2022

# Senate Standing Committee on Community Affairs Submission

*"Fertility is not a given"*

IVF MEDICAL DIRECTORS GROUP

IVF MEDICAL DIRECTORS GROUP | 119 Buckhurst Street South Melbourne VIC 3205

# Contents

14 December 2022

Attn: Ms Potida Youhorn

Committee Secretary
Senate Standing Committees on Community Affairs
PO Box 6100
Parliament House
Canberra ACT 2600

Dear Ms Youhorn,

**RE: Universal Access To Reproductive Healthcare**

Please find attached our submission to the Senate Standing Committee on Community Affairs References Committee conducting an inquiry into Universal Access to Reproductive Healthcare.

Thank you for your invitation to provide a submission to the Senate standing committee on community affairs inquiry into universal access to reproductive healthcare.

The IVF Medical Directors Group (IVFMDG) is a body made up of the medical directors of all Reproductive Treatment Accreditation Committee (RTAC) licensed fertility clinics that provide Assisted Reproductive Treatments (ART) to patients in both Australia and New Zealand. The IVFMDG was established in 1989 to ensure the provision of safe, efficacious, accessible and affordable reproductive treatments for patients in Australia and New Zealand.

The IVFMDG achieves these objectives through the self-regulatory processes of RTAC, which supervises annual auditing of all clinics to ensure the services they provide comply with a code of conduct, guaranteeing safe and efficacious operation of clinics in the provision of ART.

The scope of ART includes: in-vitro fertilisation (IVF), intra-uterine insemination (IUI), intracytoplasmic sperm injection (ICSI), ovulation induction (OI), frozen embryo transfer (FET), cycle monitoring, gamete collection and storage, donor services, genetic counselling and services (PGT), ART specific pathology; and other surgical and pharmaceutical processes. ART clinics are responsible for assisting patients experiencing infertility to deliver approximately 15,000 newborn babies each year.

Clinic operations are a complex and diverse group of services, and this submission is an attempt to detail, contextually, operationally, and from a patient perspective, the engagement of Australian patients in securing appropriate fertility diagnosis and treatments.

We would welcome the opportunity for members of the IVFMDG to appear before the committee to deliver further evidence which may be of assistance in the Committee's considerations.

Yours faithfully,

Rick Forbes

IVF Medical Directors Executive

# 1. Term Of Reference 'A.' – Cost and Accessibility of Contraceptives

The availability of safe, efficacious, accessible and affordable contraceptives is fundamental to planning fertility and is strongly supported by the IVFMDG. Improving education processes for both women and men in the use and appropriateness of currently available contraceptive options would be an important initiative by government. ART clinics have been active in providing funding and support to the Fertility Matters Foundation, which is currently developing education modules for introduction into Australian schools to provide younger Australians with comprehensible information about contraceptive methods. The improved educational information made available in the past two decades has significantly reduced unplanned pregnancies of women under 19 years of age. Any measure which can improve the broader understanding of the place and utilisation of pharmacological contraception is to the broader benefit of the community and specifically enables appropriate planning of conception.

# 2. Term Of Reference 'B.' - Cost And Accessibility Of Reproductive Healthcare, Including Pregnancy Care And Termination Services Across Australia, Particularly In Regional And Remote Areas

In assessing accessibility to reproductive healthcare and pregnancy care, Australia must be proud that its prenatal, postnatal and obstetric care rates in the top five nations in all measurable performance criteria relating to safety and efficacy. Affordability of services is still prone to regional variation, and the various existing schemes to improve access still require improvement. Access to ART is affected by:-

1. Geography
2. Affordability

Patients experiencing infertility can find it difficult to secure an appropriate diagnosis and subsequent treatment in regional and rural areas. Accessibility and affordability are inextricably linked, particularly in rural and regional areas. Affordability can be more difficult for patients located in rural and regional areas. More assistance is needed in providing funding, enabling patients to access appropriate diagnoses and treatment.

## 1.1 Clinic Classification

There are established RTAC ART clinics in every state and territory in Australia. These ART clinics vary in service offerings and are classified differently under the RTAC Code of Practice (CoP). Under the RTAC CoP, a clinic either falls under the definition of an "ART unit"[1] or a "satellite unit".[2] The difference between an "ART unit"[3] and a "satellite unit"[4] is determined by whether they have a resident ART laboratory facility co-located on-site. Accessibility has been described in addressing the committee's terms of reference by adopting a categorisation of ART clinics with reference to the service offering. In preparing this submission, we have determined the measure of accessibility based on the presence of an ART unit and not a satellite unit.

A categorisation of clinics has been adopted in table 1 based on a broad description of the differing treatment offerings available in Australian ART clinics.

[1] Reproductive Technology Accreditation Committee RTAC, 'Code of Practice for Assisted Reproductive Technology Units' (2021), p 26, s 4 (definition of 'ART Unit').
[2] Ibid p 28, s 4 (definition of 'Satellite Unit').
[3] ART Unit definition: A facility with a laboratory collecting or preparing human gametes and/or embryos for therapeutic service, possibly across a range of sites of clinical activity. Where the collection of gametes/embryos takes place at a different site to the preparation, the two sites are considered to be a single ART Unit.
[4] Satellite Unit definition: A satellite unit is a unit that does not have a resident laboratory or laboratory facilities.

**Table 1. ART Clinic Classification**

| Clinic Service Description | Acronym | Services Provided |
|---|---|---|
| Full-Service, Pathology And Genetics | FSPG | 1. IVF<br>2. IUI<br>3. ICSI<br>4. OI<br>5. FET<br>6. Cycle Monitoring<br>7. Pathology (Andrology, Endocrinology, Infectious Disease Testing, Tumour Marker Testing)<br>8. Genetics (PGT-A, PGT-M, PGT-SR, NIPT) |
| Full-Service, Pathology | FSP | 1. IVF<br>2. IUI<br>3. ICSI<br>4. OI<br>5. Cycle Monitoring<br>6. FET<br>7. Pathology (Andrology, Endocrinology, Infectious Disease Testing, Tumour Marker Testing) |
| Full-Service | FS | 1. IVF<br>2. IUI<br>3. ICSI<br>4. OI<br>5. Cycle Monitoring<br>6. FET |
| Subsidiary Clinic | SC | 1. Oocyte Pick Up<br>2. Pathology Specimen Collection |

**Key To Table 1. ART Clinic Classification:**

- IVF: In-Vitro Fertilisation
- IUI: Intrauterine Insemination (Otherwise Known As Artificial Insemination (AI))
- ICSI: Intracytoplasmic Sperm Injection
- OI: Ovulation Induction
- FET: Frozen Embryo Transfer
- In ART Clinics, ART Related Pathology Includes*:
  i. Endocrine Pathology Includes Tests For:
     - Pituitary And Gonadal Function
     - Pregnancy
     - Androgen Profiles
     - Thyroid Function
     - Growth Hormone
     - Insulin-Like Growth Factor (Igf1)
  ii. Andrology Pathology Includes:
     - Semen Analysis
     - Sperm Antibodies
     - Sperm DNA Fragmentation Assays
     - Sperm Binding Assays
     - Sperm Penetration Assays
  iii. ART Associated Tumour Marker Pathology Includes:
     - Cancer Antigen 125 (CA125) (Used In The Diagnosis And Management Of Ovarian Cancer)
  iv. ART Associated Infectious Disease Testing
     - Hepatitis B
     - Hepatitis C
     - HIV
     - HTLV
     - Syphilis
     - Varicella
     - Rubella
     - Cytomegalovirus (CMV), ZICA
- In ART Clinics, ART Associated Genetic Testing Includes:
  i. Karyotyping For Aneuploidies, Rearrangements And Microdeletions
  ii. Analysis Of Chromosomal Regions For Specific Constitutional Genetic Abnormalities
  iii. Molecular Testing For Inherited Diseases By Genome-Wide Methods (Whole Genome Sequencing (WGS))
  iv. Preimplantation Genetic Testing (PGT)
     - For Aneulploidy (PGT-A)
     - For Specific Inheritable Monogenic Genetic Disorders (PGT-M)
     - For Structural Rearrangements (PGT-SR)
  v. Non-Invasive Prenatal Testing (NIPT)

## 2.2 Clinic Service Offering

RTAC-accredited clinics, while meeting the RTAC code of practice, offer differing services to meet patient needs. Clinics based in capital cities and major centres generally have greater resources and can provide a wider range of services for patients than those based in rural and regional areas. This is not inconsistent with the broader range of medical services and concentration of resources in other medical specialities. [5]

Graphics 1 - 9 provide geographic heatmaps that display the concentration of treatment availability.

## 2.3 Clinic Distribution

ART clinic distribution is clustered, with the highest concentration in the major metropolitan centres on the eastern seaboard of Australia.[6] Regional clinics vary in their service offering compared to the full-service clinics in metropolitan centres.

The Australian Bureau Of Statistics (ABS) publishes and maintains The Australian Statistical Geography Standard (ASGS),[7] which provides definitions of remoteness. Remoteness areas divide Australia into five classes of remoteness based on a measure of relative access to services.
The Five Classes Are:

1. Major Cities of Australia
2. Inner Regional Australia
3. Outer Regional Australia
4. Remote Australia
5. Very Remote Australia

Access to services is measured using the Accessibility And Remoteness Index Of Australia (ARIA+), 'ABS Structures' defined and maintained by the ABS.

[5] Australian Institute of Health and Welfare, 'Rural and Remote Health' (Research Paper, AIHW, 07/07/2022).
[6] For reference, see Graphic 1. Distribution of ART Clinics around Australia.
[7] ABS, 'Australian Statistical Geography Standard' (Standard, Australian Bureau of Statistics).

## 2.4 Initiatives That Support Regional Access To ART

Commonwealth and state initiatives are in place, supporting rural and regional patients in gaining access to medical specialists, general practitioners and other allied health professionals.

The Rural Health Outreach Fund (RHOF) supports outreach initiatives that improve access for patients in rural, regional and remote areas.[8] Unlike state-based initiatives, which aim to reimburse patients for reasonable costs, including travel and accommodation, the RHOF supports the delivery of outreach health services. However, the design of this program has not resulted in any significant improvement in patient access to specialist services delivered in ART. A new approach must be found to meet the objectives of providing patients affordable access to ART services. Access to state systems varies according to meeting criteria that are not consistent across all states.

[8] Cth Department of Health, 'Rural Health Outreach Fund' (2021).

**Table 2. State-Based Remote Patient Access Scheme Eligibility Summary**

| State | Remote Patient Access Scheme Eligibility | Distance Threshold |
|---|---|---|
| **NSW.**[9] | • Be a resident of NSW or Lord Howe island<br>• Be enrolled with Medicare<br>• Not be receiving, or eligible for, financial assistance for travel and accommodation from third-party insurance or other Australian government services<br>• Be referred for treatment at their nearest health service<br>• Receive treatment at an approved health service. | • Travel from their residence for treatment at least 100km (one way), or at least 200 km in a week, by making multiple trips to and from treatment. |
| **VIC.**[10] | • Be a Victorian resident<br>• Live in a Department of Health & Human Services designated rural health region<br>• Be receiving specialist medical treatment from a medical practitioner registered with Medicare Australia and recognised as a specialist in a particular specialty under the H*ealth Insurance Act 1973* (Cth) as per schedule 4 of the *Health Insurance Regulations 1975* (Cth). | • Need to travel more than 100 kilometres one way or an average of 500 kilometres a week for one or more weeks. |
| **QLD.**[11] | • Eligible for Medicare<br>• Be a permanent Queensland resident or person of no fixed address, or a student living at a Queensland boarding school or university campus.<br>• Have an eligible referral for an approved specialty.<br>• Unable to use telehealth. | • Required to travel more than 50 kilometres (one way) (from the public hospital or public health facility closest to their permanent address) to attend the nearest eligible specialist health service. |
| **SA.**[12] | • Be a permanent South Australian resident<br>• Be enrolled in Medicare and receive treatment claimable through Medicare<br>• Not receive, or be eligible for, financial assistance for travel and accommodation through another provider, and have claimed any available benefits from a private health fund first, if applicable<br>• Have an appointment with or receive treatment from the nearest recognised medical specialist or approved medical specialist service. | • Be travelling more than 100km from their residence to their appointment or treatment location. |

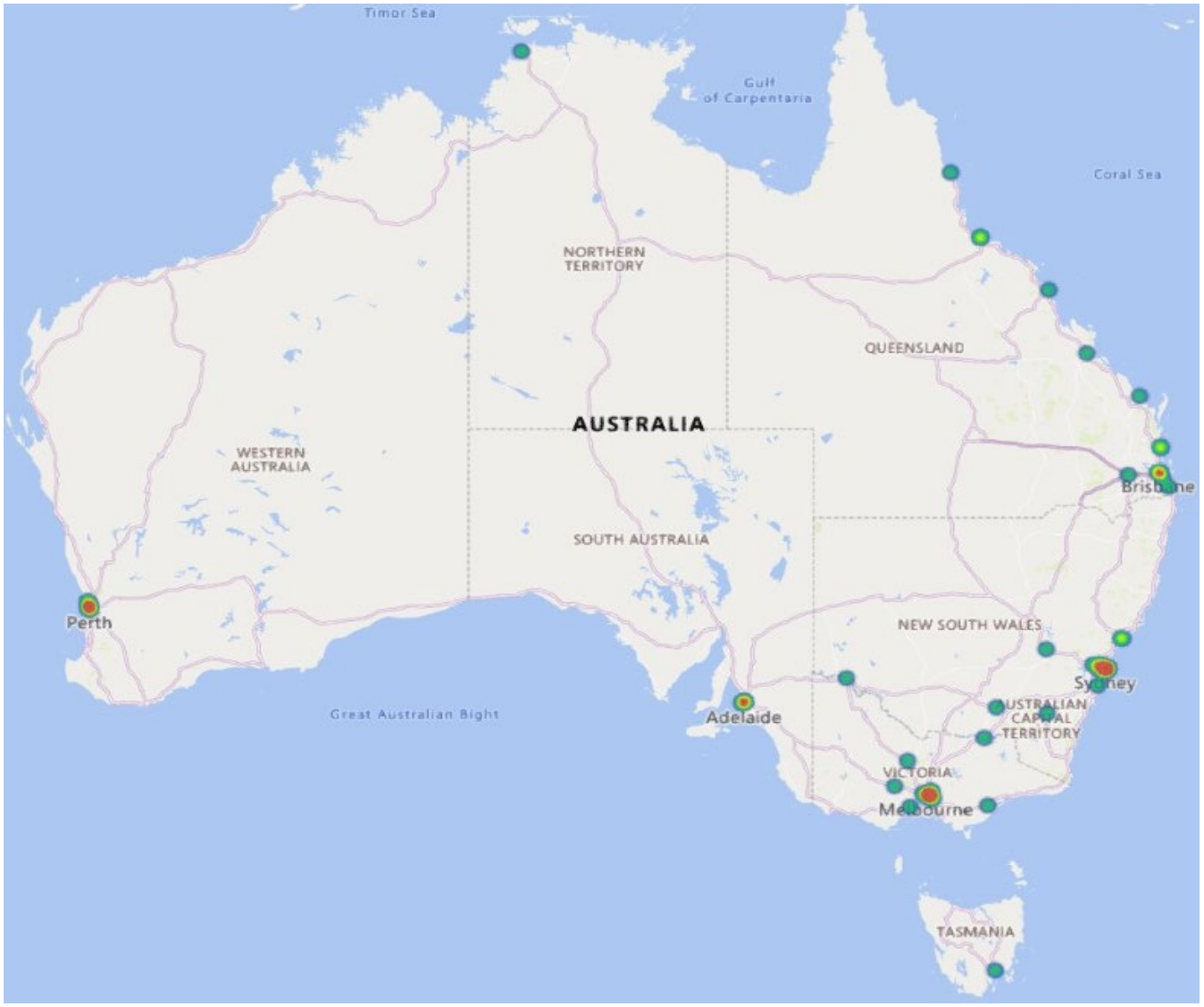
[9] NSW Department of Health, 'Isolated Patients Travel and Accommodation Assistance Scheme (IPTAAS)' (2022).
[10] VIC Department of Health, 'Victorian Patient Transport Assistance Scheme (VPTAS)' (2022).
[11] QLD Department of Health, 'Patient Travel Subsidy Scheme (PTSS)' (2018).
[12] SA Department of Health, 'Patient Assistance Transport Scheme (PATS)' (2022).

| State | Remote Patient Access Scheme Eligibility | Distance Threshold |
|---|---|---|
| **WA.**[13] | • Be a permanent resident of Western Australia<br>• Be enrolled in Medicare and receive treatment claimable through Medicare<br>• Not receive, or be eligible for, financial assistance for travel and accommodation through another provider, and have claimed any available benefits from a private health fund first, if applicable<br>• Have an appointment with or receive treatment from the nearest recognised medical specialist or approved medical specialist service. | • Be travelling more than 100km from their residence to their appointment or treatment location. |
| **TAS.**[14] | • Be a Tasmanian permanent resident;<br>• Be travelling by the least expensive form of transport;<br>• Have a PTAS application form signed by your referring medical specialist, oral/maxillofacial surgeon or rural GP referring you to the nearest appropriate specialist;<br>• Be receiving treatment claimable under Medicare from a recognised medical specialist; and<br>• Not be entitled to financial assistance through another scheme, e.g. motor accident insurance board (MAIB), department of veterans affairs (DVA), workers compensation, or other compensable schemes. | • If you live more than 50 kilometres (one way) from the nearest oncology or dialysis treatment centre<br>• If you live more than 75 kilometres (one way) from the nearest appropriate specialist medical service<br>• More than 75 kilometres (one way) to access lymphoedema treatment<br>• You can only receive financial support for interstate treatment if it is unavailable in Tasmania. |
| **NT.**[15] | • Are an Australian citizen or permanent resident and currently residing in the Northern Territory.<br>• Are eligible for Medicare.<br>• Have a current referral to the nearest approved specialist medical service in th e Northern Territory;<br>• Access to the patient assistance travel scheme (pats) ceases for ART patients on the first live birth. | • Live more than 200km away (one way) from the nearest approved specialist medical service, or travel more than 400k cumulatively per week for oncology or renal treatment. |
| **ACT.**[16] | • A permanent resident of the act<br>• Enrolled, or eligible to be enrolled with Medicare, including asylum seekers<br>• Not receiving, or eligible for, financial assistance for travel and accommodation from third-party insurance or other Australian state and territory government services<br>• Referred for medical care interstate by an act or Queanbeyan registered medical professional<br>• Referred to the service closest to the act that provides the medical care you need | • No explicit distance threshold. |

[13] WA Department of Health, 'Patient Assisted Travel Scheme (PATS)' (2022).
[14] TAS Department of Health, 'Patient Travel Assist Scheme (PTAS)' (2022).
[15] NT Department of Health, 'Patient Assistance Travel Scheme (PATS) Guidelines' (2017).
[16] ACT Department of Health, 'Interstate Patient Travel Assistance Scheme (IPTAS)' (2020).

There are unbreakable links between cost, accessibility and affordability. For The RHOF to achieve its original objectives of providing affordable and accessible services a redesign is important to ensure that choice and affordability are made available to patients in rural and regional areas. Particularly access to bulk-billed services, which are more predominant in major centres.

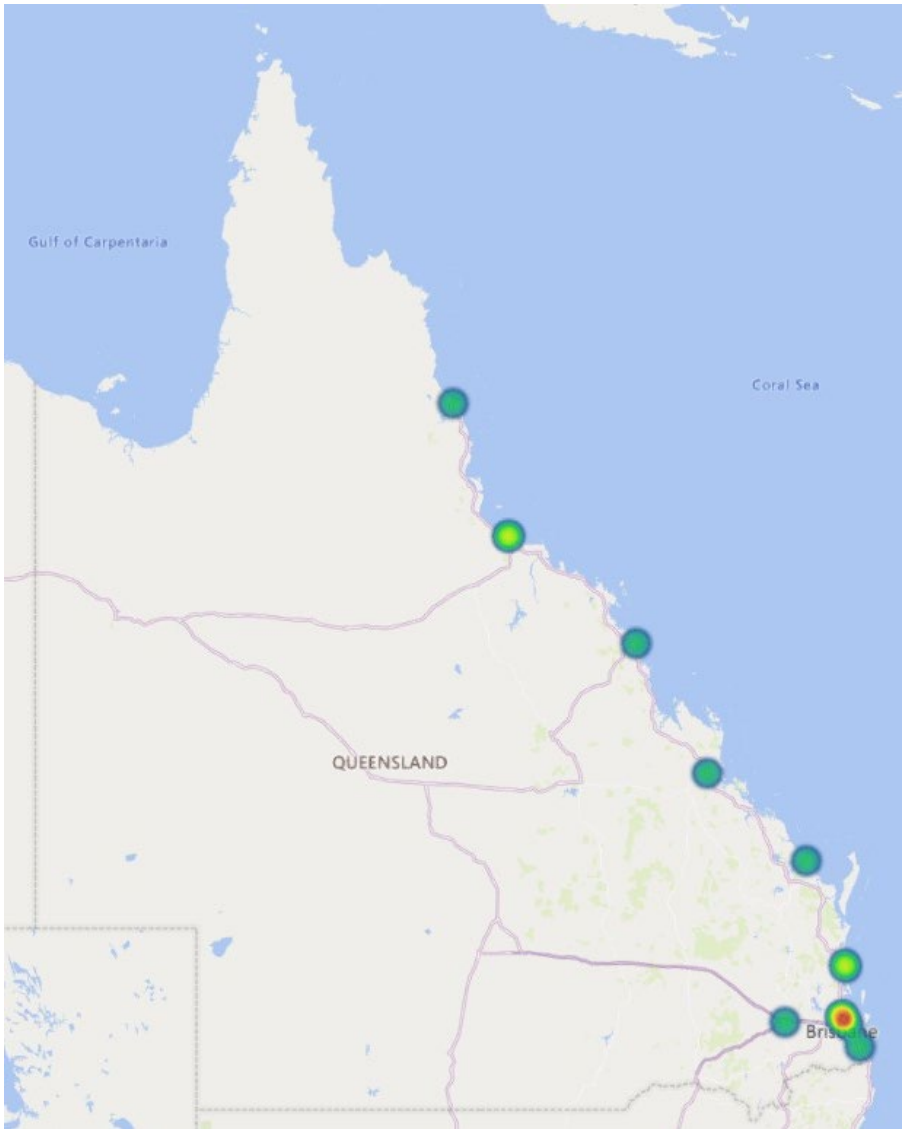
**Graphic 1: Distribution Of ART Clinics Around Australia**



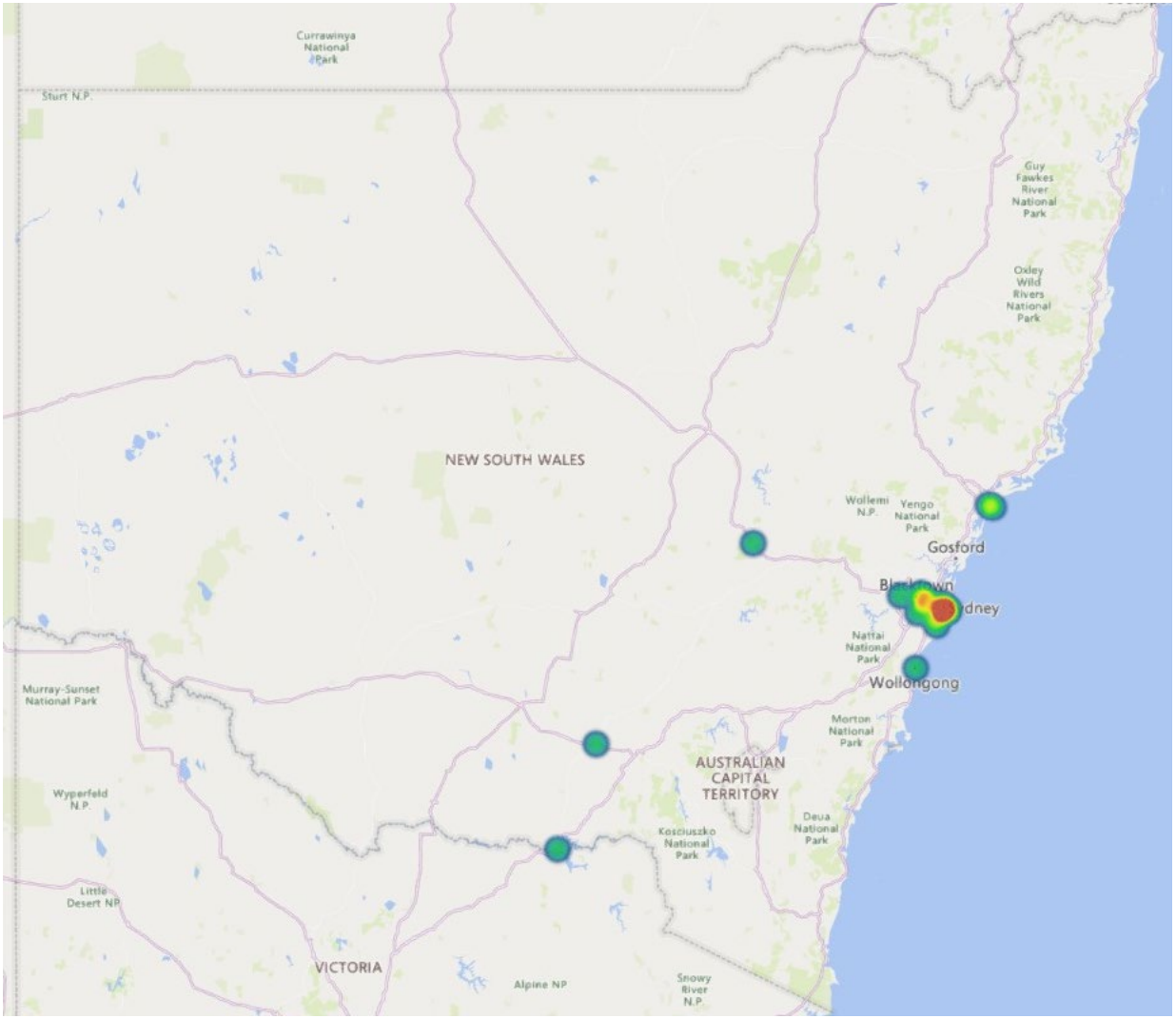
**Graphic 2. Distribution Of Clinics In Western Australia**

**Graphic 3. Distribution Of ART Clinics In The Northern Territory**

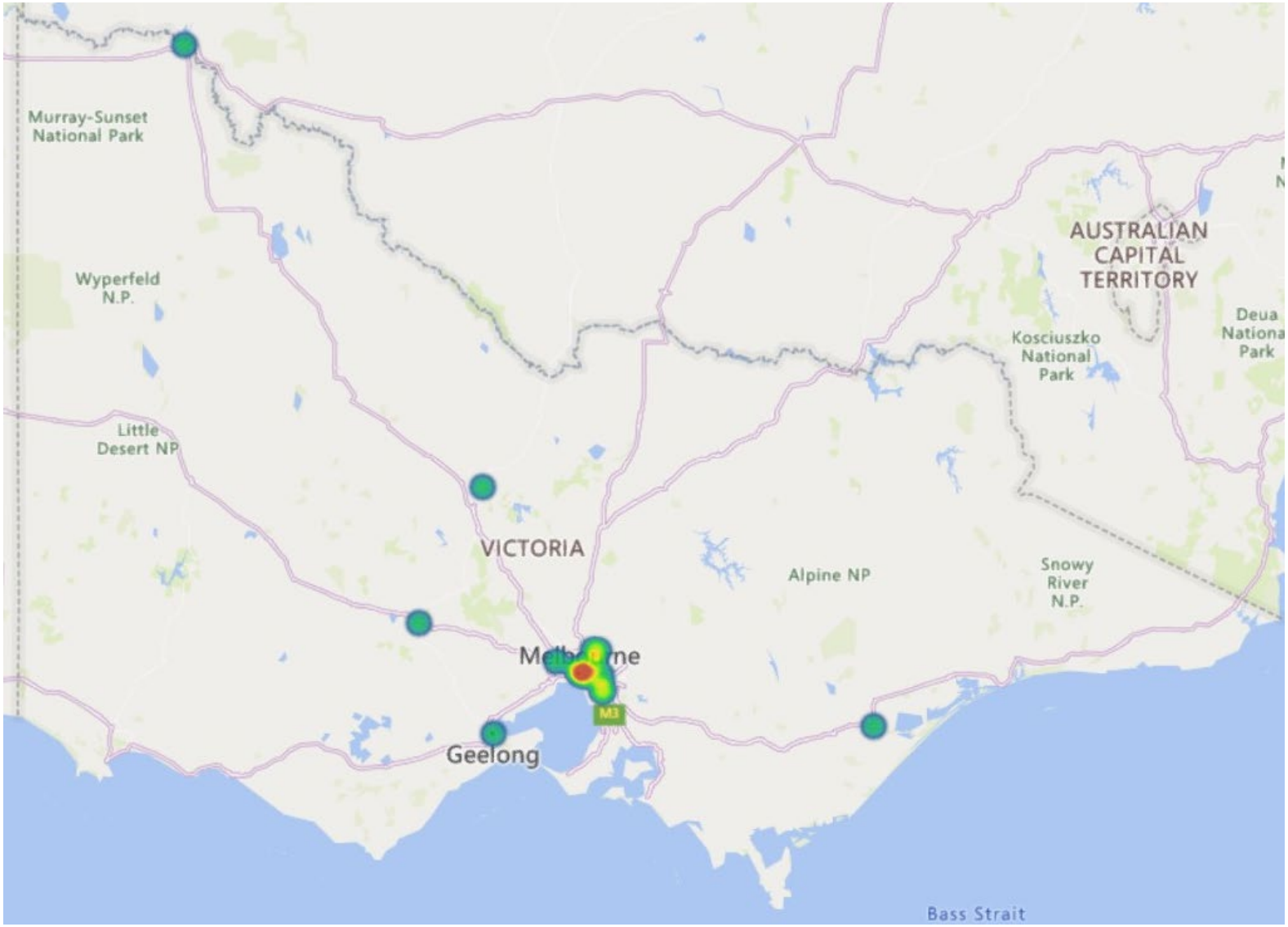
**Graphic 4. Distribution Of ART Clinics In Queensland**



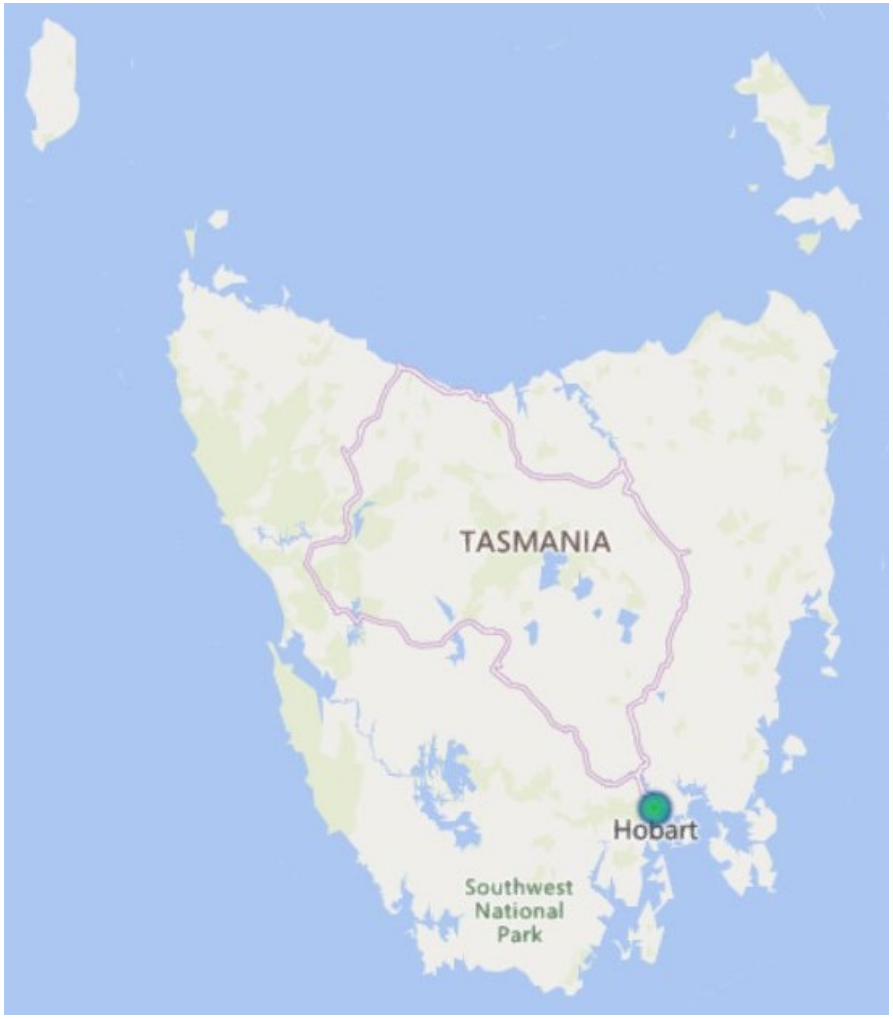
**Graphic 5. Distribution Of ART Clinics In New South Wales**



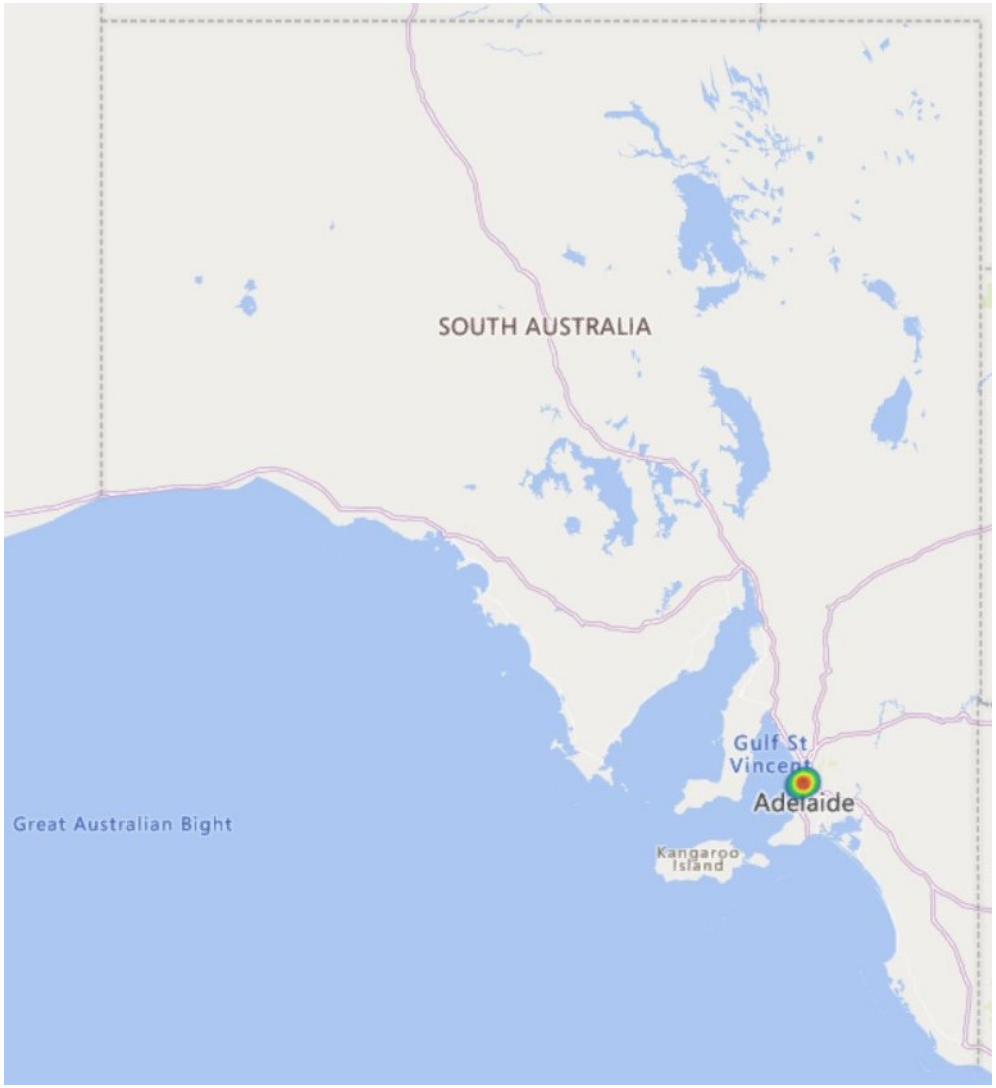
**Graphic 6. Distribution Of ART Clinics In Victoria**



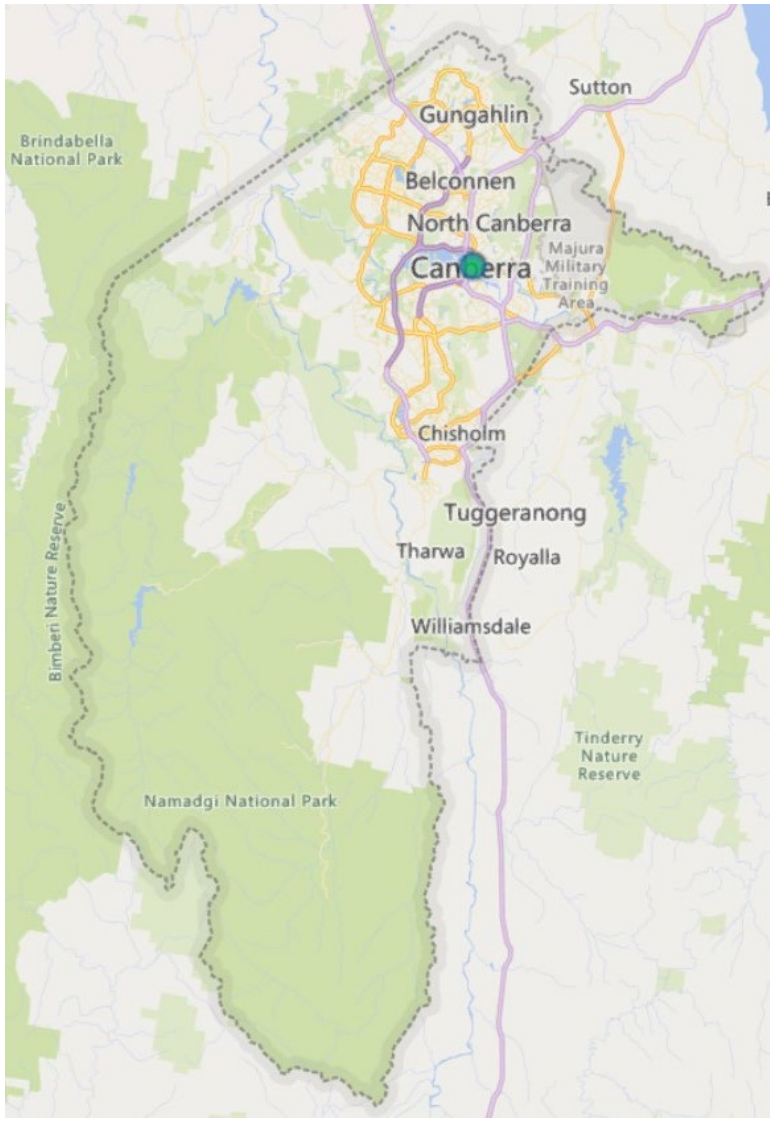
**Graphic 7. Distribution Of ART Clinics In Tasmania**



**Graphic 8. Distribution Of ART Clinics In South Australia**



**Graphic 9. Distribution Of ART Clinics In The Australian Capital Territory**



## 2.5 Differences In Costs For ART Services

### 2.1.1 Socio-Economic Status And Access To ART

Labour force data shows that people aged 15 and over living in metropolitan areas are more likely to be employed than those living outside these areas. This may be due to lower opportunities and access to work outside metropolitan areas and a smaller range of employment and career opportunities in these areas.[17]

People living in rural and remote areas generally have lower incomes and pay higher prices for food and services.[18] From 2017 to 2018, Australians living outside capital cities had, on average, 19% less household income per week than any capital city and 30% less mean household net worth.[19]

Several studies have analysed the difference in access to assisted reproductive treatment in Australia.[20] A study conducted in 2016 found significant variation in assisted reproductive technology usage between Australian postcodes after adjusting the socio-economic status, remoteness, jurisdiction and the need for fertility treatment.[21] For example, women in the second most advantaged SES quintile had 86% reduced access to treatment compared with women in the most advantaged quintile. Women in the most disadvantaged quintile had a 16% reduction in access compared to women in the most advantaged quintile. In general, those women who live in regional and remote areas had a 12% reduction in access to treatment after accounting for SES, jurisdiction and the need for fertility treatment.[22]

Special consideration needs to be given to patients experiencing infertility to provide affordable access, given that services are concentrated in major urban centres. In particular, the bulk billed services in regional areas are negligible compared to offerings in the major capital cities.

[17] ABS, 'Labour force status by age (detailed), greater capital city and rest of state (ASGS) and sex, January 1991 onwards' (Research Paper, Australian Bureau of Statistics).
[18] NRHA, 'Income inequality experienced by the people of rural and remote Australia' (Submission, National Rural Health Alliance Inc.).
[19] Ibid.
[20] Iolanda S. Rodino, Sonja Goedeke and Sarah Nowoweiski, 'Motivations and experiences of patients seeking cross-border reproductive care: the Australian and New Zealand context' (2014) 102(5) *Fertility and Sterility* 1422-1431; Katie Harris et al, 'Socio-economic disparities in access to assisted reproductive technologies in Australia' (2016) 33(5) *Reproductive BioMedicine Online* 575-584.
[21] Harris et al (n 18).
[22] Georgina M. Chambers et al, 'The economic impact of assisted reproductive technology: a review of selected developed countries' (2009) 91(6) *Fertility and Sterility* 2281-2294.

# 3. Term Of Reference 'C.' - Workforce Development Options For Increasing Access To Reproductive Healthcare Services, Including GP Training, Credentialing And Models Of Care Led By Nurses And Allied Health Professionals;

People living in rural and remote areas face barriers to accessing healthcare due to the challenges of geographic spread, low population density, limited infrastructure, and the high cost of delivering rural and remote healthcare. Patients living in rural and remote areas bear the brunt of workforce shortages and maldistribution of ART services. There is a worldwide shortage of qualified ART specialists, scientists and nurses. This is reflected in the significant decline in the rate of full-time equivalent (FTE) medical practitioners per 100,000 population outside of major urban areas. This has particular implications for rural and regional areas where there is a proven historical record of difficulty in attracting specialist medical services into rural and remote areas.[23]

## 2.1 Royal Australian And New Zealand College Of Obstetricians And Gynaecologists (RANZCOG) Fellowship

The Royal Australian and New Zealand College Of Obstetricians and Gynaecologists (RANZCOG) Fellowship is the admission to the specialty of Obstetrics And Gynaecology. It demonstrates to governments and the community that a Fellow has met the required level of competence to deliver unsupervised services and any obstetric or gynaecology setting in Australia and New Zealand. The Fellowship training program is six years of hospital-based training and assessment and entails four years of foundational training, and two years of advanced training. In ART clinics, all medical and clinical directors are experienced Fellows of RANZCOG.

## 2.2 Certificate Of Reproductive Endocrinology And Infertility (CREI) Subspecialty Training

The Royal Australian and New Zealand College of Obstetricians and Gynaecologists offers five subspecialty training programs for certification in gynaecological oncology (CGO); maternal fetal medicine (CMFM); obstetrical and gynaecological ultrasound (COGU); reproductive and endocrinology and infertility (CREI); and urogynaecology (CU). The CREI subspecialty training program is undertaken after completing general specialisation (Fellowship of the Royal Australian and New Zealand College of Obstetricians and Gynaecologists) in obstetrics and gynaecology. CREI indicates that doctors have completed a minimum of three additional years of full-time training in all aspects of reproductive endocrinology and infertility, such as IVF, recurrent miscarriage, laparoscopic surgery, and hysteroscopic surgery. It is estimated that a total of 15 years of medical training is required to become a CREI subspecialist.

[23] ABS, 'Labour force status by age (detailed), greater capital city and rest of state (ASGS) and sex, January 1991 onwards' (n 17).

## 2.3 Telehealth

Telehealth is a critical component of healthcare across Australia. Specialist consultations through telehealth have facilitated safe and timely community access to essential assisted reproductive treatment throughout the pandemic. These services provide additional access pathways to assisted reproductive treatment, particularly for rural and regional patients with limited access to services in their local area. Since the advent of electronic prescribing and pathology referral, telehealth arrangements have become a complete package for remote management of ART patients. This has enabled ART clinicians to plan and manage cycles for patients where a face-to-face examination is not medically indicated. Medicare funding of telehealth to enable equitable access for patients to ART has been, and continues to be, vital.

## 4. Term Of Reference 'D.' - Best Practice Approaches To Sexual And Reproductive Healthcare, Including Trauma-Informed And Culturally Appropriate Service Delivery;

Pelvic infections are significant causes of infertility, primarily as a result of tubal damage in women accessing ART. Damage to the fallopian tubes from infections may be due to adhesions, tubal mucosal damage, or tubal occlusion that interferes with normal ovum transport. Infections most commonly related to infertility include gonorrhoea, chlamydia, and resultant pelvic inflammatory disease. Some of the consequences of these infections which impact fertility include ectopic pregnancy, infertility, chronic pelvic pain, hydrosalpinx, and tubo-ovarian abscess. Compromised tubal function can occur after external or internal injury. Most often, tubal infertility is the result of infection. Pelvic inflammatory disease is an acute infection in which organisms are sent to the uterus and fallopian tubes from the cervix. Chlamydia is predominant in the infertile population and may be detected in up to 90% of women screened.[24]

Chlamydia infection is the most prevalent bacterial sexually transmitted infection (STI) recognised around the world and was diagnosed 86,916 times in Australia in 2021.[25] Chlamydia does not only affect women's fertility, it causes dramatic genetic damage in sperm, leading to male infertility. Men with chlamydia have more than three times the normal level of DNA fragmentation in their sperm. Appropriate antibiotic treatment for affected males can help restore the genetic integrity of the affected sperm, restoring fertility. Women with tubal damage or pelvic inflammatory disease resulting from chlamydia or gonorrhoea infection are offered gynaecological surgery and pharmaceutical treatments to remedy the damage prior to commencing fertility treatment.

Particular populations experience disproportionate representation in chlamydia diagnosis. In 2021, chlamydia incidence among HIV-positive gay and bisexual men was 1.5 times higher than among HIV-negative gay and bisexual men.[26] Clinical guidelines recommend offering chlamydia testing to all young people annually, and more frequently to patients who are deemed to be higher risk.[27]

Most STI's among people between the ages of 15 and 29 years old remain undiagnosed and untreated, highlighted the need for further testing to be regularly offered to sexually active adolescents and young adults. Often, it is only when these young people unsuccessfully attempt to conceive spontaneously and are referred for fertility treatment that these diagnoses are made. ART clinics routinely screen patients for blood-borne and STI's as part of the initial patient workup as well as infections that may affect the viability of a pregnancy,

[24] Gabriel Ånestad et al, 'Infertility and chlamydial infection' (1987) 48(5) *Fertility and Sterility* 787-790.
[25] Jonathan King et al, 'HIV, viral hepatitis and sexually transmissible infections in Australia' (Annual Surveillance Report, Kirby Institute, UNSW Sydney, 2022).
[26] Ibid.
[27] Australasian Society for HIV Viral Hepatitis and Sexual Health Medicine (ASHM), 'Australian STI management guidelines for use in primary care' (Management Guidelines, 2021).

or the health of the child to be born. Infection with chlamydia, donovanosis, gonorrhoea, HTLV, HIV, HSV1 and HSV2 has potential health implications for the newborn.

ART clinics form a critical part in symptomatic and asymptomatic STI screening, diagnosis and treatment.

Effective measures to reduce the incidence of STIs within both targeted groups and the wider community could reduce the incidence of STIs with their potential damage to fertility and genetics. The campaign to reduce the incidence of donovonosis in targeted indigenous communities has been highly successful in reducing the incidence from 36 cases to only two cases reported since 2012.[28] A strong public education program may be able to address the gap between reported cases and the incidence rates, which many medical practitioners believe that incidence rates may be up to four times higher than reported rates for STIs.

There are a number of infections that patients presenting for infertility treatment at ART clinics may be screened for:-

- Chlamydia
- Cytomegalovirus (CMV), ZICA
- Donovanosis
- Gonorrhoea
- Hepatitis B
- Hepatitis C
- Human Immunodeficiency Virus (HIV)
- Human T-lymphotrophic virus 1 (HTLV)
- Rubella
- Syphilis
- Varicella

[28] F J Bowden, 'Donovanosis in Australia: going, going…' (2005) 81(5) *Sexually Transmitted Infections* 365-366; Skye McGregor, Hamish McManus and Richard Gray, 'HIV, viral hepatitis and sexually transmissible infections in Australia' (2022).

## 5. Term Of Reference 'E.' - Sexual And Reproductive Health Literacy;

Sexual and reproductive health literacy is integral to access to reproductive healthcare. A study published in 2012 in human reproduction investigated American male and female undergraduate university student fertility intentions and 'Fertility Literacy'.[29] in that study, the average participant reported their knowledge of fertility issues as slightly greater than 'Somewhat Educated'. About half of the participants believe that they Are either 'educated' or 'very educated' regarding fertility issues. Women and men gained most of their fertility knowledge from school (46%), family (20%), friends (9%) and doctors/gynaecologists (5%). Women were more likely to report gaining fertility knowledge from their family doctor or gynaecologist.

In 2020, Your Fertility surveyed more than 700 Australians, which found that most respondents (58%) believe a woman's fertility starts to decline from age 35 or older. Only 31% knew the decline starts at around age 30. The survey also found that most respondents overestimated IVF success rates, which works for about half of all people who try it. Most respondents thought a woman in her 20s had a 35% to 50% chance of having a baby following one cycle of IVF and the real chances were close to 30%. Similarly, most respondents overestimated the chance of IVF working for a woman in her 40s, with many estimating success rates of 20% plus.[30]

The trend of overestimating success rates of ART coupled with a misunderstanding of the age at which both male and female fertility markedly declines gives rise to significant issues and even involuntary childlessness if men's and women's reproductive decisions are based on inaccurate perceptions.[31]

Participants generally perceived themselves as being educated about fertility issues in Your Fertility and Human Reproduction studies. Both men and women vastly overestimated the ages at which female fertility starts to decline. Studies on societal trends in developed countries also demonstrate an increase in age for first-time mothers.[32] In the Human Reproduction study, only 2% of female participants plan to have their first child at age 35 or

[29] Brennan D. Peterson et al, 'Fertility awareness and parenting attitudes among American male and female undergraduate university students' (2012) 27(5) *Human Reproduction* 1375-1382.
[30] Ibid.
[31] Sara Deatsman, Terrie Vasilopoulos and Alice Rhoton-Vlasak, 'Age and fertility: a study on patient awareness' (2016) 20(3) *JBRA assisted reproduction* 99; Yael Hashiloni-Dolev, Amit Kaplan and Shiri Shkedi-Rafid, 'The fertility myth: Israeli students' knowledge regarding age-related fertility decline and late pregnancies in an era of assisted reproduction technology' (2011) 26(11) *Human reproduction* 3045-3053.
[32] Karin Hammarberg and Maggie Kirkman, 'Infertility in resource-constrained settings: moving towards amelioration' (2013) 26(2) *Reproductive BioMedicine Online* 189-195; Søren Ziebe, Paul Devroey and on behalf of the State of the ART Workshop Group, 'Assisted reproductive technologies are an integrated part of national strategies addressing demographic and reproductive challenges' (2008) 14(6) *Human Reproduction Update* 583-592; Mark P. Connolly et al, 'The costs and consequences of assisted reproductive technology: an economic perspective' (2010) 16(6) *Human Reproduction Update* 603-613.

older – the complex decision-making process occurs when women must balance childrearing with education, career aspirations, health and partner selection.[33]

Should a young woman's educational and career goals become of greater importance as she ages, she may postpone motherhood to accommodate these other priorities, whether this postponement is consistent with her original plans for parenthood or not.[34]

The inclusion of fertility health education in the Australian curriculum offers an opportunity to integrate and connect with other learning areas, particularly humanities and social sciences.

## 5.1 The Fertility Matters Foundation

The Fertility Matters Foundation is a not-for-profit health education charity started by Candice Thum (nee reed) and Rebecca Featherstone, two of Australia's first IVF children. The Foundation is focused on increasing fertility health knowledge across Australia, starting with youth. The Foundation derives its membership from patients, IVFlings (a colloquialism for children born via IVF or other assisted conception methods), clinicians and interested parties. The Foundation has secured a groundswell of support in remedying the significant fertility knowledge deficit in reproductive-aged adults identified in the aforementioned studies.

With the assistance of the ART sector, the Foundation has developed several education modules that cover an introduction to fertility health, myth-busting common misconceptions about fertility, and a module dedicated to the unique challenges faced by the LGBTQIA+ community and fertility. Fertility health education is strength-based, addressing physical, social and emotional challenges in the modules; these modules also encourage positive practices concerning individual reproductive health. Through the modules, the Foundation's objective is not to encourage or advocate for teenage pregnancy. Rather, it is the intent to arm reproductive aged people with relevant, timely, and easy to understand information about their fertility through a medium which has the best chance of getting the message across.

[33] Peterson et al (n 24).
[34] Connolly et al (n 27).

## 6. Term Of Reference 'F.' - Experiences Of People With A Disability Accessing Sexual And Reproductive Healthcare;

The Commonwealth Medicare Benefits Schedule (MBS) contains a number of procedures which may be used in treating people with a disability. In reproductive healthcare, patients with an congenital, iatrogenic or acquired disability may access treatments with rebates for gynaecological and Assisted Reproductive Treatment. There are a number of gynaecological item numbers that deal with remedying physiological causes of infertility that arise as a result of congenital absence, or malformation of, the female reproductive tract. For male patients with spinal injuries or medical induced impotence a specific item number exists in the ART MBS items for collection of semen for the purposes of analysis, storage or assisted reproduction.[35]

[35] Department of Health, 'Medicare Benefits Schedule', December 2022) Item Number 13290.

# 7. Term Of Reference 'G.' - Experiences Of Transgender People, Non-Binary People, And People With Variations Of Sex Characteristics Accessing Sexual And Reproductive Healthcare;

## 7.1 Unregulated Donor Market

RTAC-Accredited ART clinics in Australia have provided regulated donor sperm services. Due to increased demand, supply shortages and cost, an unregulated secondary market has emerged to provide donor sperm on request to patients.[36] this differs from the occasional private arrangement between friends, which may lead to home self-determination. The rising unregulated donor sperm has seen local and overseas donors travel from state to state, offering insemination services virtually to anyone who wishes to pay for it. Stories have been reported in the press of donors fathering hundreds of pregnancies.[37]

The advantages of a regulated and accredited donor sperm supply are:

- All donors have medical and family history screening which is available to the recipients
- All donors and recipients have professional counselling prior to treatment and as an ongoing service
- All donors have reliable infectious disease testing prior to sperm being used
- All donor sperm has a quarantine period before use and is retested for infectious diseases
- Most sperm donors now have genetic carrier screening
- Accurate records are kept of donor, recipient and children
- These records are audited for compliance
- There are strict family limits for each donor, limiting the number of fathered children
- Most importantly, the service guarantees that children can access their records at the age of 18 years, and bilateral anonymity is prohibited
- Sibling registers are now being offered through the clinics
- Counselled and stepped introduction services are offered for offspring to meet.

The dangers of unregulated donor sperm supply are:

- Medical and family history screens may be absent or unchecked
- There is usually no professional counselling to the parties involved – donor or recipient
- Infectious disease testing may be absent, patchy or misleading
- There are no quarantine periods at all. The sperm is fresh and unfrozen and represents a significant disease transmission risk

[36] Henrietta Cook and Farrah Tomazin, 'The man behind Australia's private sperm donor boom', *The Age* (online, 23/5/2021).
[37] Cindy Lever, 'Australia's most prolific sperm donor has fathered 23 children in a year', *News.com.au* (online, 15/10/2021).

- Expensive gene carrier screening is mostly absent
- Records of donations and recipients are cursory or absent
- Audit of records and outcomes is non-existent
- There are no family limits. There are reliable press reports of donors fathering several hundred children.[38]
- There is no guarantee that the children will have access to their donor records or ever have an opportunity to meet the donor or learn of their origins
- Counselling services are unavailable at any point in the process for the child.

The use of unregulated, untested donor sperm poses significant risks to patients. The unregulated donor sperm market has many drivers, including access to supply, lack of bureaucracy, minimal invasiveness and cost. Cost factors are significant, and it is clear that the child's best interests are not protected.

In 2019, an issues paper commissioned by the Gorton review in Victoria into assisted reproductive treatment identified the emergence of unregulated, online forums for sourcing gamete donations and surrogacy services. The nature of these activities is such that it is not possible to quantify the extent of the issue. It does, however, run the risk of prospective parents being open to exploitation. A 60 Minutes segment, *Babies at First Sight,* highlighted the risks some people take to start a family. The report followed "joe donor", the american sperm donor who claimed to have fathered more than a hundred children in the us and was in Australia, offering donations to women seeking to conceive a child. The program interviewed several women who valued either the anonymity he offered or the ability to access sperm without going to click procedures and having a waiting period. The program highlighted the risks some people were willing to take to form a family.[39]

Donor conception and surrogacy services in many countries remain primarily unregulated, and while many have reported positive treatment experiences in other jurisdictions, there remain significant risks for those seeking treatment. The exploitation risk can be even more significant when people travel overseas to seek treatment that might be prohibitively expensive or unavailable in Australia. Many countries which have been popular destinations have banned overseas surrogacy due to concerns about the exploitation of financially vulnerable women. Legislative changes in those jurisdictions have happened at short notice, leaving the fate of children to be born to parents who reside outside these countries, with those individuals personally devastated that their hopes of becoming parents have not been realised and out of pocket financially. Data on the number of Australian people travelling overseas for donor or surrogacy cases is unavailable; however, the Department of Immigration and Border Protection estimates that it deals with approximately 250 offshore surrogacy cases nationally each year.[40]

[38] 'Dateline: Meet the super sperm donor who has nearly 100 children.', *SBS Dateline* (2/11/2021); 'Sperm donor plans to father 2500 children', *60 Minutes Australia* (Gareth Harvey, 18/2/2019).
[39] 'Babies at first sight', *60 Minutes* (60 Minutes, 18/11/2019).
[40] Interview with Ms Frances Finney, Assistant Secretary, Permanent Visas and Citizenship Programme, Department of Immigration and Border Protection, House of Representatives Standing Committee on Social Policy and Legal Affairs, 26/02/2015).

All the developments which protect the child that have evolved from formal donor sperm programs over the past two decades are absent in the unregulated programs. Affordable access to regulated donor sperm services is therefore essential for patients and vital for children.

# 8. Term Of Reference 'H.' - Availability Of Reproductive Health Leave For Employees;

## 8.1 Economic Argument For ART

### 8.1.1 Education

Since the 1970s, total fertility rates (TFR) have fallen substantially in most developed countries. The declining birth rates and increasing percentages of childless women accelerate population ageing and have become a major demographic problem in the developed world. The causes of these negative fertility trends are not fully understood because various factors, such as education, income, marital status, and labour market conditions, are likely to influence fertility.[41] Research has shown a significant negative correlation between women's educational attainment and fertility. However, a causal link is difficult to establish because of potential reverse causality and selection of unobservable factors. The controversy about the empirical evidence for the education-fertility-nexus draws attention to the importance of various institutional conditions such as labour market flexibility, childcare availability, and a broad range of policies that vary across jurisdictions.[42]

The Australian Bureau of Statistics (ABS) census data shows a marked increase in the median maternal age since the 1970s. In 1970, the median maternal age was 25.55. In 2021 (the latest available), the median maternal age was 31.7 - an increase of 6.15 years to 2021.[43] this increase is attributable, in part, to an increase in female participation rates in tertiary education and higher levels of academic qualification attainment. In Germany, for example, it was found that increased education permanently reduced fertility – where one additional year of schooling reduces the number of children by more than 0.1 and increases the probability of childlessness by about two – five percentage points.[44]

Many complex factors, including at both a macro level and a micro level, influence fertility rates. At the macro level, institutional, economic and cultural factors loom large in people's fertility decision-making. This includes the costs and benefits of having children and the societal norms around parenthood and lifestyle.

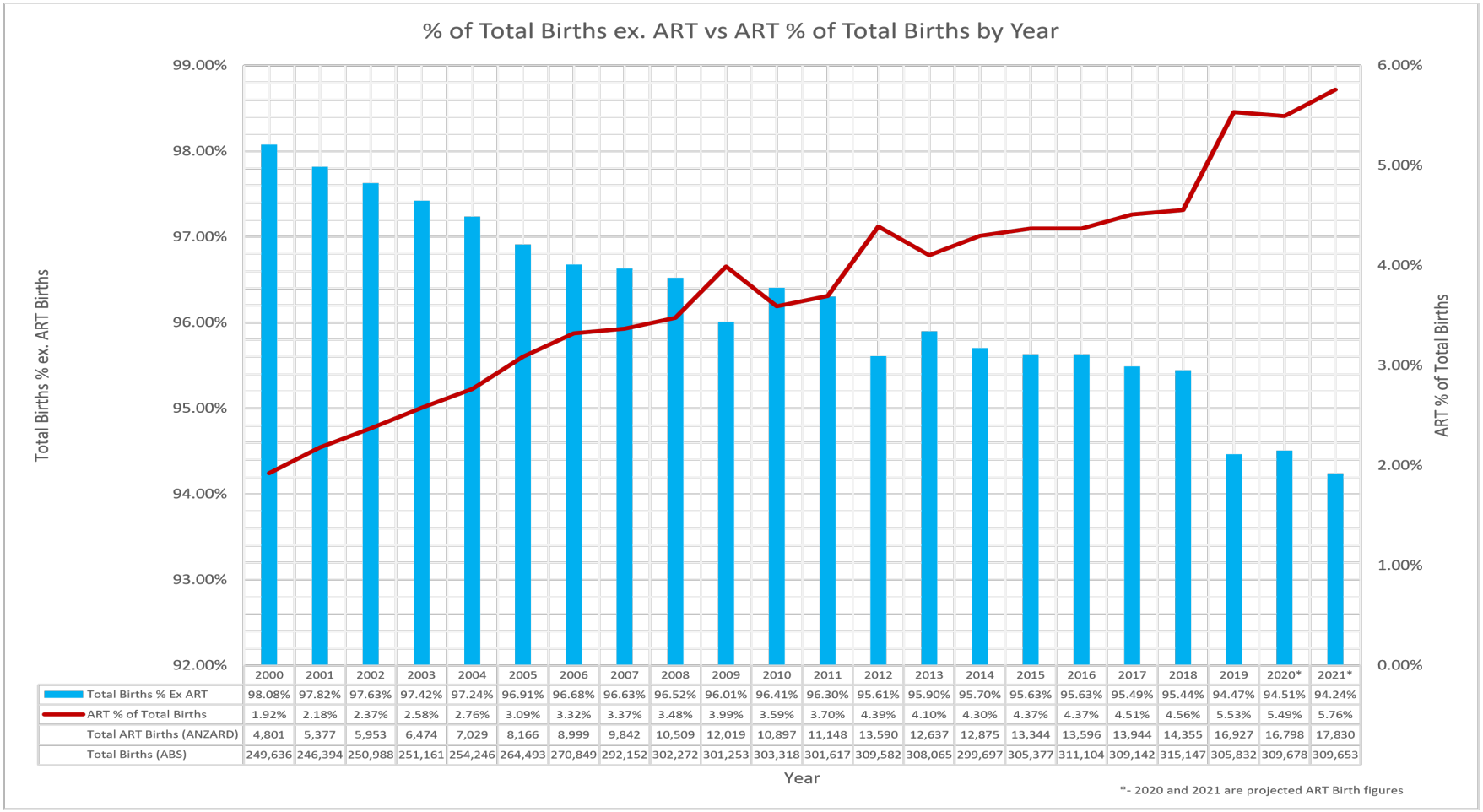
The macro-level factors are affected by policy settings, including childcare and paid parental leave.[45] At the micro-level, factors such as age, relationship status, and level of education interact with the macro-level factors that influence people's fertility decisions.

[41] Kamila Cygan-Rehm and Miriam Maeder, 'The effect of education on fertility: Evidence from a compulsory schooling reform' (2013) 25 *Labour Economics* 35-48; Alexis Leon, 'The effect of education on fertility: evidence from compulsory schooling laws' (2004) *unpublished paper, University of Pittsburgh*.
[42] Ralf Steinhauser et al, 'Impacts of Policies on Fertility Rates' (Research Paper, Australian National University Centre for Population, March 2022).
[43] ABS, 'Births, Australia' (Research Paper, Australian Bureau of Statistics, 25/10/2022).
[44] Cygan-Rehm and Maeder (n 36).
[45] Harris et al (n 20).

### 8.1.2 Population Growth Rate

Australia is experiencing a population decline due to a low fertility rate, low migration and increasing median maternal and paternal age.[46] The attached graphic 'Australian overall population growth' shows a significant drop off from 2019 through 2021 (latest available). The percentage of total births excluding ART versus ART percentage of total births by year graphic clearly shows the increasing percentage of ART births against total births in Australia by year. If ART births are taken out of the calculation, Australia's population replacement rate would be severely negative. It is unlikely that an increase in migration alone would be enough to remedy the significant population replacement rate deficit, and more needs to be done to facilitate natural population replacement. ART, therefore, is a fundamental element in economic growth and management.

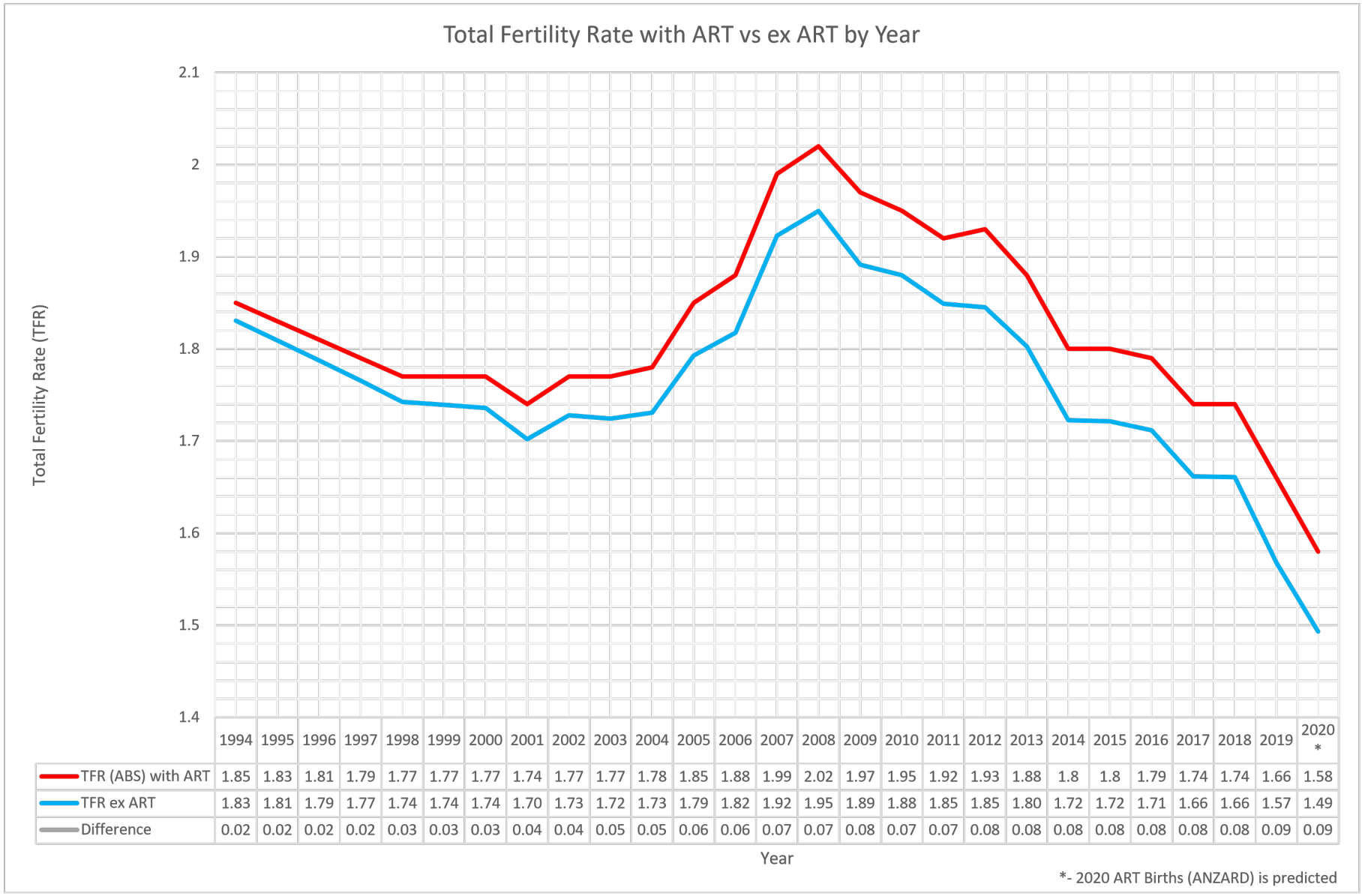
[46] ABS, 'National, State and Territory Population' (Research Paper, Australian Bureau of Statistics, 21/09/2022); ABS, 'Births, Australia' (n 38).



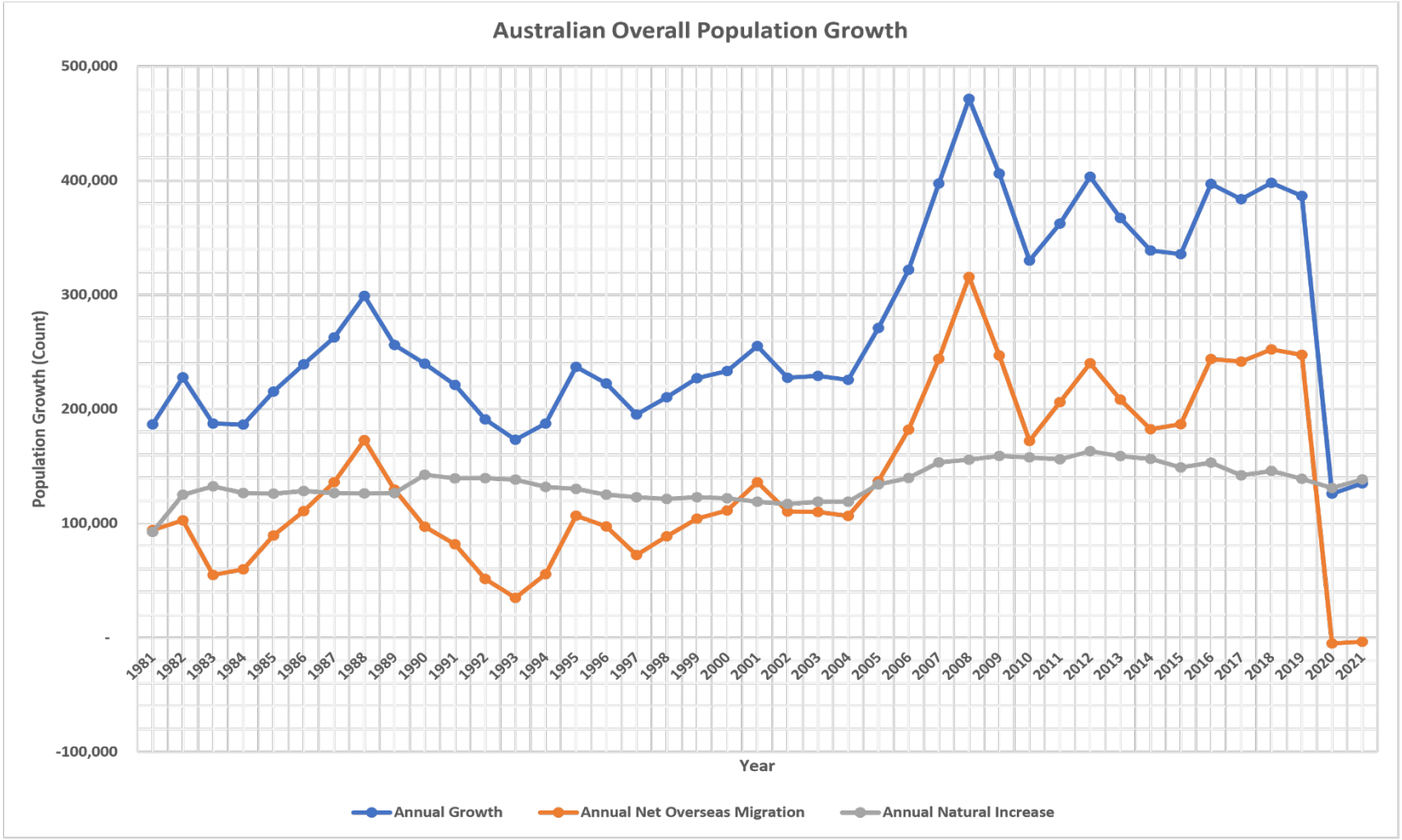

| | 2000 | 2001 | 2002 | 2003 | 2004 | 2005 | 2006 | 2007 | 2008 | 2009 | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 | 2016 | 2017 | 2018 | 2019 | 2020* | 2021* |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Total Births % Ex ART | 98.08% | 97.82% | 97.63% | 97.42% | 97.24% | 96.91% | 96.68% | 96.63% | 96.52% | 96.01% | 96.41% | 96.30% | 95.61% | 95.90% | 95.70% | 95.63% | 95.63% | 95.49% | 95.44% | 94.47% | 94.51% | 94.24% |
| ART % of Total Births | 1.92% | 2.18% | 2.37% | 2.58% | 2.76% | 3.09% | 3.32% | 3.37% | 3.48% | 3.99% | 3.59% | 3.70% | 4.39% | 4.10% | 4.30% | 4.37% | 4.37% | 4.51% | 4.56% | 5.53% | 5.49% | 5.76% |
| Total ART Births (ANZARD) | 4,801 | 5,377 | 5,953 | 6,474 | 7,029 | 8,166 | 8,999 | 9,842 | 10,509 | 12,019 | 10,897 | 11,148 | 13,590 | 12,637 | 12,875 | 13,344 | 13,596 | 13,944 | 14,355 | 16,927 | 16,798 | 17,830 |
| Total Births (ABS) | 249,636 | 246,394 | 250,988 | 251,161 | 254,246 | 264,493 | 270,849 | 292,152 | 302,272 | 301,253 | 303,318 | 301,617 | 309,582 | 308,065 | 299,697 | 305,377 | 311,104 | 309,142 | 315,147 | 305,832 | 309,678 | 309,653 |

47

[47] Jade E Newman, Repon C Paul and Georgina M Chambers, 'Assisted reproductive technology in Australia and New Zealand 2019' (2020) *Sydney, Australia: National Perinatal Epidemiology and Statistics Unit, University of New South Wales*; ABS, 'Births, Australia' (n 38).




| | 1994 | 1995 | 1996 | 1997 | 1998 | 1999 | 2000 | 2001 | 2002 | 2003 | 2004 | 2005 | 2006 | 2007 | 2008 | 2009 | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 | 2016 | 2017 | 2018 | 2019 | 2020 * |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| TFR (ABS) with ART | 1.85 | 1.83 | 1.81 | 1.79 | 1.77 | 1.77 | 1.77 | 1.74 | 1.77 | 1.77 | 1.78 | 1.85 | 1.88 | 1.99 | 2.02 | 1.97 | 1.95 | 1.92 | 1.93 | 1.88 | 1.8 | 1.8 | 1.79 | 1.74 | 1.74 | 1.66 | 1.58 |
| TFR ex ART | 1.83 | 1.81 | 1.79 | 1.77 | 1.74 | 1.74 | 1.74 | 1.70 | 1.73 | 1.72 | 1.73 | 1.79 | 1.82 | 1.92 | 1.95 | 1.89 | 1.88 | 1.85 | 1.85 | 1.80 | 1.72 | 1.72 | 1.71 | 1.66 | 1.66 | 1.57 | 1.49 |
| Difference | 0.02 | 0.02 | 0.02 | 0.02 | 0.03 | 0.03 | 0.03 | 0.04 | 0.04 | 0.05 | 0.05 | 0.06 | 0.06 | 0.07 | 0.07 | 0.08 | 0.07 | 0.07 | 0.08 | 0.08 | 0.08 | 0.08 | 0.08 | 0.08 | 0.08 | 0.09 | 0.09 |

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[48] ABS, 'Births, Australia' (n 38), ABS, 'National, State and Territory Population' (n 41).

## 8.2 Fertility Treatment Leave

There are reliable media reports of women using all of their paid leave for the year and having to fit embryo transfer appointments in during their lunch break.[49] As a result, public and private sector organisations have announced treatment leave options for employees, as well as extensions to carer leave provisions for those accompanying their partner to the ART appointment.[50] This growth in the provision of fertility treatment leave demonstrates increasing awareness by employers of the enormous strain that ART has on women undergoing treatment and their partners.

[49] Wendy Tuohy, 'Australia's first claim for 'reproductive leave' gets ACTU backing', *The Age* (online, 12/09/2022).
[50] Jerome Dorisamy, 'DLA Piper introduces fertility leave policy', *Lawyers Weekly* (online, 30/09/2021). Westpac, 'Westpac offers paid leave for employees undergoing fertility treatment' (Media Release, 29/11/2022).

# 9. Term Of Reference 'I.' - Any Other Related Matter.

## 9.1 Legislative Differences – Surrogacy Acts

Professor Sonia Allan And Mr Michael Gorton were independently commissioned by the Western Australian government and the Victorian government to review the legislation governing assisted reproductive technology and surrogacy.[51] Both reviews noted cases of trafficking and exploitation spanning the last two decades reported in China, Europe, Thailand, and Nepal. The reviewers observed that some Australians travel overseas to engage in commercial surrogacy. Neither recommended the legalisation of commercial surrogacy.

In her final report, Professor Allan concluded that the commonwealth citizenship and passport laws, the lack of uniformity of extraterritorial prohibitions across the state, and the current Western Australian law, which serves to exclude certain people from accessing altruistic surrogacy in Western Australia, may lead some people who are seeking surrogacy to travel to other jurisdictions where:

- "they can access surrogacy when they cannot ordinarily in Western Australia
- The commercial nature of surrogacy leads to greater vulnerability of women willing to act as surrogate mothers
- There are significantly fewer requirements placed on the intending parents than in Western Australia, other states of Australia, or the Australian Capital Territory."[52]

In general, patients will experience different access to services depending on the jurisdiction in which a patient resides. This is because of the differences in legislation and the regulatory structure for the provision of ART between jurisdictions. The Australian Capital Territory, New South Wales and Queensland, surrogacy laws have extraterritorial reach - meaning that the offence provisions of that jurisdiction surrogacy legislation apply even if the surrogacy arrangement took place elsewhere in Australia overseas and that person to commit the offence is ordinarily a resident of that jurisdiction with extraterritorial provision. This is not the case for other jurisdictions with surrogacy legislation.

[51] Sonia Allan (WA), *The Review of the Western Australian Human Reproductive Technology Act 1991 and the Surrogacy Act 2008 (Part 1)* (Report No 1); Sonia Allan (WA), *The Review of the Western Australian Human Reproductive Technology Act 1991 and the Surrogacy Act 2008 (Part 2)* (Report No 1); Michael Gorton (VIC), *Final Report of the Independent Review of Assisted Reproductive Treatment* (Report, May 2019).
[52] Allan, *The Review of the Western Australian Human Reproductive Technology Act 1991 and the Surrogacy Act 2008 (Part 2)* (n 46).

## 9.2 Legislative Differences – Assisted Reproductive Treatment Acts

The regulation and oversight of ART clinics in Australia occurs via general and specific laws and regulations. The general regulation of professional health protection practitioners in Australia requires that they be registered, adhere to the general law, and follow professional codes of conduct.

Victoria and Western Australia have comprehensive legislation that governs the provision of ART.[53] in New South Wales and South Australia; their respective ART acts cover certain aspects of ART provision.[54] In the Northern Territory, Australian Capital Territory, Queensland, and Tasmania, no strict legislation governing the provision of ART exists.

Nationally, a self-regulatory system operated by the fertility society of Australia and New Zealand (FSANZ) and RTAC set out specific standards of practice across Australia. This system applies to all licensed ART clinics.[55] The National Health and Medical Research Council 'ethical guidelines on the use of assisted reproductive technology in clinical practice and research' sets out ethical principles that all ART clinics in Australia should follow.[56]

[53] *Assisted Reproductive Treatment Act 2008* (VIC) ('*Assisted Reproductive Treatment Act 2008*'); *Human Reproductive Technology Act 1991* (WA) ('*Human Reproductive Technology Act 1991*').
[54] *Assisted Reproductive Treatment Act 1988* (SA) ('*Assisted Reproductive Treatment Act*'); *Assisted Reproductive Technology Act 2007* (NSW) ('*Assisted Reproductive Treatment Act 2007*').
[55] RTAC (n 1).
[56] NHMRC, 'Ethical Guidelines on the use of Assisted Reproductive Technology in Clinical Practice and Research' (2007).

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