FERTILITY SOCIETY
OF AUSTRALIA AND NEW ZEALAND

RTAC
REPRODUCTIVE TECHNOLOGY ACCREDITATION COMMITTEE

Findings, Recommendations and Framework for an Australian 10 Year Fertility Roadmap

November 2024

Professor the Hon. Greg Hunt and Dr. Rachel Swift

With grateful thanks to MinterEllison for their assistance during the process.

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Glossary

ANZARD: *Australian and New Zealand Assisted Reproduction Database*; a data repository tracking assisted reproductive technology (ART) outcomes and safety measures across Australia and New Zealand since 1979.

ART (Assisted Reproductive Technology): Broad category of medical treatments to aid conception, including in vitro fertilization (IVF), intracytoplasmic sperm injection (ICSI), and intrauterine insemination (IUI).

Carrier Screening: Genetic testing performed before or during pregnancy to determine if prospective parents carry genes for certain genetic disorders. Expanded Reproductive Carrier Screening (ERCS) is proposed to screen a larger number of conditions under the Mackenzie's Mission.

Council of Australian Health Ministers: The coordinating body for health policies across Australia's states and territories, proposed to oversee the development of a uniform national fertility law.

Donor Registry: A proposed centralized Australian national database to track and store information about egg, sperm, and embryo donors to ensure transparency and access to genetic information for donor-conceived individuals.

Embryo Transfer (ET): A procedure within IVF where an embryo is placed into the uterus to initiate pregnancy.

ERCS (Expanded Reproductive Carrier Screening): A proposed, comprehensive genetic screening program for a wide array of genetic disorders, supported by Mackenzie's Mission, to improve pregnancy outcomes and reduce genetic disorder risk.

FSANZ (Fertility Society of Australia and New Zealand): Professional organization for fertility and reproductive health experts, supporting practice standards, research, and patient safety in ART.

ICSI (Intracytoplasmic Sperm Injection): A specialized IVF procedure where a single sperm is directly injected into an egg to facilitate fertilization, commonly used when there are male fertility issues.

IUI (Intrauterine Insemination): A less invasive ART method where sperm is directly introduced into the uterus around ovulation to increase chances of fertilization.

IVF (In Vitro Fertilization): A widely used ART process where eggs are fertilized by sperm outside the body, and embryos are then implanted in the uterus.

Mackenzie's Mission: An initiative funded by the Australian government through the MRFF, providing expanded carrier screening for genetic conditions to reduce genetic disorders in newborns.

MRFF (Medical Research Future Fund): Australian government fund supporting health and medical research, proposed to finance the Australian National Fertility Research Mission.

Multiple Births: Instances where a pregnancy results in more than one baby (e.g., twins or triplets), often a risk associated with ART, but managed through practices like Single Embryo Transfer (SET).

National Fertility Law: A proposed national legal framework to standardize ART and donor regulations across Australian states and territories, addressing differences in access, safety, and rights.

National Fertility Research Mission: A proposed MRFF-funded initiative supporting fertility research for a decade, focusing on ART and IVF safety, effectiveness, and technological advancement.

PGT (Preimplantation Genetic Testing): Genetic testing performed on embryos created through IVF to identify potential genetic disorders before embryo transfer, aiming to reduce hereditary conditions in offspring.

Reproductive Technology Accreditation Committee (RTAC): The organization accrediting ART clinics in Australia and New Zealand, proposed to be made independent for enhanced regulation and oversight.

RTAC Code of Practice: Guidelines setting safety and quality standards for ART clinics; compliance with this code is necessary for clinic accreditation.

SET (Single Embryo Transfer): Practice of transferring only one embryo during IVF to reduce multiple birth risks and related complications, a common practice in Australia and New Zealand.

Uniform National Fertility Law: Proposed legislation for standardized ART and donor guidelines across Australia's states and territories, focusing on equitable access, patient safety, and the rights of donor-conceived individuals.

Your IVF Success: A government-funded public platform providing prospective IVF patients with clinic-specific success rates, educational resources, and predictive tools for informed decision-making.

Executive Summary:
Framework and Emerging 10 Year Roadmap

Australia and New Zealand have two of the safest and most successful Assisted Reproductive Technology and IVF programs in the world.

In 2021,
20,690 babies
were born in Australia and New Zealand through IVF.

The 2021 Australian and New Zealand Assisted Reproduction Database (ANZARD) report found that "of these, 18,594 (89.9%) were from treatments performed in Australian ART Units, and 2,096 (10.1%) were from New Zealand ART Units."

Most notably, the number of couples and individuals seeking assisted reproductive technology (ART) to achieve pregnancy, and birth is expected to rise significantly over the coming decade. Alongside which there is a continuing rise in the median age of mothers at the time of birth, which brings associated fertility challenges. Furthermore, the median age of the father is also increasing. Data shows that advancement in a father's age is associated with greater delay in conception and additional complications during pregnancy. Other factors driving increased demand for ART include greater access by prospective parents who may not be able to naturally conceive, and increased numbers of couples seeking IVF to avoid inherited genetic conditions given expanded national carrier screening programs.

The primary goal of these programs is to allow as many couples and individuals to conceive safely, who might otherwise not be able to do so. These programs aim to support the birth of healthy children through ART in general, and IVF in particular.

The Fertility Society of Australia and New Zealand (FSANZ) serves as a central body for healthcare professionals, scientists and researchers working in fertility and reproductive medicine, promoting high standards of practice, research, and education. Against this background, FSANZ should consider a 10 Year Fertility Roadmap based on four key pillars:

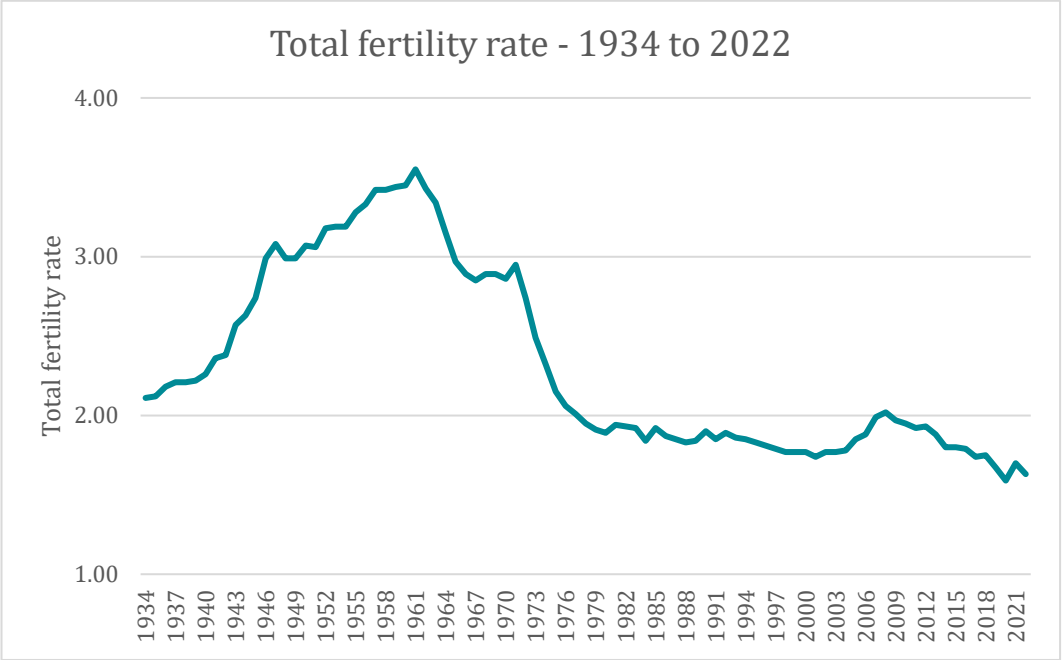
1	2	3	4
Governance	**Safety and Efficacy**	**Access**	**Research and Technology**

This in turn should contribute to >

1. Uniform National Laws to be developed and adopted by the Australian States and Commonwealth through the National Council of Health Ministers; and
2. The development of an Australian National Fertility Plan co-ordinated through the National Council of Health Ministers.

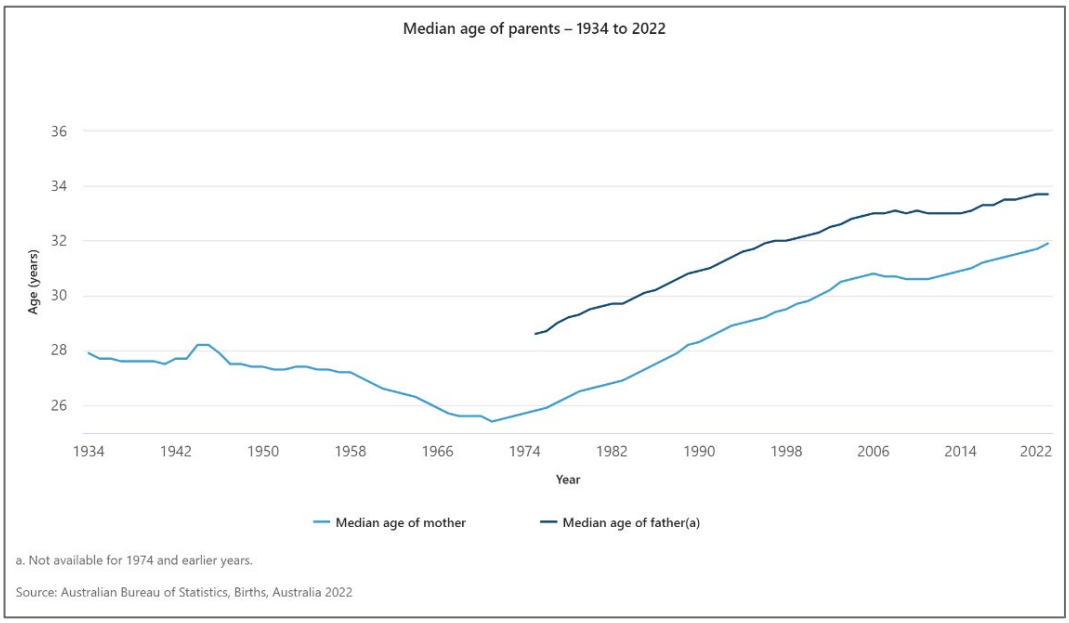
Introduction and National Trends: Declining Fertility and Increased IVF & ART in Australia

Australia's birthrate has declined from a total of 3.5 per woman in 1960 to 1.63 in 2022.
This is consistent with overall global trends and is more magnified in OECD member countries.



Data for 2022 shows a decrease of 9,312 births registrations. This follows higher birth registrations in 2001.
Source: Australian Bureau of Statistics, Births, Australia 2002

This declining fertility rate is associated with both a decreased overall birth rate and the median age of the mother increasing from 25.4 in 1971 to 31.9 in 2022.



This OECD wide trend, although less pronounced in Australia, has three important long-term implications for the nation:

First, there are long-term economic implications of a lower birth rate.

The Australian Treasury Intergenerational Report in 2021 concluded:

> *The Australian Economy is projected to grow at a slower pace over the next 40 years than it has over the past 40 years… Slower population growth is the main reason for the expected slowdown in economic growth.*[1]

As one submission noted, "this raised concerns that for the first time in an Intergenerational Report, the population projection is being revised downwards."

The national implication is an unbalanced population distribution, an increase in resources required to support the non-working population in areas such as health, aged care and welfare, and a commensurate decrease in the working and tax paying population as a percentage of the total national population.

Second, a later age of conception of either parent is associated with lower levels of natural fertility.

Once you turn 36, your chance of conceiving naturally is halved compared to your chance at 20 years of age. At the age of 41, this chance falls to just 4%. That's the success rate for couples per month of trying when the female is aged 41 to 42.

WHY IS THIS?

"While a woman is born with 2 million eggs, these are the only eggs she will ever have. By the time she hits puberty that number has already dropped to 400,000. And as age progresses, the egg quantity and quality continues to decline."[2]

Third, a later age of conception therefore leads to an increased role for IVF in particular, and ART more generally, in supporting individual conception and national birth rates.

The National Perinatal Epidemiology and Statistics Unit (NPESU) at UNSW has shown that between 2010 and 2017 for example, ART contributed to an increase in women having babies at an older age. This trend has been ongoing and is projected to continue.

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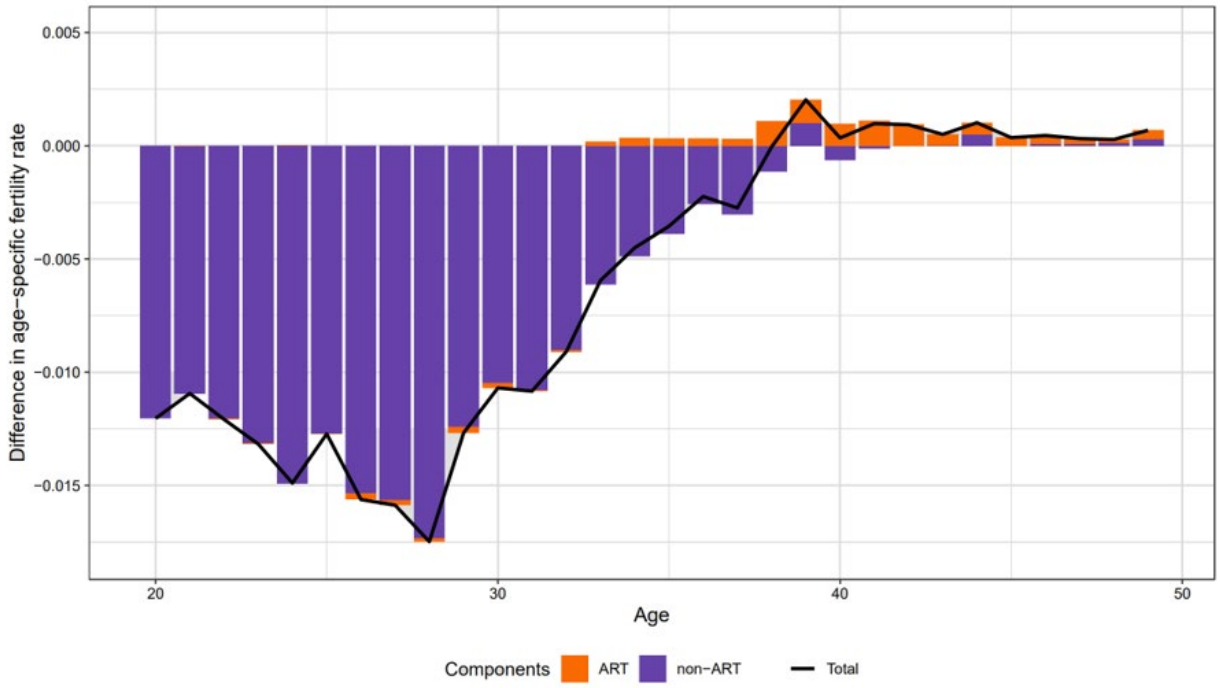
1 Australian Government. Department of the Treasury. 2021 Intergenerational Report. Available from URL: https://treasury.gov.au/publication/2021-intergenerational-report as cited in Aust N Z J Obstet Gynaecol 2024; 1–5

2 IVF Australia Age and Female Fertility Guide ivf.com.au. The authors are aware that some studies have presented differing data on lifetime egg reserves.

NPESU Change in fertility by age including IVF and natural conception



Source: Lazzari E, Potancokova M, Sobotka T, Chambers G (2023) Pop Res Pol Rev 42(6).

Against that background, Australia has one of the highest rates of ART utilisation, combined with one of the lowest net costs and best quality and safety outcomes of ART internationally.

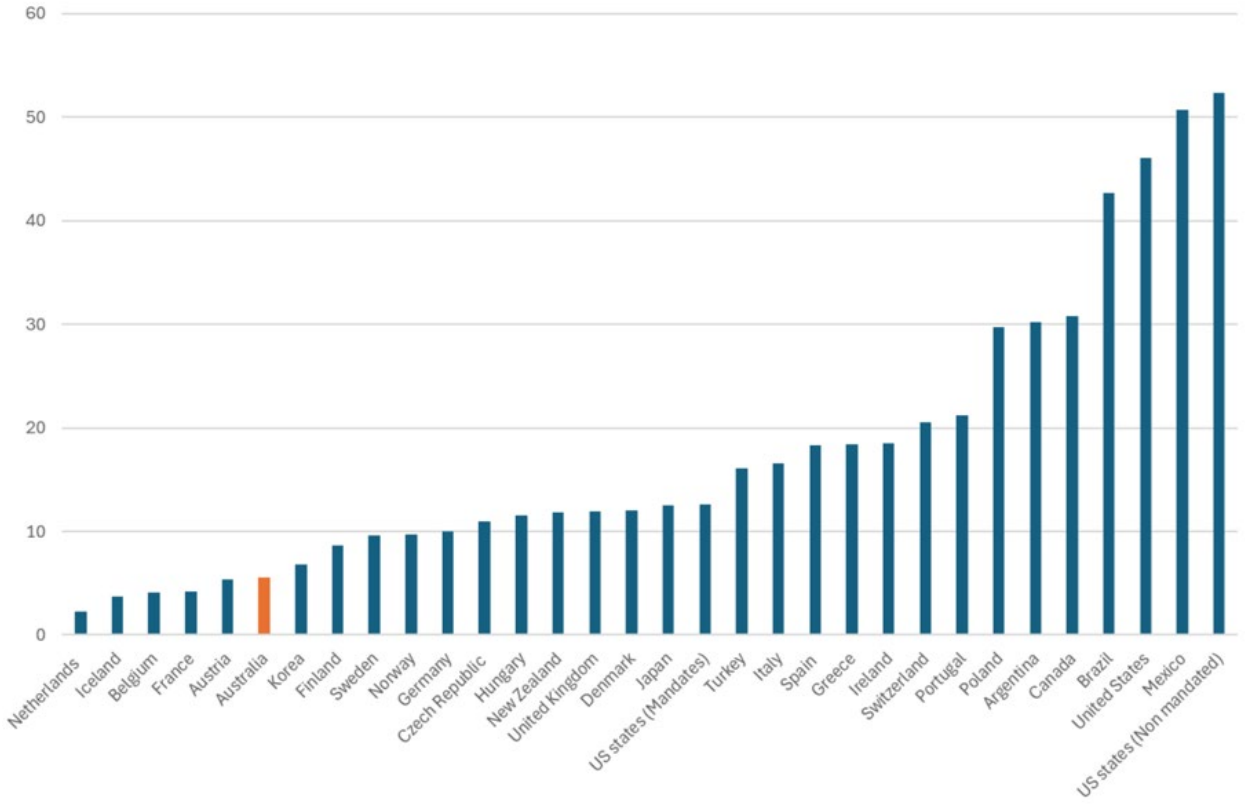
NPESU Contribution to Total Fertility Rate

Country	Level of access to ART	Increase in TFR	Government funding support	Cost of one IVF cycle as percentage of disposable income
USA	Low	1.30%	None	52% in States without insurance 13% in States with insurance
Czechia	Median	3.60%	Government funding with restrictions on age (39 years) & number of cycles (3-4)	11%
Australia	High	5%	Supportive government funding with no restrictions	6%

Sources: Tierney & Cai (2019). FnS 112: 1136-1143. Lazzari E, Chambers G. (2023). Pop Res Pol Rev 42(6). Kocourková J eta (2013) Nature Scientific Reports. 13:10854

In that context, a landmark UNSW comparison confirmed that Australia currently has the sixth most internationally affordable ART based on the average cost of a fresh ART cycle, with costs expressed as a percentage of net disposable income.

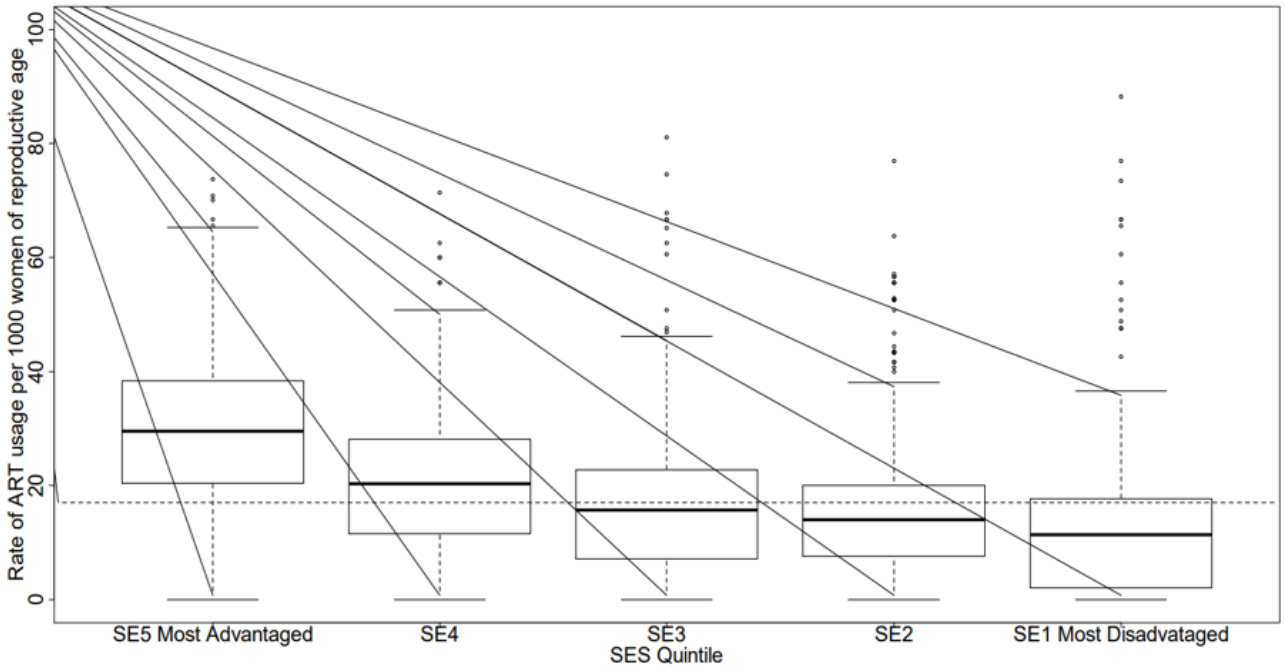
NPESU "ART Affordability"



Source: Chambers GM, et al (2014). Fertility and Sterility; 101(1) 191-198. [Plus Editorial] http://dx.doi.org/10.1016/j.fertnstert.2013.09.005

ART is nevertheless a significant economic burden on families, with up to $10,000 in out-of-pocket costs per treatment cycle in some cases. This is particularly so for lower socio-economic disadvantaged parents with the lowest rates of utilisation being for women in the most disadvantaged SES quintile.

NPESU "ART utilisation per 1000 women of reproductive age, Australia"



Source: Harris K, ... Chambers GM (2016).RBMO http://dx.doi.org/10.1016/j.rbmo.2016.07.012

Against this background, approximately 6% of Australian children are born through ART in general and IVF in particular with that number growing in both real and percentage terms and expected to grow significantly over the coming decade.

It is therefore recognised there is need for a long-term, 10-year, Fertility Roadmap to ensure Australia and New Zealand maintain and improve their world-leading access and outcomes in ART in general, and, IVF in particular. This Roadmap will respond to the changing demographics demand and enhanced technological capability, including but not limited to Carrier Screening and Preimplantation Genetic Testing. In this context, the Roadmap is intended to help further improve governance, safety, efficacy, access, affordability, research and outcomes in IVF and ART more generally.

1. Governance

The primary issue raised in interviews and submissions is that the difference in laws and standards across over 40 pieces of legislation in 9 jurisdictions within Australia significantly impacts children, parents, donors, and the cost of ART in general, and, IVF in particular.

In Australia, the lack of uniformity and consistency in legislation leads to varying rules regarding limits on the number of families a donor can contribute to and IVF regulation procedures. This creates challenges and potential risks for:

Children:

Differences in donor laws and the lack of an Australian national register means that there is an increasing risk of children of serial or prolific donors unknowingly meeting and potentially partnering and having children of their own as adults. This is particularly so where there is unregulated donation in some communities. There should be a single national health standard for egg and sperm donation to ensure consistency and safe futures for children conceived by ART in general, and, IVF in particular.

There should also be a single national standard on the rights of children to seek information regarding their genetic parentage. Consideration should therefore be given to ensuring children have the right to know who donated under previous consent models and to families who are otherwise unaware that their genetic heritage differs from their social heritage.

Parents and Donors:

Given restrictions on egg donation and reported national shortages of donor eggs and sperm, there has been a growing reliance on imported gametes which may raise concerns about availability and traceability.

There should therefore be a single national health standard for egg and sperm donation to ensure consistency and safe futures for parents and donors involved in the IVF process.

There should also be a single national standard on the rights of donors for when children born from their donation choose to seek information regarding their genetic parentage.

Providers:

The friction caused by multiple laws in multiple jurisdictions increases the cost of co-ordinating IVF and therefore increases the costs of IVF to families which in turn also reduces access to IVF for many marginal, disadvantaged or lower socio-economic families.

Key Recommendations for Governance could therefore include:

Recommendation **1**

It is recommended that the Australian States and Territories work with the Commonwealth, patients, clinicians and the sector to develop a Uniform National Fertility Law for IVF which would be passed by a lead jurisdiction and adopted by others.

Recommendation **2**

The development process be facilitated through the Council of Australian Health Ministers supported by a Steering Committee composed of representatives from patients, donor conceived individuals, fertility specialists, industry experts, FSANZ professional groups (nursing, psycho-social, scientific and clinical) and legal practitioners with fertility expertise.

Recommendation **3**

As with other National Uniform Laws, while States and Territories would be strongly encouraged to maintain consistent laws there would be the capacity to vary specific sections to accommodate historic or other perspectives.

Rather than a State or Territory opting out of the National Fertility Law if there were an item that was not acceptable to that jurisdiction, the recommended approach would be for the jurisdiction to adopt the National Fertility Law and maintain a specific variation commensurate with the particular difference or reservation. Nevertheless, all jurisdictions would be strongly encouraged to adopt the National Fertility Law in full and if not to adopt the fewest possible number of variations.

Three key components of the National Fertility Law stand out. The establishment of a National Standard for donation, the harmonisation of the rights of both donors and children, and the creation of a single unified National Register to house donors and donor-conceived child information, ensuring the child's fundamental right to know about their biological origins.

In the current framework of assisted reproduction, the lack of a centralized, national system for tracking and storing genetic information of donors and donor-conceived individuals creates significant challenges in managing essential medical information. Without such a system, there is a heightened risk that individuals may be unaware of critical genetic links, leading to missed opportunities for early detection and prevention of hereditary conditions. Moreover, the absence of comprehensive records undermines the transparency and traceability of medical histories, which is crucial for ensuring donor-conceived individuals can make informed healthcare decisions. To address these pressing issues, it is vital to establish a single, National Donor Register and genetic bank that securely stores donor information and ensures access to genetic identities, thereby supporting informed medical care and the safeguarding of individual health.

Some submissions noted that well intended State Laws had inadvertently contributed to the search for either unregulated black-market donations or made access to IVF more difficult.

Whilst surrogacy was beyond the scope of this review, its role in conception was highlighted in response to recommended changes to the scope of infertility. It is therefore recommended that a similar review is conducted to see national uniform legislation to address surrogacy.

> *We believe the development of this section of a National Uniform Law would need to take a broad view and consider the unintended consequences of existing legislation experienced by many Australian prospective parents today. We believe that much state legislation ignores many of these factors including the unregulated black market for sperm and international donor tourism. Unfortunately, some changes made in good faith in the past have had the unintended consequences of reducing access and increasing costs for patients who want the safety of a regulated sperm or egg donor program. Much of these practices have forced prospective parents into expensive, or dangerous situations which need to be addressed."*

In this context, the following recommendations would help establish consistency in Australia for parents, children, donors, providers, practitioners and regulators.

Recommendation **4**

Develop a single National Health Standard for egg and sperm donation to ensure consistency and safety across all jurisdictions. This standard should cover donor limits and IVF regulation procedures.

Recommendation **5**

Establish a Single National Standard that guarantees the rights of children to seek information about their genetic parentage and respects the rights of donors regarding progeny seeking such information. All donors should be required to sign a declaration regarding any previous donations.

Recommendation **6**

Create a single Australian National Register and genetic bank for donors and donor-conceived individuals, which provides a centralized system for tracking and accessing critical genetic information. This system would ensure that medical professionals and individuals are alerted to significant hereditary conditions and that donor-conceived children and their families can contribute important genetic information to the registry.

The National Register should also oversee donor limits agreed upon by the States, Territories and Commonwealth. Subject to advice by the NHMRC these limits may take into account geographic and demographic elements. This process could be supported by assigning a single national ID, including assignment of an ID to the donors of any gametes imported into Australia. All clinics would use the unified ID for imported donor gametes, facilitating consistence and transparency.

The National Register would facilitate transparency and traceability, enabling informed healthcare decisions and supporting the overall well-being of those involved. Crucially, the National Register would prioritise data security and be designed to integrate with international donor databases. The National Register would uphold the child's fundamental right to access their biological origins by securely housing and providing access to genetic information. This would provide the opportunity for donor-conceived individuals to learn about their heritage and identity.

Existing state and territory donor registries are encouraged to integrate with the National Register, reducing redundancy and supporting a unified national system. These state and territory-based registries are successfully linked to relevant local birth, death, and marriage registers. Therefore, the National Donor Register would need to establish effective connections with these state and territory registers, ensuring a comprehensive and accessible approach to record-keeping.

Reproductive Technology Accreditation Committee (RTAC)

In Australia, the Reproductive Technology Accreditation Committee (RTAC) accreditation is mandatory for ART clinics to operate, ensuring compliance with standards for quality, safety, and patient care. However, in New Zealand, while RTAC accreditation is encouraged and followed by many clinics, it remains voluntary rather than a legal requirement. This distinction arises because Australia enforces RTAC guidelines through regulatory bodies as part of the legal framework, while New Zealand does not mandate compliance, leaving the decision to individual clinics based on best practice and patient trust.

RTAC was established by FSANZ and provides accreditation for registration by the Joint Accreditation System of Australia and New Zealand (JAS -ANZ).

RTAC oversees and implements the Australian and New Zealand Code of Practice and implements the International Code of Practice. The Scheme Rules “define the requirements for bodies providing audit and certification to these codes” (FSANZ RTAC Scheme & Code of Practices - fertilitysociety.com.au).

Although RTAC operates independently, its independence is sometimes questioned, and there are concerns about whether it has the capacity to handle the anticipated growth in IVF services and the ART sector across Australia and New Zealand.

Given this context and the evolving landscape, RTAC will need to adapt to adequately serve the future requirements, both domestically and as an international accreditation provider for ART clinics throughout the Asia-Pacific region.

The recent settlement of a major IVF provider case in relation to pre-implantation genetic testing for aneuploidy (niPGT-A) reaffirms the importance of continued improvement in both techniques and standards within the Australian IVF and related services sector. While the case was not within RTAC’s current scope and settlement did not include acknowledgement of liability by any parties, other cases of patient concern underline the broader need for both a fully and visibly independent RTAC as provider regulator. They also highlight the necessity for RTAC to be fully resourced to effectively carry out its responsibilities.

In light of these concerns, it is recommended that changes be made to RTAC to equip it for the next 10 years and beyond.

Recommendation **7**

RTAC be established as a body independent of FSANZ with its own independent constitution, funding and Board.

Recommendation **8**

The establishment of an Independent RTAC could occur either under the Australian Uniform National Law or as a company limited by guarantee. Australian States and Territories should work with the Commonwealth, patients, clinicians and the sector to develop an agreed model for RTAC.

Although it would ultimately be a matter for the Australian Commonwealth and States, the recommended model for RTAC is based on the Your IVF Success model and could contain five key pillars.

Recommendation **9**

Establish an Independent RTAC based on, but not limited to, the following five key pillars:

1. **An Independent not-for-profit company set up by Guarantee with FSANZ, the Australian Commonwealth and the States as equal shareholders.**
2. **A Board comprising seven members, two members nominated by FSANZ, two from the provider sector and two by the Government (being one from State Health Departments and one from the Commonwealth) and an Independent Chair.**
3. **Increase certification and review capabilities, including through appointment of a full-time CEO with experience from the provider sector and a strong background in quality processes, legal regulation, and policy matters. It has been suggested that this review process could be conducted over a three-year period with different elements reviewed in each year of that cycle.**
4. **Recognition of RTAC within the Australian Uniform National Fertility Law.**
5. **A review of the user experience of data provided on Your IVF Success to identify what data and format is of greatest value to current and future users of ART & IVF. Provision of IVF treatment and outcome data to publicly accessible webpage (currently Your IVF Success).**

An important feature of RTAC's independence is that it should be separated from full reliance on funding from the provider sector that it regulates. A hybrid funding model, drawing on both Australian Government and private funding, would allow for more comprehensive review functions, while also ensuring both independence and appropriate contributions on a *pro rata* basis from the sector.

Recommendation **10**

Funding for RTAC should be based on a hybrid model of industry sector support and Australian Government funding. It is recommended that, in order to increase review capabilities and the ability to respond to complaints, RTAC have a Budget of $4m per annum commencing in 2025/26, to be indexed by 5% per annum to accommodate growth in IVF uptake. The proposed funding mechanism would be 50% by IVF providers and 50% by Governments with 25% coming from the Commonwealth and 25% from States and Territories on a pro rata basis. Funding should be agreed in 5-year cycles.

Recommendation **11**

The revised RTAC should establish a formal complaints review process. Subject to the views of States and Commonwealth, this could include a four-stage process:

STAGE 1	**Initial Complaints: Patients should first direct their complaints to the treating IVF clinic. Clinics are mandated to report all complaints to RTAC.**
STAGE 2	**Unresolved Complaints: If a complaint remains unresolved, it should be escalated to the relevant State or Territory Ombudsman, Commissioners, APRHA, or Complaints Office, as per the current FSANZ Complaints Handling Process. Clinics must notify RTAC in writing about any unresolved complaints.**
STAGE 3	**Any complaints submitted to RTAC which concern individual patient care will be referred to the treating clinic. If these are unresolved then they will be referred to the relevant authority. If a complaint is about the general operation of a clinic or of RTAC then these will be considered. Any legal matters should be referred to the relevant State authority. If RTAC identifies safety of efficacy concerns or breaches of the Code of Practice, then they will have graduated powers to respond as set out in Recommendations 17 and 19.**
STAGE 4	**Any complaints about the operation or actions of RTAC itself that cannot be resolved, should be referred to an appropriate body to be agreed to with the States and Territories to ensure appropriate independence.**

Recommendation **12**

RTAC should be able to issue licence certificates that licensed facilities be required to display, as part of its new scope of practice under the new legislation.

It is also advised that RTAC be indemnified under legislation from suit other than for wilful malfeasance. This however would be a matter for consideration as part of the legislative process.

As part of the Australian National Fertility Law, consideration should also be given to RTAC having graduated powers that could compel providers to undertake certain actions, desist from certain actions or refrain from certain activities until such time as safety or compliance were determined. A graduated set of powers would give greater flexibility to RTAC and providers.

A number of submissions and interviews identified the fact that RTAC's limited powers (which effectively encompass all or nothing certification of ART providers), limit their ability to support, encourage or require continuous improvement. Additionally, a clear set of benchmarks should be utilised when assessing clinics. Benchmarks may include documentation, processes for obtaining consent, laboratory and clinical outcomes.

Recommendation **13**

RTAC should have a graduated set of powers which would allow it to issue requirements for rectification or provision of information or to ensure that actions were taken or not taken until such time as rectification was completed.

Finally, it is important that there is an independent process for reviewing RTAC itself to ensure continued maintenance of regulator independence and standards. The process of independent review should be incorporated into the establishment of the Australian National Fertility Law for completion by 1 July 2026 and thereafter once every five years.

Recommendation **14**

RTAC itself should be reviewed independently as part of the process for establishing the Australian National Fertility Law and thereafter every five years.

Establishment of an Australian National Fertility Law overseeing ART and IVF, coupled with a donor registry is a natural response to social and technical developments. It will however need to be accompanied with continuously increased oversight of individual clinics and providers to maximise patient safety and the efficacy of IVF in Australia.

2. Safety and Efficacy

The public online platform, Your IVF Success, affirms Australia has one of the safest and most effective IVF Programs in the world. As early as 2012, the NPESU produced the Australian and New Zealand Reproductive Database (ANZARD) Annual Report, which highlighted that the region had the lowest multiple birth rates in the world:

> *Australia and New Zealand are world leaders when it comes to safe IVF practice thanks to their focus on single-embryo transfer, according to the Assisted Reproductive Technology in Australia and New Zealand 2012 report by the National Perinatal Epidemiology and Statistics Unit at UNSW Australia.*
>
> ——
>
> *The report confirms that Australia and New Zealand are leaders in this field of medicine. Multiple births are by far the greatest health risk to mothers and babies from IVF, and multiple embryo transfer clearly increases this risk. Australia and New Zealand share one of the lowest rates of IVF multiple births in the world (6.5%).*
>
> ——
>
> *The vast majority (76.3%) of IVF cycles in both countries involve single-embryo transfer. For comparison, multiple birth occurs in about 30% of IVF births in the United States and in about 18% in the United Kingdom.*
>
> ——
>
> *"These results make Australia and New Zealand the safest region in the world for women to have IVF," says **Associate Professor Mark Bowman**, Past President of the Fertility Society of Australia (FSA), which funds the annual report and national IVF register.*
>
> ——
>
> *"Australia and New Zealand have the lowest ART multiple birth rates of any region in the world and yet maintain consistently high success rates," he says.*

Analysis completed by ANZARD in July 2024 for the report 'Assisted Reproductive Technologies – How Australia Compares', emphasises the continued high patient safety experienced in Australia.

Single embryo transfer (SET) rates are a mark of ART safety because it markedly reduces the risk of multiple birth. The SET rates vary among countries and regions. Australia has been a world leader in SET rates and thus low multiple birth rates.

In 2021, 94% of ART cycles performed in Australia were SET, resulting in a multiple birth rate of 3%. Global average is around 16%.

The reforms proposed in Section 1 aim to simplify and align governance within a uniform national framework and to support population level safety, convenience and efficacy.

In addition to the macro level reforms, continuously improving clinical oversight is a fundamental task going forwards.

While there were a variety of views on RTAC, one submission noted the contribution which RTAC and the Code have made to having a world leading set of safe outcomes for ART and IVF.

> *Australia and New Zealand have two of the safest and most successful Assisted Reproductive Technology and IVF programs, in the world." It is our belief that a major contributor to this success is the professional industry standard that has been used to accredit units since the 1980s, that has evolved over four decades in line with evolving technology and community expectations.*
>
> *Significantly, that evolution has included a major restructuring in moving to independent certifying bodies, which are themselves audited and accredited by JASANZ. These certifying bodies audit and recommend accreditation and/or corrective actions of individual units to RTAC, ensuring independence from RTAC and FSANZ in the assessment process. Care needs to be taken when reassessing any part of the current RTAC Code of Practice, updated 2024, which is a major contributor to these world class programs."*

Maintaining and enhancing the safety and efficacy of ART in general, and, IVF in particular is paramount for parent and child well-being and the success of the procedures. To ensure the highest standards, the following recommendations are therefore proposed to support patient safety and continued improvement of individual clinics.

Accreditation and Certification

An important feature of the RTAC Code of Practice which was widely identified, is that it can be adapted and modified quickly to respond to either changing practices, events or international research. Consequently,

the continued clinical oversight of FSANZ – coupled with an Independent RTAC – was widely viewed as an appropriate balance.

Recommendation **15**

The foundation for licensing of ART units should be compliance with the RTAC Code of Practice. RTAC should have the power to withhold, grant or vary licences depending on compliance with the Codes. This power should be vested in an independent and properly resourced RTAC.

To provide additional oversight and independence in the setting of the Code itself, it is also recommended that clinically qualified representatives with experience in treating fertility should be appointed by the Commonwealth, the States collectively, the New Zealand Government and RANZCOG.

Recommendation **16**

FSANZ continue as the governing body for the Australian and New Zealand Code of Practice and should include the RTAC CEO. An advisory board should be established with membership including four fertility-experienced, clinically qualified representatives with one each appointed by the Commonwealth, the States collectively, the New Zealand Government and RANZCOG and professional groups (nursing, psycho-social, scientific and clinical), a patient representative to provide feedback and guidance to FSANZ.

A number of submissions highlighted the importance of both systemic and clinic level psychological support. Psychological support during Assisted Reproductive Technology (ART) treatment is critically important, as the emotional toll of infertility can be profound. Patients often experience stress, anxiety and grief as they navigate the complexities of treatment and the uncertainty of outcomes. Effective psychological support helps patients cope with these challenges, offering strategies to manage emotional distress and providing a safe space to express their feelings. Beyond the immediate relief, this support plays a vital role in helping patients come to terms with their infertility diagnosis, fostering resilience and enabling them to make informed, empowered decisions about their reproductive future. By addressing the psychological aspects of infertility, healthcare providers can significantly enhance the overall well-being and success of those undergoing ART treatment.

The data shows that IVF treatment can be highly successful, with over a third of women achieving a live birth within their first complete ART cycle and 57% by the sixth cycle. The estimated cumulative live birth rate could reach 76% by the sixth cycle if all women continued treatment. However, this success is contingent upon patients enduring multiple treatment cycles, which can be physically and emotionally taxing.

To increase the chances of success, it is crucial to provide comprehensive psychological support, helping patients to participate most effectively in the appropriate number of treatment cycles to facilitate the best outcomes.

There was strong and widespread feedback that the Code of Practice should have clear standards which are enforceable through the provision, withholding or variation of licences.

Recommendation **17**

The Code of Practice should include strong and clear accreditation criteria for ART Units including:

Patient Support:

i. **Informed Consent: Ensure that all patients undergoing ART procedures provide informed consent after being thoroughly educated about the risks, benefits, and alternatives. This includes clear information about the evidence-base for optional or adjuvant treatments, potential risks of harm or complications, success rates, and the use of their data.**

ii. **Psychological Support: Provide comprehensive psychological support services for ART patients to help them cope with the emotional and mental stress associated with infertility treatments. This includes counselling, support groups and mental health resources. Medicare funding for psychological support and counselling could be delineated with a separate Medicare code from the Medicare code funding the clinical care for ART.**

iii. **Patient Feedback Mechanisms: Implement robust feedback mechanisms to gather patient experiences and insights. Clinics could integrate Patient Reported Outcome Measures (PROMs) and Patient Experience Measures (PREMS) within their own systems, allowing immediate, responsive interactions with patients. This feedback will support continuous improvement in ART practices and enhance patient education. RTAC could also consider whether linking PROMs and PREMs data with patient outcomes would offer further benefits to patient safety and inform future standards.**

Licensing of ART Units: strengthen RTAC authority by providing a mechanism through which an ART clinic can be refused a licence for various reasons, such as:

i. **Non-Compliance with Standards: If the ART Unit fails to comply with the Code of Practice and guidelines set by NHMRC, a licence can be denied or conditions imposed. This includes deficiencies in procedures, equipment, staff qualifications and quality control measures.**

ii. **Inadequate Corrective Actions: During the assessment process, if issues are identified and the ART Unit does not adequately address these issues or fails to provide sufficient evidence of corrective actions, RTAC can refuse to issue a licence or require rectification.**

iii. **Poor Assessment Results: If the ART Unit performs poorly during the on-site assessment, showing significant non-conformities or a lack of adherence to best practices, RTAC can decide against licensing the ART Unit or require rectification.**

iv. **Ethical and Legal Violations: If there are ethical concerns, legal violations, or evidence of misconduct within the ART Unit, RTAC can refuse a licence to uphold the integrity and reliability of the licensing process or require rectification.**

v. **Incomplete or Misleading Information: Providing incomplete, inaccurate or misleading information during the application or assessment process can result in a refusal of licence or a requirement of rectification.**

Recommendation **18**

Real-time reporting: Identify and address any safety concerns by establishing real-time reporting systems for adverse events and complications related to ART procedures with a target of 1 July 2026 subject to readiness.

RTAC should have a role in ensuring that clinical research with the context of ART clinics adheres to ethical and regulatory requirements. This responsibility is particularly crucial in light of recent legal developments that highlight the significant financial and reputational risks ART clinics can face when ethical and regulatory requirements are not strictly followed.

A number of submissions identified the spread of donors' advertising on websites and apps where the safety and standards were not aligned with those in clinical care. Whilst clear that what happens between two consenting adults should not be legislated, there is scope to manage the advertisement on these platforms. This has been increasingly important in response to the growing occurrence of serial donors and the psychosocial and consanguinity risks that arise from these behaviours.

All websites and platforms whether domestically or internationally registered should be legally required to keep records, and to have them produced/available for inspectors or on notice, with the same requirements as required of IVF clinics by state legislation and RTAC.

Currently, only NSW, ACT and Qld allow the private donation to go on the current registries. NSW states that the parties may give notice: s.33A ART Act. The ACT donor register starts in March. Under ss.54 and 56 of the ART Act, either of the parents, the donor, or the clinic can notify the register. In Queensland, all adults involved in a donor conception must notify the central registry for it to be added: s.47 ART Act, this requirement will be effective from 2026. At present a donor conceived person is not able to add the private donation that resulted in their conception. While it may not assist them directly, it may assist donor conceived siblings, parents of those, descendants of those, and clinics to ensure there is compliance with the family limits.

Recommendation **19**

As part of the development of uniform fertility law across Australia a provision should be introduced, to safeguard the advertising of donation of gametes and associated services in a digital environment. The purpose of this law (which may require legislation at Commonwealth level) would be three-fold. First, to prevent against prolific donation over and above agreed national limits. Second to ensure the safety and awareness of risks of all parties participating in donation outside of a clinic setting. Third to ensure the traceability of the donation process and secure the rights of the child.

The following elements could be included:

- The ID of the would-be donors be stored by any online platform as a pre-requisite for advertising or participating in online discussion of gamete donation and related services.

- Once ID has been obtained all users searching for gamete donation or related services must be provided with online information about the risks and steps to protect their safety and the safety of any future children.
- The website/app would be required to provide the name and ID of every would-be donor to the National Donor Registry within 60 days of donor sign-up. Clinics which may propose to undertake ART from a donor, should be able to search the donor on the national registry to identify compliance with safety requirements.

All parties searching for donors or advertising as donors must receive a written recommendation from the website or platform advising them to list all resulting births voluntarily to the National Register.

Any of the adults involved in a private donation, or the clinic whether it occurred before or after the commencement of the national central registry (donor, donor's partner, any of the parents), or the donor conceived person upon reaching 16 can provide information to the central registry to ensure that the donation appears on the register.

Recommendation **20**

Review the governance and practice of clinical research within the context of ART clinics to ensure that all ethical and regulatory requirements are fulfilled, and that clinical innovation is based on rigorous and independently validated pre-clinical and other research data, including randomised controlled trials where appropriate.

One area of professional development which has been raised, although not with universal support, is certification for ART practitioners, including fertility specialists, nurses and embryologists. This would have the benefit of establishing consistent standards across the sector. The risk, as has been seen in some sectors, is inadvertently excluding competent current practitioners and potentially creating a workforce exodus or shortage.

Therefore, careful consideration of the impact and the model would be required. It is suggested, but not raised to the level of a formal recommendation, that a pilot model certification program be developed on a voluntary basis for ART practitioners, including fertility specialists, nurses and embryologists. The pilot program should ensure that all personnel involved in ART procedures have the necessary skills and knowledge to perform their roles safely and effectively. This program should be developed carefully to ensure appropriate recognition of skills for ongoing providers with a target of 1 July 2026, subject to readiness.

In addition to the pilot program, there should also be strong consideration of an enhanced continuous professional development program for ART practitioners.

Recommendation **21**

Develop a requirement for ongoing professional development and training for ART practitioners to keep them abreast of the latest advancements and innovations in the field. This includes accredited workshops, conferences, and other educational activities with a target of 1 July 2026 subject to readiness. Where existing CPD requirements which are already in place such as those provided in RANZCOG these should continue, the new requirement would be to ensure that those service providers which do not have ongoing CPD as part of their required ongoing accreditation have ongoing CPD.

By ensuring improved governance coupled with enhanced clinic level safety and efficacy, Australia and New Zealand have the potential to consolidate the world's strongest and safest ART and IVF sector. However, in order for all Australian and New Zealand prospective parents to be able to participate, there are still improvements to be made in terms of access to fertility support.

3. Access

IVF access in Australia is determined by three primary factors being funding, legal access, and education and awareness. In addition, proximity to services can be a barrier to regional and remote patients including geographic access options. While over 20,000 children are born in Australia and New Zealand each year through IVF there are nevertheless potential actions in each of these three areas which can assist in improving access to safe and effective IVF.

Reducing economic barriers to IVF

Australia has broad based support for ART in general, and IVF in particular, based on Medicare Rebates for qualifying prospective parents undertaking treatment. However, the cost is not fully met in most cases via public funding, which therefore requires significant private contributions that accumulate with each additional cycle. There are no significant broad-based medical exclusions to access, nor are the number of cycles capped or age limits imposed.

While there are some State based programs in Australia to assist public patients, these are limited and inconsistent, often with long waiting periods. As age, health and other personal factors impact the success of treatment for prospective parents, the appeal of quick, seemingly simple, but unregulated black-market transactions for donor sperm used in home inseminations grows. To ensure the safety of these prospective parents and promote the long-term health and well-being of their children, it is essential to reduce economic barriers and improve access to both ART and affordable high-quality, traceable donor gametes.

New Zealand has a hybrid public and private program with public patients given full coverage but with highly prescribed clinical criteria including BMI, age and smoking status as qualifying factors. While the age and other limitations encourage greater success, they limit the pool of prospective parents. One consequence is that New Zealand has a significantly lower rate of children born to IVF than Australia.

A number of submissions highlighted the long-term economic as well as the human contribution of children born to IVF. One particular UK study which was highlighted found that “the lifetime discounted value of net taxes from an IVF-conceived child with mother aged 35 is £109 939 compared with £122 127 for a naturally conceived child. The lifetime undiscounted net tax contribution for the IVF-conceived child and naturally conceived child are £603 000 and £616 000, respectively”. Consequently, “an investment of £12 931 to achieve an IVF singleton is actually worth 8.5-times this amount to the UK Treasury in discounted future tax revenue. The analysis underscores that costs to the health sector are actually investments when a broader government perspective is considered over a longer period of time.”[3]

In order to assist access in both countries the following key recommendations for improved access could include:

[3] Connolly et.al, 2009, Assessing long-run economic benefits attributed to an IVF-conceived singleton based on projected lifetime net tax contributions in the UK. Human Reproduction, Vol 24, No.3, pp 626-632

Recommendation **22**

Australian States and Territories work with the Commonwealth, patients, clinicians and the sector to develop a National Partnership Agreement for Public Patient IVF. This Agreement could follow a similar format to the National Partnership on Public Dental Services for Adults.

While the distribution mechanism for public access could be a matter for individual States, in essence there are two broad options.

First, some jurisdictions may choose to establish public IVF units, such as the current Victorian trial. Alternatively, some jurisdictions may choose to provide a low-income subsidy to women which can be redeemed through private clinics as a supplement to the existing Medicare rebate. This is the format of the proposed NSW model.

While the form of public patient access may differ between States, there should be national uniformity on the threshold for low income and disadvantaged support at the individual level. It is recommended that concession card status be the primary operating distribution threshold for public patient access.

Recommendation **23**

A National Partnership Agreement for Public Patient IVF could be comparable to the Partnership Agreement on Dental Services. It would be funded by the Commonwealth but administered by the States and Territories on a pro rata basis.

Although there were differing views on public facilities versus public support for low-income patients, there was a clear view that if public facilities are established that should be done through a transparent tendering process and any provider must be able to provide care at a cost equivalent level.

Recommendation **24**

A National Partnership Agreement for Public Patient IVF would provide services to Australians from low- and limited-income backgrounds, such as concessions card holders, and could include prescribed groups with disadvantages and poor access to ART in general, and IVF in particular, such as First Nation and Torres Strait Islander Australians or Māori groups.

New Zealand may wish to consider a program of partial support or rebate for patients who are not lower income or who do not meet the requirements such as BMI. This could be a partial payment such as the Medicare rebate for cycles undertaken irrespective of in which system the treatment occurs. This could help overcome lower utilisation among some population groups, particularly Māori groups, who were identified by some interviewees as inadvertently disadvantaged in access to ART in general, and, IVF in particular, by the current rules.

Reducing Discriminatory Barriers to IVF Access

In Australia, while Medicare access to support ART in general, and, IVF in particular, is broadly available, there are long standing barriers to access based on clinical definitions of fertility. In this context, there was near universal support in interviews and submissions for non-discriminatory access to fertility treatment in Australia.

One contributor expressly outlined the change in patient cohorts and the consequent need for non-discriminatory access to ART in general, and, IVF in particular:

> *"The world of Australian families has significantly changed. Nowadays many of our patients are single people or couples in same-sex relationships.*
>
> *It is a serious anomaly that while heterosexual couples receive Medicare support to resolve their fertility problems and have their families, people in other family circumstances (such as same sex couples or single women freezing their eggs) receive no support at all for their fertility problems.*
>
> *Future governments should consider this serious anomaly in planning future funding to allow the same access to fertility treatment for people outside traditional male female relationships. The ten-year plan for fertility should include a recognition of the strategic importance of fertility for the nation and support for non-discriminatory access to fertility treatment."*

In that context alongside uniform national legislation, the most widely supported recommendation to the inquiry was the need for non-discriminatory access to fertility treatment.

This view has been recently supported by the August 2024 joint statement of ANZSREI (Australian and New Zealand Society for Reproductive Endocrinology and Infertility) along with FSANZ and RANZCOG on the definition of infertility and the importance of non-discriminatory access to publicly funded IVF and ART.

"Definition of Infertility: Consensus Statement

August 2024

ANZSREI (Australian and New Zealand Society for Reproductive Endocrinology and Infertility), has extended its definition of Infertility. This extension is consistent with the American Society of Reproductive Medicine (ASRM) definition of Infertility which was accepted by the ASRM in 2023. These extensions are outlined below. This extension in definition has been endorsed by FSANZ (Fertility Society of Australia and New Zealand) and RANZCOG (Royal Australian and New Zealand College of Obstetricians and Gynaecologists).

The extensions are made to improve inclusiveness and equitable access to reproductive care irrespective of relationship status, sexual orientation or gender identity.

The revised definition states that infertility is a disease condition or status characterised by any of the following:

1. The inability to achieve a successful pregnancy based on a parent's medical, sexual and reproductive history, age, physical findings, diagnostic testing, or any combination of those factors.
2. The need for medical intervention, including, but not limited to, the use of donor gametes or donor embryos in order to achieve a successful pregnancy either as an individual or with a partner.
3. In patients having regular, unprotected intercourse and without any known aetiology for either partner suggestive of impaired reproductive ability, evaluation should be initiated at 12 months when the female partner is under 35 years of age and at 6 months when the female partner is 35 years of age or older.

Nothing in the definition should be used to deny or delay treatment to any individual, regardless of relationship status or sexual orientation."

Recommendation **25**

The ANZREI expanded Definition of Infertility be adopted as the basis for expanded and non-discriminatory access to IVF and ART. State and Medicare support for ART in general and IVF in particular, should be available to prospective parents wishing to conceive who are unable to do so or who need donor eggs, sperm, or embryos in order to achieve a successful pregnancy.

A significant anomaly which was identified during the course of interviews and submissions was the difference in legal identity and rights of children born through IVF and sperm donation depending upon the marital or partnership status of the mother.

One submission highlighted that single parents by choice are now the largest group using donor sperm. This has created an unintended outcome whereby donors cannot claim parentage if the recipient mother is partnered, but they can if the recipient mother is single.

> *In recent decades, single mothers by choice (SMCs) have emerged as a new and rapidly growing non-traditional family structure in Australia and other parts of the world. SMCs are unpartnered women who choose to have a child, usually via some form of assisted conception, with the intention that they be their child's sole parent.*
>
> *While the exact number of SMC in Australia is unknown, according to the Victorian Assisted Reproductive Treatment Authority (2023; VARTA) Annual Report, single women are the largest group using donor sperm (53%) followed by same sex relationships (36%) and people in heterosexual relationships (11%).*

Recent legal cases under the Family Law Act 1975 (Cth) concerning the question of parentage of a donor-conceived child of an unpartnered woman have indicated that a sperm donor may be regarded under the law as the father. This has created an unintended outcome for SMCs whereby Federal Government Agencies such as Services Australia and the Australian Passport Office require them to establish (to varying degrees of proof) and/or undertake a process to verify that there is no person who is a parent or has parenting responsibilities under the Family Law Act, before administrative processes such as non-applicability of child support scheme

rules, the assessment of eligibility for sole parenting allowance, childcare benefits and family tax benefits can be made, or a donor-conceived child's passport can be issued. Further, the potential exists for donors to claim parentage of children conceived using their genetic material if the recipient mother is single.

Problem >

S 60H of the Family Law Act (1975) outlines parentage of children born as a result of artificial conception procedures.

At present, unpartnered women who conceive using artificial conception procedures are omitted/not included in S 60H of the Family Law Act (1975; FLA) leaving SMCs and their children without the same legal protection and certainty provided to heterosexual and homosexual couples who use donor sperm to conceive their children.

Donors to lesbian and heterosexual couples are expressly excluded from legal parentage by s 60H, but no identical provision applies when the woman is unpartnered. The result is that sperm donors to SMCs, whether known or unknown (i.e., a donor from a fertility clinic), may apply to be legal parents.

Furthermore, SMCs may experience unnecessary delay and administrative barriers in applying for Commonwealth benefits and securing identification documents such as passports.

A number of unpartnered women have come before the Family Court in matters where sperm donors have successfully applied for legal parentage. In these cases, judges have determined that s 60H does not apply to unpartnered women because they do not fit into any of the scenarios addressed by the section.

The Family Law Council in its report of parentage and the FLA in 2013 raised this concern stating that the FLA has a 'discriminatory effect' in relation to single women as opposed to women with partners. The prospect of unknown donors being legal parents has serious ramifications for SMCs and their children (and donors), particularly in Victoria, where parents can apply for "early access" to their sperm donor's identity, with his consent, through the VARTA Central Register. Victorian SMCs are now frequently meeting their child's "unknown" donor while their child is still a minor, often unaware they are putting themselves and their children at legal risk.

Solution >

Urgent amendment of S 60H of the Family Law Act (1975) to include unpartnered women and their children stating that a donor is not taken to be a parent, aligning the rights of unpartnered women with the rights of heterosexual and lesbian couples."

A review of supporting State legislation and administrative processes and the relevant Federal Government Agencies should be undertaken to ensure that their design, contact points and requirements are family-centred and no more than legally necessary to achieve their purpose.

Recommendation **26**

It is recommended that the Australian National Fertility Law review and align the rights of unpartnered individuals and their children with the rights of partnered couples and consider;

- **Amending the Family Law Act to remove discrimination based on marital status for donor recipients and their children.**
- **Reviewing Federal Government administrative processes to ensure that they work in a fair and non-discriminatory fashion for all families.**
- **Supporting State legislation is reviewed to remove discrimination based on marital status for donor recipients and their children.**

Improving Access through Education

Evidence shows there is low community awareness about fertility and the factors that affect it, especially among men. This is in part because most fertility related information targets only women. A key pathway to improving access and reproductive outcomes is through public education providing education on lifetime fertility factors and options for both men and women. This would involve a greater role for community and patient education and awareness. At the same time, building awareness across the community of national fertility needs may also assist in increasing gamete and embryo donation.

Recommendation **27**

Australian State & Territory and New Zealand governments engage pedagogy experts to assist in the development of nationally appropriate school-based curriculum on fertility. As part of this process, FSANZ engage with the state and federal Ministers for Health and Education.

Recommendation **28**

Australian State & Territory and New Zealand governments work with FSANZ as well as Public Health and Community engagement experts to develop a wider community education campaign on fertility health promotion to enhance awareness of fertility and the factors that affect it. This should include campaign elements that specifically target men. This should include a campaign to address donor shortages and increase awareness about donation.

4. Research and Technology

Australia has one of the world's leading IVF Research programs through the combined work of our universities, the NH and MRC and the IVF and ART sector represented by FSANZ. However, given the prevalence of IVF which now accounts for over 6% of births in Australia and the expected growth, it is recommended that there should be a single National Fertility Mission conducted through the MRFF to help address declining national birth rates in both Australia and New Zealand.

ANZARD, Your IVF Success and Your Fertility Information

Australia has the oldest and arguably the most comprehensive IVF treatment and birth outcome data set in the world in the form of ANZARD (The Australian and New Zealand Assisted Reproduction Database) which has been in operation since 1979.

It also has one of the world's leading IVF prediction tools in the form of the public online platform *Your IVF Success*.

The ANZARD annual report has been fundamental in promoting the safety and success of Australia and New Zealand's IVF systems and remains critical to maintaining these standards. More recently, the public online platform Your IVF Success has provided information to help individuals and couples navigate the process of IVF.

While the current model is globally leading, there is the potential to improve the breadth of information provided to Australian IVF patients which in turn will support patient choice, procedural safety, success rates and research outcomes. This should include integrating Your Fertility Information, an online platform that provides trustworthy information and resources for the public about fertility health, infertility prevention, infertility treatment, donor conception and surrogacy. IVF patients should also be provided with evidence-based information about the risks, benefits and costs of IVF adjuvants and options. This information should be based on current evidence and provided in various formats to accommodate different levels of health literacy including translations for people from non-English speaking backgrounds. Consultation with patients on the data that is most valuable and how it can be most effectively communicated will strengthen Your IVF Success. Furthermore, ensuring that reporting data considers the goals of the patients including egg freezing and embryo banking as part of overall lifetime fertility goals.

The annual report, funded by FSANZ, relies on data provided by ART clinics from Australia and New Zealand. The NPESU collates and manages this data and is commissioned by FSANZ to produce a report each year. To ensure the long-term sustainability and continued excellence of this resource, there is a need for an ongoing funding model.

The Australian Federal Government funded YourIVFsuccess.com, a public online platform that provides information and tools to help individuals and couples navigate the process of IVF. It offers access to success rate data from Australian IVF clinics, educational resources about fertility treatments and a personalized treatment estimator. The platform aims to support informed decision-making by offering transparency and insights into the IVF process, helping users better understand their chances of success and explore different

fertility options. Your IVF Success funding announced in 2019 is due to expire in mid-2025. This funding should be formalised to allow for the long-term stability of both an Australian Reproductive Database and the public online platform.

A number of submissions also highlighted the importance of expanded data collection including Intrauterine Insemination (IUI) treatment outcomes, as well as metrics aligned with boarder fertility goals for both Australian and New Zealand governments. Currently, RTAC licensing requirements mandate that clinics collect and report IVF cycle data and outcomes. These requirements could be reviewed to ensure the relevance of current data points and potentially expanded to cover ART more broadly, including IUI cycle outcomes.

Recommendation **29**

The Australian Federal Government should commit to 5-year funding plan for The Australian Reproductive Database, the publication of that data on an annual basis and the Your IVF Success Website (currently provisioned for with an Australian Federal Government grant).

To ensure Your IVF Success website best responds to the needs of patients an independent review of previous clinic patients should be conducted to understand what data is most valuable and how it informs decision making.

Reproductive outcome data should be made available for research. If there were to be a new five-year funding model it would be appropriate for the collation, management and hosting of reproductive outcome data to be subject to an open and competitive tender process.

The Australian Reproductive Database would therefore carry out three primary data roles: custodian of the IVF and fertility treatment data set, custodian of the public online platform (Your IVF Success) and its related data for research.

Funding would need to be allocated to establish and maintain the Australian National Donor Registry. Funding should be provided over five years including funds for the development of the National Donor Registry.

Provisions should be made to enable sharing of data on reproductive outcomes between New Zealand and Australia for the purposes maintaining the safety, efficacy and success of reproductive care outcomes across both countries

Recommendation **30**

The Australian National Donor Registry be established with the Australian Federal Government to commit $2m to establish the Registry and $1m per annum for five years to maintain and operate the Registry.

Total Commonwealth of Australia funding to support IVF administration under a low operating-cost model would be $5.3m per annum. This would comprise

$1.3m
for The Australian Reproductive Database, which is currently housed by the NPESU at the UNSW.

$1m
for the public online platform Your IVF Success and data set managed in conjunction with The Australian Reproductive Database

$2m
for the Australian National Donor Registry

$1m
as the Commonwealth contribution for a shared cost independent RTAC.

There is an inadvertent risk that the publishers of the public online platform Your IVF Success and The Australian Reproductive Database, as well as the new donor registry, could be sued by patients who are disappointed by their outcomes, by clinics that do not accept the statistics, or others. To mitigate against this risk, it would be appropriate to amend the 2002 Human Reproduction Act to indemnify the publishers and operators of The Australian Reproductive Database against consequential suits resulting from publication of relevant information, other than as a result of wilful misfeasance.

Carrier Screening

Whilst patient rebates through a Medicare item number currently apply to three genetic conditions, research through the MRFF funded Mackenzie's Mission Program shows that covering more conditions holds significant benefit to Australia, to families and to children born through IVF, by helping to reduce the risk of catastrophic and potentially terminal or lifelong genetic conditions in newborns.

The current process of using a Medicare item number to offer free screening is a critical step forward.

One option is, therefore, continuing to expand the range of conditions covered via Medicare funded Carrier Screening with the goal of achieving the full 1,300 conditions recommended through the Mackenzie's Mission MRFF Program.

An alternative model proposed by Australian Genomics in their submission is to offer Expanded Reproductive Carrier Screening (ERCS) through a nation-wide screening program, similar to that of Bowel Cancer Screening. Any screening program at scale would need to be partnered with the appropriate genetic counselling to manage both the biological underpinnings of screening, but also any considerations related to insurance or other post-screening considerations.

The background to this recommendation is MSAC application 1637. MSAC supported an initial program for Medicare funded Carrier Screening for Cystic Fibrosis, Fragile X and Spinal Muscular Atrophy. *"Expanded reproductive carrier testing of couples for joint carrier status of genes associated with autosomal recessive and X-linked conditions"* was considered by MSAC in July 2022. At that meeting,

MSAC did not recommend public funding for the full 1,300 conditions proposed, however, the Public Summary Document (PSD) for 1637 recognised the unmet need for, and inequity of access to, ERCS in Australia. MSAC recommended that the Department of Health and Aged Care consider the most appropriate implementation methodology of ERCS, noting the need for infrastructure and coordination more conventionally associated with screening programs than Medicare-subsidised item numbers.

In considering the entirety of service provision for ERCS, Australian Genomics has submitted that an organised national screening program offers advantages in terms of governance; public awareness and information provision; referral and consent processes; provision of services for diverse population groups; sample collection, processing and testing; post-test counselling and clinical referral; and, critically, data management and security. It also allows for consistency in the information and handling provided to identified high risk couples.

Delivery of ERCS as an organised national screening program has the potential to mitigate many of the risks associated with population-scale genomic testing and provides opportunities for health system efficiency and economies of scale, while ensuring equity of access to all Australians who want ERCS.

Recommendation **31**

The Australian Government consider an Expanded National Carrier Screening Program to offer all Australian parents access to screening conditions proposed under Mackenzie's Mission. Alternatively, the Government support the expansion of the current Medicare funded Carrier Screening Model conditions recommended under the MRFF funded Mackenzie's Mission Research Program. Access to PGT to be expanded in parallel with expanded carrier screening for couples identified as being at risk of carrying a listed condition.

Donation for Research & Medical Research Future Fund Mission

Several submissions highlighted that patient safety and success rates of IVF are hampered by legal research frameworks that need updating.

Some submissions highlighted that, at present, it is too onerous a process for most clinics to apply for an NHMRC training licence, and thus as the law stands, clinics are unable to utilise material within their clinic that has ceased to grow and/or has been deemed non-transferable which is then simply discarded. Under NHMRC guidelines, these are classed as 'excess embryos' and even if a training licence were in place, the clinic requires patient consent for their 'unsuitable for transfer embryos' to be used for training.

(https://www.nhmrc.gov.au/sites/default/files/documents/attachments/embryo-research-licence/additional-information-on-obtaining-consent.pdf.)

One submission noted the need for an option of broad consent for IVF participants to offer donation of surplus or unviable materials for subsequent research or use by other prospective parents. This includes the capacity both for an upfront general consent for surplus eggs, sperm or embryos to be used for either or both of research, training or donation to other prospective parents. It also includes a dynamic consent model which would allow donors to subsequently change their decisions for any prospective use including the right to discard unused or unviable material.

Donation of reproductive materials for research is currently limited by several factors, primarily: the lack of information and understanding of potential ART patients of the opportunities for donation to research; the requirement that donation can only occur to identified current research projects; and unwieldy consent procedures that result in significant quantities of frozen gametes and embryos being discarded.

Consideration should be given to the adoption of three changes to current consent procedures:

1. The implementation of a dynamic consent interface for the maintenance of valid consent across the treatment period. Such online platforms are often used by genomic biobanks; within the context of ART, the implementation of an online consent platform for maintaining valid consent could also work as a means of providing clear and up-to-date information about research donation opportunities.

2. The removal of the requirement for specific consent. A model of broad consent is again becoming common in genomic research; it entails that rather than secondary consent having to be obtained to use biobanked material or data in subsequent research projects, initial consent is sufficiently broad as to be relevant for a variety of research uses. In the ART context, broad consent could be tailored to allow for consent to certain applications of research that may be considered controversial for some patients (e.g. research that involves embryo destruction).

3. Replacing the current requirement that abandoned reproductive materials (i.e., materials where the owner is no longer responding to contact from the clinic, which may include not paying storage fees) be discarded upon reaching storage limits. This is resulting in significant numbers of oocytes and other reproductive material being discarded when it could be used in research to enhance the safety and efficacy of ART procedures. Instead, then, the 'default' option for abandoned materials could be changed from discard to donation to research. That this is the disposition outcome in the situation of abandonment would need to be clear from the start of treatment, something which could be managed through robust and fit for purpose consent procedures such as a dynamic consent platform.

Consideration should also be given to how these changes would interface with existing NHMRC licencing requirements to balance safety and facilitate future fertility research.

Recommendation **32**

All Australian clinics should be required to provide patients with a standard form optional donor consent with a plain English guide that would allow prospective IVF patients to donate surplus or unviable eggs, sperm or embryos or any combination thereof to research without the need for a subsequent second consent. Nationally accepted content forms could be authorized by RTAC. The Uniform National Law could contain any necessary legislative amendments. Patients should be given the option of identifying the nature of the research or donation of surplus or non-viable material. Counselling should be made available at the point of egg or sperm collection to support individuals to make informed decisions about their overall fertility journey and the implications of donation.

A National Donor Bank may include either or both of two primary functions. First, the Bank may involve donation of eggs, gametes or embryos by others through a virtual network in which clinics may choose to participate. Second, it could also involve the contribution of excess materials for research.

While it is a matter for FSANZ first and Governments subsequently as to whether either or both of those functions are established, there was significant support through submissions and interviews for broader access to donated eggs, gametes or embryos, so as to reduce reliance on imported and black-market donations with potentially lesser or, in the case of the black markets, no standards, for maintenance and provenance of donated material. This is particularly important for single mothers and same sex couples as well as others who may have difficulty in obtaining donated eggs, gametes or embryos within Australia.

Equally, there was strong support for a National Research Bank of excess materials for research and training to help ensure that Australian clinicians and clinical practice remain world leading and continue to improve.

In the case of donation for IVF, while up front consent is recommended it would be necessary to give potential donors both understanding and express choice about donation for IVF purposes to known recipients, to the broader clinic or to the virtual National Donor Bank. Donors should also have the option of a secondary consent prior to use. In addition, it would be crucial to offer psychological counselling for participants who consent to use of their surplus eggs, sperm, or embryos to other prospective parents. This counselling should address the emotional and psychological implications, helping participants fully understand the potential impact on themselves and their future. Donors should also have the option for reassessment of their consent, through dynamic consent, ensuring that the decision to donate aligns with their current values and emotional state.

A separate upfront consent is recommended for contribution of excess material to research with the option of a general donation to research or training or both. There should also be the option of a secondary consent prior to use and the ability to reassess consent.

It has also been proposed that those clinics and institutes requiring human embryos of a certain stage for research could apply to their HREC for ethics approval.

All eggs, sperm and embryos could be allocated from the National Donor Bank on a yearly basis. All excess embryos from the project would be returned to the Bank at the end of the project and be returned to the pool for reallocation.

An important consideration is that a National Fertility Research Mission under the MRFF could potentially be funded without having to seek additional funds from within the unallocated portion of the MRFF Missions forward projections under the existing 2nd Revised MRFF 10 Year Plan.

Recommendation **33**

The Australian Government establish a 10-Year National Fertility Research Mission as a new mission under the Medical Research Future Fund. The steering committee for the mission should be comprised of members with the appropriate expertise across fertility research and commercialisation, with at least one scientist having expertise in reproductive technology research, such as from Scientists in Reproductive Technology (SIRT).

Recommendation **34**

The 10-Year Nationality Fertility Research Mission would seek to address the following actions through multidisciplinary research:

Improving Australia's birth rate.	Benchmarking of Australia's IVF safety and effectiveness by global comparison.	Assessment and evaluation of emerging global technologies and techniques, including IVF options and adjuvants, to further improve IVF safety and effectiveness.
Use of broader ART techniques and practices to increase Australia's IVF safety and effectiveness.	Continued expansion of carrier screening as standard of care to reduce the number of children born with life threatening or debilitating genetic conditions.	Consideration of the emerging science around most effective ovulation stimulation procedures, timing and ages.
Consideration of future egg storage programs and practices in Australia and New Zealand.	Identification of global best practice for education of prospective parents.	Ongoing assessment of psychosocial implications and outcomes following ART use to ensure the practice reflects and promotes patient best interests.
	Longitudinal studies on the long-term health of ART offspring.	

Conclusion and Next Steps

FSANZ has developed its 10-Year Fertility Roadmap based on four key pillars:

1	2	3	4
Governance	Safety and Efficacy	Access	Research and Technology

These pillars and the associated recommendations aim to improve the safety, efficacy and IVF experience for patients and ultimately help increase the number of healthy babies born through ART in Australia and New Zealand.

This in turn should contribute to the development of an Australian National Fertility Plan co-ordinated through the National Council of Health Ministers.

In order to translate the FSANZ Fertility Roadmap into concrete policy action and patient benefits, it is strongly recommended that the Australian and State and Territory Governments commit to a 10-year National Fertility Plan. This Plan would itself have a series of components including a National Fertility Law, National Donor Registry, National Donor Bank, a 10-Year MRFF Fertility Mission and a National Fertility Roundtable.

Recommendation **35**

The Australian Government develop a National Fertility Plan which includes the following components:

- **National Fertility Law**
- **National Donor Registry**
- **National Donor Bank**
- **A 10-Year MRFF Fertility Mission**
- **A National Fertility Roundtable which would help establish Terms of Reference for both the Mission and the proposed law.**

Ultimately, Australia now has over **300,000 children that have been born through IVF** and this is increasing by over 20,000 new lives being brought into the world each year. Changing social needs and technological capabilities mean that the number of healthy babies is likely to increase significantly in the next 10 years. Against that background, FSANZ stands ready to work with the Australian, New Zealand and State Governments, clinicians and researchers, and above all else the Australian and New Zealand community in establishing a 10 Year National Fertility Plan to help improve safety, efficacy and access to IVF in Australia and New Zealand.

List of Australian Laws relating to IVF

1. *Health Insurance Act 1973 (Commonwealth)*
2. *Human Services (Medicare) Act 1973 (Commonwealth)*
3. *Mitochondrial Donation Law Reform (Maeves Law) Act 2022 (Commonwealth)*
4. *National Health Amendment (Pharmaceutical Benefits Scheme) Act 2012 (Commonwealth)*
5. *NHMRC Ethical guidelines on the use of assisted reproductive technology in clinical practice and research 2017 (updated 2023) (Commonwealth)*
6. *Private Health Insurance Act 2007 (Commonwealth)*
7. *Prohibition of Human Cloning for Reproduction Act 2002 (Commonwealth)*
8. *Research involving Human Embryos Act 2002 (Commonwealth)*
9. *Research Involving Human Embryos Regulations 2017 (Commonwealth)*
10. *Assisted Reproductive Technology Act 2024 (ACT)*
11. *Parentage (Surrogacy) Amendment Bill 2003 (ACT)*
12. *Assisted Reproductive Technology Act 2007(NSW)*
13. *Assisted Reproductive Technology Regulation 2014 (NSW)*
14. *Status of Children Act 1996 (NSW)*
15. *Status of Children Regulation (2019 (NSW)*
16. *Surrogacy Act 2010 (NSW)*
17. *Surrogacy Regulation 2016 (NSW)*
18. *Human Assisted Reproductive Technology Act 2004 (NZ)*
19. *Status of Children Act 1978 (NT)*
20. *Status of Children Regulations 1996 (NT)*
21. *Surrogacy Act 2022 (NT)*
22. *Surrogacy Regulations 2022 (NT)*
23. *Surrogacy Act 2010 (QLD)*
24. *Assisted Reproductive Treatment Act 1988 (SA)*
25. *Assisted Reproductive Treatment Regulations 2010 (SA)*
26. *Surrogacy Act 2019 (SA)*
27. *Surrogacy Regulations 2020 (SA)*
28. *Human Cloning for Reproduction and Other Prohibited Practices Act 2003 (TAS)*
29. *Surrogacy Act 2012 (TAS)*
30. *Assisted Reproductive Treatment Act 2008 (VIC)*
31. *Assisted Reproductive Treatment Regulations 2019 (VIC)*
32. *Health Services (Health Services Establishments) Regulations 2013 (VIC)*
33. *Health Services Act 1988 (VIC)*
34. *Status of Children Act 1974 (VIC)*
35. *Status of Children Regulations 2014 (VIC)*
36. *Artificial Conception Act 1985 (WA)*
37. *Human Reproductive Technology Act 1991 (WA)*
38. *Human Reproductive Technology Regulations 1993 (WA)*
39. *Human Tissue and Transplant Act 1982 (WA)*
40. *Human Tissue and Transplant Regulations 2024 (WA)*
41. *Surrogacy Act 2008 (WA)*

List of interview-based contributors to review

Interviewees	Organisation
Prof. Gordon Baker	Former FSANZ President (1988-1989)
Associate Prof. Kiri Beilby	Monash University
Tiffany Boughtwood	Australian Genomics
Associate Prof Sally Catt	Monash University
Dr. Fleur Cattrall	MelbourneIVF
Professor Georgina Chambers	Director National Perinatal Epidemiology and Statistics Unit, UNSW
Dr. Anne Coffey	Far North Fertility, Cairns
Dr. Chris Copeland	Chair, RTAC
Prof. Martin Delatycki	Victorian Clinical Genetics Services
Mr. Rick Forbes	FSANZ
Mr. Michael Gorton, AM	Principal, Russell Kennedy Lawyers
Dr. Matilda Haas	Australian Genomics
Dr. Karin Hammarberg	Monash University
Dr. Richard Henshaw	Past Chair of IVF Medical Directors, ANZ
Associate Prof. Peter Illingworth	Virtus Health
Dr. Molly Johnston	Monash Bioethics Centre
Ms. Rebecca Kerner	Chair, ANZICA
Dr. Sarah Lensen	University of Melbourne
Associate Prof. John McBain, AO	Former FSANZ President (1992)
Dr. Simon McDowell	Fertility Associates NZ
Prof. Catherine Mills	Monash Bioethics Centre
Dr. David Molloy	Director, Medical Affairs, Virtus Health
Ms. Jayne Mullen	Chairperson, Scientists in Reproductive Technology
Ms. Kate Munnings	CEO, Vitrafy
Mr. David Nathan	City Fertility
Mr. Stephen Page	Page Provan Lawyers
Dr. John Peek, CNZM	Fertility NZ
Dr. Adrianne Pope	Adrianne Pope Consulting
Prof. Stephen Robson	President, AMA & Former President RANZCOG
Ms. Rachel Samson	Clinical Psychologist & Reg 7 Family Consultant Federal Circuit and Family Court of Australia
Dr. Petra Wale	President, FSANZ

Written submissions to review

A list of submissions to this review by organisation or individual, noting some contributors provided both a written submission and participated in an interview. Some submissions have also been received on the basis of anonymity & confidentiality.

Interviewees	Organisation
Adora Fertility	
Australian and New Zealand Infertility Counsellors Association (ANZICA)	
A/Prof. Kiri Beilby	Monash University
Elisha Birch	
Tiffany Broughtwood	Australian Genomics
Prof Georgina Chambers	University of NSW
Katherine Dawson	
The Hon. Shannon Fentiman MP	Minister for Health, Queensland
Fertility Society of Australia & New Zealand (FSANZ)	
Fertility NZ	
Rick Forbes	
Genea	
Dr. Karin Hammarberg	Monash University
Prof. Jane Halliday & A/ Prof. Sharon Lewis	Murdoch Children's Research Institute
Prof. Roger Hart	University of Western Australia
Dr. Alexandra Harvey	Virtus Health Pty Ltd
Ashleigh Holt	
Charmaine Kai	
Dr. Rebecca Kelley	Melbourne IVF
Rebecca Kerner	ANZICA
Dr. Sarah Lensen	The University of Melbourne
Dr. Raelia Lew	
Kathy Mantelos	
Stephanie Mathews	Stephanie Anne
Dr. Myvanwy McIlveen	Newcastle Fertility Specialists
Monash IVF Group	
Ian Morison	
Kate Munnings	Vitrafy Life Sciences
Newlife IVF	
NHMRC Consultation Submission on Governance Standards IVF ART Australia FSANZ July 2024	
Prof. Robert Norman & Prof. Helena Teede Joint submission	Robinson Research Institute, University of Adelaide
Prof. Robert Norman, Independent submission	Robinson Research Institute, University of Adelaide
Stephen Page (two submissions)	Page Provan
Hon. Ryan Park MP	Minister for Health, NSW
Dr. John Peek	Fertility NZ
The Hon. Chris Picton MP	Minister for Health and Wellbeing, SA
Rainbow Families Incorporated	
Lisa Ransome	Seeds for Hope Perinatal Psychology
Reproduction in Society Group, Monash Bioethics Centre, Monash University	
Rachel Samson	Clinical Psychologist & Consultant to Federal Circuit and Family Court of Australia
The Hon. Amber-Jade Sanderson MLA	Minister for Health, WA
The Hon. Rachel Stephen-Smith MLA	Minister for Health, ACT
Nandi Segbedzi, Lynden Costin & Michelle Galea (three submissions)	Australian Solo Mothers by Choice
Desmond Soares	
Paul Stokes	Coastal IVF
Meike Suggars & Feona Wadsworth	DCP Hub
The Hon. Mary-Anne Thomas MP	Minister for Health, Victoria
Virtus Health	
Dr Petra Wale	Personal Submission
Dr Petra Wale	FSANZ
Tim Yeoh	Genea

Key Facts

Key stats from the 2021 Australian and New Zealand Assisted Reproduction Database (ANZARD) Report

111,253 ART treatment cycles were performed in Australian and New Zealand ART Units in 2021 (102,157 and 9,096, respectively), representing an overall increase of **16.3% from 2020**

Of the 111,253 initiated ART cycles,

20,690 babies were born.

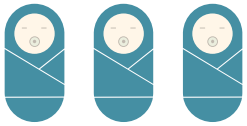
Of these, 18,594 (89.9%) were from treatments performed in Australian ART Units and 2,096 (10.1%) were from New Zealand ART Units.

Of the 108,273 autologous and recipient cycles,

11.9% were undertaken by **single female** and

4.1% by **female-female intending parents**.

The proportion of births that were twins or triplets was **3%**



Women used their own **eggs or embryos** in

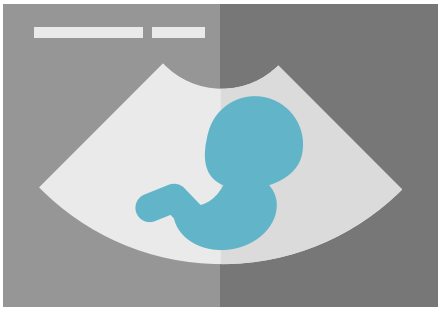
95% in 2021

62.3% were fresh cycles, and

377.3% were thaw cycles

Over a third (37.1%) of women who commenced ART in 2018 or 2019 achieved a **live birth in their first ART cycle**. After three complete ART cycles, women had between 53.6% and 63% chance of achieving a live birth.

There were **5,881** fertility preservation cycles performed in 2021, representing an increase of **61.5% from 2020.**



Full List of Recommendations

1. It is recommended that the Australian States and Territories work with the Commonwealth, patients, clinicians and the sector to develop a Uniform National Fertility Law for IVF which would be passed by a lead jurisdiction and adopted by others.

2. The development process be facilitated through the Council of Australian Health Ministers supported by a Steering Committee composed of representatives from patients, donor conceived individuals, fertility specialists, industry experts, FSANZ professional groups (nursing, psycho-social, scientific and clinical) and legal practitioners with fertility expertise.

3. As with other National Uniform Laws, while States and Territories would be strongly encouraged to maintain consistent laws there would be the capacity to vary specific sections to accommodate historic or other perspectives.

4. Develop a single National Health Standard for egg and sperm donation to ensure consistency and safety across all jurisdictions. This standard should cover donor limits and IVF regulation procedures.

5. Establish a Single National Standard that guarantees the rights of children to seek information about their genetic parentage and respects the rights of donors regarding progeny seeking such information. All donors should be required to sign a declaration regarding any previous donations.

6. Create a single Australian National Register and genetic bank for donors and donor-conceived individuals, which provides a centralized system for tracking and accessing critical genetic information. This system would ensure that medical professionals and individuals are alerted to significant hereditary conditions and that donor-conceived children and their families can contribute important genetic information to the registry.

   The National Register should also oversee donor limits agreed upon by the States, Territories and Commonwealth. Subject to advice by the NHMRC these limits may take into account geographic and demographic elements. This process could be supported by assigning a single national ID, including assignment of an ID to the donors of any gametes imported into Australia. All clinics would use the unified ID for imported donor gametes, facilitating consistence and transparency.

7. RTAC be established as a body independent of FSANZ with its own independent constitution, funding and Board.

8. The establishment of an Independent RTAC could occur either under the Uniform National Law or as a company limited by guarantee. Australian States and Territories should work with the Commonwealth, patients, clinicians and the sector to develop an agreed model for RTAC.

9. Establish an Independent RTAC based on, but not limited to, the following five key pillars:

   - An Independent not-for-profit company set up by guarantee with FSANZ, the Australian Commonwealth and the States as equal shareholders.
   - A Board comprising seven members, two members nominated by FSANZ, two from the provider sector and two by the Government (being one from State Health Departments and one from the Commonwealth) and an Independent Chair.

- Increase certification and review capabilities, including through appointment of a full-time CEO with experience from the provider sector and a strong background in quality processes, legal regulation, and policy matters. It has been suggested that this review process could be conducted over a three-year period with different elements reviewed in each year of that cycle.
- Recognition of RTAC within the Australian Uniform National Fertility Law.
- A review of the user experience of data provided on Your IVF Success to identify what data and format is of greatest value to current and future users of ART & IVF. Provision of IVF treatment and outcome data to publicly accessible webpage (currently Your IVF Success).

10. Funding for RTAC should be based on a hybrid model of industry sector support and Australian Government funding. It is recommended that, in order to increase review capabilities and the ability to respond to complaints, RTAC have a Budget of $4m per annum commencing in 2025/26, to be indexed by 5% per annum to accommodate growth in IVF uptake. The proposed funding mechanism would be 50% by IVF providers and 50% by Governments with 25% coming from the Commonwealth and 25% from States and Territories on a pro rata basis. Funding should be agreed in 5-year cycles.

11. The revised RTAC should establish a formal complaints review process. Subject to the views of States and Commonwealth, this could include a four-stage process:

    - **Initial Complaints**: Patients should first direct their complaints to the treating IVF clinic. Clinics are mandated to report all complaints to RTAC.
    - **Unresolved Complaints**: If a complaint remains unresolved, it should be escalated to the relevant State or Territory Ombudsman, Commissioners, APRHA, or Complaints Office, as per the current FSANZ Complaints Handling Process. Clinics must notify RTAC in writing about any unresolved complaints.
    - **Any complaints submitted to RTAC** which concern individual patient care will be referred to the treating clinic. If these are unresolved then they will be referred to the relevant authority. If a complaint is about the general operation of a clinic or of RTAC then these will be considered. Any legal matters should be referred to the relevant State authority. If RTAC identifies safety of efficacy concerns or breaches of the Code of Practice, then they will have graduated powers to respond as set out in Recommendations 17 and 19.
    - **Any complaints about the operation or actions of RTAC itself** that cannot be resolved, should be referred to an appropriate body to be agreed to with the States and Territories to ensure appropriate independence.

12. RTAC should be able to issue licence certificates that licensed facilities be required to display, as part of its new scope of practice under the new legislation.

13. RTAC should have a graduated set of powers which would allow it to issue requirements for rectification or provision of information or to ensure that actions were taken or not taken until such time as rectification was completed.

14. RTAC itself should be reviewed independently as part of the process for establishing the Australian National Fertility Law and thereafter every five years.

15. The foundation for licensing of ART units should be compliance with the RTAC Code of Practice, as well as the International Code of Practice. RTAC should have the power to withhold, grant or vary licences depending on compliance with the Codes. This power should be vested in an independent and properly resourced RTAC.

16. FSANZ continue as the governing body for the Australian and New Zealand Code of Practice and should include the RTAC CEO. An advisory board should be established with membership including four fertility-experienced, clinically qualified representatives with one each appointed by the Commonwealth, the States collectively, the New Zealand Government and RANZCOG and professional groups (nursing, psycho-social, scientific and clinical), a patient representative to provide feedback and guidance to FSANZ.

17. The Code of Practice should include strong and clear accreditation criteria for ART Units including:

Patient Support:

i. Informed Consent: Ensure that all patients undergoing ART procedures provide informed consent after being thoroughly educated about the risks, benefits, and alternatives. This includes clear information about the evidence-base for optional or adjuvant treatments, potential risks of harm or complications, success rates, and the use of their data.

ii. Psychological Support: Provide comprehensive psychological support services for ART patients to help them cope with the emotional and mental stress associated with infertility treatments. This includes counselling, support groups and mental health resources. Medicare funding for psychological support and counselling could be delineated with a separate Medicare code from the Medicare code funding the clinical care for ART.

iii. Patient Feedback Mechanisms: Implement robust feedback mechanisms to gather patient experiences and insights. Clinics could integrate Patient Reported Outcome Measures (PROMs) and Patient Experience Measures (PREMS) within their own systems, allowing immediate, responsive interactions with patients. This feedback will support continuous improvement in ART practices and enhance patient education. RTAC could also consider whether linking PROMs and PREMs data with patient outcomes would offer further benefits to patient safety and inform future standards.

Licensing of ART Units: strengthen RTAC authority by providing a mechanism through which an ART clinic can be refused a licence for various reasons, such as:

i. Non-Compliance with Standards: If the ART Unit fails to comply with the Code of Practice and guidelines set by NHMRC, a licence can be denied or conditions imposed. This includes deficiencies in procedures, equipment, staff qualifications and quality control measures.

ii. Inadequate Corrective Actions: During the assessment process, if issues are identified and the ART Unit does not adequately address these issues or fails to provide sufficient evidence of corrective actions, RTAC can refuse to issue a licence or require rectification.

iii. Poor Assessment Results: If the ART Unit performs poorly during the on-site assessment, showing significant non-conformities or a lack of adherence to best practices, RTAC can decide against licensing the ART Unit or require rectification.

iv. Ethical and Legal Violations: If there are ethical concerns, legal violations, or evidence of misconduct within the ART Unit, RTAC can refuse a licence to uphold the integrity and reliability of the licensing process or require rectification.

v. Incomplete or Misleading Information: Providing incomplete, inaccurate or misleading information during the application or assessment process can result in a refusal of licence or a requirement of rectification.

18. Real-time reporting: Identify and address any safety concerns by establishing real-time reporting systems for adverse events and complications related to ART procedures with a target of 1 July 2026 subject to readiness.

19. As part of the development of Australian uniform fertility law a provision should be introduced, to safeguard the advertising of donation of gametes and associated services in a digital environment. The purpose of this law (which may require legislation at Commonwealth level) would be three-fold. First, to prevent against prolific donation over and above agreed national limits. Second to ensure the safety and awareness of risks of all parties participating in donation outside of a clinic setting. Third to ensure the traceability of the donation process and secure the rights of the child.

20. Review the governance and practice of clinical research within the context of ART clinics to ensure that all ethical and regulatory requirements are fulfilled, and that clinical innovation is based on rigorous and independently validated pre-clinical and other research data, including randomised controlled trials where appropriate.

21. Develop a requirement for ongoing professional development and training for ART practitioners to keep them abreast of the latest advancements and innovations in the field. This includes accredited workshops, conferences, and other educational activities with a target of 1 July 2026 subject to readiness. Where existing CPD requirements which are already in place such as those provided in RANZCOG these should continue, the new requirement would be to ensure that those service providers which do not have ongoing CPD as part of their required ongoing accreditation have ongoing CPD.

22. Australian States and Territories work with the Commonwealth, patients, clinicians and the sector to develop a National Partnership Agreement for Public Patient IVF. This Agreement could follow a similar format to the National Partnership on Public Dental Services for Adults.

23. A National Partnership Agreement for Public Patient IVF could be comparable to the Partnership Agreement on Dental Services. It would be funded by the Commonwealth but administered by the States and Territories on a pro rata basis.

24. A National Partnership Agreement for Public Patient IVF would provide services to Australians from low- and limited-income backgrounds, such as concessions card holders, and could include prescribed groups with disadvantages and poor access to ART in general, and IVF in particular, such as First Nation and Torres Strait Islander Australians or Māori groups.

25. The ANZREI expanded Definition of Infertility be adopted as the basis for expanded and non-discriminatory access to IVF and ART. State and Medicare support for ART in general and IVF

in particular, should be available to prospective parents wishing to conceive who are unable to do so or who need donor eggs, sperm, or embryos in order to achieve a successful pregnancy.

26. It is recommended that the Australian National Fertility Law review and align the rights of unpartnered individuals and their children with the rights of partnered couples and consider;

- Amending the Family Law Act to remove discrimination based on marital status for donor recipients and their children.
- Reviewing Federal Government administrative processes to ensure that they work in a fair and non-discriminatory fashion for all families.
- Supporting State legislation is reviewed to remove discrimination based on marital status for donor recipients and their children.

27. Australian State & Territory and New Zealand governments engage pedagogy experts to assist in the development of nationally appropriate school-based curriculum on fertility. As part of this process, FSANZ engage with the state and federal Ministers for Health and Education.

28. Australian State & Territory and New Zealand governments work with FSANZ as well as Public Health and Community engagement experts to develop a wider community education campaign on fertility health promotion to enhance awareness of fertility and the factors that affect it. This should include campaign elements that specifically target men. This should include a campaign to address donor shortages and increase awareness about donation.

29. The Australian Federal Government should commit to 5-year funding plan for The Australian Reproductive Database, the publication of that data on an annual basis and the Your IVF Success Website (currently provisioned for with an Australian Federal Government grant). Reproductive outcome data should be made available for research. If there were to be a new five-year funding model it would be appropriate for the collation, management and hosting of reproductive outcome data to be subject to an open and competitive tender process.

30. The National Donor Registry be established with the Federal Government to commit $2m to establish the Registry and $1m per annum for five years to maintain and operate the Registry.

31. The Australian Government consider an Expanded National Carrier Screening Program to offer all Australian parents access to screening conditions proposed under Mackenzie's Mission. Alternatively, the Government support the expansion of the current Medicare funded Carrier Screening Model conditions recommended under the MRFF funded Mackenzie's Mission Research Program. Access to PGT to be expanded in parallel with expanded carrier screening for couples identified as being at risk of carrying a listed condition.

32. All Australian clinics should be required to provide patients with a standard form optional donor consent with a plain English guide that would allow prospective IVF patients to donate surplus or unviable eggs, sperm or embryos or any combination thereof to research without the need for a subsequent second consent. Nationally accepted content forms could be authorized by RTAC. The Uniform National Law could contain any necessary legislative amendments. Patients should be given the option of identifying the nature of the research or donation of surplus or non-viable material. Counselling should be made available at the point of egg or sperm collection to support individuals to make informed decisions about their overall fertility journey and the implications of donation.

33. The Australian Government establish a 10-Year National Fertility Research Mission as a new mission under the Medical Research Future Fund with a representative from Scientists in Reproductive Technology (SIRT) to be included in the steering committee for the mission.

34. The 10-Year Nationality Fertility Research Mission would seek to address the following actions through multidisciplinary research:

- Improving Australia's birth rate.
- Benchmarking of Australia's IVF safety and effectiveness by global comparison.
- Assessment and evaluation of emerging global technologies and techniques, including IVF options and adjuvants, to further improve IVF safety and effectiveness.
- Use of broader ART techniques and practices to increase Australia's IVF safety and effectiveness.
- Continued expansion of carrier screening as a standard of care to reduce the number of children born with life threatening or debilitating genetic conditions.
- Consideration of the emerging science around most effective ovulation stimulation procedures, timing and ages.
- Consideration of future egg storage programs and practices in Australia and New Zealand.
- Identification of global best practice for education of prospective parents.
- Ongoing assessment of psychosocial implications and outcomes following ART use to ensure the practice reflects and promotes patient best interests.
- Longitudinal studies on the long-term health of ART offspring.

35. The Australian Government develop a National Fertility Plan which includes the following components:

- National Fertility Law
- National Donor Registry
- National Donor Bank
- A 10-Year MRFF Fertility Mission
- A National Fertility Roundtable which would help establish Terms of Reference for both the Mission and the proposed law.

FERTILITY SOCIETY
OF AUSTRALIA AND NEW ZEALAND

RTAC
REPRODUCTIVE TECHNOLOGY ACCREDITATION COMMITTEE