produced in the testes.

Stem cells

Stem cells are 'unspecialised' cells that have the potential to develop into 'specialised' cell types in the body (for example blood cells, muscle cells or nerve cells). This can be either for growth and development, or for replenishment and repair.

Storage licence

A licence granted by the CEO of the Department of Health to a person or group of persons that authorises the licensee to carry out any procedure related to the storage of sperm, eggs or embryos, and any approved research related to such storage.

Surrogacy arrangement

An arrangement whereby a person (surrogate) agrees to carry a child on behalf of another person and their partner (if any), with the intention:

a) that a child born as a result of the pregnancy has parenting responsibilities and legal parentage transferred to the intended parent(s) (whether by court order, adoption, agreement or otherwise)

b) of transferring custody or guardianship for a child born as a result of the pregnancy to the intended parent(s).

Surrogacy can be:

- **Traditional surrogacy:** surrogate conceives with her own eggs, with sperm from an intended parent or a sperm donor.
- **Gestational surrogacy:** surrogate conceives after transfer of an embryo resulting from fertilisation of an egg from an intended parent or an egg donor with sperm from an intended parent or a sperm donor.

Surrogacy Act 2008

An Act legislating arrangements for surrogate births and children born under those arrangements and for related purposes (website). These arrangements are required to interact with other legislation including:

- the *Births, Deaths and Marriages Registration Act 1998*
- the *Children and Community Services Act 2004*
- the *Family Court Act 1997*
- the *Guardianship and Administration Act 1990*
- the *Human Reproductive Technology Act 1991*
- the *Interpretation Act 1984*.

Surrogate

A general term that refers to an individual who carries a pregnancy for another individual or couple. This report uses the term surrogate, rather than surrogate mother or birth mother, to acknowledge that some surrogates do not identify as the mother to the child they carry in a surrogacy arrangement.

Uterus (womb)

The reproductive organ that supports the developing fetus.

Abbreviations

AARB	ART Advisory and Review Board
AHPRA	Australian Health Practitioner Regulation Agency
AI	Artificial insemination
ANZARD	Australia and New Zealand Assisted Reproduction Database
ANZICA	Australian and New Zealand Infertility Counsellors Association
ART	Assisted Reproductive Technology
BDM	Registry of Births, Deaths and Marriages
CEO	Chief Executive Officer of the WA Department of Health
COAG	Council of Australian Governments
CREI	Certification in Reproductive Endocrinology and Infertility
DCIS	Donor Conception Information Service
ET	Embryo transfer
FSANZ	Fertility Society of Australia and New Zealand
GIFT	Gamete intra-fallopian transfer
HaDSCO	Health and Disability Services Complaints Office
HFEA	UK Human Fertilisation and Embryology Authority
HLA	Human Leukocyte Antigen
HRT	*Human Reproductive Technology Act 1991*
HTT	*Human Tissue and Transplant Act 1982*
ICSI	Intracytoplasmic sperm injection
ISPD	Information and System Performance Directorate
IUI	Intra-uterine insemination
IVF	In vitro fertilisation
KEMH	King Edward Memorial Hospital
LARU	Licensing and Accreditation Regulatory Unit
LGBTI+	Lesbian, Gay, Bisexual, Trans and Gender Diverse and Intersex
MBS	Medicare Benefits Schedule
MEP	ART and Surrogacy Ministerial Expert Panel
MNS	Midwives Notification System
MRS	Minimally responsive state
NHMRC	National Health and Medical Research Council
NPESU	National Perinatal Epidemiology and Statistics Unit
OHSS	Ovarian hyperstimulation syndrome
PCU	Post-coma unresponsiveness
PGT	Preimplantation genetic testing
PHCR	*Prohibition of Human Cloning for Reproduction Act 2002*
RANZCOG	Royal Australian and New Zealand College of Obstetricians and Gynaecologists
RIHE	*Research Involving Human Embryos Act 2002*
RTAC	Reproductive Technology Accreditation Committee
RTC	Reproductive Technology Council
SAT	State Administrative Tribunal
SCNT	Somatic cell nuclear transfer
VARTA	Victorian Assisted Reproductive Treatment Authority

Appendix 2: Ministerial Expert Panel for ART and Surrogacy Terms of Reference

Assisted Reproductive Technology and Surrogacy Legislation Ministerial Expert Panel[111]

1. Purpose

The Assisted Reproductive Technology (ART) and Surrogacy Legislation Ministerial Expert Panel (MEP) will provide advice to the WA Government to assist in the development, consultation and implementation of new legislation for ART and surrogacy in Western Australia.

2. Background

In 2018, the WA Government commissioned the independent review of the Western Australian *Human Reproductive Technology Act 1991* (HRT Act) and the *Surrogacy Act 2008* (Surrogacy Act) undertaken by Associate Professor Sonia Allan (Allan Review). The Government Response to the Allan Review was tabled in Parliament on 18 August 2021 and was accompanied by a commitment to the development of new ART and surrogacy legislation in Western Australia. The Allan Review made a total of 122 recommendations of which 67 recommendations relate to the HRT Act and 55 recommendations relate to the Surrogacy Act.

Overall, the Government supported most of the recommendations (supported or supported in principle 73 recommendations, and did not support 6 recommendations, with 43 recommendations noted or for further consideration) which will provide a strong foundation for new legislation in this complex and sensitive area while at the same time safeguarding public and professional confidence. The Government committed to providing for better, less burdensome regulation for ART and surrogacy which benefits those who need help to have a family, ART service providers, and the wider community.

A number of recommendations made in the Allan Review were identified by the Government as requiring further consideration, in order to identify and consider the implications of the recommendation for new legislation. The development and introduction of the new ART and surrogacy legislation in WA is being supported by the establishment of a Ministerial Expert Panel (MEP) which will provide advice to government and undertake targeted consultation with key stakeholders for those areas requiring further deliberation and consultation.

3. Role

The MEP will take the findings and recommendations of the Allan Review and the Government Response to the Allan Review, including consideration of the recommended regulatory framework and areas requiring further consultation, and consider the detail of how new legislation could be implemented safely and appropriately in Western Australia.

As such, the MEP's remit is to consider both the 'what' and 'how' of new ART and surrogacy legislation using the Government Response to the Allan Review as a starting point.

The MEP will provide advice in the form of a final report on those areas supported by government for adoption and propose positions on those areas identified as requiring further consideration and consultation to meet the needs of the Western Australian community.

111 As published on the Ministerial Expert Panel for Assisted Reproductive Technology and Surrogacy Legislation webpage on the Department of Health website.

The MEP will do this by:

- seeking expert advice on specific elements of new ART and surrogacy legislation; and
- undertaking a targeted consultation on specific topics for which further consultation has been identified as required.

This consultation will be based on topics identified by the Government Response to the Allan Review as requiring further consideration and consultation, as well as any identified by the Minister for Health, the Premier, the Department of Health, the Department of Communities and Department of Justice.

The MEP will communicate and engage with targeted stakeholders with a range of perspectives, harnessing their expertise and experience to develop advice on the access, safeguards, and practical considerations required to develop new legislation for ART and surrogacy.

The MEP will consult with the following (including but not limited to):

- consumers including persons accessing (or seeking to access) ART and surrogacy, donors, and persons born from ART
- gender and sexually diverse advocacy groups
- Aboriginal and culturally and linguistically diverse groups
- ART service providers from fertility clinics
- the Western Australian Reproductive Technology Council
- medical, nursing and allied health professionals providing ART and surrogacy services
- legal professionals and organisations
- research institutes and regulatory bodies
- other subject matter experts.

The MEP will develop and endorse policy positions and recommendations on specific elements for new ART and surrogacy legislation which will be considered by Government to develop instructions for the final Bill. This body of work will be supported by Department of Health staff.

The MEP should, at all times, apply the best interests of the WA community to all discussions and decisions over and above their own personal interests.

The role of the MEP is not to:

- replicate the consultations undertaken by the Allan Review
- consider the argument 'for' or 'against' new ART and surrogacy legislation
- focus on the detail of any implementation required for the new ART and surrogacy legislation
- draft the legislation – to be drafted by the Parliamentary Counsel's Office based on drafting instructions provided by the department which reflect the Government's final policy positions.

4. Membership

The MEP membership will represent the interests of:

- consumers accessing ART and surrogacy, donors, and persons born from ART
- fertility clinics and ART industry sector
- medical professionals providing ART and surrogacy services
- other professionals delivering services representing health and science professions
- legal professionals practicing in the relevant areas of surrogacy and/or ART
- ethicists
- research and regulatory bodies.

4.1 Chair

The Independent Chair will be appointed by Cabinet, on the recommendation of the Minister for Health. The role of the Chair is to:

- provide clear direction to facilitate a rigorous and timely decision-making process
- determine any items that require out-of-session consideration by the MEP
- act as the lead liaison between the MEP and Minister for Health
- lead the consultation process, including facilitating one-on-one consultation sessions with key stakeholders as required
- lead the development of policy positions and legislative recommendations
- be the representative of the MEP for media requests and inquiries with the approval of the Minister for Health
- ensure the MEP Terms of Reference are applied throughout the term of the MEP
- provide ownership of the agenda.

The Deputy Chair will be appointed by Cabinet, on the recommendation of the Minister for Health, and will act as Chair in his or her absence.

4.2 Members

The role of a member is to:

- contribute to constructive debate on issues raised
- participate in targeted consultation as required
- provide advice to the Chair on all matters relevant to these Terms of Reference
- consider and review documents and/or issues out of session as required
- provide advice on policy positions and legislative recommendations.

Membership consists of:

- **Professor Roger Hart** – Chair, Fertility Specialist, Researcher, Professor of Reproductive Medicine at The University of Western Australia, Medical Director of Fertility Specialists of Western Australia, National Medical Director of City Fertility, Head of Reproductive Medicine Service at King Edward Memorial Hospital (KEMH).
- **Dr Louise Farrell OAM** – Deputy Chair, Consultant Obstetrician and Gynaecologist, and Head of Colposcopy Services, KEMH. Former Vice-President of the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG), Chair of the WA Branch of the RANZCOG, and previous Clinical Director (Obstetrics and Gynaecology) at St John of God Hospital Subiaco.
- **Dr Angela Cooney** – General Practitioner with expertise in reproductive health, women's health and working with LGBTQI+ clients. Former Medical Director of Family Planning WA (now Sexual Health Quarters).
- **Dr Ian Hammond AM** – retired Consultant Gynaecologic Oncologist. Former Clinical Professor, School of Women's and Infants Health, The University of Western Australia. Previous Chair and Member of National Cervical Screening Program Committees and Expert Advisory Groups.
- **Mr Martin Kavanagh** – Barrister and Solicitor with extensive experience in family law and family violence orders with particular interest in surrogacy, LGBTQI+ legal issues, State Administrative Tribunal, Guardianship and Administration, Hague Convention (Child Abduction) matters, and international family law (particularly Ireland, USA, England and Wales).
- **Ms Rachel Oakeley** – Barrister with a special interest in family law, infertility law and surrogacy matters including complex property, parenting, adoption, child protection, child support and international cases. Registered arbitrator and nationally accredited mediator chairing family law mediations and providing advocacy services to instructors from family law practices.
- **Fiona Seaward SC** –Acting Deputy State Solicitor – Public and General Litigation at the State Solicitor's Office. Ms Seaward provides legal advice to government and practices as counsel in a broad range of matters, with a particular emphasis on public law and constitutional law. Ms Seaward is a former Commissioner of the Law Reform Commission of Western Australia.
- **The Hon Dr Sally Talbot MLC** – Member for South West Region, Chair of the Standing Committee on Legislation, former Chair, Deputy Chair and Member of various Parliamentary Committees including the Select Committee into Public Obstetric Services and the Joint Select Committee on End of Life Choices.

4.3 Attendees

The Chair may invite non-members to participate if they are considered to be directly involved in the matters at hand or have expertise to assist in advising on matters as required.

4.4 Accountability

The MEP will report to the Minister for Health as required.

4.5 Proxy membership

Nil proxy.

5. Resources

The MEP will be supported by staff in the Minister for Health's office and the Department of Health who will:

- undertake a secretariat role including compilation of agendas, document distribution and other coordination functions.
- provide research, analysis and evaluation, including the identification and management of emerging issues, risks and trends at local, national and international levels and develop policy proposals and options to support the work of the MEP.
- prepare reports, briefs and submissions (such as Cabinet and Parliament documents, Ministerial Briefs and correspondence, and discussion papers) on the legislative, regulatory and policy issues related to ART and surrogacy.
- coordinate and support targeted stakeholder consultations and seek advice to resolve key issues and provide advice and input into the development of legislation and regulation.

6. Operating Procedures

6.1 Meeting frequency

- meetings will be held at a minimum of one meeting every month for two hours.
- the Minister or the Chair may convene additional meetings on an as needs basis to progress the work in the timeframe specified by the Minister.

6.2 Quorum

A quorum will consist of at least four MEP members.

6.3 Meeting documentation

- all meeting documentation intended for the MEP's consideration (including but not limited to reports, presentations, briefing notes) are to be provided to the Secretariat a minimum of five working days prior to the meeting.
- late papers will only be circulated with approval from the Secretariat and Chair.
- at the discretion of the Chair, items may be considered out of session if deemed appropriate to review and/or requiring immediate attention in advance of a scheduled meeting.

6.4 Records

A decision and action log will be maintained by the Secretariat.

7. Term

The MEP will operate from May 2022 to December 2022 – or until such time as the Minister for Health determines the panel has completed its function.

8. Conflict of Interest

A declaration of conflict of interest is required where a member has competing professional or personal interests. In this instance and on advice from the Chair, the member will either refrain from voting and/or participating in consensus decision making or retire from the room for that agenda item. All declarations of conflicts of interest will be recorded in the minutes.

9. Confidentiality

MEP members will be in receipt of information that is regarded as confidential. Members acknowledge their responsibility to maintain confidentiality of all information that is not in the public domain and will maintain all documents in a confidential manner separate from any other business or responsibilities.

Ministerial Expert Panel Guiding Principles

Background

The MEP will abide by fundamental principles to guide the new ART and surrogacy legislation development and targeted consultation process.

The Guiding Principles are drawn from the:

- Fertility Society of Australia Reproductive Technology Accreditation Committee Code of Practice for ART Units
- National Health and Medical Research Council (NHMRC) *Ethical Guidelines on the Use of ART in Clinical Practice and Research*, and
- WA Health Code of Conduct.

MEP Guiding Principles

- ART activities must be conducted in a way that shows respect to all involved.
- the interests and wellbeing of the person who may be born as a result of an ART activity must be the central important consideration in all decisions about the activity.
- ART activities must be undertaken in a manner that minimises harm and maximises the benefit to each individual or couple involved in the ART activity, any persons who may be born as a result of the activity, and any other child within the family unit who may be affected by that birth.
- decision-making in the clinical practice of ART must recognise and take into account the biological connections and social relationships that exist or may be formed as a result of the ART activity.
- decision-making in the clinical practice of ART must recognise and respect the autonomy of all relevant parties, promoting and supporting the notion of valid consent as a fundamental condition of the use of ART.
- decision-making in the clinical practice of ART must recognise that social relationships and social context may affect an individual's or a couple's decision-making and be sensitive to cultural and spiritual differences.
- processes and policies for determining an individual's or a couple's eligibility to access ART services must be just, equitable, transparent and respectful of human dignity and the natural human rights of all persons, including the right to not be unlawfully or unreasonably discriminated against.
- the provision of ART must be underpinned by policies that support effective and efficient practices that minimise interventions not supported by evidence of successful clinical outcomes.
- the provision of ART must be transparent and open to scrutiny, while ensuring the protection of the privacy of all individuals or couples involved in ART and persons born, to the degree that is protected by law.
- ART activities must be carried out in compliance with existing laws and regulatory frameworks, and must also comply with relevant professional and accreditation standards.
- all people, including health practitioners, have the right to be shown respect for their culture, beliefs, values and personal characteristics.

Appendix 3: Other state and territory approaches to ART (Table 1) and surrogacy (Table 2)

Table 1 – Assisted reproductive technology – state and territory approaches

Issues	ACT	New South Wales	Northern Territory	Queensland	South Australia	Tasmania	Victoria	Western Australia
Current Legislation	None	*Assisted Reproductive Technology Act 2007*	None	None	*Assisted Reproductive Treatment Act 1988*	None	*Assisted Reproductive Treatment Act 2008*	*Human Reproductive Technology Act 1991*
Current Regulatory Authority	Self-regulation[112]	Registration via Ministry of Health	None[113]	Self-regulation	Registration via Dept for Health and Wellbeing	Self-regulation	Registration via Victorian Assisted Reproductive Treatment Authority (VARTA)	Licensing via Reproductive Technology Council (RTC)
ART Eligibility	No criteria in law. NHMRC Guidelines followed[114]	No criteria in law. NHMRC Guidelines followed	No criteria in law. NHMRC Guidelines followed	No criteria in law. NHMRC Guidelines followed	A person must be unlikely to become pregnant other than by ART (includes non-medical factors for single people and same sex couples), or there is a risk of transmitting a genetic defect, disease or illness	No criteria in law. NHMRC Guidelines followed	A woman must be unlikely to become pregnant (includes non-medical factors for single people and same sex couple), unable to carry a pregnancy or give birth, or at risk of transmitting a genetic	A couple/woman cannot become pregnant due to medical reasons, or there is risk of transmitting a genetic abnormality or infectious disease. A couple must be married or in a de facto relationship

112 Self-regulation includes following the NHMRC's *Ethical guidelines on the use of assisted reproductive technology in clinical practice and research*, the Reproductive Technology Accreditation Committee (RTAC) Code of Practice, and all other necessary medical, professional, and commercial licensing and registration requirements.

113 Fertility services in the Northern Territory can be provided by South Australian clinicians operating under guidelines consistent with South Australian legislation.

114 The NHMRC's *Ethical guidelines state* "processes and policies for determining an individual's or a couple's eligibility to access ART services must be just, equitable, transparent and respectful of human dignity and the natural human rights of all persons, including the right to not be unlawfully or unreasonably discriminated against. In determining an individual's or a couple's eligibility to access ART services, there must be no unlawful or unreasonable discrimination, for example, on the basis of: • race, religion, sex, sexual orientation, relationship status, gender identity or intersex status, social status, disability or age • the reason(s) for seeking assisted conception • refusal to participate in research."

Issues	ACT	New South Wales	Northern Territory	Queensland	South Australia	Tasmania	Victoria	Western Australia
							abnormality or disease	and must be of the opposite sex to each other
Age restrictions for ART	No age limit in law. Clinics to follow NHMRC guidelines	No age limit in law. Clinics to follow NHMRC guidelines	No age limit in law. Clinics to follow NHMRC guidelines	No age limit in law. Clinics to follow NHMRC guidelines	No age limit in law. Clinics to follow NHMRC guidelines	No age limit in law. Clinics to follow NHMRC guidelines	No age limit in law. Clinics to follow NHMRC guidelines	ART not permitted if the reason for infertility is age-related
Release of identifying donor information	NHMRC Guidelines followed[115]	Donor-conceived persons born after 2010 will be able to access information about their donor (at 18 in 2028). Before this date requires donor consent	NHMRC Guidelines followed	NHMRC Guidelines followed	Donor-conceived persons may access information with donor consent	NHMRC Guidelines followed	Donor-conceived persons may access information about their donor regardless of when they were conceived. Contact may be limited by either party via a contact veto	Donor-conceived persons born after 2004 may access information about their donor from age 16. Before 2004 requires donor consent
Current donor conception register	NHMRC Guidelines followed[116]	The Central Register holds all mandatory information	NHMRC Guidelines followed	NHMRC Guidelines followed	Donor Conception Register being established	NHMRC Guidelines followed	The Central Register holds required information. A Voluntary Register holds information for other people such as extended relatives	The Reproductive Technology Register contains all mandatory information. A voluntary register exists for those not eligible to access identifying information about donors, offspring and siblings

115 Since the 2004 edition the *NHMRC Ethical Guidelines on the use of ART* have stated that clinics should not use donated gametes unless the donor has consented to the release of identifying information to any donor-conceived person. Persons conceived using ART procedures are entitled to know their genetic origin, with donors being advised of this.

116 *NHMRC Ethical Guidelines on the use of ART* state that clinics must ensure that all relevant information about parties involved in donor conception programs or surrogacy arrangements are recorded so that this information is available to potential recipients of the donation, any persons born, and/or the gamete or embryo donors. Information about all parties involved in a donor conception program or surrogacy arrangement must be kept indefinitely (or at least for the expected lifetime of any persons born); in a way that is secure but is accessible to any relevant party.

Issues	ACT	New South Wales	Northern Territory	Queensland	South Australia	Tasmania	Victoria	Western Australia
Storage of gametes and embryos	NHMRC Ethical Guidelines followed (no prescribed limits)	No prescribed limit for own use gametes/ embryos 15-year limit for donated gametes/ embryos (extension possible via Secretary of the Ministry of Health)	NHMRC Ethical Guidelines followed (no prescribed limits)	NHMRC Ethical Guidelines followed (no prescribed limits)	NHMRC Ethical Guidelines followed for own use (no prescribed limits) 15-year limit for donated gametes (extension possible via Minister for Health)	NHMRC Ethical Guidelines followed (no prescribed limits)	10 years for gametes (20 years for future infertile children/ young adult). 5 years for embryos (extension possible via Patient Review Panel)	No prescribed limit for gametes, 15-year limit for embryos (extension possible via RTC)
Posthumous use of gametes	Removal and use permitted with evidence the deceased was planning a family with the surviving partner	Removal and use permitted if consent prior to death	Removal permitted if reasonable belief the deceased would have consented. Use permitted in line with NHMRC	Removal permitted with reasonable belief or consent from next of kin. Use permitted in line with NHMRC	Removal permitted if reasonable belief the deceased had planned a family. Use (semen only) permitted if consent prior to death	Removal permitted with reasonable belief or consent from next of kin. Use permitted in line with NHMRC	Use permitted if consent prior to death. Patient Review Panel approval required. Includes use of gametes/ embryos in a surrogate	Removal permitted if reasonable belief the deceased would have consented. Use currently banned
Pre-implantation genetic testing, saviour siblings and sex selection	PGT, Tissue Typing, and medical sex selection permitted following NHMRC Guidelines	PGT, Tissue Typing, and medical sex selection permitted following NHMRC Guidelines	PGT, Tissue Typing, and medical sex selection permitted following NHMRC Guidelines	PGT, Tissue Typing, and medical sex selection permitted following NHMRC Guidelines	PGT, Tissue Typing, and medical sex selection permitted following NHMRC Guidelines	PGT, Tissue Typing, and medical sex selection permitted following NHMRC Guidelines	PGT and Tissue Typing permitted. Sex selection for medical reasons permitted with approval from Patient Review Panel	PGT permitted. Tissue Typing not permitted. Sex selection for medical reasons permitted
Research involving human gametes or embryos	Permitted with NHMRC licence	Permitted with NHMRC licence	Not undertaken due to lack of legislation	Permitted with NHMRC licence	Permitted with NHMRC licence	Permitted with NHMRC licence	Permitted with NHMRC licence	Not currently undertaken due to inconsistency with Commonwealth law
Reciprocal IVF	Undertaken	Undertaken	Undertaken	Undertaken	Undertaken	Undertaken	Undertaken	Not currently permitted as medical requirement to access ART

Table 2 – Surrogacy – state and territory approaches

Issues	ACT	New South Wales	Northern Territory	Queensland	South Australia	Tasmania	Victoria	Western Australia
Current Legislation	*Parentage Act 2004*	*Surrogacy Act 2010*	*Surrogacy Act 2022*	*Surrogacy Act 2010*	*Surrogacy Act 2019*	*Surrogacy Act 2012*	*Assisted Reproductive Treatment Act 2008*	*Surrogacy Act 2008*
Approval body	Self-regulation	Self-regulation	Self-regulation	Self-regulation	Self-regulation	Self-regulation	Approval via Patient Review Panel (PRP)	Approval via Reproductive Technology Council (RTC)
Advertising[117]	Illegal for both intended parent(s) and surrogates	Permitted for both intended parent(s) and surrogates	Permitted for both parties	Illegal for both parties	Permitted for both parties	Illegal for both parties	Illegal for both parties	Permitted for both parties
Eligibility	Intended parent(s) must be married or de facto (same or opposite sex). Intended parent(s) must be 25 or older and surrogates 18 or older. One intended parent must have a genetic connection to the child	Intended parent(s) can be a single person or a couple with a medical or social need for surrogacy. Both intended parent(s) and surrogate must be 25 or older	Intended parent(s) can be a single person or couple (regardless of sex). There must be a medical or social reason. Both the intended parent(s) and surrogate must be 25 or older	Intended parent(s) can be a single person or couple (regardless of sex). There must be a medical or social reason. Surrogate s must be 25 or older	Intended parent(s) can be a single person or couple (regardless of sex). There must be a reason that they cannot become pregnant, either medical or social. Both intended parent(s) and surrogates must be 25 or older	Intended parent(s) can be a single person or couple (regardless of sex). An eligible woman must be unable to carry a baby or give birth or would give birth to a child with a genetic disorder. Surrogates must be 25 or older and have previously given birth to a live child	Intended parent(s) must be infertile or unable to carry a baby or give birth. This includes single and same sex couples. Surrogates must be 25 or older and have previously given birth to a live child	Intended parent(s) include single women or opposite sex couples where the woman is unable to conceive a child due to medical reasons, would likely conceive a child with a genetic abnormality or disease; or is unable for medical reasons to give birth. Surrogates must be 25 or older and have previously given birth to a live child

117 For all Australian states and territories commercial surrogacy is prohibited, and where advertising is permitted, no fee can be paid for advertisement, statement, or publication.

Issues	ACT	New South Wales	Northern Territory	Queensland	South Australia	Tasmania	Victoria	Western Australia
Residency requirements	Not stipulated	The intended parent(s) must reside in NSW at the time of the hearing of the parentage order application	The intended parent(s) must reside in NT at the time of the hearing of the parentage order application, however the Court may dispense with this requirement in exceptional circumstances	The intended parent(s) must reside in Qld when applying for the parentage order	The intended parent(s) and surrogate must be an Australian citizen or permanent resident. No other residency requirements	The court may make a parentage order if each party to the surrogacy arrangement, at the time the arrangement was entered into, was resident in Tasmania	The Court can make substitute parentage orders if the commissioning parents were ordinarily resident in Victoria at the time the child was conceived	An application can be made for a parentage order only if the arranged parents reside in WA
Mandatory prerequisites	Counselling and an assessment are requirements for the court to grant a parenting order	Counselling and independent legal advice is mandatory	Counselling and independent legal advice is mandatory	Counselling and independent legal advice is mandatory	Counselling and independent legal advice is mandatory. Each intended parent must provide the surrogate a criminal history report	Counselling and independent legal advice is mandatory	Approval required by PRP. Legal advice and counselling are mandatory	Approval required by the RTC. Counselling, independent legal advice and an independent psychological assessment mandatory
International commercial surrogacy	Overseas commercial surrogacy punishable by law[118]	Overseas commercial surrogacy punishable by law	No extraterritorial provision	Overseas commercial surrogacy punishable by law	No extraterritorial provision	No extraterritorial provision	No extraterritorial provision	No extraterritorial provision. Parents bringing a child into WA born via international commercial surrogacy are unable to apply for a legal parentage order under current law

118 Extraterritorial provision in surrogacy legislation allows those states to criminalise intended parent(s) who utilise commercial surrogacy overseas, however these penalties have never been utilised, as it could impact on the welfare of the child.

Issues	ACT	New South Wales	Northern Territory	Queensland	South Australia	Tasmania	Victoria	Western Australia
Parentage at birth	The surrogate is recognised as the birth parent, with any partner recognised as the other parent. Intended parent(s) must apply to the court for a parentage order when the child is between 6 weeks and 6 months	The surrogate is recognised as the birth parent, with any partner recognised as the other parent. Intended parent(s) must apply to the court for a parentage order no earlier than 30 days after birth, and no later than 6 months after birth	The surrogate is recognised as the birth parent, with any partner recognised as the other parent. Intended parent(s) can apply to the court for a parentage order no earlier than 30 days after birth, and no later than 180 days following birth	The surrogate is recognised as the birth parent, with any partner recognised as the other parent. Intended parent(s) must apply to the court for a parentage order no earlier than 28 days after birth, and no later than 6 months	The surrogate is recognised as the birth parent, with any partner recognised as the other parent. Intended parent(s) can apply to the court for a parentage order no earlier than 28 days after birth, and no later than 6 months following birth	The surrogate is recognised as the birth parent, with any partner recognised as the other parent. Intended parent(s) must apply to the court for a parentage order no earlier than 30 days after birth, and no later than 6 months after birth	The surrogate is recognised as the birth parent, with any partner recognised as the other parent. Intended parent(s) must apply to the court for a parentage order no less than 28 days and no more than 6 months after birth	The surrogate is recognised as the birth parent, with any partner recognised as the other parent. Intended parent(s) must apply to the court for a parentage order no earlier than 28 days after birth, and no later than 6 months after birth

Appendix 4: Consultation summary – responses to the Public Discussion Paper

Summary of responses to the Public Discussion Paper or correspondence to the Ministerial Expert Panel on ART and surrogacy

No.	Summary of key issues in submission – 18 members of the public and 22 professionals or organisations
1	• Surrogacy – supports expansion to single men and same-sex couples
2	• Surrogacy – request for a trauma informed strategy to how the Ministerial Expert Panel considers surrogate children
3	• Feedback on the recent decision to develop a Donor Conception Information Service at King Edward Memorial Hospital
4	• Support for an approved list of preimplantation genetic testing conditions to streamline the process • Support for mitochondrial research and testing in WA • Support for preimplantation genetic testing for human leukocyte antigen (HLA) typing as per NHMRC Ethical Guidelines • Request that new laws are worded in a way that does not hinder new and emerging technologies
5	• Request to be a member of the Ministerial Expert Panel as an ART participant
6	• Highlights the importance of data matching between ART data and other health data
7	• Surrogacy – supports expansion to single men and same-sex couples
8	• Recommends that new legislation have strong formal guiding principles • Recommends a single Act for ART and surrogacy (to remove contradictions between both current Acts) • Suggests an approval body retain oversight of gamete and embryo storage limits • Suggests adoption of the UK Human Fertilisation and Embryology Authority Welfare Check for prospective parents to ensure the welfare of the child • Supports strong data linkage to ensure effective monitoring for safety
9	• Recommends strong data management • An annual report on reproductive technology treatments undertaken and birth outcomes is still needed • Data linkage between Reproductive Technology Registers and the Midwives Notification of birth data must be enabled • Data linkage between the Reproductive Technology Registers and other state and Commonwealth datasets for research purposes should be facilitated with appropriate ethics approvals
10	• Surrogacy – supports expansion to single men and same-sex male couples
11	• Presents arguments for why all surrogacy should be prohibited

No.	Summary of key issues in submission – 18 members of the public and 22 professionals or organisations
12	• Shared a media story on online unregulated sperm donors and an academic paper on the sociodemographic and psychological characteristics of intended parents, surrogates, and partners involved in Australian surrogacy
13	• Surrogacy – supports expansion to single men and same-sex male couples • Recommends increased clarity and flexibility regarding the reimbursement of costs to surrogates • Requests that most pre-surrogacy requirements (legal, counselling) be removed • Does not support penalties for engaging in overseas commercial surrogacy
14	• Supports the removal of discriminatory provisions for ART and surrogacy and supports the use of gender-inclusive language • Supports the retrospective removal of anonymity for donors and donor-conceived persons having access to this information • Supports the posthumous use of gametes • Supports reciprocal IVF for female same-sex couples • Any approval body for surrogacy should be independent from fertility clinics • Recommends increased clarity and flexibility regarding the reimbursement of costs to surrogates • Suggests there are increased options to advertise for a surrogate needed • Does not support penalties for engaging in overseas commercial surrogacy
15	• Surrogacy – supports expansion to single men and same-sex couples • Recommends increased clarity and flexibility regarding the reimbursement of costs to surrogates • Suggests there are increased options to advertise for a surrogate needed • Does not support penalties for engaging in overseas commercial surrogacy • The legal agreement for surrogacy should be the only pre-requisite to an arrangement
16	• Presents arguments against all IVF, all preimplantation genetic testing and all forms of surrogacy
17	• The Reproductive Technology Council should be replaced with co-regulatory system • Supports donor-conceived persons having access to information about the donor • Birth certificates should not divulge a person's donor status, only a supplementary letter should state this • Clinics and non-profit third-party agencies should be able to recruit surrogates • Does not support penalties for engaging in overseas commercial surrogacy
18	• Argues for commercial surrogacy
19	• Presents arguments for all surrogacy to be prohibited
20	• Clinics should be regulated more closely e.g. five-family limits • Supports right to know for donor-conceived persons and suggests strong intermediary support for this • Argues for time limits for donor storage to ensure there aren't donor-conceived persons born to much older donors • Against Tissue Typing for saviour siblings

No.	Summary of key issues in submission – 18 members of the public and 22 professionals or organisations
21	• Counsellors should still be required to be eligible for ANZICA membership to ensure that specialist knowledge • Remove discriminatory provisions around access to ART and surrogacy • Additional counselling should be required for donors, recipients, intended parents, surrogates and their partners • Free counselling and support should be provided to individuals seeking information from donor registers prior to the release of information • Supports donor-conceived persons having access to information about the donor • Supports donors, recipients, and donor-conceived persons to have the right to non-identifying information about the number, gender, and year of birth of any donor-siblings • Intermediary and support services should contact donors and donor-conceived persons in special circumstances (e.g. serious heritable disease identified) • Supports adult donor-conceived persons requesting changes to their birth certificates to reflect their genetic origins • Does not support recommendation from Allan Review that pre-surrogacy psychological assessments be repealed
22	• Does not broadly support retrospective removal of donor anonymity • Does not support addendums to birth certificates as this removes a parent's right to disclose a donor conception status to children • Supports reciprocal IVF for same-sex female couples
23	• Questions what rights an embryo donor has to information about their donor offspring should the offspring die or move overseas
24	• Remove discriminatory provisions around access to ART and surrogacy • Supports a proposed advisory body to replace the Reproductive Technology Council • Counsellors should still be required to be eligible for ANZICA membership to ensure that specialist knowledge • Supports donor-conceived persons having access to information about the donor • Requests the removal of storage limits • Supports the posthumous use of gametes (with ANZICA counselling for the surviving partner) • Do not support recommendation from Allan Review that pre-surrogacy psychological assessments be repealed • Recommends additional counselling throughout a surrogacy journey • Suggests that surrogacy arrangements should only use known gamete donation • Asks for clarification concerning the use of donated sibling gametes by non-genetic siblings

No.	Summary of key issues in submission – 18 members of the public and 22 professionals or organisations
25	• The posthumous use of gametes should ensure that the deceased is not treated as a donor and is therefore named as a parent on the birth certificate (this has impacts on the *Artificial Conception Act 1985*)
26	• Supports the removal of discriminatory provisions around access to ART and surrogacy • Supports reciprocal IVF for same-sex female couples • Argues new legislation should forgo legal advice for surrogacy arrangements with clinics drafting the agreement instead • Does not support the retrospective removal of anonymity for donors • Argues that donors should not be allowed identifying information about donor offspring • Argues surrogacy arrangements should be enforceable • Supports the removal of gamete/embryo storage limits • Supports research on excess ART embryos • Does not support regulation of add-on treatments • Makes arguments for commercial surrogacy
27	• Does not support any IVF, any surrogacy, any genetic testing, or posthumous use of gametes
28	• Supports gender-inclusive language in anew new legislation • Supports less prerequisites for surrogacy to make it more streamlined
29	• Supports equitable access to ART and surrogacy • Supports reciprocal IVF for same-sex female couples • Supports continued regulation of clinics but has heard negative feedback about the Reproductive Technology Council • Supports NHMRC Ethical Guidelines on storage limits for gametes and embryos • Supports NHMRC Ethical Guidelines on posthumous use of gametes • Supports donor-conceived persons having access to information about the donor • Argues that gestational surrogates need not ever be on the birth certificate • Supports NHMRC Ethical Guidelines on preimplantation genetic testing • Supports NHMRC Ethical Guidelines on research of excess ART embryos • Supports education and wider sharing of knowledge around add-on treatments • Supports the unenforceability of surrogacy arrangements • Support the current prerequisites for surrogacy arrangements • Does not support an additional welfare check for surrogacy as this is not undertaken in other states • Supports additional advertising for surrogates • Does not support penalties for overseas commercial surrogacy

No.	Summary of key issues in submission – 18 members of the public and 22 professionals or organisations
30	• Supports the Reproduction Technology Council being abolished • Argues that surrogacy should not need approval from an approvals body • Supports equitable access to ART and surrogacy • Supports donor-conceived persons having access to information about the donor • Supports posthumous use of gametes • Supports NHMRC Ethical Guidelines around storage limits for gametes and embryos • Supports preimplantation genetic testing • Supports research on excess ART embryos • Supports reciprocal IVF for same-sex female couples • Supports investigations into the efficacy of experimental treatments and how this is presented to ART participants • Supports more clearly defined reimbursements for surrogates and some additions • Supports continued use of the psychological assessment as a surrogacy pre-requisite • Supports wider advertising and recruitment for surrogates • Does not support criminalising commercial surrogacy overseas
31	• Supports gender-inclusive language • Supports greater access to ART and surrogacy for transgender people
32	• Surrogacy – Supports expansion to single men and same-sex couples • Supports donor-conceived persons having access to information about the donor, as well as people born via surrogacy • Supports proposal for storage limits of gametes and embryos • Supports the posthumous use of gametes • Supports preimplantation genetic testing • Supports research on excess ART embryos • Does not support welfare checks on intended parents as isn't required for coital reproduction • Argues for non-gendered language on birth certificates • Argues for overseas surrogacy parentage orders being recognised in Western Australia
33	• Supports legislation to regulate mitochondrial donation and other emerging technologies • Supports equitable access to ART and surrogacy • Supports NHMRC Ethical Guidelines to regulate preimplantation genetic testing • Supports the safeguarding of health information related to mitochondrial donation
34	• Surrogacy – supports expansion to single men and same-sex couples

No.	Summary of key issues in submission – 18 members of the public and 22 professionals or organisations
35	• Argues for protections for donors who operate outside of clinic oversight • Argues for a shorter cooling off period for known donors • Surrogacy – supports expansion to single men and same-sex couples • Supports Medicare expansion for surrogacy as this impacts LGBTI+ people disproportionately
36	• Surrogacy – supports expansion to single men and same-sex couples • Broadly supports donor-conceived persons (and people born via surrogacy) having access to information about the donor or surrogate • Argues that embryos be donated to research if owners cannot be contacted following agreed storage limits being reached • Supports NHMRC Ethical Guidelines to regulate preimplantation genetic testing • Supports an easier process for surrogacy – does not support welfare checks • Argues for a larger list of reasonable expenses for surrogacy • Supports advertising and recruitment of surrogates • Does not support any penalties for overseas commercial surrogacy
37	• Supports the Allan Review recommendation that an ART Advisory body membership include a donor-conceived person, donor and recipient • Strongly opposed to the imposition of penalties and fines in relation to a donor-conceived person seeking contact with their donor • Supports notification on birth certificates – argues for accurate birth certificates from the outset • Argues for research into the impacts of both posthumous use of gametes on children and surrogacy on children • Supports welfare checks on all prospective parents prior to an ART treatment
38	• Surrogacy – supports expansion to single men and same-sex couples
39	• Surrogacy – supports expansion to single men and same-sex couples • Supports removing counselling for unknown donors to a surrogacy arrangement • Argues for removing any specific age restrictions for surrogacy

No.	Summary of key issues in submission – 18 members of the public and 22 professionals or organisations
40	• Supports the best interests of the child principle • Supports retrospective removal of donor anonymity and the release of identifying information to donor-conceived persons • Against VARTA's model of informing donors prior to the release of information and the 4-month delay to seek a response from the donor as it risks donor-conceived persons choosing commercial DNA tests and contacting the donor direct • Supports the right of donors to state contact preferences prior to identifying information being released to donor offspring • Argues for an integrated birth certificate with donor information that is additional to original certificate, not a replacement one • Argues the need for a better system to facilitate contact between donor-conceived siblings • Argues the need for Donor Conception Services to access 'search tools' to conduct search and outreach to biological families • Consider VARTA's model for a donor's right to contact donor offspring • Argues requirement for a WA Central Register (preferably including international donors) to monitor family limit • Doesn't support reciprocal IVF unless for medical reason • Argues a regulator should have the right to contact donor conception participants when there are exceptional circumstances (for example, when a donor discloses a hereditary illness) • Notes that language used needs to be strengthened to make clear the importance of relationships – the donor is not the child's donor, but the mother's donor, and a donor should be called a biological father or mother
41	• Argues that the current medical assessment, counselling and patient psychosocial history assessment by fertility clinic staff is sufficient • New legislation should explicitly address commercial surrogacy and not remain silent • Against imposing penalties on overseas commercial surrogacy arrangements • Argues that current altruistic surrogacy arrangements inherently have a commercial aspect through engagement of fertility clinics that operate on a business model
42	• Surrogacy – supports expansion to single men and same-sex couples • Supports a streamlined process around surrogacy arrangements

Theme of response	#
Expansion of ART and surrogacy eligibility to same-sex couples and single males	19
Do not support penalties for engaging in overseas commercial surrogacy	11
Support donor-conceived persons having access to information about the donor and a donor matching service	10
Not for profit advertising and brokerage for surrogacy should be expanded	9
Support storage limits being removed and replaced by decisions between clinics and ART participants	8
Support a streamlined process for preimplantation genetic testing, including a list of pre-approved conditions	7
Do not support additional welfare of the child checks for surrogacy (as want a streamlined process)	7
Support the posthumous use of gametes	7
Suggests a more streamlined process for surrogacy pre-approval	6
Support reciprocal IVF for same-sex females couples	5
Expansion and clarity on reasonable expenses during a surrogacy arrangement	5
Support research on excess ART embryos, including enabling mitochondrial research	5
Agree that new laws need strong guiding principles	4
Support a continued oversight body in lieu of the Reproductive Technology Council, including an appeals option for ART participants	4
All surrogacy should be prohibited	4
Ensuring data linkage is possible between different health datasets	3
WA should consider introducing commercial surrogacy	3
Do not support the retrospective removal of donor anonymity	3
Support the use of gender-inclusive language in new legislation	3
Support the continued ban of commercial surrogacy or introduction of criminalisation for overseas commercial surrogacy	2
Questions or concerns around unregulated sperm donation	2
Do not support research on excess ART embryos	2
Do not support preimplantation genetic testing	2
Do not support reciprocal IVF	2
Do not support the posthumous use of gametes	1
Do not support IVF in general	1
Clarity needed around legal parentage following the posthumous use of gametes	1
Enable better financial access to ART	1
Enable identifying information between donor siblings	1

Appendix 5: Consultation summary – Donor Conception Survey results

268 responses received

Question: How do you describe your gender?	
Female	81.72%
Male	13.06%
Non-binary	2.61%
Prefer not to answer	1.12%
Did not answer	0.75%
I use a different term	0.75%
Total	100.00%

Question: What is your age?	
31-49	66.42%
50-64	18.28%
18-30	8.58%
65+	4.10%
Prefer not to answer	1.12%
Did not answer	1.12%
Under 18	0.37%
Total	100.00%

Question: Are you a current resident of WA?	
Yes	82.09%
No	16.42%
Did not answer	1.49%
Total	100.00%

Question: Have you been party to a donor conception process in WA (as a donor/ donor recipient); or are you a donor-conceived person who was conceived in WA?	
Yes	73.13%
No	26.12%
Did not answer	0.75%
Total	100.00%

Question: What is your experience of donor conception (or donor status)?	
A donor recipient or intended donor recipient	53.10%
Donor-conceived	19.64%
A donor or intended donor	12%
An interested community member	8.36%
A provider of donor conception services	4%
Prefer not to answer	2.9%
Total	100.00%

Question: For people who are donor-conceived at what age did you become aware you were donor-conceived?
50 responses – average age of 22 years, youngest age from birth, oldest age 50 years

Question: For people who are donor-conceived is the age of a donor at the time of their donation important to you?	
Yes	92.59%
No	5.55%
Did not answer	1.86%
Total	100.00%

Question: Do you support retrospectively removing anonymity for donation before 1 December 2004? This would enable all people who are donor-conceived the right to access identifying information about the donor, where records are available?	
Yes – Fully support	61.94%
Yes – Partially support	13.81%
Did not answer	8.96%
No – Do not support	8.58%
Unsure or undecided	6.72%
Total	100.00%

Question: Do you support donor recipient parents receiving identifying information about the donor following the birth of their child?	
Yes – Fully support	53.73%
Yes – Partially support	16.42%
Unsure or undecided	10.07%
No – Do not support	9.70%
Did not answer	9.70%
Prefer not to answer	0.37%
Total	100.00%

Question: Do you support an ongoing 'contact register' service facilitating contact between donors, donor-conceived people, donor-siblings and recipient parents, with their consent? Note: this would enable donors, donor-siblings, and people who are donor-conceived (or their parent(s) if they are under 16 years) to specify the contact they may want with the other parties. Initial contact would be facilitated by the register, with free counselling offered to all parties.	
Yes – Fully support	79.85%
Did not answer	9.33%
Yes – Partially support	7.09%
No – Do not support	2.24%
Unsure or undecided	1.49%
Total	100.00%

Question: In some jurisdictions, people who are donor-conceived, or recipient parents, face a penalty (fine) if they do not comply with a contact register preference. Do you support this idea?	
No – Do not support	42.91%
Unsure or undecided	22.76%
Yes – Partially support	13.43%
Yes – Fully support	10.82%
Did not answer	9.70%
Prefer not to answer	0.37%
Total	100.00%

Question: It is proposed that donors be actively notified by fertility clinics of all live births resulting from their donation, including the sex and year of birth of the child(ren). Do you support this idea?	
Yes – Fully support	58.58%
Yes – Partially support	15.67%
Did not answer	9.70%
Unsure or undecided	8.21%
No – Do not support	7.84%
Total	100.00%

Question: It is proposed that, upon request, people who are donor-conceived be provided with non-identifying information regarding any donor-siblings, including their sex and year of birth, where this information is known. Do you support this idea?	
Yes – Fully support	69.40%
Yes – Partially support	12.69%
Did not answer	9.70%
Unsure or undecided	4.85%
No – Do not support	3.36%
Total	100.00%

Question: It is proposed that people who are donor-conceived, or their parent(s) if under 16 years, can voluntarily register on a Donor Connect Register. This Register will store their contact preference to enable donors or any donor-siblings to access identifying information about them. Do you support this idea?	
Yes – Fully support	78.36%
Did not answer	9.33%
Yes – Partially support	8.21%
Unsure or undecided	2.61%
No – Do not support	1.49%
Total	100.00%

Question: It is proposed that people who are donor-conceived, or their parent(s) if under 16 years, would require mandatory free implications counselling before identifying information about their donor is disclosed, subject to any contact register preference. Do you support this idea?	
Yes – Fully support	50.75%
Yes – Partially support	19.03%
No – Do not support	12.31%
Did not answer	9.70%
Unsure or undecided	8.21%
Total	100.00%

Question: It is proposed that a note be added on future original birth certificates advising that further information relating to the child's birth is held by the Registry of Births, Deaths and Marriages (BDM). This note could be added either: a) at the time of registration of the birth of the donor-conceived person, or b) where official records are available, and a birth certificate is re-issued at the request of the donor-conceived person over 16 years. Which option do you support? Both options may be supported.	
a) At the time of registration of birth	40.87%
b) Where a birth certificate is re-issued	33.55%
Unsure of undecided	13.62%
Neither	11.96%
Total	100.00%

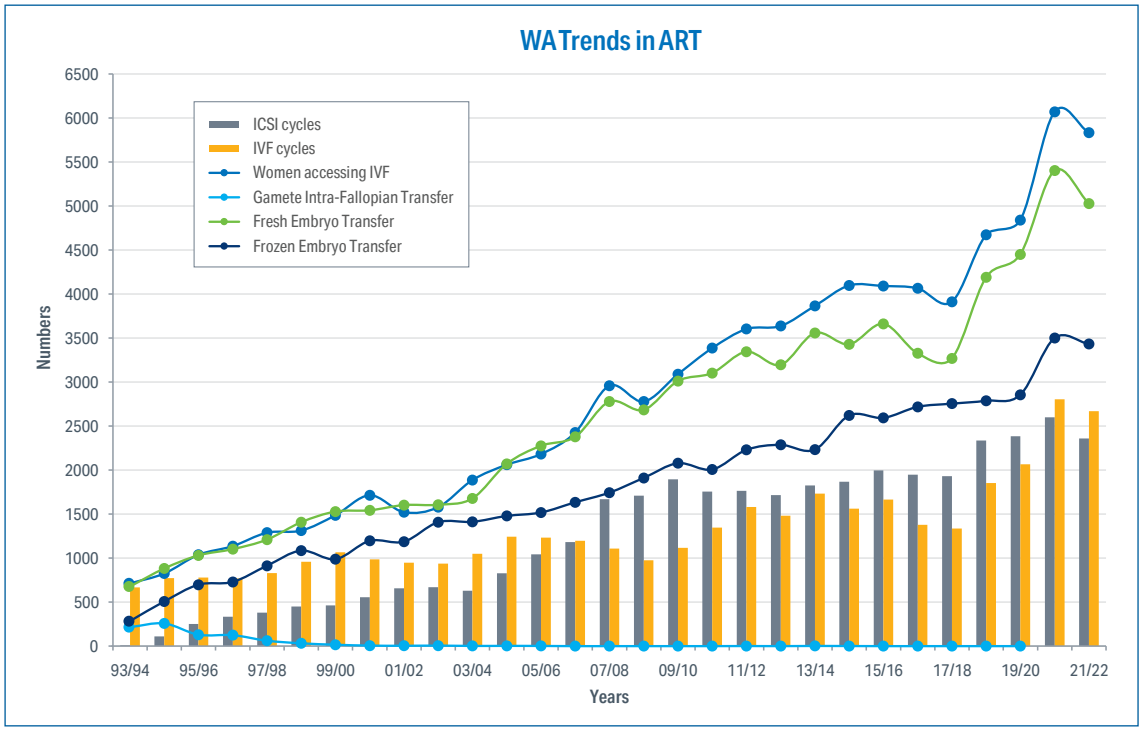
Question: It is proposed that, where official information is available, people who are donor-conceived will be able to request a replacement birth certificate that contains information about their genetic and birth heritage. Do you support this idea?	
Yes – Fully support	51.87%
No – Do not support	14.18%
Unsure or undecided	13.06%
Yes – Partially support	10.45%
Did not answer	9.33%
Prefer not to answer	1.12%
Total	100.00%

Question: The Department of Health will manage a Donor Connect Register and offer support services (including counselling) to all parties involved in a donation. What aspects of this register and its support services would be most important to you?	
Theme of response	#
Support a free service with free counselling	20
The service should help connect donor siblings via identifying information	14
Support the sharing of important genetic medical information	9
Support retrospective removal of donor anonymity and matching with donor-conceived persons	9
Support counselling, but not mandatory counselling	8
Education and advice should be offered, including advice on genealogical searching	5
General support for a Donor Connect Register	5
The service should provide free genetic testing	4
Ensure the service is run separately from fertility clinics	4
Ensure strong data management and that privacy is maintained	4
The process for accessing the service should be straightforward and streamlined	4
Counselling should be offered over a long-term period	3
Do not support the retrospective removal of donor anonymity	2
General support for contact veto options	2
The service should offer free legal advice, particularly around donor rights and parentage	2
Any service needs to be adequately staffed and funded to ensure delays are minimal	2
Do not support identifying information being released about siblings	1

Question: Currently WA limits the number of families that can be created from a single donor (including the donor's own family). This limit is currently 5. In Victoria the limit is 10 families. Would you support the WA limit increasing to 7 families?	
No – it should remain at 5	39.55%
Yes – it should increase to 7	26.49%
No – it should be less than 5	14.55%
Unsure or undecided	9.70%
Did not answer	9.33%
Prefer not to answer	0.37%
Total	100.00%

Question: If you have any further comments relating to donor conception, please share these below.	
Theme of response	#
Maintain the five-family limit for donations or reduce it further	12
The service should help connect donor siblings via identifying information	7
Support counselling but not mandatory counselling	5
Do not support the retrospective removal of donor anonymity	4
Ensure any information held at BDM is not on the actual baby's birth certificate	4
Reciprocal IVF should be permitted in WA	4
General support for a Donor Connect Register	3
Support the sharing of important genetic medical information	3
Increase the current five-family limit on donations to ensure a supply of gametes	3
Support retrospective removal of donor anonymity and matching with donor-conceived persons	3
All surrogacy should be prohibited	2
Surrogacy processes should be streamlined, and eligibility opened to same-sex couples	2
Concerns regarding unregulated sperm donation	2
The government should do more to encourage sperm donation	2
Do not support penalties for breaking contact preferences or vetoes	1
All donor records from clinics prior to the *HRT Act 1991* should be collected by the Department of Health	1
Any service needs to be adequately staffed and funded to ensure delays are minimal	1
Do not support identifying information being released about siblings	1
The service should provide free genetic testing	1
Wider education around donor conception with GPs, teachers and other professionals	1
Posthumous use of gametes or embryos should not treat the deceased as a donor	1
Do not support the criminalisation of overseas commercial surrogacy	1
The government should support the setup of self-help groups to support various cohorts	1
Commercial surrogacy should be considered	1
The service must ensure strong data management and that privacy is maintained	1

Appendix 6: Trends in assisted reproductive technology treatments in WA



Source: Data presented are from the WA Reproductive Technology Council Annual Reports.

Estimated births from surrogacy arrangements (births in WA compared with births overseas)[119]

Year	Western Australia	Overseas
2012	Based on information provided in RTC reports for the period 2012–2021, an estimated18 children were born via approved surrogacy arrangements in Western Australia.[120]	27
2013		24
2014		26
2015		24
2016		21
2017		16
2018		17
2019		23
2020		28
2021		22
Total	18	231

119 Estimates provided by Stephen Page, principal of Page Provan, family and fertility lawyer, lecturer in Ethics and the Law in Reproductive Medicine in the Masters of Reproductive Medicine, University of New South Wales.

120 The RTC reports in line with the National Health Information Standards and Statistics Committee Guidelines (2017) where values fewer than five are not reported.

Appendix 7: References to decision-making capacity in WA legislation

Legal presumption about a person's capacity:

s4(3) Every person shall be presumed to be capable of –

a. looking after his own health and safety;

b. making reasonable judgements in respect of matters relating to his person;

c. managing his own affairs; and

d. making reasonable judgements in respect of matters relating to his estate,

until the contrary is proved to the satisfaction of the State Administrative Tribunal.

(extract from the *Guardianship and Administration Act 1990*)[121]

s13(1) For the purposes of this Act, an adult is presumed to have the capacity to make a decision about a matter relating to himself or herself unless the adult is shown to not have that capacity.

(extract from the *Mental Health Act 2014*)[122]

The *Mental Health Act 2014* also provides what is required to be demonstrated when assessing capacity:

s15 For the purposes of this Act, a person has the capacity to make a decision about a matter relating to himself or herself if another person who is performing a function under this Act that requires that other person to determine that capacity is satisfied that the person has the capacity to –

a. understand any information or advice about the decision that is required under this Act to be provided to the person; and

b. understand the matters involved in the decision; and

c. understand the effect of the decision; and

d. weigh up the factors referred to in paragraphs (a), (b) and (c) for the purpose of making the decision; and

e. communicate the decision in some way.

(extract from the *Mental Health Act 2014*)

121 *Guardianship and Administration Act 1990* s 4.

122 *Mental Health Act 2014* s 13(1) s 15.

Appendix 8: Valid consent – Fertility Society of Australia and New Zealand – Reproductive Technology Accreditation Committee – Code of Practice for ART Units[123]

The organisations/ART unit must:

a) ensure that treatment only occurs with valid consent, as defined by the NHMRC Ethical guidelines on the use of ART in clinical practice and research (2017 or more recent review), and in New Zealand as defined by any guidelines or advice issued by ACART

b) ensure that consent is written, signed and dated. Documentation must include a signed statement by the treating clinician confirming that all relevant provision of information and counselling requirements have been satisfied

c) have a process whereby clinical staff ensure that valid consent is obtained from all patients, donors and/or surrogates (and, where relevant, their spouses or partners) before treatment commences

d) obtain consent from the patient for their de-identified patient and treatment information to be recorded in the Australian and New Zealand Assisted Reproductive Technology Database (ANZARD) and that their ANZARD information may be used for population analysis, research projects, and the publication of clinic success rates (Australian clinics only) and that the patients identifying information may be reviewed by regulatory bodies for the purpose of licensing and RTAC accreditation

e) ensure that where an interpreter is required a health care interpreter must be used and the use of this service must be noted on the consent. The definition of a health care interpreter is in section 4 definitions

f) provide patients with information that is accurate, timely and in formats appropriate to the patient

g) provide evidence of implementation and review of policies and procedures which define the consenting process.

123 Fertility Society of Australia and New Zealand, Reproductive Technology Accreditation Committee - Code of practice for assisted reproductive technology units (October 2021) 2.3.

Appendix 9: Preimplantation genetic testing – NHMRC criteria for ethical acceptability[124]

The National Health and Medical Research Council (NHMRC) *Ethical guidelines for assisted reproductive technology in clinical practice and research* (2017) state that clinicians should consider the following criteria when assessing the ethical acceptability of the use of preimplantation genetic testing (PGT):

- current evidence and expert opinion on the impact of the condition, disease or abnormality on the quality of life of the person who would be born, including the anticipated symptoms, age-of-onset and the degree/spectrum or severity of the condition, disease or abnormality
- the concerns of the intended parent(s) about their ability to care for a person born with the condition, disease or abnormality
- the availability and accessibility of therapies or interventions to reduce the severity, delay onset or minimise the impact of the condition, disease or abnormality
- the limitations of the technology, including the likelihood of false positive and false negative results
- the experiences of individuals and families living with the condition, disease or abnormality
- the potential for stigma to influence the perceived impact of the condition, disease or abnormality on the quality of life of the person who would be born
- the extent of social support available to the intended parent(s) and to the person who would be born.

124 NHMRC Ethical Guidelines on the use of ART (2017), 8.16.1, p 74.

Appendix 10: Posthumous collection of gametes – NHMRC criteria for valid consent[125]

Collection and storage of gametes from a deceased person or a person who is dying and lacks the capacity to provide valid consent

8.21 Obtain valid consent from a spouse or partner

The acceptability of a spouse or partner making decisions regarding the collection of gametes warrants serious ethical consideration because of the enduring consequences of these decisions on any person who would be born and the potential for the spouse or partner to have a conflict of interest (i.e. a grieving spouse or partner may be focused on their own desire to have a child, rather than the broader implications for the person who would be born, or the wishes of the person who is deceased or dying). For these reasons, court authority is required before a clinician may facilitate the collection of gametes from a person who is deceased or is dying and lacks the capacity to provide valid consent.

8.21.1 With appropriate legal authority, clinics may facilitate the collection of gametes from a deceased person or a person who is dying and lacks the capacity to provide valid consent if:

- the request to do so has come from the spouse or partner of the deceased or dying person, and not from any other relative
- the gametes are intended for use by the surviving spouse or partner for the purposes of reproduction
- there is some evidence that the dying or deceased person would have supported the posthumous use of their gametes by the surviving partner, or at the very least, there is no evidence that the deceased or dying person had previously expressed that they do not wish for this to occur
- the surviving spouse or partner provides valid consent for the collection and storage of the gametes (see paragraphs 4.5 and 4.6.3 – 4.6.5)
- the proposed collection and storage has been approved by an appropriate court authority.

125 NHMRC Ethical Guidelines on the use of ART (2017), 8.21, p 80.

Appendix 11: NHMRC Ethical guidelines for the care of people in post-coma unresponsiveness (vegetative state) or a minimally responsive state[126]

1.3 Principles

The provision of care is an expression of our fundamental humanity and connectedness with others, and of our common sense of obligation to promote good and do no harm. People in PCU or MRS are highly vulnerable because of their total dependence on others. They are owed a particular duty of care to promote their interests and protect them from exploitation, abuse and neglect. That duty is likely to extend over a long period of time.

Decisions about the care of people in PCU or MRS should:

a) demonstrate respect for all aspects of human dignity, including the worth, welfare, rights, beliefs, perceptions, customs and cultural heritage of all involved

b) respect, where these are ascertainable, the values, beliefs and previous wishes of the person in PCU or MRS

c) recognise the needs of all those directly involved – including people in PCU or MRS, families, friends, health professionals, and other carers – to be:
   i. involved in decisions that affect the person in PCU or MRS
   ii. given accurate and timely information
   iii. realistically educated about the person's situation, care and prospects
   iv. assisted, when necessary, to deal with their own responses in their particular situations

d) give due regard to justice, particularly in relation to the responsible use of resources. This includes ensuring so far as possible that there is:
   i. fair distribution of the benefits of or access to goods and services
   ii. equality of opportunity
   iii. no unfair burden on any members of the community or on particular groups; and
   iv. no abuse, neglect, exploitation or discrimination

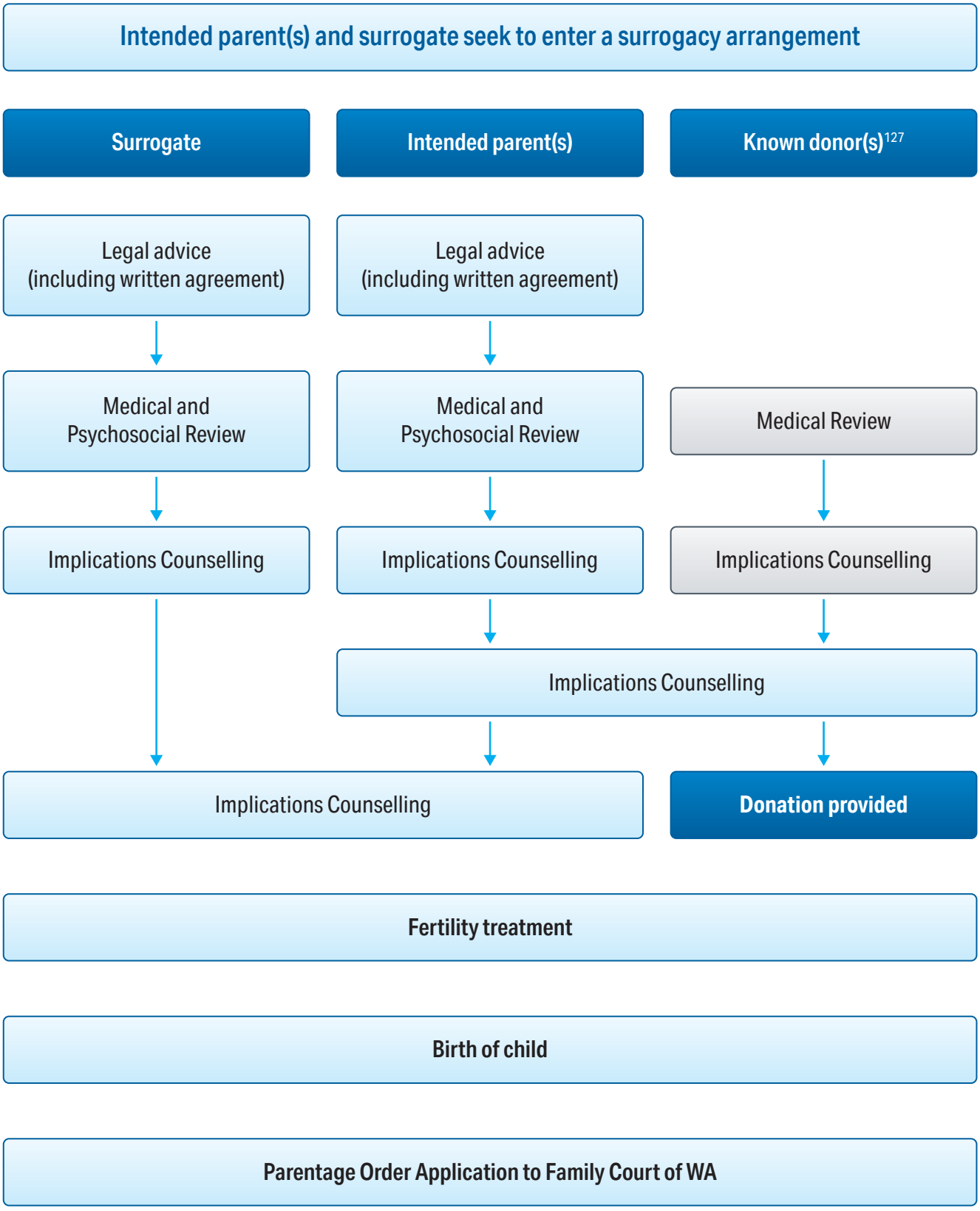
e) respect the basic rights of people in PCU or MRS, including:
   i. the right of individuals to be treated with respect
   ii. the right of individuals to life, liberty, and security
   iii. the right of individuals to have their religious and cultural identities respected
   iv. the right of individuals to self-determination, including by advance care planning or representation
   v. the right to access health care that is appropriate to their needs
   vi. the right of individuals to privacy and confidentiality
   vii. the recognition that human beings are social beings with social needs; and
   viii. the right to approach death peacefully

f) give due regard to the rights and duties of those who care for people in PCU and MRS, and the duties of the community both to people in PCU or MRS, and to their carers (family, professional and other)

g) respect the limitations of medical treatment, in relation to achievable goals.

126 NHMRC Ethical Guidelines for the Care of People in Post-Coma Unresponsiveness (Vegetative State) or a Minimally Responsive State (2008), p 3.

Appendix 12: Steps in a surrogacy arrangement



127 The medical review and individual implications counselling for known donors are standard for all donations, and not additional to the surrogacy arrangement. Joint counselling between the known donors and intended parents is specific to a surrogacy arrangement and required by the Fertility Society of Australia and New Zealand.

Appendix 13: Comparison of existing responsibilities of Department of Health and Reproductive Technology Council under the *Human Reproductive Technology Act 1991* and proposed responsibilities under proposed ART legislation

Function and responsibility	Existing WA legislation	Proposed WA legislation
Providing advice to the Minister and/or CEO in relation to: • reproductive technology matters • evaluation or monitoring of licensee compliance • public education • administration and enforcement of Act.	The RTC is currently responsible for providing advice to the Minister and the CEO. Sections 12, 13, 14(1)(a), 14(1)(b) of the *Human Reproductive Technology Act 1991.*	New Advisory Body to continue to have a role of providing advice to the Minister as requested by the Minister or on its own initiative. New Advisory Body to have a modified role of providing advice to the CEO upon request. However, the advice is no longer a requirement of the CEO's roles.
Education function, including: • promoting informed public debate • consulting with bodies representing the public on ethical, social, economic and public health issues • communicating and collaborating with other bodies having similar functions.	The RTC is currently responsible for the education and public collaborating function. Sections 14(1)(g) and 14(1)(h) of the *Human Reproductive Technology Act 1991*.	This function is not proposed to be included in the future legislation, and instead will fall to the CEO supported by the Department of Health Licensing and Accreditation Regulatory Unit. This function is not proposed to be included in the future legislation. However, the new Advisory Body may still seek to do this without legislation.

Function and responsibility	Existing WA legislation	Proposed WA legislation
Licensing of ART providers, including: • granting licences • imposing conditions • issuing licence exemptions • regulating the provision of ART treatments and procedures provided by licensed ART providers. Enforcement action, including: • suspending, cancelling or revoking licences • summary disciplinary determinations • referral of disciplinary matters to the State Administrative Tribunal.	CEO, supported by Department of Health, is currently responsible for: • granting licences • imposing conditions • issuing licence exemptions • suspending, cancelling or revoking licences • summary disciplinary determinations • referral of disciplinary matters to the State Administrative Tribunal. Current responsibilities of the CEO contained in sections 27(1), 28, 28A, 30, 31, 32, 36, 36A, 37, 38 of the *Human Reproductive Technology Act 1991*. RTC is currently responsible for providing advice to the CEO on: • licensing matters • administration and enforcement of legislation • summary disciplinary determinations. RTC is also responsible for: • preparing a Code of Practice • providing approval for protocol manual and amendments and approvals for innovative procedures. Current responsibilities of the RTC contained in sections 14(1)(b), 14(1)(c), 14(3), 37(1a) of the *Human Reproductive Technology Act 1991* and Directions 7.7, 9.2, 9.3, 9.5.	The CEO, supported by Department of Health Licensing and Accreditation Regulatory Unit, to be responsible for all licensing of ART providers, including regulating the provision of ART treatments and procedures and enforcement actions. Review of licensing and enforcement decisions to go to the State Administrative Tribunal. No longer a requirement for the new Advisory Body to provide advice in relation to all licensing and disciplinary matters. In the first instance – advice to CEO on licensing and disciplinary matters under the new Act will be provided by Department of Health Licensing and Accreditation Regulatory Unit staff. However, the CEO can request advice/ guidance on a range of specialist matters from experts on the new Advisory Body as required. The new Act will provide for a full suite of enforcement powers to enable the CEO to decide which should be employed and when.

Function and responsibility	Existing WA legislation	Proposed WA legislation
Maintaining the Reproductive Treatment (RT) Registers and report information as specified in the Directions to the Minister for Health and the CEO. Licensed ART providers to report information required under the directions.	CEO, supported by the Department of Health, is currently responsible for maintaining the Reproductive Treatment (RT) Registers. Section 45 of the *Human Reproductive Technology Act 1991*.	CEO to continue with this role supported by the Department of Health. Licensed ART providers to continue to report information to the CEO. Births Deaths and Marriages (BDM) to report additional information regarding details of children born via donor conception or surrogacy to the CEO.
Managing donor conception data including: • collecting and storing information • providing donor linking services • facilitating the exchange of information and contact between consenting parties.	Originally, the Department of Health established and maintained a Voluntary Register. In 2019 this function was transferred to an independent agency. Currently, these functions are being returned to the Department of Health.	This function will be managed by the CEO supported by the Department of Health Licensing and Accreditation Regulatory Unit, the Donor Conception Information Service and the Information and System Performance Directorate (ISPD) at the Department of Health.
Approving research, including on any human egg or gametes collected in the course of an in vitro fertilisation and intended for subsequent use in an artificial fertilisation procedure.	RTC currently responsible for all approving research. Sections 14(1)(d), 14(1)(e), 14(1)(f), 20(2), 20(4) of the *Human Reproductive Technology Act 1991* and Direction 9.7.	The new Advisory Body is no longer required to approve research as this function will now be a condition of the ART licence.
Approving extension of time for storage of gametes.	RTC currently responsible for approving applications for an extension of time for storage of gametes. Section 24(1a) of the *Human Reproductive Technology Act 1991* and Direction 6.11.	This function is no longer required to approve extensions of time, statutory limits on storage time should be removed and replaced with contractual agreements.

Function and responsibility	Existing WA legislation	Proposed WA legislation
Approving the import and export of gametes, embryos or eggs undergoing fertilisation for use in an artificial fertilisation procedure where donation of human reproductive material has been involved into and out of the state.	RTC currently responsible for all approval required. Directions 6.2, 6.3, 6.4, 6.5. and 6.6.	New Advisory Body to continue to have a role to provide approvals, but in the more limited circumstances of where established import/export criteria are not met. Exceptional circumstances will be required for approval.
Approval of the use of donated games, embryos or eggs undergoing fertilisation created using donated gametes in an artificial fertilisation procedure that may result in more than 5 recipient families in exceptional circumstances.	The RTC is currently responsible for providing approvals to exceed the 5 recipient families requirement. Direction 8.2	The New Advisory Body to continue to have this role, with a review to the State Administrative Tribunal.
Approving applications to undertake diagnostic procedures involving an embryo.	The RTC is currently responsible for providing approvals for diagnostic procedures. Direction 9.10	The New Advisory Body will continue with a modified form of this function. The MEP recommends that licensed ART providers be permitted to undertake testing for monogenic and single gene disorders and testing for structural chromosomal arrangements using a list of approved conditions for which genetic testing can be conducted without the need for further approval. For conditions not included on the approved list, the New Advisory Body, after receiving advice from a gene review panel, will consider and provide approval. The new Advisory Body will also be responsible for approving the addition of a condition to the approved list.

Function and responsibility	Existing WA legislation	Proposed WA legislation
Approving posthumous use of gametes, reproductive tissue or embryos.	Currently, posthumous use of gametes or embryos is prohibited. Direction 8.9	The new Advisory Body will have the function of approving posthumous use of gametes, reproductive tissue or embryos subject to and in accordance with established conditions. This approval will extend to posthumous use of both: • previously stored gametes, reproductive tissue or embryos for intended reproductive purposes in the absence of written consent from a now deceased person • posthumously collected gametes or reproductive tissue.
Approving of surrogacy arrangements.	Currently, the RTC is responsible for approving surrogacy arrangements. Section 17 of the Surrogacy Act.	Before fertility treatment is provided, the licensed ART provider must be satisfied that all legislative prerequisites have been met. A licensed ART provider who has concerns regarding a proposed surrogacy arrangement will be able to submit these concerns to the AARB for review and advice.

Appendix 14: Access to information for parties to donor conception using gametes and embryos donated in WA

The WA *Human Reproductive Technology Act 1991* (HRT Act) came into full operation on 8 April 1993. Prior to this there was no requirement for information to be recorded by the Department of Health regarding donor conception.

Cohort	HRT Act	Proposed new legislative approach
Pre-1993 Donor-conceived cohort	• No Reproductive Technology (RT) Registers held by the Department of Health – there was no Act mandating data collection • Records may be available from fertility clinics • Donor anonymity was assured by clinics collecting and storing sperm at this time.	• No data on donations or birth outcomes held by the Department of Health • Voluntary Register was developed as a policy initiative from 2002 to facilitate matching of donor-conceived persons (or parents if child under 18 years) with donors, where information is available and could be verified by a clinic. This service will be referred to from now as the Donor Conception Information Service (DCIS) • DCIS may enable matching of donor-conceived persons with donors and other relatives[128] where the parties have joined the DCIS, and information is subsequently available and has been verified • Implications counselling is strongly recommended where identifying information is shared about parties • All parties can lodge with the DCIS a preference for the type of contact, including no contact, with other parties should there be a match and where information can be verified from a fertility clinic.
Pre-1993 Donor cohort	• No RT Registers held by the Department of Health • Records may be available from fertility clinics • Donor anonymity was assured by clinics collecting and storing sperm.	• No data on donations or birth outcomes held by the Department of Health • All parties can lodge with the DCIS a preference for the type of contact, including no contact, with other parties should there be a match and where information can be verified from a fertility clinic • Implications counselling offered by the DCIS where information is available and verified, prior to any identifying information being shared • DCIS may facilitate matching at the request of the donor-conceived person, where information is available in the Department of Health and can be verified by the clinics.

128 For the purpose of this policy document relatives are defined as a donor-conceived person, a donor, parent/s of donor-conceived persons, donor siblings and the donor's legal children.

Cohort	HRT Act	Proposed new legislative approach
1993–2004 Donor-conceived cohort	• Recipient identifying information held on RT Registers.[129] • Donor identifying information held on RT Registers • Donor anonymity assured by clinics collecting and storing sperm • No information about birth outcomes held on RT Registers, including identifying information about children.	• No data on birth outcomes of donations held by the Department of Health • Donor-conceived persons will be able to access identifying and non-identifying information about their donor via the DCIS, where information is available and verified by the clinic • Implications counselling encouraged where identifying information is shared about any matched parties • The DCIS may enable matching of donor-conceived persons with other relatives where the parties have joined the DCIS and information is available and verified • All parties can lodge with the DCIS a preference for contact, including no contact.
1993–2004 Donor cohort	• Recipient identifying information held on RT Registers • Donor identifying information held on RT Registers • Donor anonymity assured by clinics collecting and storing sperm • No information about birth outcomes held on RT Registers, including identifying information about children.	• No data on birth outcomes of donations held by the Department of Health • Retrospective removal of a donor's anonymity to enable donor-conceived persons to access identifying information about their donor • The DCIS to enable information sharing and matching of a donor with donor offspring, where information is available and verified by the clinic • Donors can request identifying information about their donor offspring, which would be released only where there is a match and with the consent from the donor-conceived person, should the DCIS be able to locate the now adult donor-conceived person to lodge their consent • Donors may request non-identifying information about their donor offspring, which will be released • Implications counselling encouraged where identifying information is shared about any matched parties • All parties can lodge with the DCIS a preference for contact, including no contact.

129 The WA Department of Health began collecting records relating to donor conception from 1993 including identifying information about donors, however there may be gaps in this information provided by the clinics; or the information may be inaccurate due to on-transfer of gametes between clinics. No identifying data was collected by the Department of Health regarding donor-conceived offspring, therefore matching of donors to offspring or matching of other parties requires verification with the licenced fertility clinic where the procedure was done. Information from exempt practitioners may not have been provided or cannot be verified.

Cohort	HRT Act	Proposed new legislative approach
2004 to enactment of new legislation Donor-conceived cohort[130]	• Right to identifying information about their donor from age 16 • Donor identifying information held on RT Registers • Recipient identifying information held on RT Registers • No identifying information about donor-conceived persons held on RT Registers.	• Right to access identifying and non-identifying information about their donor, where information is verified, from age 16. Implications counselling is encouraged • Right to know sex and year of birth of donor siblings • The DCIS will enable matching of consenting parties (donor, donor siblings and other relatives) where records are held • Implications counselling encouraged where identifying information is shared about any matched parties • All parties can lodge with the DCIS a preference for contact, including no contact.
2004 to enactment of new legislation Donor cohort	• Identifying information held on RT Registers • Consented (prior to donation) to identifying information being accessible by donor offspring from age 16 • No identifying information of donor-conceived children held on RT Registers.	• Right to know sex and year of birth of donor offspring • The DCIS to enable matching where records are held and with the consent of all parties • Donors can request identifying information about their adult donor offspring, which would be released only where there is a match and with the consent from the adult donor-conceived person, should the DCIS be able to locate the donor-conceived person to lodge their consent • Implications counselling encouraged where identifying information is shared about any matched parties • All parties can lodge with the DCIS a preference for contact, including no contact.

130 This cohort of donor-conceived persons were conceived on or after 1 December 2004, when the HRT Act required all gamete or embryo donors to consent to the release of their identifying information to donor offspring from 16 years of age.

Cohort	HRT Act	Proposed new legislative approach
Proposed legislation Donor-conceived cohort	• Identifying information to be held on RT registers and by Births, Deaths and Marriages (BDM) • Donor identifying information to be held on RT Registers and by BDM • Recipient identifying information held on RT Registers and by BDM.	• Right to identifying information about their donor from age 16 via DCIS. Implications counselling encouraged • Right to know sex and year of birth of donor siblings • The DCIS to enable matching with donor, donor siblings and other relatives where requested, and information about the parties can be verified • Implications counselling encouraged where identifying information is shared about any matched parties • All parties can lodge with the DCIS a preference for contact, including no contact.
Proposed legislation Donor cohort	• Identifying information to be held on RT Registers and by BDM • Consent (prior to donation) to identifying information being accessible by donor offspring from age 16; and to recipients from the registration of the birth of the child.	• Right to know sex and year of birth of donor offspring – clinics to advise donors of this. Information can only be provided in the year after a child's birth • Can request identifying information about adult donor offspring or recipients (if offspring is under age 16). This is released only with consent of the donor-conceived person or the parents, should the DCIS be able to locate the donor-conceived person for them to provide their consent and lodge a contact preference • Implications counselling encouraged where identifying information is shared about any matched parties • The DCIS to enable matching with other relatives • All parties can lodge with the DCIS a preference for contact, including no contact.

Cohort	HRT Act	Proposed new legislative approach
Proposed legislation Recipient cohort	• Identifying information to be held on RT Registers and by BDM • Donor identifying information to be held on RT Registers and by BDM • Identifying information about their donor-conceived child to be held on RT Registers and by BDM.	• Right to identifying information about their child's donor once birth registered with BDM • Right to know non-identifying information (limited to sex and year of birth) of donor siblings of their donor-conceived child • Implications counselling encouraged where identifying information is shared about any matched parties • DCIS to enable matching with other relatives • All parties can lodge with DCIS a preference for contact, including no contact.

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