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Assisted Reproductive Technology: Regulation and Access – ACT Government Response

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Assisted Reproductive Technology: Regulation and Access

ACT Government Response

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Executive Summary

Assisted Reproductive Technology (ART) gives many people the chance to have children that they may not otherwise have had. ART is used to help people of diverse genders and sexualities achieve pregnancy, for a range of different reasons.

In April 2021, Dr Marisa Paterson MLA presented a motion to the ACT Legislative Assembly regarding the regulation and access to ART services in the ACT (Appendix A). This report draws on research and insights from ART consumers, donor-conceived people, fertility providers and government officials to respond to the matters raised in that motion.

Access and support

There are various barriers to accessing ART in the ACT, with cost being the most frequently cited. All ART services in the ACT are provided privately, with no low-cost or public options available. While Medicare rebates apply to some elements of ART treatments, only those who are considered 'medically infertile' are eligible for rebates. It is common for people to access ART due to 'social infertility'– for example, because they are in a same-sex relationship or are single. LGBTIQ+ people and single people often incur further significant costs if they need to use donor gametes. A survey of ACT consumers of ART services indicated a desire for greater accessibility and affordability in the ACT.

Experiences of accessing ART and relevant support services in the ACT tend to vary. While most consumers who contributed to this work indicated their experiences using ART in the ACT were mostly or very positive, other people had negative experiences. There is limited specialist support or counselling services for donor conceived people and their families. Some LGBTIQ+ consumers indicated that some ART providers have a limited understanding of LGBTIQ+ fertility and care needs. Other people indicated varying experiences with counselling provided by ART clinics, with some finding it helpful, whereas others found it distressing. Some consumers were unable to access counselling due to limited availability. Consultation confirmed that there is a need for support services to focus on the overall wellbeing of the person, rather than the ART process, and the positive benefits of peer support cannot be overlooked.

Regulatory framework

While four other states (Victoria, New South Wales, Western Australia and South Australia) have legislated to regulate the use of ART, the ACT does not have a regulatory framework specific to ART. In the ACT, the *Parentage Act 2004* addresses the legal parentage of children conceived through procedures such as ART, including those born through surrogacy arrangements.[1] The *Human Cloning and Embryo Research Act 2004* regulates the use of human embryos created by ART (or other means).[2]

All ART providers must comply with national legislation regarding the use of embryos and are also subject to the National Health and Medical Research Council (NHMRC)'s *Ethical guidelines on the use of assisted reproductive technology in clinical practice and research*

[1] *Parentage Act 2004* (ACT).

[2] *Human Cloning and Embryo Research Act 2004* (ACT).

(the NHMRC Guidelines).[3] Additionally, ART providers must be licensed by the Fertility Society of Australia and New Zealand's Reproductive Technology Accreditation Committee (RTAC). This requires them to comply with the RTAC's Code of Practice.[4] Where there is any conflict in the requirements of these regulations, compliance with national and state legislation overrides the requirements of guidelines.

While the experiences of consumers were mostly or very positive, donor conceived adults reported significant difficulties with the way in which ART has historically operated. The absence of a regulatory framework or central register of information in the ACT makes it challenging, or near impossible, for donor conceived people to access information about their donor. Accessibility of this information is of utmost importance to many donor conceived people so that they are aware of heritable health conditions, can learn about their heritage (including culture and genetic origins), and to potentially contact their donor and/or any siblings. Identification of any relatives is vital, to avoid unknowingly entering into an intimate relationship with a sibling or cousin.

There are several key matters for consideration in Dr Paterson's motion regarding determining whether to introduce legislation to regulate ART in the ACT. One is whether there should be a register of donor gametes, to enable donor conceived people to access information about their genetic origins, their donor and any siblings. The other is whether there would be any impacts on gender and sexuality diverse (LGBTIQ+) Canberrans if a new regulatory framework was introduced.

Based on research and feedback from stakeholders, there is evidence of a need to introduce legislation to regulate ART in the ACT. This legislation should include the establishment of a central register of donor gametes. Any proposed legislation should be developed in consultation with stakeholders, and particular consideration should be given to the rights of donor conceived people.

The *Mitochondrial Donation Law Reform (Maeve's Law) Act 2021* (Cth) will commence on 2 October 2022, unless proclaimed at an earlier date. The Act will be implemented in a two-stage approach, with stage one expected to take several years. This Commonwealth legislation does not impose any urgent time constraints for the ACT to make any legislative or licensing changes in the immediate future.

Next Steps

Based on the findings of this report, the ACT Government will:

- Work to develop a regulatory framework for ART in the ACT, including establishing a register for donor information, in consultation with stakeholders.
- Explore options for increasing affordability and accessibility of ART, including a potential low-cost ART service in the ACT.

[3] The National Health and Medical Research Council (NHMRC). Ethical guidelines on the use of assisted reproductive technology in clinical practice and research. [Internet]; 2017. Available from: https://www.nhmrc.gov.au/art.

[4] Fertility Society of Australia and New Zealand. Code of Practice for Assisted Reproductive Technology Units [Internet]. Melbourne: Fertility Society of Australia and New Zealand; 2021, Available from: https://www.fertilitysociety.com.au/code-of-practice/#copanz

- Work with the Commonwealth Government to explore opportunities to improve access to specialised support or counselling services for donor conceived people and their families.
- Advocate to the Commonwealth Government to expand the eligibility criteria for accessing Medicare rebates to include people accessing ART treatment due to 'social infertility'.
- Encourage ART providers to expand availability of counselling appointments and to offer counselling at no cost, where it is not already. Counselling and support services should be focused on the wellbeing of the individual and the rights of the donor conceived child, rather than the ART process, and should be culturally appropriate and inclusive.
- Encourage all ART clinics to undertake LGBTIQ+ cultural competency training and to use inclusive and gender-neutral language in ART treatment and practice.
- Encourage ART providers to promote access to peer support networks.

Terminology

ACT means the Australian Capital Territory.

ACTHD means the ACT Health Directorate.

ART means Assisted Reproductive Technology, defined as the application of laboratory or clinical techniques to gametes and/or embryos for the purposes of reproduction.

Donor means a person who gives sperm or egg(s) for use by a person other than their spouse or partner in a reproductive procedure.

Donor conceived person means a person conceived using donor gametes.

Donor gametes means sperm or egg(s) given to an individual or couple for their reproductive use.

IUI means intrauterine insemination.

IVF means in-vitro fertilisation.

LGBTIQ+ is the term respectfully used to refer to people of diverse genders and sexualities. It is not intended to be limited to people who identify as lesbian, gay, bisexual, trans and/or gender diverse, intersex and/or queer.

Medical infertility means the inability to conceive or have children due to medical reasons, for example, endometriosis or abnormal sperm production.

Mitochondrial donation means a new ART which can help some women who carry a mitochondrial genetic defect avoid passing on severe mitochondrial disease to their biological children.

NHMRC means the National Health and Medical Research Council.

OI means ovulation induction.

Parent is the caregiver of a child. The intended parent is the individual or couple who seeks to have a baby using ART. Parents may be biologically related to the child as the mother/father/birthing parent, but may also be connected to the child through emotional/legal/kinship relationships.

Perinatal loss includes miscarriage, stillbirth, neonatal death (up to 28 days old) or termination after diagnosis of an abnormality in the developing foetus.

RTAC means the Reproductive Technology Accreditation Committee of the Fertility Society of Australia and New Zealand's.

Social infertility means the inability to have children because of social factors, rather than medical reasons, for example, same-sex relationships or being single.

VARTA means the Victorian Assisted Reproductive Treatment Authority.

WHM means Women's Health Matters.

Background

The motion

In April 2021, Dr Marisa Paterson MLA presented a motion to the ACT Legislative Assembly regarding the regulation and access to ART services in the ACT (see Appendix A). The motion calls on the ACT Government to:

- review the availability of support services for individuals and couples choosing to access ART to ensure that appropriate information and care are readily available—pre, during and post treatment;
- investigate and review comparable ART regulatory arrangements in other states and territories;
- consider establishing a regulatory framework for ART in the ACT, including consideration of the position of sexuality and gender diverse couples;
- consider the establishment of a register that will contain mandatory information in relation to all births resulting from ART treatment where donor gametes are used;
- support the welfare of donor conceived people by providing regulated access to identifying information about their donor and links to siblings from the central register looking to connect;
- consider the potential impact of the Mitochondrial Donation Law Reform (Maeve's Law) Bill 2021 currently being considered by the Commonwealth Parliament and related issues on the ACT's current legislative arrangements;
- consider the accessibility of ART for individuals coming from low socio-economic backgrounds;

- report back to the Legislative Assembly no later than August 2022 on findings.

What is ART?

ART is defined as 'The application of laboratory or clinical techniques to gametes and/or embryos for the purposes of reproduction,'[3] which involves 'clinical treatments; counselling services; and laboratory procedures for the assessment and preparation of human oocytes, sperm or embryos'.[4] This can include:

- in vitro fertilization (IVF);
- gamete intrafallopian transfer;
- ovulation induction (OI);
- intracytoplasmic sperm injection;
- embryo or gamete cryopreservation;
- surgical sperm recovery;
- oocyte, semen or embryo donation;
- embryo biopsy or non-invasive sampling for preimplantation genetic testing;
- gestational and traditional surrogacy; and
- intrauterine insemination (IUI).[4]

Use of ART

In Australia, it is estimated that 1 in 6 couples experience some form of infertility.[3] The use of ART is increasing with more than 1 in 25 births resulting from ART.[3] Based on the most recent available data, in 2019 there were 81,049 ART treatment cycles reported by clinics in Australia and 15,158 children were born following ART treatments.[5]

ART providers in the ACT

There are currently three private ART providers in the ACT:

- COMPASS Fertility;
- Genea; and
- IVF Australia.

Costs to access ART

Various costs are associated with accessing ART. Some services may be eligible for Medicare rebates, providing the treatment is 'necessary to appropriately treat a patient's medical infertility'.[6] These services include consultations, pathology, and diagnostic imaging services,

[5] Newman, J., Chambers, G. and Paul, R., 2022. *Assisted reproductive technology in Australia and New Zealand 2019*. Sydney: National Perinatal Epidemiology and Statistics Unit, the University of New South Wales.

[6] Services Australia. 2021. *Education guide - Billing assisted reproductive technology services*. [online] Available at: https://www.servicesaustralia.gov.au/education-guide-billing-assisted-reproductive-technology-services [Accessed 18 May 2022].

as well as semen preparation, monitoring of fertilisation and embryo development, insemination, and preparation of gametes or embryos for transfer or freezing.

Services required as part of ART treatment will vary depending on an individual or couple's specific needs. Costs associated with treatment can include:

- consultations with a fertility specialist;
- relevant tests – for example, egg reserve, sperm tests and genetic screening; and
- fertilisation and insemination.

Consultation

To inform the response to Dr Paterson's motion, views were sought from ART consumers, fertility providers, donor-conceived people and government officials. The following stakeholders engaged in the consultation process:

- ACT Human Rights Commission
- A Gender Agenda
- Donor Conceived Australia
- Fertility Research Centre, New South Wales
- Fertility Society of Australia and New Zealand
- Genea
- IVF Australia / Virtus Health
- Meridian
- New South Wales Ministry of Health
- Office of LGBTQ+ Affairs, CMTEDD
- Queensland Department of Health

In total, eleven meetings were held in May 2022, conducted largely via video-conferencing technologies.

ACTHD also engaged Women's Health Matters (WHM) to explore the experiences of ART consumers in the ACT. WHM conducted a public survey, which received 175 responses from diverse genders, including LGBTIQ+ Canberrans, aged 16 years or over, who live in the ACT and have experienced difficulties trying to get pregnant or become a parent.[7] WHM also conducted a focus group with six participants, and separately interviewed three people who were unable to participate in the focus group.

The results of this research were provided to ACTHD in a report titled *Assisted Reproductive Technology in the ACT: experiences of trying to get pregnant or become a parent* (the WHM report)[7] which has been used to inform this response. A copy of this report is publicly available on the WHM website.

The government thanks everyone who contributed their time and valuable insights to this process.

[7] Women's Health Matters. Assisted Reproductive Technology in the ACT: Experiences of trying to get pregnant or become a parent. ACT: Women's Health Matters; 2022.

Response to the motion

Accessibility of ART

Summary of key findings:

- Cost is the primary prohibiting factor in accessing ART services.
- Medicare rebates should be accessible for anyone who chooses to use ART services, regardless of their infertility being due to social or medical reasons.
- Improving affordability and accessibility, potentially through a low-cost service in the ACT, would address a significant barrier to access.
- The establishment of a low-cost option in the ACT would need to be further explored to determine feasible options.

ART is used to help people achieve pregnancy and can be accessed for a range of reasons. Historically, ART has primarily been used as an infertility treatment in heterosexual relationships,[8] however is increasingly being used by people of a diverse range of genders, sexualities and family structures. ART can also be accessed to reduce the risk of a genetic disease or abnormality being inherited by a child.[8] For many single people and people in same-sex or gender diverse couples, ART is one of the few options for becoming parents.[7] Access to ART by LGBTIQ+ identifying people is explored later in this report.

Overall, most experiences of using ART in the ACT were considered positive by consumers, with two-thirds of respondents to the WHM survey finding their experiences mostly or very positive, meaning one-third were viewed as mostly or very negative.[7] Factors influencing experiences of ART services include the quality-of-service provision and communication from the provider; having trustworthy and expert staff; the effectiveness of the service (i.e. success in having a baby or becoming a parent); cost of the service; and the impact on mental wellbeing.[7]

WHM explored the notion of why people choose to access, and not access, ART services. The cost of services was cited as the top consideration in decision-making, including why people did not access ART.[7] Other commonly cited factors influencing the decision to access services is a person's desire to have a baby or become a parent, as well as their age or the age of one's partner.[7] The possibility that someone could still become pregnant without ART was a common factor in the decision to not use ART. Consumers indicated they would be more likely to access ART treatment if a bulk-billing or low-cost service is established in the ACT, if the Medicare rebate amount is increased, and if eligibility to access the Medicare rebate is expanded.[7]

The financial impact of ART was the most widely raised issue by consumers and stakeholders. This section explores the costs of ART services as a primary barrier in the accessibility of ART.

[8] Victorian Assisted Reproductive Treatment Authority. What is Assisted Reproductive Technology? [Internet]. October 2021 [cited 17 May 2022]. Available from What is assisted reproductive technology (ART)? | VARTA

Costs

ART costs can vary depending on the state or territory where the service is being offered, which clinic is providing ART, and what services are required. Stakeholders advised that ART services in the ACT can cost over $10,000, depending on the treatments required, if the person is eligible for Medicare rebates, if donor gametes are required, and whether multiple cycles are necessary. In the ACT, ART is available through private health services. Additional costs are also required for surrogacy or donated sperm, disproportionately impacting LGBTIQ+ and single people.

A major report by the Australian Longitudinal Study on Women's Health found that between 1996 and 2020, the average out-of-pocket expense for women using ART was $7,535 per woman, ranging from $0 to $59,378.[9] The following table published by IVF Australia offers an indication of costs for ART services.[10]

Table 1. IVF Australia treatment costs.

Treatment Costs correct at 1 January 2022	Cycle payment	Estimated out of pocket costs for an initial cycle in a calendar year	Estimated out of pocket costs for a subsequent cycle in a calendar year
IVF cycle	$10,275	$5,274	$4,685
ICSI cycle	$11,055	$5,570	$4,981
Frozen embryo transfer	$3,797	$2,405	$2,232
Intrauterine Insemination	$2611	$2,060	$1,912
Ovulation induction	$950	$700	$700

Service	Cost	Medicare Rebate
Embryo freeze	$625 (includes 6 months storage)	Nil
Sperm freeze	$475 (includes 6 months storage)	Nil
Surgical sperm collection – transcutaneous	$675	Yes
Surgical sperm collection - open	$850	Yes

In addition to Medicare rebates, individuals can access rebates for ART services covered by their private health insurance, if applicable. However, these rebates may be inadequate and potentially associated with waiting periods. Despite Medicare and private health insurance rebates, there are still significant out-of-pocket costs associated with accessing ART, which is a barrier for people wishing to access these services. To assist with these costs, some private clinics offer payment plans or access to 'buy now, pay later' platforms as Afterpay or Zip pay. In limited circumstances, individuals may choose to access their superannuation to assist in paying for fertility treatments either on compassionate grounds or if they can demonstrate severe financial hardship.[11] Others seek treatment from more affordable

[9] Chan HW, Mishra G. Australian Longitudinal Study on Women's Health: Reproductive Health Policy Brief. [Internet]. Women's Health Australia. February 2019 [cited 17 May 2022]. Available from: 2019_Major-Report_Reproductive-Health-Policy-Brief.pdf (alswh.org.au)

[10] IVF Australia. IVF Treatment Costs. 2022. [Internet] Available at: https://www.ivf.com.au/ivf-cost/ivf-costs [Cited 18 May 2022].

[11] Access my Super. Accessing Super for IVF [Internet]. 20020 [cited 31 May 2022]. Available from: Accessing Super For IVF – Access My Super

services in other jurisdictions, such as NSW, and even contemplate moving to another jurisdiction to be closer to these services.[7]

> *"We could get a rebate but honestly it was just too expensive to contemplate IVF for us. If we hadn't found the Sydney clinic that bulk bills, we wouldn't have been able to do IVF."*[7]

There are no low-cost or ACT Government funded options for ART services in the ACT and there is a desire for better access to low-cost, subsidised treatment. As part of its report, WHM recommends that "the ACT Government consider establishing or supporting the establishment of a public fertility service or other low-cost option for ART in the ACT, with a focus on inclusiveness and access for LGBTIQ+ people and single people."[7]

Consumers indicated they could only access ART services because they are in a comparatively affluent financial position. Despite having good incomes, it is not uncommon for people using ART services to have to forego other expenses such as retirement savings or investments, holidays, or expenses for their existing child(ren).[7] Some consumers report having to seek financial support from other sources to continue with their ART treatment, while many have paused or stopped (or contemplated stopping) their ART treatments because of associated costs.

> *"We have had to delay treatment each time we have done a cycle, in order to be able to afford it."*[7]

> *"Without family support we wouldn't have the funds to continue at this point."*[7]

> *"IVF would be far more successful for my situation than OI, but IVF is too expensive, so I have to keep going with Ovulation Induction."*[7]

Although Medicare subsidises the cost for ART treatments, it is still common for people to spend thousands of dollars for each cycle, while some spend tens of thousands or even hundreds of thousands of dollars across a number of cycles and treatments.[7]

Medicare rebates

The eligibility for Medicare rebates for ART services was frequently highlighted by stakeholders as a barrier in the accessibility and affordability of ART. This was particularly relevant for LGBTIQ+ Canberrans who seek to access ART services. It is important to note that Medicare rebates are the responsibility of the Commonwealth Government and changing Medicare rebates or eligibility is out of scope of the ACT Government. However, the ACT Government is supportive of equity in access to Medicare rebates for ART, including for those who experience social infertility.

Infertility is when a person cannot conceive or have children.[12] Infertility caused by medical factors, such as abnormal sperm, is known as "medical infertility", while infertility caused by social factors, such as same-sex relationships, is known as "social infertility".
Currently, Medicare will only pay benefits for ART services that are deemed to be clinically relevant. To be clinically relevant, services must be accepted by the medical profession as necessary to appropriately treat a patient's medical infertility.[6] To be eligible for Medicare

[12] Healthdirect. Infertility. [Internet]. June 2020. [Cited 24 May 2022]. Available from: Infertility - causes, resources and support | healthdirect

rebates, some people who would otherwise be considered socially infertile, such as single people or people in relationships where neither body produces sperm, have had to first establish medical infertility by paying full cost for cycles of IUI and OI.[7]

However, consumers reported differences across providers, with some willing to support those with social infertility to access the Medicare rebates, while others were unwilling to do so.[7] This is often at the discretion of the treating practitioner and could be considered discrimination.

> *"[A]fter lots of trouble with the first doctor we changed to a new doctor, [who]… signed on for us to have the Medicare rebate. And with their clinic we were able to access a huge online database of donors. Which then moved us forward in the process much faster."*[7]

> *"I am a single woman attempting IVF with donor sperm. There is a 10-month waiting list for local sperm so I got overseas. It is extremely expensive and cost me $1600 per vial. The most frustrating is not being able to access Medicare straight away as a single woman. I had to do 2 rounds of IUI to be deemed "infertile" to be able to access Medicare. The whole process has cost $28,000 and that's only 2 rounds of IUI and 1 round of IVF. The system is definitely hard for single women."*[7]

Accessibility of ART for people from low socio-economic backgrounds.

It is challenging to obtain data about the impact of demographic characteristics, such as socio-economic status, on access to ART services. However, it is clearly evident that access to ART services in the ACT is limited to those who can afford it, and cost is a prohibitive factor for a large number of people who may otherwise want to access these services.

ACT residents travel to other jurisdictions to access more affordable ART services. However, high costs associated with travel and accommodation is prohibitive and can render this option inaccessible to people from low socio-economic backgrounds.[7]

> *"[F]or lower income families [the lack of bulk billed options in Canberra] potentially means giving up on their journey before it begins, or going up to Sydney for the opportunity to conceive within their budget."*[7]

The establishment of a low-cost service in the ACT would improve accessibility of ART services for those who may otherwise not be able to afford these services.
The establishment of a low-cost option in the ACT will need to be further explored to determine feasible options.

Affordable models

Low cost or government-subsidised ART services are available in Victoria and New South Wales. Across the rest of Australia, the information available indicates that lower cost ART services are not offered via publicly funded clinics. Instead, patients need to access private fertility services at their own expense.

Victoria

In 2019, the Victorian Department of Health commissioned a review into ART services to better understand the barriers associated with accessing ART treatments. The review

identified the need for affordable ART services to be considered an essential component in delivering more inclusive healthcare for patients.[13] The review noted that Victoria has seen an increase in competition within the fertility provider market, resulting in several low-cost private clinics.[13] The out-of-pocket costs to patients accessing ART treatments from these clinics range from $600 to $1,500 after Medicare rebates. Some clinics also offer delayed payment plans to further reduce the financial barriers for accessing ART services.[13]
The Victorian 2021-22 budget committed to establishing public fertility care services. Public hospital facilities will be improved to enable ART service delivery, and free treatment cycles and fertility care services are also offered.[14]

New South Wales

NSW currently has three publicly funded ART clinics enabling them to provide ART services at a significantly lower cost than their private counterparts. These facilities comprise of the Westmead Fertility Centre, the Fertility and Research Centre at the Royal Hospital for Women, and the Royal Prince Alfred Hospital IVF Clinic.[15] From January 2020, the NSW Government invested in providing low-cost IVF services at these clinics, as well as a $500 rebate to help cover out-of-pocket costs associated with eligible fertility tests.[15] Under this NSW Affordable IVF Initiative, access to low-cost services will be expanded in the 2022-23 budget to offer a rebate of up to $2000 for fertility treatment and fertility testing at the above listed services, in addition to private fertility clinics.[15] The expansion of this initiative also includes the provision of five days of paid fertility treatment leave for NSW public servants.

Availability of support services

Summary of key findings:

- Counselling services are routinely offered by ART providers in the ACT, although uptake of this service is low.
- Mandatory counselling as part of donor arrangements can be improved.
- Uptake of counselling would be greater if it was free and appointment availability was expanded to outside of business hours.
- Counselling and support services should be focused on the wellbeing of the individual, rather than the ART process, and should be culturally appropriate.
- Peer support and online networks are highly valued by consumers. ART providers should promote access to these support networks.
- Specialist counselling and support services should be readily accessible for donor conceived people.

[13] Gorton, M. Helping Victorians create families with assisted reproductive treatment: Final Report of the Independent Review of Assisted Reproductive Treatment. VIC Department of Health; May 2019 [Cited 1 May 2022]. Available from: Review of Assisted Reproductive Treatment in Victoria | Engage Victoria

[14] Victoria State Government. Media Release: Public IVF to make starting a family easier for Victorians. [Internet]. May 2021 [cited 30 May 2022]. Available from: 210512 - Public IVF To Make Starting A Family Easier For Victorians.pdf (premier.vic.gov.au)

[15] NSW Health. Improving affordability and access to IVF services in NSW. [Internet]. May 2022 [cited 30 May 2022]. Available from: Improving affordability and access to IVF services in NSW - Maternal and newborn

Counselling

For donor conceived people, support services are available through Donor Conceived Australia (DCA). DCA aims to be the peak body for donor conceived people in Australia and offer online and in-person support networks including national support groups. This enables donor conceived people to meet and discuss their experiences. DCA also offers referrals for medical, legal, or other support to professionals with a lived experience of donor conception and experience working in this area.[16] It is important to ensure that donor conceived people in the ACT have access to specialist counselling and are adequately supported to learn about their genetic origins. This counselling and support could be offered through existing service providers or through the provision of funding to a trusted external organisation.

The provision of support services, including counselling, is a requirement of both the NHRMC Guidelines and the RTAC Code of Practice. The NHMRC Guidelines state *"Clinics must provide accessible counselling services from professionals with appropriate training, skills, experience and competency to support individuals and couples in making decisions about their treatment, before, during and after the procedures."*[3] Similarly, the RTAC Code of Practice sets a requirement for ART services to appoint, or ensure access to, a senior counsellor.[4] The ART service must also have a policy for access to emergency after-hours psychological care.

In the ACT, participation in counselling is optional for people undergoing some ART treatments, and mandatory in other circumstances. Counselling is mandatory in donor conception arrangements, including both surrogacy and sperm donation. It is a requirement of the RTAC Code of Practice that all donors, partners, recipients and surrogates, and their partners, undertake counselling.[4] In circumstances where the donor is known, all parties must participate in an additional joint counselling session.[3] The NHMRC Guidelines make provisions for what information should be discussed for people undertaking this process.

Fertility providers in the ACT reiterated that anyone donating their sperm or eggs is required to go through a counselling process to ensure all parties are fully informed about the donor conception process. The recipient parent(s), donor and the donor's partner (if applicable) are all counselled as part of this process, which canvasses topics about what information must be disclosed by the donor and the fact the donor conceived person may seek to contact the donor in the future. Counselling also includes education about raising a donor conceived person, including information about how to talk to the donor-conceived person about their genetic origins. This counselling process should centre around the rights and the needs of donor conceived people – both when they are children (in accordance with the UN Convention on the Rights of the Child)[17] and when they are adults.

The WHM report found that most people had been offered professional counselling by their ART provider, which was usually offered for no extra cost and promoted in a non-stigmatising way.[7] Some consumers also received check in calls from nurses, which were appreciated and was the primary emotional and psychological support in some instances. Despite the offer of professional counselling, most people did not use these services. Where counselling was used, it was primarily accessed before or during ART treatment, rather than after, and it was of a high quality. However, it was noted that some consumers felt

[16] Donor Conceived Australia [Internet]. [Cited 24 May 2022]. Available from: https://www.donorconceivedaustralia.com.au/

[17] United Nations. Convention on the Rights of the Child [Internet]. September 19990 [updated 2002; cited 19 May 2022]. Available from: https://www.ohchr.org/en/instruments-mechanisms/instruments/convention-rights-child

counselling was focused on the ART process itself, rather than providing a holistic counselling service that addressed other issues relevant to the consumer.[7]

Views of consumers on whether they had received enough support around the time of their treatment varied, with roughly equal numbers feeling like they did and did not.[7] For those who felt they did not receive enough support, it was generally because counselling was not offered, or was associated with additional costs. For some people where counselling was offered, they were unable to access this service due to limited appointment availability, or because the counselling was not seen as supportive or appropriate.[7]

> *"At [our clinic] we were invited to get free ongoing counselling with their in-clinic counsellor. She was empathetic and inclusive and supported us through years of treatment and our stillbirth."*[7]

> *"There was limited counselling available through the clinic. Usually only in very limited hours which was difficult to co-ordinate with work, given it already stuffs up your schedule. Also, we were offered one session per cycle. It is absolutely not enough."*[7]

Many consumers identified that the care and support offered by providers could be improved, to focus on the mental health and wellbeing of service users.[7] This could be addressed through a requirement for all staff to undertake mental health training.

However, the mandatory counselling for donor conception arrangements was often not viewed as supportive, and in some cases felt distressing and discriminatory.[7]

> *"At [one clinic] they made us do mandatory counselling with a counsellor who was heteronormative, and clearly not experienced with queer couples and she grilled us about 'how will this baby go with no father?' She really made us feel like we were being tested if we were worthy parents. She set herself up as the gate keeper for parenting. Even though straight couples do not have to do counselling to be parents."*[7]

Given the emotional demand that ART can have, it is important that counselling services are offered to all users, are preferably free and available at a time that suits them. Counselling and support services should be focused on the wellbeing of the individual, rather than the ART process, and should be culturally appropriate. The WHM report recommended that appointment availability is expanded so that counselling is accessible by anyone who wishes to access this service.[7] Counsellor support should be embedded in the process if treatment was not successful. The offer of support services should extend beyond the treatment period and be made available throughout pregnancy and post-pregnancy as required, whether this is through the ART providers themselves or via referrals to external services.[7] Specialist support and counselling services should be available to donor conceived people and their families.

Available information and peer support

Most people felt they had received accurate, user-friendly, accessible information from ART providers to assist in making decisions about treatment.[7] However, access to peer support and online networks is highly valued and considered an important avenue to obtain additional information and help advocate for effective treatment,[7] with many people

receiving support from peers, family members, friends and online networks. Some ART providers supplied information about support networks and other services, however consumers indicated they would value more opportunities to engage with peers to share experiences, learn from each other, and feel less alone in the process.[7]

There is a need for peer support networks to be inclusive, with some jurisdictions offering LGBTIQ+ specific support groups. As part of their report, WHM recommend that "the ACT Government, together with stakeholders, investigate ways to help create and promote options for peer support for people undergoing ART."[7]

> *"[The clinic staff] were very good when it started, but when it comes to the rear end and it's not successful I feel like I wasn't confident going for the support [the clinic] had because it was all very clinical. So I would have preferred if I … had been in touch with other people who are going through the same thing, shared experiences."*[7]

> *"I feel very lucky I had quite a few friends going through IVF journeys at similar times. So we would catch up fairly regularly and just knowing a person and seeing them in person was really nice to be able to debrief."*[7]

> *"[T]he other element that we still haven't really found is the LGBTQ specific support group… I think in Sydney they do have that sort of forum… [T]here's something about being in a group of people at the same time while you're all doing [IVF] together…[Meeting] once a quarter or something, once a month, I don't know. Once a cycle to just have space where you could actually talk to other queer people living in Canberra doing IVF would have been helpful."*[7]

WHM's report recommended that ART providers encourage access to peer support and online networks, noting the important role these play in supporting people undertaking ART.

Perinatal loss

It is important to acknowledge perinatal loss as a part of ART. There is a need for ART services to provide adequate support to people who experience miscarriage or stillbirth following ART treatment. The WHM report found that consumers believed the support offered by ART providers for pregnancy loss was not adequate.[7] It was identified that following perinatal loss, follow-up from an ART clinic often focused on future ART treatments, rather than the support and care required following a loss.

> *"[E]ven when they give you a call and say the results, I've had people ask me: So unfortunately it hasn't worked, so when do you want to start the next cycle? You're on day one already, you're on day three already... and that's where I thought, it was like, I'm a person, you know? Give me that respect. Show that respect."*[7]

> *"I just kind of would have really appreciated just a bit more of that personal contact, to be like, I've heard this has happened to you. This is what to expect. And I just felt that was really lacking. And I felt super disappointed in that because I don't know, I've never had a miscarriage before, I've never done an egg collection before."*[7]

Providing adequate support for parents and families through the complex experience of pregnancy loss is crucial. ART providers should ensure adequate support is available to

people who experience perinatal loss. Availability of external support services, such as Red Nose and SANDS, should be promoted and referral pathways established where relevant. The ACT Government is committed to providing the right maternity care at the right time and to protecting and promoting the health and wellbeing of infants, parents and families. A review into supports and services for pregnancy loss was encompassed in the Joint Maternity Project led by ACTHD. This project was responsible for the development of a comprehensive plan to provide a holistic approach to maternity system reform underpinned by a focus on individualised care, equity, and evidence. The resulting plan, *Maternity in Focus: The ACT Public Maternity System Plan 2022-2032* has been released.

ART regulatory arrangements

Summary of key findings:

- All ART providers are required to comply with the NHMRC Guidelines and RTAC Code of Practice, in conjunction with any national and state or territory legislation.
- Four jurisdictions have an ART regulatory framework and a central register of donor conceived information. Of these, two jurisdictions (WA and VIC) have an oversight body.
- There have been various government inquiries at the federal and jurisdictional levels that have considered introducing regulation for ART and the merits of establishing registers for donor conceived gametes. State governments have progressively introduced legislation to regulate ART.

There is currently no national legislation specifically regulating ART in Australia. ART providers must comply with the NHMRC Guidelines on the use of ART in clinical practice and research.[3] All ART providers are also licensed and accredited by the RTAC and are required to comply with their Code of Practice.[4] Additionally, ART providers must comply with requirements in national legislation regarding the use of embryos, as well as any specific state laws that regulate ART.

There have been several inquiries and reviews into ART regulation across Australia, including:

- In 2011 the Australian Parliament, by resolution of the Senate, completed a Committee of Inquiry to assess the regulation of donor conception practices in Australia.[18]
- In 2012, the Parliament of Victoria tabled an Inquiry into Access by Donor-Conceived People to Information About Donors.[19]

[18] Commonwealth of Australia. Donor Conception Practices in Australia. Canberra (AU). February 2011 [cited 30 May 2022]. Available from: Donor conception practices in Australia – Parliament of Australia (aph.gov.au)

[19] Parliament of Victoria. Inquiry into Access by Donor Conceived People to Information About Donors. September 2010 [updated March 2012; cited 30 May 2022]. Available from: Parliament of Victoria - Inquiry into Access by Donor-Conceived People to Information About Donors (Interim Report, 56th Parliament)

- In 2012, the Parliament of NSW conducted an inquiry into the management of information relating to donor conception.[20]
- In 2017, the Tasmanian Government completed an Inquiry into Donor Conception Practices in Tasmania.[21]
- In 2019, the Victorian Government published the final report of the independent review of Assisted Reproductive Treatment.[13]
- The Queensland Government are currently undertaking an inquiry into the rights of donor conceived people.

Notably, a recommendation of the 2011 Australian Parliament's Inquiry was that "jurisdictions including Queensland, Tasmania, the Northern Territory, and the ACT should as a matter of priority establish a regulatory framework for the provision of ART services."[18]

Overview of legislation and registers

Table 2 summarises the existing legislation and regulation that applies to ART in Australia.

Table 2. Existing ART legislation and regulation in Australia.

	VIC	NSW	WA	SA	NT	QLD	TAS	ACT
Legislation	*Assisted Reproductive Treatment Regulations 2009* & *Assisted Reproductive Treatment Amendment Act 2016.*	*Assisted Reproductive Technology Act 2007* & *Assisted Reproductive Technology Regulations 2014.*	*Human Reproductive Technology Act 1991* & *Human Reproductive Technology Act Directions 2004.*	*Assisted Reproductive Treatment Act 1988* & *Assisted Reproductive Treatment Regulations 2010.*	No. However, SA clinicians provide reproductive medicine services in the NT and must adhere to SA's legislation providing it does not conflict with NT's laws.	No	No	No
Register of donor conceived information	Yes	Yes	Yes	Yes	No	No	No	No
National guidelines	Reproductive Technology Accreditation Committee's *Code of Practice.*							
	NHMRC's *National Ethical Guidelines on the use of assisted reproductive technology in clinical practice and research.*							
National legislation	*Research Involving Human Embryos Act 2002*							
	Prohibition of Human Cloning for Reproduction Act 2002 and *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006*							
	National Health (IVF Program) Special Arrangement Amendment (instrument under the *National Health Act 1953*)							
	Mitochondrial Donation Law Reform (Maeve's Law) Act 2022							

[20] Parliament of NSW. Managing information related to donor conception. April 2014 [cited 30 May 2022]. Available from: Managing information related to donor conception (nsw.gov.au)

[21] Parliament of Tasmania. Inquiry into Donor Conception Practices in Tasmania: Final Report. December 2017 [cited 30 May 2022]. Available from: House of Assembly Community Development and Environment, Resources and Development Committee (parliament.tas.gov.au)

The NHMRC Guidelines enable the framework for conducting ART within clinical practice and research settings. The guidelines are intended to:

- support the ART framework for the provision of services;
- be viewed in conjunction with legislation at the state and territory levels to facilitate a robust framework for ART;
- ensure wellbeing for children born as a result of ART treatments;
- ensure decision-making processes within clinical practices delivering ART recognise the social relationships and context may impact an individual's or couple's decision making including maintaining sensitivity to cultural and spiritual differences; and
- ensure the provision of ART services are transparent and open to scrutiny with the goal of protecting the privacy of all parties including persons born to the degree that is protected under Australian law. [3]

The RTAC sets standards for the provision of ART using a Code of Practice and grants licenses for the practice of ART in Australia. The purpose of the Code is to:

- promote continuous improvement in the provision of quality care;
- provide the framework and criteria for auditing and licensing ART providers; and
- ensure audits of ART providers are constructive, non-adversarial and independent.[4]

Penalties for infringement under the RTAC Code of Practice include a letter from the RTAC chairman outlining the guidelines and infringement. Where a second breach occurs, a request for an explanation is made by the RTAC to the clinic. Should the explanation be deemed unacceptable a warning letter is issued and any subsequent infringements may result in limited or total loss of accreditation.[4]

In the ACT, ART clinics are subject to regulation under the Public Health Act 1997 (ACT) if they perform procedures that are declared public health risk procedures. Under the *Public Health Act 1997* (ACT), ART clinics may be required to be licensed as Health Care Facilities and comply with other requirements under the Public Health (Health Care Facility) Code of Practice 2021 (No 1) (ACT) designed to support quality and safety in the delivery of health services. The Code of Practice will apply to an ART clinic if it performs a declared public health procedure, such as the use of intravenous sedation. The Code of Practice does not contain specific requirements or protections for patients and people born from ART.

While there is some overlap with the exercise of regulatory functions under the Public Health Act 1997 (ACT) and those being considered for ART clinics, regulators would need to develop an understanding of the novel technical aspects of ART as well as the ethical, legal and social issues associated with this specialised healthcare and these impacts will be considered in the development of a regulatory framework.

In NSW, South Australia, Victoria and Western Australia, state laws require adherence to the RTAC Code of Practice for legislative registration or licensing purposes. In those states, significant fines may also be imposed for breaching the code.

At a national level, the *Prohibition of Human Cloning for Reproduction Act 2002* defines an accredited ART centre as a 'person or body accredited to carry out assisted reproductive technology by the Reproductive Technology Accreditation Committee of the Fertility Society of Australia'.[22] As a result, it is currently an offence in Australian Commonwealth law to use human embryos in any way without RTAC licensing.

[22] *Prohibition of Human Cloning for Reproduction Act 2002* (Commonwealth)

Comparable ART regulatory arrangements in other states and territories

The table below provides an overview of the comparable regulatory arrangements for ART in jurisdictions across Australia. Further, it also considers the registry arrangements for donor gametes in these jurisdictions.

Table 3. ART regulatory arrangements across Australian jurisdictions.

Jurisdiction	Summary of Arrangements	Register of donor gametes
Commonwealth	Commonwealth legislation for ART relates to cloning, research involving human embryos and IVF drugs covered by the Pharmaceutical Benefits Scheme. Section 33 of the *Research Involving Human Embryos Act 2002* empowers inspectors to act on behalf of the NHMRC Licensing Committee to search premises and assess the clinic's compliance with the *Research Involving Human Embryos Act 2002*.	There is currently no national donor conception register.
Victoria	Key objectives of Victoria's legislation include: • ensuring there is appropriate regulation of ART services (including self-insemination) in Victoria; • ensuring there is an appropriate regulatory framework for the suite of procedures carried out under the ART Act; • ensuring provisions are made with respect to surrogacy arrangements; • establishing the Victorian Assisted Reproductive Technology Authority (VARTA); • providing for VARTA to maintain the Central and Voluntary Registers. The legislation also includes provisions to limit total number of offspring a donor can produce, which is a maximum of 10 families.	The legislation requires VARTA to maintain two donor conception registers - one mandatory ('central register') and one voluntary. Under Victoria's legislation, all donor conceived people, regardless of when they were born, have the right to access identifying information about their donors, without the donor's consent. The registers include information about: • the donor(s) • the woman who underwent treatment using donated gametes, and her partner (if any); and • the donor conceived person. Information held on the registers may include details such as full name, date of birth, medical history of the donor, and information about any people conceived from their gametes (available information can vary depending on the completeness of historical records).
New South Wales	The objectives of NSW's ART Act include: • preventing the commercialisation of human reproduction; and • protecting the interests of the person born as a result of the ART treatment, the gamete donor, and the woman undergoing ART treatment.	The NSW Ministry of Health manages a mandatory register that includes information about every child born from ART treatment using donated gametes, or born through surrogacy, who was conceived after 1 January 2010. The register enables adult donor conceived people to seek identifying information about: • the full name, sex and date of birth of the donor;

Table 3. ART regulatory arrangements across Australian jurisdictions.

Jurisdiction	Summary of Arrangements	Register of donor gametes
	The ART Act aims to achieve these objectives by requiring ART providers to be registered with the NSW Ministry of Health. In accordance with the Act, ART providers must advise the NSW Ministry of Health of key changes impacting provision of ART. These include, but are not limited to, change of premises, and changes in counsellors or medical practitioners providing ART services.	• the name of the person who gave birth to the child; and • the full name, and date and place of birth of the gamete donor and any relevant health information. Information separately obtained by the NSW Ministry of Health (for example, in response to requests for information from ART clinics) is also collected about donor gametes and donor conceived people conceived prior to 2010.

Western Australia	WA's legislation established the the Western Australian Reproductive Technology Council (the Council), which regulates ART in WA. Key objectives of the legislation include:
	• regulating and providing guidance in the use of ART through:
	  ○ the establishment of the Council,
	  ○ implementation of a Code of Practice; and
	  ○ the imposition of licensing requirements.
	• ensuring ART standards are suitable;
	• allowing beneficial technological developments in ART, and discouraging or prohibiting those that are neither proper nor suitable;
	• supporting the welfare of ART participants and any child born from ART, including ensuring relevant consents are obtained; and
	• ensuring welfare, equity and community standards are considered when providing ART treatments.
		WA's Department of Health manages a mandatory donor conception register, which includes information about anyone who was donor conceived on or after 1 December 2004. In WA, any donor conceived person aged 16 years or over, who was born on or after 1 December 2004, has a right to the name and date of birth of their donor. Other information collected about the donor includes their:
		• ethnic background;
		• physical description;
		• personal interests and hobbies;
		• marital status;
		• health and family history;
		• education and occupation; and
		• an optional personal statement.
		There is also a voluntary service provided by JIGSAW DNA Connect, which supports donor conceived people, their parents and children, and donors to voluntarily share information with one another.

Table 3. ART regulatory arrangements across Australian jurisdictions.

Jurisdiction	Summary of Arrangements	Register of donor gametes
South Australia	South Australia's Minister for Health is responsible for oversight of the ART legislation. For a medical practitioner to be certified and able to perform ART procedures, the following criteria must be met: • the medical practitioner must hold the appropriate qualifications and licenses to perform an ART procedure prescribed by regulation or other such considerations; • the medical practitioner must be a fit and proper person to perform this type of procedure; and • the grounds of religious or conscientious objection to the performance of a procedure must not be considered as grounds for the removal of a license to practice.	In November 2021, South Australia passed an amendment to its ART Act, which requires the Minister for Health to maintain a register of donor conceived births. Information collected for the register includes: • the donor's full name and nominated contact address; and • the full name and nominated contact address of the ART recipient. • the full name of any child born from ART; and • any other information required by the regulations, and any other information that the Minister sees fit. SA Health is working with ART clinics to input historical data into the register.
Queensland	Queensland does not have legislation regarding the provision of ART services. A Parliamentary Inquiry is currently underway, which is considering, among other matters, whether a register of donor gametes should be established.	Not applicable.
Northern Territory	Northern Territory does not have a regulatory framework surrounding the provision of ART services.	Not applicable.
Tasmania	Tasmania does not have a regulatory framework surrounding the provision of ART services.	Not applicable.
Australian Capital Territory	While there is no specific legislation relating to ART in the ACT, the *Parentage Act 2004* addresses the legal parentage of children conceived through procedures such as ART. The *Human Cloning and Embryo Research Act 2004* regulates the use of human embryos created by assisted reproductive technology (or other means).	Not applicable.

Establishment of a regulatory framework for ART

Summary of key findings:

- There is a need to establish a regulatory framework for ART in the ACT, including a central register for donor gametes. This should be undertaken in consultation with stakeholders.
- Careful consideration should be given to the impact of regulation on donor conceived people.
- All ART clinics should undertake LGBTIQ+ cultural competency training.
- Promote the use of inclusive and gender-neutral language in ART treatment and practice.
- Any legislation introduced to regulate ART should use inclusive, gender-neutral language.

There were diverse views amongst stakeholders about the need to establish a regulatory framework for ART in the ACT. Some people advocated strongly for the establishment of a register to enable donor conceived people to access identifying information about their donor, including relevant medical information. This register could also enable donor conceived people, donors, and donor conceived siblings to contact each other, where they mutually consent to do so.

Other stakeholders were satisfied with the rigour of the current regulations for ART in Australia, particularly the requirements of RTAC Code of Practice and the NHMRC Guidelines, which require ART clinics to collect information about donors, including pertinent medical history. They argued that additional regulation could create unnecessary regulatory burden, especially given several states in Australia each have different legislative requirements for providers of ART. The NHMRC guidelines currently prescribe various requirements for the provision of ART services, including for counselling and collecting information for donor conceived people.[3] Some stakeholders argued that the current regulation provides more flexibility than legislation would – for example, when there are changes in best practice or if other regulatory issues emerge that need addressing.

Many stakeholders opined that there should be a nationally consistent regulatory framework and register, rather than independent legislation and registers in each state or territory. In the absence of a national model, stakeholders suggested legislation introduced in the ACT should be consistent with NSW or Victoria.

The WHM report identified that if regulation were to be developed, consumers would support greater accountability for providers.[7] This could encompass a requirement for honesty, transparency, ethical practice, attention to patient feedback, and professional standards related to qualification and training requirements. It was noted that profit of a provider should not be the primary goal of ART, rather that practitioners should be required to act in people's interests. Consumers would also like consideration given to the ability to move material between clinics, which is currently prohibited by some providers, but could

benefit consumers and ensure their choice of provider, and potential changing of providers, is respected.[7]

Consumers accessing ART identified that availability and choice of donor gametes, particularly sperm, is problematic and associated with a high cost. There is concern that the implementation of ART regulation in the ACT could result in further restrictions on the availability and accessibility of donor gametes.[7] The development of regulation should consider this concern; however, the rights and wellbeing of donor conceived people should be at the forefront.

Any proposed legislation for the ACT would need to be developed in consultation with stakeholders, to understand the impact of any regulations and to scope what should be included. Factors to consider include:

- whether a proposed framework affects accessibility and affordability of ART;
- the rights of donor conceived people;
- limits on the number of offspring from donor gametes;
- the ability of service providers to comply with any regulations;
- how a register would operate, including the degree to which historical information could be captured;
- regulations on the posthumous use of gametes;
- how compliance with regulations would be monitored by government; and
- parameters for a register of information about donor gametes used for ART.

The impact of regulation on donor conceived people

The establishment of an ART regulatory framework would encompass requirements for the operation of a central register of donor information. Historically, there has been a culture of secrecy around donor conception, meaning many donor conceived people have not found out until late in their adulthood (if they find out at all) that their genetic history is different to what they had thought. While some donor conceived people have been told about their conception by their parents, others have found out by other means – such as using DNA testing (such as Ancestry.com or 23 and me), or through notification from VARTA.

Representatives of donor conceived people emphasised the importance of knowing their genetic history for a myriad of reasons. In addition to knowing about any heritable health conditions, there can be a desire to find out about their heritage (including culture and genetic origins), and to potentially contact their donor and/or any siblings. It is also important for donor conceived people to be able to identify any relatives, to avoid them or their children unknowingly entering into an intimate relationship with a sibling or cousins. This is particularly the case in a small jurisdiction where a donor may make many donations, each of which can be used in several separate ART processes.

A Victorian Inquiry into *Access by Donor-Conceived People to Information about Donors* found that for some donor conceived people, there is substantial stress associated with an inability to obtain information about their donor. [19] There was a clear desire for donor conceived people to have access to both identifying and non-identifying information about

their donor, and that it can be both frustrating and disheartening when this information is unable to be accessed.[19] Some parents of donor conceived people spoke about being discouraged from telling their children that they were donor conceived, due to the inability to access information about their donor. This has flow-on effects for the donor conceived person, with distress often experienced by people who learn they are donor conceived later in life. This can also impact a person's sense of identity and belonging.[19]

The establishment of an ART regulatory framework and central register of information could therefore have a significant positive impact on the wellbeing of donor conceived people and their families. Donor conceived people choosing to access this information should be adequately supported in doing so, including having access to specialised support or counselling services.

> *"The impact of anonymous donation on donor conceived children is not to be underestimated – reading the experiences of donor-conceived children completely changed how my wife and I planned to expand our family."*[7]

Consider the establishment of a register of information where donor gametes are used and the provision of regulated access to this information

Currently in the ACT, a donor conceived person can request information about their donor and key information from that person's medical history from the clinic where they were conceived. However, this relies on the person knowing which clinic to approach, that clinic still operating, and historical records from their conception being kept. During consultations, stakeholders gave examples of records being lost, destroyed (in accordance with disposal laws or through natural disasters like flooding), or key information never being recorded.

In accordance with the NHMRC guidelines, ART providers must collect identifying information about the donor and their medical history, so it can be provided to the donor conceived person when they become an adult.[3]

In Australian jurisdictions that have donor conception registers, a donor conceived person can apply to a government entity (usually the state's health department or another government body) to access information about their donor and, if known, any siblings from that donor. The information that is available, including the time period covered by the register, varies between jurisdictions, although there is typically a mechanism to voluntarily collect (register) information about donor conception occurring outside the prescribed period. Donors, donor-conceived people (including siblings), and recipient parents can typically apply to access information on the registers. Depending on the specific laws, they are able to access identifying or de-identified information, with some states requiring consent from the relevant party before identifying information can be shared. In some instances, there is a fee to access information on a register. It is important to note that this process may vary for donor conceived people born from an international donation.

Prior to establishing a register in the ACT, a detailed review of the operation of existing registers in other jurisdictions should be undertaken. Consultation should occur with donor conceived people, donors and ART providers in the ACT, to determine how they would like the register to operate. This will ensure that an ACT register will work optimally and adequately meet the needs of donor conceived people.

Consider the impact on gender and sexuality diverse people

ART is one of the main options to enable LGBTIQ+ people to become parents. LGBTIQ+ Canberrans wanting to have a baby can use at home insemination, IVF or IUI. At home insemination involves inserting the sperm at the top of the vagina.[23] Alternatively, a person who has eggs (for example, a same-sex female couple) can have IVF or IUI using donor sperm. If a person does not have eggs (for example, a same-sex male couple) they need to use an egg donor and a surrogate. Same-sex female couples can also elect to do 'egg sharing', where the eggs from one person are fertilised using IVF, with the embryo transferred to the other member of the couple.[24]

While legislation and guidelines relevant to ART do not specifically discriminate against LGBTIQ+ people in the ACT, feedback from stakeholders and consumers indicates that LGBTIQ+ Canberrans can have different experiences and face additional barriers and costs when accessing ART.

For example, we heard about:

- stigmatisation and discrimination;
- variations in providers' cultural competency providing healthcare to LGBTIQ+ people;
- not being able to access Medicare rebates for ART treatment as some providers consider them to be 'socially infertile', not 'medically infertile';
- opting for at home insemination due to concerns about how they will be treated by an ART provider, and sourcing sperm donors online to undertake at home insemination;
- additional costs and delays associated with using donor gametes, and a potential shortage of donor gametes in Australia;
- a lack of LGBTIQ+-specific support services;
- for same-sex male couples, the need to obtain a donor egg and use an altruistic surrogate, whilst complying with the requirements of the *Parentage Act 2004*;
- opting to access commercial surrogacy arrangements in other countries; and
- for gender and sexuality diverse people, needing to undertake fertility preservation before medically or surgically transitioning and/or pause gender affirming treatment to be able to carry a pregnancy. [23]

Of these barriers, the additional costs and delays associated with using donor gametes was a key concern raised by consumers.[7] It is important that any regulation of ART services in the ACT considers the possible impact on access to donor gametes.

> *"I'd like it to be easier for people to access donor sperm/eggs etc. It's incredibly time consuming (8 months!) and wastes precious time."*[7]

[23] IVF Australia. What are my options for starting a family? The LGBTQ+ Guide [Internet]. 2022 [cited 19 May 2022]. Available from: https://www.ivf.com.au/blog/what-are-my-options-for-starting-a-family-the-lgbtq-guide

[24] IVF Australia. Options for Same Sex Couples [Internet]. 2022 [cited 19 May 2022]. Available from: https://www.ivf.com.au/planning-for-pregnancy/same-sex-couples

> *"Please don't make access to donor services including international donors more difficult as it is in other States."*[7]

Guiding Principle 7 of the NHMRC Guidelines explicitly states that eligibility to access ART services cannot be subject to unlawful or unreasonable discrimination, including based on gender identity, sex, intersex status, sexual orientation or relationship status.[3] However, some stakeholders noted that providers have the discretion to determine whether someone satisfies the definition of medical infertility, resulting in differences in whether LGBTIQ+ people (and single women) are eligible to receive Medicare rebates.[7]

Some consumers raised concerns about ART service offerings being marketed to the needs of a heterosexual couple, which could be alienating and exclusionary for LGBTIQ+ people. [7] Some stakeholders described how everything from the service offerings through to the forms used by ART clinics were often heteronormative and implied that people who are not in a heterosexual couple are unwelcome.

> *"[A]ll the terminology is male/female couples, like on the…website it was talking about coming in with your partner and doing this."*[7]

> *"[T]he system doesn't really know how to deal with people who don't fit into the sort of preconceived ideas of prospective parents"*[7]

> *"[W]hen things aren't, you know that cookie cutter…relationship that turns up and gets pregnant very quickly and easily…every single time I turn up to that clinic, I have to advocate for myself or for others in the process. And yeah, it's very, very draining."*[7]

Some consumers indicated that some GPs, specialists and ART providers appear to be uninformed about the fertility needs of LGBTIQ+ people and should be required to complete mandatory LGBTIQ+ training and providing inclusive, person-centred care.[7] One of the ART providers in the ACT advised it was a member of the Pride in Health and Wellbeing program, which provides support to organisations to provide LGBTIQ+ inclusive health services.[25]

However, some consumers indicated some clinics and staff made them feel welcomed and included – for example, by starting the ART process by asking about a person's pronouns and preferred name.

> *"[The] first thing [the receptionist] did was actually ask what my pronouns were, asked what my preferred name was. She noticed that there wasn't the same name on all my medical records, like just this sort of stuff that inclusive queer people do as part of delivering inclusive services, all the small things, whereas at [the other clinic] they had insisted on calling me by my legal name and things like that. I mean, that always puts me on edge."*[7]

In establishing a regulatory framework for ART in the ACT, consideration should be given to any specific impacts on LGBTIQ+ Canberrans. This could be influenced by or occur alongside any review of the *Parentage Act 2004* (ACT) to refine and improve the operation of surrogacy in the ACT.. Consideration may need to be given to whether legislating a limit on

[25] Pride in Diversity. About Pride in Health & Wellbeing | Pride in Diversity [Internet]. 2019 [cited 19 May 2022]. Available from: https://www.prideinclusionprograms.com.au/health/

the number of offspring that can be born from a single donor could have a disproportionate impact on LGBTIQ+ people using donor gametes. For example, limits to donor offspring could consider ways to ensure that multiple donor conceived people born in a single family are siblings (i.e., have the same donor).

Impact of the Mitochondrial Donation Law Reform (Maeve's Law) Bill 2021

Summary of key findings:

- Mitochondrial donation aims to prevent the transmission of severe mitochondrial diseases. This is achieved by replacing a mother's (who is identified as at risk of passing on mitochondrial disease) DNA with healthy mitochondrial DNA from a donor's egg.
- The *Mitochondrial Donation Law Reform (Maeve's Law) Act 2021* (Cth) will commence on 2 October 2022, unless proclaimed at an earlier date.
- The Bill we be implemented in a two-stage approach, with stage one expected to take several years.
- The ACT is under no urgent time constraints to make any legislative or licensing changes in the immediate future in relation to mitochondrial donation.

Background

Mitochondrial donation is a new ART which can help some people who carry a mitochondrial genetic defect avoid passing on severe mitochondrial disease to their biological children.

Used in conjunction with IVF, mitochondrial donation techniques allow for an embryo to be produced using material containing nuclear DNA from a male and female, and the mitochondria in an egg donated by another female. This approach minimises the risk of transmission of the abnormal mitochondria from the mother to the child.

In Australia, between one in 5,000 and one in 10,000 people are likely to develop severe mitochondrial disease during their lifetime, with approximately one child per week born with a severe form of the disease. Issues which affect the mitochondria can have consequences for the entire body—muscle, brain, heart and lung function can all be severely impacted. It is often difficult to predict how an individual with mitochondrial disease might be affected, however results can include lifelong disability, ill health, poor quality of life and premature death.

Mitochondrial donation remains a contentious and emotive topic for many in the community. Many individuals and organisations hold strong views against the manipulation of human embryos for any purpose, despite the best scientific intentions.
However, enabling mitochondrial donation could prevent some children from suffering from this life-threatening disease and reduce the burden of mitochondrial disease into the future.

Commonwealth Legislation

The *Mitochondrial Donation Law Reform (Maeve's Law) Act 2021* (Cth) (the Mitochondrial Act) was passed by the Senate on 30 March 2022 and received Royal Assent on 1 April 2022. The Mitochondrial Act will commence on 2 October 2022, unless proclaimed at an earlier date. The Mitochondrial Act amends law relating to human cloning and research involving human embryos, and for related purposes. The Mitochondrial Act makes consequential and technical amendments to the:

- *Prohibition of Human Cloning for Reproduction Act 2002* (Cth);
- *Research Involving Human Embryos Act 2002* (Cth) (the Commonwealth Embryo Act)*;*
- Research Involving Human Embryos Regulations 2017;
- Therapeutic Goods (Excluded Goods) Determination 2018*;* and
- *Freedom of Information Act 1982* (Cth)*.*

As Mitochondrial donation was illegal under previous legislative frameworks, the Mitochondrial Act introduces reforms to legalise, subject to a strict licensing scheme, the creation of a human embryo, for the purpose of reproduction, that:

- contains genetic material of more than two people; and
- contains heritable changes to the genome.

The Mitochondrial Act introduces five types of mitochondrial donation licences for clinical practice, which will be administered and regulated by the Embryo Research Licensing Committee of the NHMRC, with dedicated provisions for screening and oversight of applicant and licence holders by the NHMRC.

Further, the Mitochondrial Act sets out provisions detailing the scope of authorisation for each license, with strict conditions relating to licence applications, conditions and administrative requirements. Licence holders would be subject to additional ongoing requirements.

As mitochondrial donation is a new medical technology, the Mitochondrial Act adopts a two-stage implementation approach:

- Stage one: only the first three of five licences will be available. These licences would authorise pre-clinical and clinical trial research and training activities.
- Following a review of stage one, and further legislative amendments in relation to the two clinical practice licences, mitochondrial donation could be made available in clinical practice settings under stage two with states and territories to opt-in to a national framework, if desired.

The staged approach is intended to allow for expansion of scientific evidence to ensure the safety and effectiveness of techniques and their ethical application before licences permitting mitochondrial donation in clinical practice are made available.

Implications for ACT legislative amendments

In the ACT, reproductive technologies are regulated by the *Human Cloning and Embryo Research Act 2004* (ACT) (Territory Cloning and Embryo Act). At present, Section 11 of the

Territory Cloning and Embryo Act makes it an offence to perform a mitochondrial donation procedure on a human embryo in the ACT.[22]

The ACT has (along with most other jurisdictions) enacted legislation to achieve national consistency with the relevant Commonwealth laws with respect to embryo research and human cloning, but not specifically ART.

Noting that the Mitochondrial Act will operate in two stages, the Mitochondrial Act states that the clinic selected to perform the pre-clinical trials phase (stage one) must be a 'constitutional corporation' to be granted a licence to perform mitochondrial donation. As a 'constitutional corporation' they are governed by the laws of the Commonwealth. Therefore, current ACT legislation and/or regulation will have no bearing on the implementation of stage one. However, there are two key implications for the ACT that will flow from stage two:

a. a person with a Commonwealth licence will not be able to carry out activities under a clinical practice research and training licence or clinical practice licence unless the Territory Cloning and Embryo Act positively authorises those activities; and

b. persons who are ineligible to apply for a mitochondrial donation licence under the Commonwealth Embryo Act will be unable to obtain a licence to use any mitochondrial donation techniques unless the ACT establishes a licensing scheme under the Territory Cloning and Embryo Act.

The following amendments to the *Territory Cloning and Embryo Act* would be required as part of stage two in order to give full effect to the Mitochondrial Act:

a. Positive authorisation for persons who have a clinical practice research and training licence or clinical practice licence under the Commonwealth Embryo Act to undertake those activities in the ACT.

b. Creation of a licensing scheme for all types of activities permitted under mitochondrial donation licences so that persons who are not constitutional corporations and therefore ineligible to apply for a licence under the Commonwealth Embryo Act may undertake mitochondrial donation techniques. However, the ACT could authorise the NHMRC Licensing Committee to grant a licence under the Territory Cloning and Embryo Act allowing mitochondrial donation licences that mirror those in the Amendment Bill.

c. Other amendments to the offence provisions in the Territory Cloning and Embryo Act to make it clear that a person will not commit an offence if the relevant conduct is permitted under a mitochondrial donation licence granted under the Commonwealth Embryo Act or the Territory Cloning and Embryo Act.

Further consideration would also be necessary to determine what other legislative amendments are required. Broadly, it will be necessary for the Territory Cloning and Embryo Act to be amended to:

a. authorise persons carrying out activities under a mitochondrial donation licence under the Commonwealth Embryo Act under Stage Two

b. establish a mirror licensing scheme which authorises the NHMRC Licensing Committee allowing mitochondrial donation under the Territory Cloning and Embryo Act.

The pre-clinical trials stage (stage one) is expected to take several years. ACTHD considers that the ACT is under no urgent time constraints to make any legislative or licensing changes in the immediate future. If any legislative change is required, it would be predicated on the findings of Stage One.

Findings and next steps

Several key themes have emerged in developing this report. They include:

- the importance of considering the rights of donor conceived people – both when they are children (in accordance with the UN Convention on the Rights of the Child)[26] and when they are adults;
- the need to understand people's experiences of infertility and help-seeking, including access to counselling and support services pre, during and post ART treatment;
- the rights of donors and their families;
- the significant costs associated with accessing ART are prohibitive for many people wishing to use these services, and there may be benefit for a low-cost option in the ACT;
- the positive and negative experiences of people accessing ART treatment in the ACT, including those of LGBTIQ+ Canberrans, which often include additional complexities;
- current difficulties for donor-conceived people in accessing information about their donor, such as heritable health conditions and details of siblings, under current regulatory arrangements;
- the need for reasonable limits on donor offspring – noting stricter limits may exacerbate existing sperm shortages and consequently increase costs associated with accessing donor sperm;
- inconsistencies in regulation and access across different jurisdictions, resulting in a call for nationally consistent regulation; and
- the desire for any legislation to regulate ART in the ACT to align with other jurisdictions' equivalent legislation.

Next Steps

Based on the findings of this report, the ACT Government will:

- Work to develop a regulatory framework for ART in the ACT, including establishing a register for donor information, in consultation with stakeholders.

[26] United Nations. Convention on the Rights of the Child [Internet]. September 19990 [updated 2002; cited 19 May 2022]. Available from: https://www.ohchr.org/en/instruments-mechanisms/instruments/convention-rights-child

- Explore options for increasing affordability and accessibility of ART, including a potential low-cost ART service in the ACT.
- Work with the Commonwealth Government to explore opportunities to improve access to specialised support or counselling services for donor conceived people and their families.
- Advocate to the Commonwealth Government to expand the eligibility criteria for accessing Medicare rebates to include people accessing ART treatment due to 'social infertility'.
- Encourage ART providers to expand availability of counselling appointments and to offer counselling at no cost, where it is not already. Counselling and support services should be focused on the wellbeing of the individual and the rights of the donor conceived child, rather than the ART process, and should be culturally appropriate.
- Encourage all ART clinics to undertake LGBTIQ+ cultural competency training and to use inclusive and gender-neutral language in ART treatment and practice.
- Encourage ART providers to promote access to peer support networks.

Implementation of these next steps will be informed by further stakeholder consultation, and subject to Budget approvals.

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Appendix A – Dr Paterson's motion

LEGISLATIVE ASSEMBLY FOR THE AUSTRALIAN CAPITAL TERRITORY

NOTICE OF MOTION

Marisa Paterson MLA: I give notice that I shall move –

1. That this Assembly notes that:
    a. in 2018, there were 84,064 initiated Assisted Reproductive Technology (ART) cycles in Australia and New Zealand. In the five years to 2017, the number of ART procedures increased, on average, by over 10 percent a year;
    b. ART can provide an option for individuals and couples looking to conceive and may or may not include the use of donated gametes;
    c. currently the ACT does not have any specific regulatory arrangements for ART, though these services are guided by the NHMRC's *Ethical guidelines on the use of assisted reproductive technology in clinical practice and research*;
    d. the recently established national register of IVF clinics provides some comparative data and information about the likelihood of success for individuals and couples trying to conceive which addresses some concerns about access to transparent information about IVF services;
    e. other States have legislation regulating ART, which provides a framework for ART providers and individuals and couples who choose to access these services, including for:
        i. support and counselling;
        ii. access to donor information and linking;
        iii. surrogacy;
        iv. patient access; and
        v. provider accreditation and licensing.
    f. people born as a result of donated gametes, and their parents, may find it difficult to access information about their donor, obtain information about their genetic heritage and background or find and connect with siblings born from the same donor;
    g. the Commonwealth Government is currently considering legislation regarding mitochondrial donation clinical trials with the intent to eventually become accessible through ART.
2. That this Assembly calls on the ACT Government to:
    a. review the availability of support services for individuals and couples choosing to access ART to ensure that appropriate information and care are readily available – pre, during and post treatment;

b. investigate and review comparable ART regulatory arrangements in other states and territories;
c. consider establishing a regulatory framework for ART in the ACT, including consideration of the position of sexuality and gender diverse couples;
d. consider the establishment of a register that will contain mandatory information in relation to all births resulting from ART treatment where donor gametes are used;
e. support the welfare of donor conceived people by providing regulated access to identifying information about their donor and links to siblings from the central register looking to connect;
f. consider the potential impact of the *Mitochondrial Donation Law Reform (Maeve's Law) Bill 2021* currently being considered by the Commonwealth Parliament and related issues on the ACT's current legislative arrangements;
g. consider the accessibility of ART for individuals coming from low socio-economic backgrounds; and
h. report back to the Legislative Assembly no later than August 2022 on findings.

M. Paterson

Marisa Paterson MLA
23 April 2021

ACT Health acknowledges the Traditional Custodians of the land, the Ngunnawal people. ACT Health respects their continuing culture and connections to the land and the unique contributions they make to the life of this area. ACT Health also acknowledges and welcomes Aboriginal and Torres Strait Islander peoples who are part of the community we serve.

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