Section 81 - Investigation of ART providers in QLD

Final Report

OFFICE OF THE HEALTH OMBUDSMAN

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Acknowledgement

The Office of the Health Ombudsman acknowledges the traditional Aboriginal and Torres Strait Islander custodians of the lands and seas on which we support the provision of safe and quality healthcare and pays respect to Elders past, present and emerging.

The Office of the Health Ombudsman recognises, respects and values Aboriginal peoples' and Torres Strait Islander peoples' cultures and is committed to providing a culturally safe and sensitive complaint management service.

Foreword

This report is provided to the Minister for Health, Mental Health and Ambulance Services and Minister for Women, the Hon Shannon Fentiman MP (the Minister), in response to her direction to undertake an investigation under section 81 of the *Health Ombudsman Act 2013* (the Act) into assisted reproductive technology/treatment (ART) providers within Queensland.

This investigation has provided an important opportunity to independently review the quality and safety of services within this health sector, one that can bring so many benefits to consumers through the creation of a family that may otherwise not have been possible.

The creation of a family using ART services can be an emotionally and physically challenging journey, which can result in wonderful outcomes. In Australia and New Zealand there were 20,440 live births following ART treatment in 2021,[1] demonstrating the significant impact that ART providers have in helping people to achieve their wish to become a parent. At the same time there is much at stake for consumers, donors and donor-conceived children in the processes and outcomes of ART treatment, and adverse events and non-compliant practices can have significant impacts for those affected.

The Office of the Health Ombudsman (OHO) receives healthcare complaints from across Queensland and is often one of the first points of contact when things go wrong with health service provision. While the OHO's investigation is focused on identifying potential systemic issues warranting attention in the provision of ART services in Queensland, this report also recognises positive practices and responses by ART providers in respect of the issues which have been examined. The OHO has identified examples of ART providers demonstrating a commitment to continuous improvement in response to incidents and complaints, and this is fundamental to achieving safe, quality services. As this investigation focused on the identification of systemic issues, and to maintain confidentiality of parties involved, ART providers have been identified by an alphabetical code rather than by name.

Throughout the investigation the OHO received cooperation from ART providers,[2] the Fertility Society of Australia and New Zealand (and its Reproductive Technology Accreditation Committee), and Certifying Bodies, who audit ART providers. The provision of data, information and feedback from all of these sources, together with advice from an Expert Panel, has enabled a thorough examination of the issues and areas of focus for this investigation. I acknowledge the time and efforts made by all of these organisations to provide input on the key themes identified in this investigation and feedback on the preliminary findings and recommendations as they were being developed.

This investigation would however not have been possible but for the preparedness of ART consumers to share their deeply personal experiences through their complaints. These complaints provide a vital window into the quality and safety of services, and the significant and sometimes lifelong impacts when things go wrong. I acknowledge and thank the ART consumers who shared their concerns and perspectives through their complaints and a complainant survey. This report contains accounts of adverse events which occurred during the provision of ART services, and it is important to acknowledge the trauma and distress experienced by these consumers and the gravity of the issues they have raised. The investigation has shone a light on these experiences and enabled the consideration of these adverse events, as well as the issues raised in individual complaints to the OHO, from a systemic perspective.

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[1] Assisted Reproductive Technology in Australia and New Zealand, Annual Report 2021.

[2] ART providers have been identified by an alphabetical code rather than by name.

This investigation has identified significant systemic issues in practices by ART providers and gaps and risks in the current self-regulatory regime in Queensland.

It is pleasing that the investigation also identified improvements in practices and technological advancements which are being implemented by ART providers and FSANZ-RTAC to address historical issues, and that there was broad support for the proposed regulation of ART services in Queensland and the establishment of a donor conception register.

I trust that the detailed findings and recommendations from this investigation will contribute to achieving service improvements and strengthened safeguards and protections which will benefit everyone who uses these services across Queensland.

Dr Lynne Coulson Barr OAM

Health Ombudsman

28 June 2024

Executive Summary

On 2 November 2023, the Minister for Health, Mental Health and Ambulance Services and Minister for Women, the Hon Shannon Fentiman MP (the Minister), directed the Office of the Health Ombudsman (OHO) to undertake an investigation under section 81 of the *Health Ombudsman Act 2013* (the Act) into assisted reproductive technology/treatment (ART) providers within Queensland.

The investigation has identified systemic issues affecting ART consumers in Queensland and I have made recommendations to improve the practices and procedures of ART providers in respect of issues of quality and safety of services and associated safeguards for consumers, donors and donor-conceived children. The investigation was conducted in three phases, with interim reports on phases 1 and 2 provided to the Minister in accordance with section 177(1) of the Act.

Outcomes and recommendations from this investigation complement the work that has been undertaken by Queensland Health in relation to proposed legislative changes to the ART regulatory regime. The investigation will also inform the effective implementation of the Queensland Government's Legal Affairs and Safety Committee's report *Inquiry into matters relating to donor conception information*.

The initial scope of the investigation included the examination of any identified issues, non-compliance or adverse events associated with:

1. The handling of gametes and embryos, including collection, labelling, storage and transportation
2. Screening techniques for gametes, embryos and donors used in Queensland
3. Record keeping including donor and recipient information sharing and compliance with updating records relating to changes in donor's health information
4. Maximum donation and distribution of gametes within Australia

During Phase 1, additional issues were identified which were approved by the Minister to form part of the OHO's investigation. The additional issues for investigation included:

5. Provision of adequate information to allow consumers to provide informed consent when choosing ART treatment
6. Sperm quality: relating to consumers using donated sperm where there is an expectation that the sperm will be of good quality and where the use of poor-quality sperm may impact on the consumer's choice of ART treatment or requirement to use intracytoplasmic sperm injection (ICSI)
7. Sex[3] selection: relating to the use of sex selection in contravention of the National Health and Medical Research Council Guidelines (NHMRC Guidelines)
8. Discarding of gametes and/or embryos (genetic or biological material)[4]: relating to concerns raised by consumers about the delays and issues associated with the destruction of gametes and/or embryos, impacting on consumers.

[3] On the terminology used: while 'sex selection' and 'gender selection' are often used interchangeably (generally among the public and even within ART provider settings) it should be noted that the OHO (as do several ART providers and experts consulted) is conscious of the distinction between 'sex' and 'gender'. As such, this investigation considers 'sex' in the context of ART to be biologically (genetically) determined (and preferentially used in this investigation, which is medical in nature), while 'gender' is considered to be a social construct and fluid in its determination (and largely beyond the remit of this investigation, unless expressly identified as a potential issue). This is also addressed in this report in the section *Use of non-discriminatory forms*. Thus, the intention of the OHO is to appropriately refer to these terms herein as extensively as possible (balancing its interchangeable use within the general public and related OHO complaints).

[4] The original scope of the investigation referred to the disposal of genetic or biological material. This has been amended to respectfully refer to the discarding of gametes and/or embryos in alignment with the NHMRC Guidelines.

The investigation also examined the following themes identified from the analysis of complaints and information obtained for this investigation:

9. Current mechanisms for the oversight of ART services and applicable standards
10. Open disclosure and the management of complaints and adverse events by ART providers
11. Impacts on consumers identified in responses to complaints and adverse events.

In accordance with the Minister's direction, the investigation involved the review of data from active and closed OHO matters (including complaints and enquiries) to assist in the identification of systemic issues within this sector. The investigation also obtained and examined records related to compliance with the Fertility Society of Australia and New Zealand (FSANZ) Reproductive Technology Accreditation Committee (RTAC) Code of Practice and the NHMRC *Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice.* Related documentation was obtained from individual ART providers, including complaints, accreditation audit reports, and incident and adverse event reports.[5] Site visits were also conducted with three ART providers.

Theme 1: Appropriate collection, storage, identification and distribution of gametes and embryos

The OHO considered whether there are appropriate protocols and practices in place to ensure that gametes and embryos, where applicable, are appropriately collected (primarily relating to sperm), stored, identified and distributed (provided to consumers for purposes of ART) so that consumers can be assured that they are being provided with the intended (correct) biological sample/s.

Theme 1 is the most predominant theme identified in the OHO investigation, accounting for 28% of all OHO issues and 40% of all ART provider complaints. There can be significant adverse outcomes if processes are not adhered to during the early stages of fertility treatment, as any failings in this regard may mean that treatment cannot take place or is delayed. In the case of potential gamete mix up, the implications for families can be life-long. The OHO has observed issues with potential misidentification of gametes where poor record keeping appears to have been a factor. Good record keeping is a fundamental element of healthcare and is of pivotal importance when dealing with family creation.

It is acknowledged that human error and mistakes can occur in any environment, and that advances in technology, improvements in contemporary record keeping practices and regulatory guidelines are addressing some of the risks identified in historical practices of ART providers. It is however evident from complaints made to the OHO and to ART providers that appropriate collection, storage, identification and distribution of gametes and embryos continues to be an issue despite these advances. This suggests that there should be both stricter compliance with basic procedures and stronger safeguards to address these issues, including legacy issues and risks arising from historical record keeping practices.

During the investigation, the OHO undertook site visits with three ART providers, which included demonstrations of current record keeping practices. The ART providers were transparent and open during the site visits about the historical challenges with record keeping. The OHO noted that contemporary practices of radio-frequency identification (RFI) and 'RI Witness'[6] and other technological advances have made a considerable improvement in the accuracy of record keeping and reducing the risk of human error. The OHO was reassured by the information obtained during

[5] Data obtained and reviewed included: OHO complaints and enquiries; RTAC information: audits (aggregate data); complaints (received directly from the public); adverse events (reported directly from ART providers); and ART providers: audit information, complaints (received directly from patients), adverse events.

[6] RI Witness is an electronic system used in laboratories which monitors sample movement. RI Witness identifies any mismatches between the sample being reviewed and the records and will sound an alarm if this occurs.

the site visits of examples of good record keeping practices and an expressed commitment by the ART providers to maintaining these practices.

Theme 2: Screening of gametes and donors used in Queensland

Theme 2 relates to whether the extent of screening undertaken on donors and gametes is appropriate to ensure, as far as possible, that any relevant medical concerns are identified prior to undertaking ART treatment, to best ensure the safety during treatment and satisfactory outcomes of ART for consumers. This theme constituted the third largest number of OHO issues (16%) and the fourth largest number of ART provider complaints (13%).

The OHO investigation has found that screening donors for certain genetic conditions (via karyotyping [chromosome screening] and molecular testing for cystic fibrosis) are commonly undertaken on sperm donors, which is a positive finding. However, the extent of screening for other conditions (such as other common autosomal recessive conditions via carrier screening) may warrant further consideration by providers.

There are some complaints received by the OHO that include allegations that significant medical conditions of donor-conceived children have potentially been inherited from the donor. The investigation has identified areas for improvement in the requirements and processes for identification and notification of donor medical conditions, including that disclosure of medical conditions should not be left to an individual or non-medical person to determine.

Theme 3: Record keeping and provision of information

The investigation of Theme 3 considered whether information of any type relating to consumers (inclusive of donors) is managed, recorded and shared appropriately, particularly with donor recipients, including the collection and utilisation of medical information. This theme constituted 15% of OHO issues and 3% of ART provider complaints.

From the data analysed for this investigation, it appears that ART providers receive very few complaints relating to this theme, with only three complaints noted from the OHO review of provider data. Most complaints made to the OHO and to ART providers involved issues about the provision of information about donors and siblings. It is recognised that there are limits to the information that ART providers can supply to donor recipients and their offspring, and many of these complaints are likely to be resolved through the proposed introduction of a state-based central donor register.[7]

The OHO examined the quality of records that were completed by ART providers in respect of the issues in scope for this investigation. Records were found to be inconsistent across different ART providers (different businesses), and even within the same ART unit (the same company across locations). While record keeping has improved over time, particularly with the introduction of electronic records and RFI, poor record keeping has significant implications for families when an incident occurs. The OHO has identified the need to consider requirements for standardisation of key documents and records across services.

Early awareness of potential medical issues is very important to donor-conceived children and, with some conditions, prompt treatment can be key to successful management or improved outcomes. It is appreciated that this is a sensitive issue which warrants clear guidelines on the threshold and processes for disclosure. The OHO has concerns that this is not consistently managed appropriately by ART providers. The OHO recommends that ART providers must have a

[7] Following a recommendation by the Legal Affairs and Safety Committee of the Queensland Parliament in 2022, work is separately being undertaken by the Queensland Government to establish a donor conception register in Queensland.

clear policy for what should occur when significant medical history is disclosed relating to a donor-conceived child and donor. It is also recommended that there is consideration for the inclusion of obligations of ART providers in respect of such disclosure through the proposed central register and legislation regarding access to information for donor-conceived children.

From the information obtained during the site visits and through responses from ART providers, it was apparent that not all ART providers keep in regular contact with donors, whether that be in relation to checking donors' contact information or seeking updated medical information. The OHO considers that this is an important element of managing ART services, particularly when there is no donor registry in place. It should not be left to the donor to initiate contact when their circumstances change. It is recommended that ART providers develop processes to ensure that updated information from donors is not reliant on the donor to initiate contact when their circumstances change.

Theme 4: Maximum family limits of donor gametes within Queensland and Australia

The OHO's investigation has examined whether appropriate donor usage limitations are being practised for the creation of donor-conceived families to mitigate (as far as possible) the risks associated with consanguinity, as well as the mental health impacts for donor-conceived people and donors in discovering that large numbers of people are related to them. This theme constituted 3% of the issues identified in OHO complaints and 1% of ART provider complaints.

The number of reported complaints to ART providers which relate to family limits were very low, ranging from none to one complaint for each provider. While the reported number of these complaints are relatively low, the impacts and potential risks for donor-conceived children and their families are significant. It is possible that this theme may become more significant as children conceived through ART reach 18 years of age and seek familial connections via family tree databases. The interpretation of what constitutes a 'family' varies across ART providers. Maintaining the family limit requires clear guidelines on what constitutes a 'family' and avoids inconsistencies across providers and across the state.

At the interviews conducted during the site visits, the ART providers indicated that they would welcome a national consensus on the definition of a family and on appropriate limits. The definition should also recognise individual circumstances that apply when considering what is a 'family'.

Theme 5: Provision of information and informed consent

Consent is one of the cornerstones of health service delivery. It is critical that the consumer understands what they are consenting to and that the consenting process is revisited should the treatment pathway change. This is particularly important for ART treatments given the specialist and technical nature of the treatments, the evidence base for different treatments, and the emotional significance of decisions being made by consumers. The importance of valid informed consent from all parties for each specific procedure or treatment was discussed in the Gorton Review of Assisted Reproductive Treatment in Victoria.[8] In particular, the review noted the 'rapid evolution of science in ART, along with an increasingly corporate and competitive approach to service provision' requiring a clear and consistent process for informed consent. Despite this, issues relating to the consenting processes being undertaken in the provision of ART treatments, were identified as the second highest theme within the OHO issues (28%) and the second largest of the ART provider complaints (20%).

[8] Independent Review of Assisted Reproductive Treatment, May 2019, Michael Gorton.

It is noted that fertility specialists are not employed by, but are affiliated with, particular ART providers. The fertility specialist has overall responsibility for the consumer and manages the initial treatment pathway. The ART provider will follow the plan which has been developed between the consumer and the fertility specialist. In terms of the consenting process, this is undertaken by the ART provider (once the plan has been agreed to). The difficulty with the process appears to be that the ART provider's fertility nurse provides the consumer with consent forms, and only escalates to the fertility specialist if the consumer has questions about their plan or does not understand the treatment being provided. It is recognised that there needs to be clarity and a shared understanding of the respective roles and responsibilities of the ART provider, including the role of the fertility nurse and the fertility specialist in these circumstances, to ensure that the consumer is able to provide their informed consent to treatment.

Within complaints to the OHO and ART providers, concerns have been raised about whether consumers are given sufficient information to provide their informed consent to treatment, and fully understand the treatment options open to them.[9] It was identified that consumers may benefit from an information pack containing details about their treatment, to enable them to provide their informed consent, as well as information about possible complications from treatment so that the materials can be reviewed should issues arise.[10] Every consent process needs to be carefully considered as to whether it complies with the required standards. From the information examined for this investigation, the OHO concluded that consent processes warrant greater oversight in terms of the adequacy of information provided to consumers for them to provide informed consent to treatment.[11]

Theme 6: Sperm quality and ART options

Donor sperm supply and demand in Australia reflects a situation of high demand and a carefully managed supply. Demand for donor sperm is substantial, with most consumers seeking specific donor characteristics, such as hair and eye colour (and other physical characteristics often associated with certain ethnicities), height, education level, and interests. This specificity presents challenges in finding suitable donors to meet consumers' preferences. To meet demand, Australian ART providers sometimes access international gamete banks, such as the World Egg & Sperm Bank, based in the United States. These partnerships allow clinics to access a broader pool of donors and provide additional options to consumers.

Concerns around sperm quality and the subsequent ART option used were identified in 1% of OHO issues and 6% of ART provider complaints. In terms of sperm quality, the WHO Laboratory Manual for the Examination and Processing of Human Semen[12] (the WHO Manual) provides the benchmark for assessing the quality of semen. Conventional semen analyses (including quality parameters of sperm count, motility and morphology) and related clinical studies have provided important insights into the threshold values that are commonly applied in clinical practice. It is therefore generally considered to be important to consider sperm quality, as it may influence the choice of ART.

The information examined for this investigation indicates that consumers may not fully understand why procedures such as ICSI are recommended. From the cases examined there were also questions about the extent to which consumers are informed of the poor quality of the semen they

[9] Similar findings were identified in Health Care Complaints Commissioner (Vic), *Inquiry into Assisted Reproductive Treatment Practices in Victoria,* Final Report (2020) 29-30.

[10] Health Care Complaints Commissioner (Vic), *Inquiry into Assisted Reproductive Treatment Practices in Victoria,* Final Report (2020) 25.

[11] Health Care Complaints Commissioner (Vic), *Inquiry into Assisted Reproductive Treatment Practices in Victoria,* Final Report (2020) 25.

[12] *WHO Laboratory Manual for the Examination and Processing of Human Semen*. 6th ed. Geneva: World Health Organization, 2021.

have reserved for use. Consumers do appear to recognise that there is limited availability of donor sperm, but equally, they are paying for a service for which they want to maximise the chances of success. It is acknowledged that if a consumer has selected a specific sperm donor, they may be willing to use the sperm regardless of the quality (particularly if they have a previous child born using that sperm donor). The OHO has identified the need for ART providers to ensure that consumers are fully informed of the quality of donor sperm and why an ART option (such as ICSI) may be recommended.

Sperm quality parameters and potential for increased risk of genetically abnormal embryos and potentially heritable conditions should be considered in ART and discussed to a reasonable extent with consumers.

Theme 7: Sex selection

In the context of ART, the term 'sex selection' refers to the selection and transfer of an embryo on the basis of genetic sex. Intended parents seeking to select the sex of an embryo may have genetic (medical) or non-medical reasons for doing so. The NHMRC Guidelines have recognised that the use of sex selection techniques may be ethically acceptable when used to reduce the risk of transmission of a serious genetic condition, disease or abnormality. Concerns regarding allegations of inappropriate sex selection practices were identified in 5% of issues raised in complaints made to the OHO (albeit with a single provider) but were not identified in any of the ART provider complaints.

An OHO investigation into allegations of sex selection is still in progress at the completion of this systemic investigation.

The OHO did not identify any other issues raised about sex selection with individual providers during the review of adverse events and audit reports, which is unsurprising given the ethical and regulatory sensitivity of this practice. While there were limitations in the data considered in this investigation, the OHO's examination of the potential issues associated with sex selection identified the need for these issues to be considered as part of regulation and legislation around the provision of ART.

Theme 8: Discarding of gametes and/or embryos (genetic or biological material)

Decisions to discard or destroy gametes and/or embryos has particular importance and emotional significance for consumers. For some consumers, the decision to discard gametes and/or embryos is multifaceted and often highly sensitive. From data examined, 3% of OHO issues and 17% of ART provider complaints involved this theme.

ART providers have a responsibility to manage these decisions and processes with sensitivity and awareness of the impact on consumers. Section 3.9 of the NHMRC Guidelines state that 'the provision of ART must be transparent and open to scrutiny, while ensuring the protection of the privacy of all individuals or couples involved in ART and persons born, to the degree that is protected by law. Clinics must practise an open and consistent approach to ART activities. Clinics must maintain policies for each treatment and procedure available at the clinic. These policies must identify the line of responsibility in each circumstance. For example, specific policies should be developed and implemented in relation to … use, storage and discard of gametes and embryos'. Additionally, section 4.1 of the NHMRC Guidelines stipulate that clinics must ensure that before gametes are collected or embryos are created, all responsible parties should be provided with sufficient information to facilitate an understanding of the options they will have regarding the use, storage and discard of gametes or embryos. Section 4.6 of the NHMRC Guidelines stipulate

the need for specific consent for the use, storage or discard of gamete or embryos. As such, ART providers are required to have policies in place for the disposal of gametes and/or embryos.

On the basis of information considered for this investigation, the OHO is concerned that a patient-centric approach was not demonstrated by all providers. There were several situations identified by the OHO where consumers provided signed confirmation of their consent to discard embryos and/or ovarian tissue. In these instances, consumers later discovered that the disposal process was either still in progress or was completed several months, and in some cases years, after the consumer provided signed consent. This resulted in significant emotional distress for these consumers. The impact of unexpected delays or lengthy turnaround times for the disposal of gametes and/or embryos and other biological material, and the impact that this can have on consumers, should not be underestimated.

It is recommended that staff should be appropriately trained to support the consumer and signpost support services.

In some cases, there is concern that the ART provider has treated the disposal of gametes and/or embryos and other biological material as a transactional process, which is wholly inappropriate in this sector, given the emotional nature of ART for consumers.

Theme 9: ART oversight and regulation in Queensland

In the absence of legislated regulation, the quality and safety of ART services in Queensland relies on the oversight of FSANZ-RTAC as the industry regulator which, in principle, should provide the public with reassurance that standards are upheld. The OHO acknowledges the important roles performed by FSANZ as the ART sector's peak body and RTAC as the regulatory mechanism for determining and upholding standards. The OHO's investigation has, however, identified gaps and risks in the level of oversight and independence that RTAC has in the performance of its role in the current self-regulatory regime in Queensland. In other states which regulate the provision of ART services, RTAC's role is complemented by statutory requirements and independent regulatory oversight. The evidence obtained during the investigation indicates that there are gaps and risks in the current self-regulatory system in respect of ensuring the safety and quality of ART services.[13] The findings and observations of the OHO's investigation, particularly the gravity of adverse events that can occur in the provision of ART treatment, indicate a compelling case for the need for proposed legislation to regulate ART providers in Queensland and strengthen the safeguards for consumers, donors and donor-conceived people.[14]

Theme 10: Open disclosure and adverse events management

In dealing with complaints about ART services, the OHO has noted issues with providers' communication and disclosure with consumers despite the requirements for open disclosure and the principles of patient-centred care. A theme across many of the complaints is that consumers have not been provided with fulsome responses when they have raised their concerns directly with providers. In some cases, the OHO has been concerned about the provider's lack of transparency or willingness to engage with the consumer and had there been an open dialogue, it is possible that a complaint to the OHO could have been avoided. Some of the matters considered involve allegations which have a significant impact on the consumer and their children, for example, the alleged use of the incorrect sperm which has resulted in children not being biological siblings. For consumers, the discovery that their family is not biologically linked can cause substantial trauma. It

[13] Similar findings were identified in Health Care Complaints Commissioner (Vic), *Inquiry into Assisted Reproductive Treatment Practices in Victoria,* Final Report (2020) 25.

[14] Similar findings were identified in Health Care Complaints Commissioner (Vic), *Inquiry into Assisted Reproductive Treatment Practices in Victoria,* Final Report (2020) 25.

is also important that ART providers provide consumers who complain with an escalation pathway if their complaint is not resolved. It is recognised that complaints may not always have a satisfactory outcome and the ability to explore this via an independent organisation, such as the OHO, enables issues to be impartially reviewed.

Theme 11: Patient impact

The provision of ART is a stressful and emotionally demanding journey for consumers and their families. The impact is considerable and differs from any other forms of health service provision because it involves creation of a family. The RTAC Code of Practice states that 'patients and their offspring remain the most important consideration in all decisions'[15] and therefore requires ART providers to deliver a patient-centred approach to both treatment and responses to concerns. In the cases examined for this investigation, the OHO has found that this does not always occur.

Appropriate communication with consumers undergoing ART is key. An already stressful process can be made significantly more distressing if ART providers are not cognisant of the impact that poor or inappropriate interactions can have on consumers. The investigation considered that improvements can be made by ART providers in relation to consumer interactions, ensuring that a patient-centric approach is applied to all aspects of the service, whether that is managing the consenting process, dealing with an adverse event or discarding of embryos.[16]

Additional issues

Additional issues were identified during the course of the investigation that warranted recommendations.

A recommendation has been made to the Minister in relation to consideration of the establishment of an independent mechanism for review of decisions about treatment and the posthumous use of gametes and embryos, similar to the functions performed by the Victorian Patient Review Panel established under the *Assisted Reproductive Treatment Act 2008* (Vic).[17] While these issues were not examined in detail for this investigation, the issues raised about decision-making about ART treatments suggest that there is merit in considering an independent mechanism to review such decisions.

It has also been recommended that ART providers review relevant patient registration forms and include gender identity to ensure forms are non-discriminatory and respect consumers' gender identities.

People of diverse ethnicities, genders, sexual orientations, and socioeconomic and cultural backgrounds can be impacted by fertility issues. The ART sector is also affected by social changes and scientific advancements. These factors necessitate the need for ART providers to adapt to changes in societal norms, clinical practices, and legal and ethical considerations to meet the ever-evolving reproductive health needs of consumers. The investigation identified issues in respect of potential discriminatory practices concerning patient registration forms used by ART providers which pointed to the need for review of these forms.

[15] RTAC Code of Practice, 2021, Introduction.

[16] Similar findings were identified in Health Care Complaints Commissioner (Vic), *Inquiry into Assisted Reproductive Treatment Practices in Victoria,* Final Report (2020) 85.

[17] Section 82 of the *Assisted Reproductive Treatment Act 2008* (Vic) establishes this entity.

It is recommended that ART providers review relevant patient registration forms and consider the inclusion of gender identity for trans and gender diverse people to ensure forms are non-discriminatory and respect patients' identities.[18]

Human Rights Act considerations

The OHO places significant importance in *Human Rights Act* considerations and notes that it is important that any recommendations from this report do not have an unintended consequence of unreasonably restricting or diminishing the availability of donor sperm, or disproportionately increasing the cost of services, which would adversely affect individuals seeking to create families. The OHO has received representations from ART providers on these issues and notes the importance of balancing these considerations with the paramount importance of protecting the health and safety of the public in respect of the provision of ART services.

Submissions

ART providers and FSANZ-RTAC were supplied with relevant extracts of the report to provide procedural fairness and the opportunity to provide comments on the analysis and interpretation of the data and information that has formed the basis of this final report. This process was undertaken for each of the three phases of this investigation, providing considerable opportunity for input and feedback on preliminary findings and recommendations. Submissions from ART providers and FSANZ-RTAC have been considered by the OHO and reference is made to these representations where appropriate. The contributions and responses from ART providers and FSANZ-RTAC have been very helpful in enabling a robust analysis of themes considered in this final report and its recommendations.

In responses from ART providers, it is noted that there is broad support for the recommendations made by the OHO and the introduction of legislation to regulate the provision of ART services. Individual ART providers have expressed willingness to engage with the Government to develop the framework that will underpin the legislation.

Conclusion

This investigation has identified significant systemic issues relating to the provision of ART services in Queensland which warrant consideration in the proposed legislative changes to the ART regulatory regime, as well as improvements in practices by ART providers. As noted above, the findings and observations of the OHO's investigation, particularly the gravity of adverse events that can occur in the provision of ART treatment, indicate a compelling case for the need for proposed legislation to regulate ART providers in Queensland and strengthen the safeguards for consumers, donors and donor-conceived children. The investigation also identified improvements in practices and technological advancements which are being implemented by ART providers and FSANZ-RTAC to address some of the historical issues, particularly in respect of record keeping. The OHO also notes the broad support expressed in submissions from ART providers for the benefits of regulation providing a consistent framework and expected standards for both consumers and providers and complementing existing mechanisms for auditing and promoting high quality and safe practices. Detailed recommendations have been made for consideration of the Minister, FSANZ-RTAC and ART providers on ways in which the issues identified in this investigation can be addressed, and to improve the quality and safety of ART services for all Queenslanders.

[18] Similar findings were identified in Health Care Complaints Commissioner (Vic), *Inquiry into Assisted Reproductive Treatment Practices in Victoria,* Final Report (2020) 8.

Highlights from investigation findings

The OHO assessed over **1,226 data records**, which included OHO matters (complaints and enquiries received about ART services); ART provider complaints (from ART providers provided to the OHO); audits (provided by Certifying Bodies and ART providers); and adverse events (from ART providers provided to the OHO), of which **242 (approximately 21%) were within the scope** of this investigation.

Of the **OHO matters** reviewed, **66% related to services provided 5–10+ years ago**, and Themes 1 and 5 were the most represented themes (both at 28%).

Information provided by RTAC highlighted that of **non-conformities related to Identification and Traceability** (Theme 1) across all Australian states and territories and New Zealand, ART providers in **Queensland** accounted for the highest proportion **(42%)**. Additionally, of all Queensland ART provider non-conformities, Identification and Traceability was the **most highly represented theme (30%)**.

Of the **ART provider complaints** and issues identified in the **OHO matters**, **Themes 1 and 5** accounted for **60%** (40% and 20% respectively). This was followed by Themes 2 (13%), 8 (17%) and 3 (3%). Themes 9–11 were assessed qualitatively and represented in specific case studies.

In addition to the complaint data, **Theme 1** also featured dominantly in audit data and adverse events data, highlighting its significance in ensuring the integrity of ART processes. The investigation revealed various challenges, including incidents such as the misplacement of gametes, use of incorrect embryos, and mix-ups in sperm samples.

Theme 2 included allegations of inadequate donor profiling, failure to disclose medical information, and failure to appropriately test gametes, highlighting concerns about the safety of ART procedures for consumers. The investigation revealed challenges in the extent of screening for genetic conditions in donors, with some providers managing potential genetic concerns proactively while others did not.

Within **Theme 3**, the investigation identified various challenges and shortcomings in record keeping and information provision by ART providers. These included issues such as inappropriate record keeping, failure to maintain accurate contact details for donors, and inadequate disclosure of medical information to donor-conceived children and recipients. The investigation emphasises the need for standardised documentation practices, digitisation of records, and clear policies for managing significant medical disclosures to ensure transparency, accountability, and patient safety. Additionally, the recommendation for regular contact with donors and the establishment of a central donor register aims to address existing gaps and enhance communication between stakeholders in the ART sector.

Despite the NHMRC Guidelines and RTAC's Code of Practice and Technical Bulletin 3, May 2011, investigations around **Theme 4** highlight inconsistencies in adhering to family limits across ART providers. Complaints regarding the failure to maintain appropriate family limits for the use of donor sperm have been noted and the potential significance of this issue may increase as children conceived through ART reach adulthood and seek familial connections via genetic ancestry databases. Inconsistent practices in defining what constitutes a 'family' contribute to these challenges. This investigation underscores the necessity for clear legislation defining gamete donor family limits, including a precise definition of what constitutes a 'family'.

Under **Theme 5**, complaints to the OHO and ART providers have highlighted concerns about whether consumers are provided with sufficient information to give their informed consent to treatment. Cases such as those involving the failure to advise consumers of medical conditions, the incorrect use of ICSI contrary to consumer wishes, and inadequate disclosure of test results

demonstrate the importance of robust informed consent processes. The investigation reveals several challenges encountered in the consent process, including instances where consent forms were not signed by clinicians, incomplete understanding of consent forms by consumers, and errors in the completion and understanding of consent forms leading to treatment deviations. These findings underscore the need for improvements in the consent process, including clearer communication, better documentation, and enhanced consumer understanding of treatment options and associated risks.

The quality of sperm is central to **Theme 6** and plays a pivotal role in determining the appropriate ART procedure. While conventional semen analyses guide clinical decisions, factors like sperm motility and morphology significantly influence the choice between IUI, IVF or ICSI. The investigation highlights consumer concerns about the quality of donor sperm, particularly in cases where the sperm used for assisted reproductive procedures does not meet expected standards. Complaints reveal instances of poor sperm quality leading to failed fertilisation, raising significant concerns for consumers and healthcare providers alike. The investigation underscores the importance of informed consent in ART procedures.

Theme 7 explores the ethical and regulatory complexities surrounding sex selection in ART. It underscores the importance of robust regulation to address both medical and non-medical reasons for sex selection, while acknowledging the challenges posed by differing legislative frameworks across Australian jurisdictions. Site visits revealed varied approaches among ART providers to the implementation of NHMRC Guidelines regarding sex selection, with some reporting pressures from consumers to provide sex selection services. Providers navigate these challenges by implementing policies to ensure compliance, including external testing and stringent review processes, underscoring the need for clear regulatory guidance in this contentious area of practice.

Theme 8 underscores the importance of a patient-centric approach in managing decisions and the disposal of gametes and/or embryos in ART services. Complaints highlighted instances where consumers experienced emotional distress due to delays and lack of clarity in the disposal process, emphasising the need for providers to prioritise consumer wellbeing and communication.

Relating to **Theme 9**, the investigation identified that while audits conducted by Certifying Bodies generally complied with RTAC requirements, there were inconsistencies in audit reports due to differences in organisation and auditing methods. The OHO observed that auditors were rigorous in their review of ART providers, but a standardised approach to audit forms could improve reporting by identifying local and systemic issues more effectively. Adverse event reporting revealed delays in notifications, with one notable case involving a significant delay of nearly one year in reporting a gamete mix-up incident. Concerns were raised about the transparency and efficacy of the reporting process, with instances where adverse events meeting criteria for reporting were not reported to RTAC, indicating potential gaps in oversight and compliance.

Within **Theme 10**, the investigation found significant differences in how ART providers manage complaints and incidents, leading to distress and dissatisfaction for some consumers. Despite the requirement for open disclosure and patient-centred care, some providers did not demonstrate transparency or a commitment to continuous improvement in their responses to consumers. The lack of a patient-centred approach in complaint management has raised concerns, with some cases resulting in substantial trauma for consumers and their families, such as the possibility of non-biological siblings due to alleged use of incorrect sperm.

Inappropriate or insensitive communication by ART providers can significantly exacerbate the stress already experienced by consumers and was evident in **Theme 11**. As examples, a case study contained in this investigation highlighted how the use of insensitive language by ART provider staff can upset consumers, emphasising the importance of recognising the emotional significance of discussions about genetic material and family creation; while another demonstrated

the importance of timing when delivering sensitive news to consumers undergoing ART procedures, where a consumer was contacted to request verbal consent to discard embryos close to a festive period, causing distress to the consumer.

Additional issues surrounding ART included: **Withdrawal of Consent** which explores specifying conditions under which donors can withdraw consent for the use of their gametes for ART while considering the limit of such withdrawal in relation to how far a treatment cycle has progressed (e.g. reserved donor sperm versus embryos that have already been generated); consideration of the establishment of an **Independent Mechanism for Review of Decisions about ART Treatments**; and the **Use of Non-Discriminatory Forms** to ensure that the patient registration forms are inclusive and respectful of all gender identities.

Background

Assisted Reproductive Technologies/Treatments (ART) are treatments or procedures that address fertility. They can include artificial insemination (AI) and in vitro fertilisation (IVF) as well as any other related treatments or procedures.[19] ART as an acronym can refer to technology or treatment, depending on the user.[20]

At present, there is no legislation regulating ART in Queensland.[21] The regulation of ART in Queensland currently falls to the self-regulatory accreditation system requiring adherence to the *Code of Practice for Assisted Reproductive Technology Units* published by the peak body, the Fertility Society of Australia and New Zealand (FSANZ). This Code was initially developed, and subsequently revised, by FSANZ's Reproductive Technology Accreditation Committee (RTAC) who oversee the issuing of Queensland licensing and the independent auditing of the ART providers. There are 24 licensed assisted reproductive technology (ART) providers in Queensland.

Queensland ART providers are also required to comply with the *Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice* published by the National Health and Medical Research Council (NHMRC).

On 2 November 2023, the Minister, directed the OHO to undertake an investigation under section 81 of *the Health Ombudsman Act 2013* (the Act) into ART providers within Queensland. The Minister's direction was prompted by several high-profile instances of alleged adverse events and regulatory failures regarding the provision of ART services in Queensland, which indicated a potentially systemic issue. At the Minister's request, the OHO investigation served, in part, to complement work being undertaken by Queensland Health to consider proposals for legislation to regulate the provision of ART services in Queensland, and to inform effective implementation of the Legal Affairs and Safety Committee's report titled *Inquiry into matters relating to donor conception information*.

The purpose of the OHO investigation was to examine the nature of issues raised about the provision of ART services in Queensland; to determine the extent to which such issues are systemic; and to use such findings to complement Queensland Health's considerations on proposals for state legislation, by way of recommendations by the OHO to Queensland Health. The investigation findings have also resulted in recommendations for ART providers and FSANZ-RTAC.

The investigation was undertaken in three phases, with data covering the period 1 July 2014 to 15 May 2024. Phase 1 commenced on 2 November 2023 and explored OHO matters from 1 July 2014 to 31 January 2024 to identify key themes. The Minister was provided with the Phase 1 interim report on 28 March 2024. Phase 2 commenced immediately thereafter and involved further examination of identified themes, identified additional themes and issues, and covered an extended period of time (1 February 2024 to 20 March 2024). The Minister was provided with the Phase 2 interim report on 17 May 2024. This report presents Phase 3 of the ART investigation and serves as the Final Report (under section 86 of the Act) provided to the Minister on 28 June 2024.

[19] https://www.health.nsw.gov.au/art/Pages/default.aspx.

[20] ART is defined as Assisted Reproductive Treatment in the Final Report of the Independent Review of Assisted Reproductive Treatment, Victoria, May 2019.

[21] The Queensland Government has drafted the Assisted Reproductive Technology Bill 2024 which was introduced into Parliament by the Health Minister on 22 May 2024.

Alongside this investigation, the OHO also assessed and is investigating 19[22] individual complaints which were made to the OHO both before and after the announcement of this Ministerial directed investigation. At the time of publication of this report, the majority of these matters were still being progressed.

[22] As of 15 May 2024.

Introduction

Overview of Assisted Reproductive Technology/Treatment services

What is Assisted Reproductive Technology/Treatment?

ART is a group of procedures that involve the handling of human oocytes (eggs), sperm and/or embryos for the purposes of establishing a pregnancy.[23] ART services involve clinical treatments; counselling services; and laboratory procedures for the assessment and preparation of human oocytes, sperm or embryos. ART treatments and procedures include:[24]

- ovulation induction (OI)
- in vitro fertilisation (IVF)
- intracytoplasmic sperm injection (ICSI)
- embryo or gamete cryopreservation
- surgical sperm recovery;
- oocyte, semen or embryo donation
- embryo biopsy for preimplantation genetic testing (PGT)
- gestational and traditional surrogacy
- intrauterine insemination (IUI, also known as AI).

Three commonly used ARTs are described below:

- IUI: Sperm (either donor or patient) is inserted into the uterus of a patient at the time of, just before, or just after ovulation. This can be performed during a natural menstrual cycle or medicated cycle that assists with follicular development and/or ovulation.
- IVF: Eggs are retrieved (collected) from a donor or a patient and fertilised using donor or patient sperm, outside the body in an embryology laboratory environment. Fertilised eggs then give rise to embryos that grow for 3–5 days (approximately) in the laboratory, whereafter they can be transferred to a recipient uterus (called an embryo transfer).
- ICSI: Similar to IVF, however, in this process, eggs are fertilised by an embryologist by selecting a single sperm under a microscope and injecting it into the egg using a microneedle.

Each ART treatment involves several stages and is generally referred to as an ART treatment cycle. The embryos transferred to a woman can either originate from the cycle in which they were created (fresh cycle) or be frozen (cryopreserved) and subsequently thawed for transfer to a recipient's uterus at a later stage (frozen cycle).[25,26]

The choice of ART (particularly IUI, IVF or ICSI) is multifaceted and relies on the experience and expertise of the managing clinician (fertility specialist) in consultation with the consumer(s).

[23] Assisted reproductive technology in Australia and New Zealand 2021 | National Perinatal Epidemiology and Statistics Unit (NPESU) (unsw.edu.au), accessed on 20 November 2023.

[24] As described by the RTAC Code of Practice (revised October 2021).

[25] Assisted reproductive technology in Australia and New Zealand 2021 | National Perinatal Epidemiology and Statistics Unit (NPESU) (unsw.edu.au), accessed on 20 November 2023.

[26] It is also possible to have eggs frozen and combined with sperm at a later date to create embryos that can be frozen / used fresh in a treatment cycle.

Considerations included in such consultations can also include the possible use of donated gametes (sperm and/or eggs), particularly for same sex couples.

It is estimated that more than 1.8 million ART cycles were undertaken globally in 2020 and more than 6 million children have been conceived using ART over the past three decades.[27] According to the Australia and New Zealand Assisted Reproductive Database (ANZARD), 102,157 cycles were undertaken in 2021, representing 19.6 cycles per 1,000 women of reproductive age (15–44 years), and resulting in 18,594 babies (representing approximately 6% of births in Australia).[28,29] In Queensland, ART services are not available through the public health system and are only available through private clinics across the state. Consumers are responsible for bearing the cost of the treatment; however, consumers may be eligible for reimbursement through Medicare (for example if diagnosed with medical infertility[30]) or private health insurance.[31]

ART in Australia

The regulation of ART in Australia is underpinned by a framework for the conduct of ART (both in clinical practice and research), which includes the overarching ethical guidelines established by the NHMRC, Commonwealth legislation, and state and territory legislation. Setting of standards for the performance of ART in Australia is the responsibility of RTAC, which is a professional group of the Board of the FSANZ. These standards are established and maintained through an audited Code of Practice (which relies on the RTAC Scheme[32] of rules, which defines the requirements for bodies providing audits and certification to the Code of Practice) and the granting of licences to practise ART within Australia.[33]

RTAC has attempted to align their Code of Practice with the regulatory and legislative requirements. However, there may be differences in detail between the Code of Practice, NHMRC Guidelines, and legislation and associated regulations relevant to ART that have been proclaimed by various governments. In such cases, as a general rule, when state or territory legislation is inconsistent with Commonwealth legislation then the state/territory law will be invalid to the extent of the inconsistency. Likewise, state/territory legislation will override any inconsistency with regulations/guidelines and the RTAC Code of Practice.

Regulation

National Health and Medical Research Council (NHMRC) Guidelines

The NHMRC is a federal statutory body, which developed the *Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research* (the NHMRC Guidelines).

The NHMRC first issued guidelines on ethical aspects of research related to assisted reproductive technology (ART) as Supplementary Note 4 (In Vitro Fertilisation and Embryo Transfer) to the then Statement on Human Experimentation (NHMRC 1966). These guidelines were rescinded when the

[27] Dyer S, Chambers GM, de Mouzon J, 'International Committee for Monitoring Assisted Reproductive Technologies world report: assisted reproductive technology 2008, 2009 and 2010', *Hum Reprod* 2016; 31: 1588-1609.

[28] www.unsw.edu.au/content/dam/pdfs/research/2023-12-npesu/2024-01-Assisted-Reproductive-Technology-in-Australia-and-New-Zealand-2021.pdf

[29] Australian Institute of Health and Welfare 2022, National Perinatal Data Collection annual update 2021.

[30] Gorton M, *Review of assisted reproductive treatment: consultation paper* (2018), p. 12.

[31] https://www.qld.gov.au/health/children/pregnancy/fertility, accessed on 20 November 2023.

[32] www.fertilitysociety.com.au/wp-content/uploads/RTAC-Scheme-20-December-2021.pdf

[33] RTAC Code of Practice | Fertility Society AU & NZ

National Health and Medical Research Council Act 1992 came into force.[34]

Since 1992, the Australian Health Ethics Committee (AHEC) has developed and revised the following ethical guidelines:[35]

- Ethical Guidelines on Assisted Reproductive Technology, 1996
- Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research, 2004 (revised 2007[36], 2017[37] and 2023[38]).

The 2004 guidelines took account of the *Prohibition of Human Cloning Act 2002* (Cwlth) (PHC Act) and the *Research involving Human Embryos Act 2002* (Cwlth) (RiHE Act). These guidelines were revised in 2007 to the extent necessitated by changes to the PHC Act and the RiHE Act brought about by the *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006*. Parts A and B of the Guidelines were revised in 2017 to ensure ongoing relevance and contemporary guidance. The Mitochondrial Donation Supplementary Section was added in 2023 to facilitate the ethical introduction of mitochondrial donation to prevent the transmission of severe mitochondrial diseases following enactment of the *Mitochondrial Donation Law Reform (Maeve's Law) Act 2022*.[39]

The NHMRC Guidelines were primarily developed for ART clinicians, scientists, nurses, researchers and governments.[40] Activities outlined in the NHMRC Guidelines must be carried out in compliance with existing laws and regulatory frameworks and professional and accreditation standards.[41]

The NHMRC Guidelines address wide-ranging aspects of ART including:

- providing guiding principles for the clinical practice of ART
- information, counselling and consent
- use of donated gametes and embryos in ART procedures
- storage of gametes and embryos
- data collection and reporting
- ethical practice of research involving human embryos and gametes
- fertility preservation
- surrogacy
- sex selection
- preimplantation genetic testing
- the collection and use of gametes posthumously.

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[34] As described in the NHMRC Ethical guidelines on the use of assisted reproductive technology in clinical practice and research 2017 (updated 2023).

[35] As described in the NHMRC Ethical guidelines on the use of assisted reproductive technology in clinical practice and research 2017 (updated 2023).

[36] https://webarchive.nla.gov.au/awa/20140401162613/http://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/e78.pdf

[37] https://webarchive.nla.gov.au/awa/20180516110110/https://www.nhmrc.gov.au/_files_nhmrc/file/guidelines/ethics/16506_nhmrc_-_ethical_guidelines_on_the_use_of_assisted_reproductive_technology-web.pdf

[38] https://www.nhmrc.gov.au/sites/default/files/2023-04/Ethical%20guidelines%20on%20the%20use%20of%20ART%20in%20clinical%20practice%20and%20research.pdf

[39] As described in the NHMRC Ethical guidelines on the use of assisted reproductive technology in clinical practice and research 2017 (updated 2023).

[40] As documented in https://www.nhmrc.gov.au/about-us/publications/art.

[41] NHMRC Guidelines, p. 11.

All ART providers must, at a minimum, comply with the NHMRC Guidelines. State/territory laws (where they exist) relating to ART treatment may also impose additional limits, conditions and restrictions.[42]

The NHMRC Guidelines are not subject to parliamentary approval. Review of the guidelines is undertaken by the appointment of a committee, public consultation, circulation of proposed draft revisions and further review / approval by the Australian Health Ethics Committee.[43] Infringement of the NHMRC Guidelines does not constitute a legal offence. For those Australian states/territories without legislation regulating ART, this leaves limited ability for enforcement, with any consequences restricted to providers who are recipients of NHMRC funding.[44]

Fertility Society of Australia and New Zealand (FSANZ) and the Reproductive Technology Accreditation Committee (RTAC) Code of Practice

The Fertility Society of Australia and New Zealand (FSANZ, also known as the Fertility Society, FSA) has established an oversight and accreditation system of ART providers through the Reproductive Technology Accreditation Committee (RTAC).[45] RTAC was established in 1987 and is a subcommittee of the FSANZ and reports directly to that Board.[46]

All persons and bodies offering ART services must be accredited by RTAC as the recognised accreditation body, or by another body prescribed by the Research involving Human Embryos Regulations 2017.[47] RTAC has set standards for the performance of ART through the development of a Code of Practice and the granting of licences to practise ART within Australia (i.e. accreditation).[48]

The accreditation of ART providers is the basis of a nationally consistent approach for overseeing ART clinical practice. Following the development and issuing of the 1996 ethical guidelines, ART providers had to obtain accreditation by a recognised accreditation body, which included compliance with relevant legislation and guidelines concerning the practice of ART, including the NHMRC Guidelines and the RTAC Code of Practice of the accreditation or licensing body.[49,50,51]

RTAC accreditation is required for ART services provided by ART providers to be eligible for Medicare funding.

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[42] For example, in Victoria, legislation governing ART is the *Assisted Reproductive Treatment Act 2008* setting the requirements for ART providers.

[43] *Report on the review of the Assisted Reproductive Treatment Act 1988* (SA), Sonia Allan, 2017, p. 32.

[44] McGray A, Smith M, Allen S, 'Access to Assisted Reproductive Technologies in Australia: Time for Legislative Change in Queensland and the Northern Territory to Remove the Ability to Discriminate Based on Relationship Status or Sexuality' (2023) 30 *JLM* 191-211, p. 193.

[45] McGray A, Smith M, Allen S, 'Access to Assisted Reproductive Technologies in Australia: Time for Legislative Change in Queensland and the Northern Territory to Remove the Ability to Discriminate Based on Relationship Status or Sexuality' (2023) 30 *JLM* 191-211, p. 193.

[46] RTAC Terms of Reference, issued January 2020. Accessed on 21 November 2023.

[47] The *Research Involving Human Embryos Act 2002* defines an accredited ART centre as a 'person or body accredited to carry out assisted reproductive technology by (a) the Reproductive Committee of the Fertility Society of Australia and New Zealand or (b) if the regulations prescribe another body or other bodies in addition to, or instead of, the body mentioned in paragraph (a)--that other body or any of those other bodies, as the case requires'.

[48] https://www.fertilitysociety.com.au/rtac-australia-new-zealand/, accessed on 20 November 2023.

[49] The Reproductive Technology Working Group (established by the Australian Health Ethics Committee) which was tasked in 1994 with redrafting the guidelines covering research and reproductive technology. The result of that was the 1996 guidelines.

[50] Ethical guidelines on the use of assisted reproductive technology, 1996, p. 3.

[51] Letter from FSANZ-RTAC to the OHO dated 4 March 2024.

The RTAC Annual Report for 2021–22 describes the accreditation process for ART providers as:

- A visit by one or two auditors from a Certifying Body and a review to confirm compliance with the Code of Practice. Once any non-conformities have been resolved, the Certifying Body can then issue a Certificate confirming compliance and a recommendation to RTAC to issue a licence.
- The RTAC Chair reviews the Certification report by the Certifying Body and decides whether to issue the licence.[52]

When a provider gains accreditation, it is issued with an RTAC accreditation number which is relevant, for example, to consumers being able to access IVF medicines via the Pharmaceutical Benefits Scheme.

There are two Certifying Bodies which currently undertake audits of ART providers in Australia and New Zealand: Certification Partner Global FZ LLC (CPG) and Global-Mark Pty Ltd.[53] The Certifying Bodies are also audited and approved by the Joint Accreditation System of Australia and New Zealand (JAS-ANZ).

Since 2009, RTAC has also issued Technical Bulletins from time to time, which are advisory / educational communications to all ART providers and bodies certifying ART providers to the RTAC Code of Practice. However, the information in these bulletins is not enforceable.[54] FSANZ-RTAC maintain that: 'While [Technical Bulletins] are not inherently enforceable, many of them eventually become part of the [Code of Practice] and thus become enforceable. This system offers great flexibility, allowing for potential changes to be tested before formal inclusion in the [Code of Practice]. However, some changes are introduced directly into the [Code of Practice] without undergoing the [Technical Bulletin] stage'.[55]

Commonwealth legislation[56]

In 2002, the Australian Parliament passed the *Prohibition of Human Cloning Act 2002* (PHC Act) and the *Research involving Human Embryos Act 2002* (RiHE Act) to prohibit human cloning and regulate certain uses of an embryo that is no longer required by the individual or couple responsible for the embryo. The RiHE Act limits the use and development of embryos during a woman's reproductive treatment to ART providers that have been accredited by RTAC.

The RiHE Act also established the Embryo Research Licensing Committee as a principal committee of the NHMRC. The *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006* (the Amendment Act) came into effect on 12 June 2007. The Amendment Act extended the range of licensable activities and changed the title of the PHC Act to the *Prohibition of Human Cloning for Reproduction Act 2002*.

The *Mitochondrial Donation Law Reform (Maeve's Law) Act 2022* came into effect on 1 October 2022. The amendments to the RiHE and PHCR Acts allow the introduction of mitochondrial donation techniques in Australia, through a staged approach and under strict regulatory conditions, to prevent transmission of severe mitochondrial disease.

[52] RTAC Annual Report, 2021-22, p. 4.

[53] DNV was also a Certifying Body during the time period considered by the OHO.

[54] The Technical Bulletins issued by RTAC (a total of 13 to date) are listed in and can be accessed electronically via https://www.fertilitysociety.com.au/code-of-practice/#tech.

[55] Letter from FSANZ-RTAC to the OHO dated 4 March 2024.

[56] As described in the NHMRC Ethical guidelines on the use of assisted reproductive technology in clinical practice and research 2017 (updated 2023).

State and territory legislation

Table 1 shows the relevant laws and regulations on ART treatment applicable to each state and territory in Australia.[57]

Table 1: ART legislation and regulations in Australia

ART Regulation across Australia: federal accreditation, ethical guidance and licensing conditions established through *Prohibition of Human Cloning for Reproduction Act 2002; Research Involving Human Embryos Act 2002*; NHMRC Guidelines (2017); and RTAC Code of Practice (2021)	
Queensland, Northern Territory, Tasmania	No specific ART legislation
Australian Capital Territory	*Assisted Reproductive Technology Act 2024*
Victoria	*Assisted Reproductive Treatment Act 2008* Assisted Reproductive Treatment Regulations 2009 *Status of Children Act 1974* Regulatory Authority – Victorian Assisted Reproductive Authority (VARTA)
South Australia	*Assisted Reproductive Treatment Act 1988* Assisted Reproductive Treatment Regulations 2010 *Family Relationships Act 1975*
New South Wales	*Assisted Reproductive Technology Act 2007* Assisted Reproductive Technology Regulations 2009
Western Australia	*Human Reproductive Technology Act 1991* Human Reproductive Technology (Licences and Registers) Regulations 1993 *Human Reproductive Technology Act Directions 2004* Regulatory Authority – Western Australia Reproductive Technology Council

Queensland, the Northern Territory[58] and Tasmania do not have legislation governing ART. However, the Queensland Government has drafted the *Assisted Reproductive Technology Bill 2024* which was introduced into Parliament by the Minister on 22 May 2024.[59]

Queensland has legislation on human embryo research and cloning (*Research Involving Human Embryos and Prohibition of Human Cloning for Reproduction Act 2003*) and surrogacy (*Surrogacy Act 2010*).

At present, regulation of ART in Queensland falls to the self-regulatory accreditation system requiring adherence to the NHMRC Guidelines and the RTAC Code of Practice, with the voluntary

[57] Karpin I and Millbank J, 'Regulation of Assisted Reproductive Technology and Surrogacy in Australia', *Routledge Handbook of Family Law and Policy*, 27 July 2020, 200-214, p. 203, accessed on 24 November 2023.

[58] While there is no specific legislation governing reproductive technology in the Northern Territory (NT), reproductive medicine services in the NT are provided by South Australian clinicians operating under guidelines consistent with the South Australian legislation - *The Review of the Western Australian Human Reproductive Technology Act 1991 and the Surrogacy Act 2008 (Report: Part 1)*, 2019 by Sonia Allan, p. 45.

[59] https://www.legislation.qld.gov.au/view/html/bill.first/bill-2024-012

adoption of international standards.[60] While noting the work undertaken by the ART industry in Australia to develop and uphold a high standard of quality and safe healthcare delivery through research, guidelines and codes of practice, self-regulation has no enforcement mechanisms or sanctions for non-compliance other than consequences for licensing and accreditation. While acknowledging that the RTAC Code of Practice mandates the reporting of adverse events and the RTAC certification requires audits by independent auditors who report results to RTAC, the monitoring of compliance in a self-regulation regime rests with the industry and is not subject to external verification, reporting or oversight. This is in contrast to regulated sectors, where independent oversight and safeguards are provided through legislation and regulations.

National Safety and Quality in Health Services Standards

The National Safety and Quality in Health Services (NSQHS) Standards were developed by the Australian Commission into Safety and Quality in Health Care in collaboration with the Australian Government, states and territories, private sector providers, clinical experts, consumers and carers.[61] Implementation of these standards is mandated in all hospitals, day procedure services and public dental services across Australia. Other healthcare providers can choose to be assessed and accredited against these standards. Specific standards have also been developed for primary care and community settings, and more recently for cosmetic surgery. The primary aims of the NSQHS Standards are to protect the public from harm, to improve the quality of health service provision and provide a nationally consistent statement about the level of care consumers can expect from health services. The standards cover areas such as Clinical Governance, including incident management, complaint systems and open disclosure of adverse events, as well as Partnering with Consumers which references the Australian Charter of Health Care Rights and Communicating for Safety. To date, it appears that these standards have not been adapted for ART services within Queensland and these elements are not incorporated within the RTAC Code of Practice.

It is, however, of note that in Victoria recent changes following the Independent Review of Assisted Reproductive Treatment (the Gorton Review),[62] public fertility care services are being rolled out throughout the state.[63] These providers will be subject to regulation governing the ART provision in the state, and may also need to comply with the NSQHS Standards[64] as a means of providing independent oversight and safeguards to the provision of these services.

Individual practitioner responsibilities

While Queensland does not have legislation governing the use of ART, providers must abide by the RTAC Code of Practice. However, it is also relevant that registered practitioners must comply with the Code of Conduct relevant to their practice area. For doctors this is *Good medical practice: a code of conduct for doctors in Australia*[65] (Code of Conduct for doctors) and for nurses, the *Code of Conduct for Nurses.*[66] While this report is considering services provided by ART providers, it is relevant that the clinical staff will be governed by their own professional obligations. Registered

[60] McGray A, Smith M, Allen S, 'Access to Assisted Reproductive Technologies in Australia: Time for Legislative Change in Queensland and the Northern Territory to Remove the Ability to Discriminate Based on Relationship Status or Sexuality' (2023) 30 *JLM* 191-211, p. 194.

[61] National Safety and Quality Health Service Standards (Second Edition), May 2021.

[62] Independent Review of Assisted Reproductive Treatment, May 2019, Michael Gorton.

[63] Department of Health, Victoria, website February 2024.

[64] Australian Commission on Safety and Quality in Health Care National Safety and Quality Standards, 2021.

[65] *Good medical practice: a code of conduct for doctors in Australia*, Medical Board, Australia Health Practitioner Regulation Agency, October 2020.

[66] *Code of Conduct for Nurses*, Nursing and Midwifery Board of Australia, Australia Health Practitioner Regulation Agency, 2018, updated June 2022.

practitioners must consider their own code of conduct and ethical responsibilities to consumers and cannot obviate their duties on the basis that it is the responsibility of the 'facility'.

It is noted that scientists do not have the same accountability as registered practitioners and do have a significant responsibility for quality control within ART services through the mandated roles of Scientific Director under the RTAC accreditation requirements.[67,68]

The involvement of individuals is not within the scope of the investigation, but the obligations of registered practitioners form part of the regulatory framework for ART.

Queensland ART market

According to ANZARD, the number of ART cycles initiated in 2021 in Australia and Queensland were 102,157 and 21,246 respectively [69]. As such, approximately 21% of ART cycles in Australia are undertaken in Queensland.

As of January 2024, there were 24 ART providers licensed by RTAC which are operating in Queensland (Appendix 1: List of ART providers in Queensland). Regional offices of the same organisation are regarded as separate entities.

[67] For ART laboratories, the clinical scientist must meet the criteria in the RTAC Code of Practice for scientific directors (National Pathology Accreditation Advisory Council Guidelines (NPAAC)). The NPAAC provides a level of accountability in relation to the role of the clinical scientist.

[68] The RTAC Code of Practice requires that an ART unit must appoint key personnel ('Personnel' being one of the Critical Criteria in the CoP which is subject to auditing), which includes a Medical Director, Scientific Director, Nurse Manager, and a Senior Counsellor.

[69] ANZARD Data 2021 https://npesu.unsw.edu.au/sites/default/files/npesu/data_collection/Assisted%20Reproductive%20Technology%20in%20Australia%20and%20New%20Zealand%202021.pdf.

Investigation scope

In accordance with the direction of the Minister,[70] the scope of the investigation included all Queensland ART providers and examination of all current and closed complaints made to the OHO about ART services. The investigation assessed information from 1 July 2014 to 15 May 2024, and was conducted in three phases, commencing on 2 November 2023 and concluding with a published report on 28 June 2024.

The initial scope of the investigation included the examination of any identified issues, non-compliance or adverse events associated with:

1. The handling of gametes and embryos, including collection, labelling, storage and transportation
2. Screening techniques for gametes, embryos and donors used in Queensland
3. Record keeping including donor and recipient information sharing and compliance with updating records relating to changes in donor's health information
4. Maximum donation and distribution of gametes within Australia

During Phase 1, additional issues were identified which were approved by the Minister to form part of the OHO's investigation. The additional issues for investigation included:

5. Provision of adequate information to allow consumers to provide informed consent when choosing ART treatment
6. Sperm quality: relating to consumers using donated sperm where there is an expectation that the sperm will be of good quality and where the use of poor-quality sperm may impact on the consumer's choice of ART treatment or requirement to use ICSI
7. Sex selection: relating to the use of sex selection in contravention with the National Health and Medical Research Council Guidelines
8. Discarding of gametes/embryos (genetic or biological material)[71]: relating to concerns raised by consumers about the delays and issues associated with the destruction of gametes/embryos, impacting on consumers

The investigation also examined the following themes identified from the analysis of complaints and information obtained for this investigation:

9. Current mechanisms for the oversight of ART services and applicable standards
10. Open disclosure and the management of complaints and adverse events by ART providers
11. Impacts on consumers identified in responses to complaints and adverse events.

[70] Letter from the Health Minister to the Health Ombudsman, 2 November 2023.

[71] The original scope of the investigation referred to the disposal of genetic or biological material. This has been amended to respectfully refer to the discarding of gametes and/or embryos.

Approach

The investigation involved the review of data from active and closed OHO matters (including complaints and enquiries) to assist in the identification of systemic issues within the Queensland ART sector. Alongside this investigation, the OHO is assessing and investigating 19[72] individual complaints which were made to the OHO both before and after the announcement of the Ministerial directed investigation. Themes and issues identified in these individual investigations progressively informed this ART investigation. Additionally, ART providers and related organisations were consulted to further explore possible issues in service provision and the challenges experienced by users of ART services in Queensland. An expert advisory panel was established under section 29 of the Act to provide advice and input on the range of issues being considered by the investigation, including expert clinical opinion on specific issues.

Based on the scope, the OHO's investigation reviewed all closed and open matters raised with the OHO related to any/all ART providers in Queensland from 1 July 2014 to 15 May 2024 to identify any recurrent (repeated complaints of a particular nature) and systemic issues (complaints of a particular nature from more than one ART unit), which were then used to develop themes.

These themes were then explored further, by obtaining related information from individual ART providers and FSANZ-RTAC through the information requirement powers of section 228 of the Act; through OHO-led ART provider site visits and interviews; and through consultation with clinical and sector experts.

Interim reports on phases 1 and 2 were provided to the Minister in accordance with section 177(1) of the Act.

[72] As of 15 May 2024.

Methodology

Information and data

Data sources

The investigation assessed OHO matters from 1 July 2014 to 15 May 2024. Additionally, ART providers were required to provide complaints and adverse event data associated with the scope of this report from 1 January 2018 to 14 March 2024. Supplementary information was provided by RTAC, Certifying Bodies, ART provider site visits by the OHO, clinical experts, an audit attendance by an OHO investigator, and consumer surveys conducted by the OHO.

Based on the above approach, data for this report was obtained for the period 1 July 2014 to 15 May 2024 from the following sources:

1. OHO matters, which included:
    a. Complaints[73]
    b. Enquiries[74]
2. RTAC information, which included:
    a. Aggregate audit (non-conformities) and adverse events data for ART providers within Australia
    b. Supporting information and documentation
3. ART providers, which included:
    a. Audit information
    b. Complaints (received directly from consumers)
    c. Adverse events
4. Certifying Bodies, which included:
    a. Audit information
    b. Interviews with key auditors.

Further to the above, information, insights and opinions were sought from:

1. Selected ART providers by way of on-site visits and interviews with key personnel:
    a. ART provider site visit information was obtained by in-person interviews under section 228 notice for three ART providers.
2. Expert ART clinical and sector governance advice by way of an Expert Panel[75] engaged by the OHO:
    a. Clinical expert opinions included those of:

[73] A complaint (or health service complaint) is a complaint about a health service or other service provided by a health service provider (sections 7, 8 and 31 of the *Health Ombudsman Act 2013*).

[74] An enquiry is contact made with the OHO by a person who is raising an issue or query that does not constitute a health service complaint or notification.

[75] An expert advisory panel was established under section 29 of the Act to provide advice and input on the range of issues being considered by the investigation, including expert clinical opinion on specific issues.

i. Prof. Robert Norman[76]

ii. Mr Michael Barry[77]

iii. Dr Karin Hammarberg[78]

b. ART governance opinions included those of:

i. Louise Johnson[79]

ii. Michael Gorton AM[80]

3. Consumers by way of surveys:

a. Consumers who had open matters with the OHO at 2 November 2023 and consented to be involved in a survey were provided with the opportunity to provide feedback to the OHO on their experiences of ART.

4. Audit attendance:

a. On 20 February 2024, an OHO investigator attended an audit as an observer.

The OHO also considered relevant inquiries, legislation, regulations and guidelines from other states and territories given the extensive work already undertaken in exploring issues occurring with the ART sector. Relevant reports included the Gorton Review[81] and the subsequent inquiry by the Victorian Health Complaint Commissioner, the *Inquiry into Assisted Reproductive Treatment Practices in Victoria* (HCC Inquiry)[82]. The review of these reports also assisted the OHO in determining a consistent approach to recommendations to improve service delivery where deficiencies were identified.

Limitations

It was beyond the scope of this investigation to complete an examination of all relevant policies and procedures from ART providers, or a review of overall consumer outcomes and experiences in using ART services in Queensland. In accordance with the Minister's direction, the OHO's investigation focused on issues identified from consumer complaints, adverse events and non-compliance by ART providers in respect of applicable requirements. Relevant policies and procedures, however, were examined in the assessment and investigation of individual matters which informed this systemic investigation. While ART providers may have relevant policies and procedures in place, this investigation has identified issues that appear to result from either lack of adherence to existing policies, practice issues or potential policy and procedural gaps that should be addressed. Complaints, adverse events, incidents and reports of non-compliance are recognised as critical sources of data for identifying potential systemic issues which warrant service improvement and/or regulatory action.

[76] BSc (Hons), MBChB (Hons), MD (Natal), MD (Hon, University of Adelaide), FRANZCOG, FRCPA, FRCPath, FRCOG, CREI, FAHMS, GAICD; Professor for Reproductive and Periconceptual Medicine at the University of Adelaide and a subspecialist in reproductive medicine (CREI) and in endocrine biochemistry (FRCPA).

[77] BSc, MCE - Scientific Director at Flinders Fertility. For over three decades Michael has been pivotal to the success of IVF technology in South Australia, leading innovation and advances in clinical embryology.

[78] RN, BSc, PhD - Senior Research Fellow in the School of Public Health and Preventive Medicine. Registered Nurse with 20 years experience as clinical coordinator of IVF programs.

[79] Former CEO of the Victorian Assisted Reproductive Treatment Authority, BSc (Hons) majoring in microbiology, Master of Regulatory Studies.

[80] Former Chair of the Victorian Assisted Reproductive Treatment Authority and Patient Review Panel, Principal at Russell Kennedy Lawyers, LLB, BCom.

[81] Independent Review of Assisted Reproductive Treatment, May 2019, Michael Gorton.

[82] Health Care Complaints Commissioner (Vic), *Inquiry into Assisted Reproductive Treatment Practices in Victoria,* Final Report (2020)

The OHO notes the following perspective on complaint data put forward by FSANZ-RTAC:

> ***Perspective on Complaint Numbers:*** *The complaints span a decade, from July 1, 2014, to March 20, 2024. To provide context, RTAC has requested data from ANZARD on the total number of ART cycles conducted in Queensland during this period. This information helps to contextualize the number of complaints relative to the volume of treatments performed.*
>
> *Based on ANZARD data, the RTAC chair estimated that there were 19,659 IVFDI cycles and 790 IUID cycles in Queensland from July 1, 2014, to March 30, 2024, averaging about 2,000 cycles per year. This report identified 234[83] complaints, which is 0.14% of all cycles in Queensland (167,000) and 1.1% of all cycles using donor sperm. It is important to note that not all the complaints were associated with donor sperm.[84]*

While it is accepted that number of complaints may represent a small proportion of total treatments, it is also important to recognise that complaints only represent a proportion of consumers who may have had an adverse experience, given the reluctance or concerns that people can have about making a complaint. The insights from complaints are therefore critical for identifying quality and safety issues in service provision and for addressing significant impacts for consumers.

It is also noted that this investigation has focused on services provided by ART providers and does not cover the roles of fertility specialists who are not employed by, but are affiliated with, particular ART providers. The need to consider the role and responsibilities of fertility specialists has been raised in submissions by ART providers, particularly in respect of Themes 5 and 6.

[83] The OHO complaint data has been subsequently updated to include complaints up to 15 May 2024

[84] Letter from FSANZ-RTAC to the OHO dated 14 June 2024

Results

OHO data

The Minister directed the OHO to review all past and current complaints relating to the provision of ART services. The complaint data is referred to throughout the report under relevant theme headings.

The OHO assessed over **1,226 data records**, which included OHO matters; Complaints (from ART providers provided to the OHO); Audits (provided by Certifying Bodies and ART providers); and adverse events (from ART providers provided to the OHO) (Table 2), of which **242 (approximately 21%)** were within the scope of this investigation.

Detailed analysis of the OHO complaint data can be found in Appendix 3B: OHO data.

Findings and observations

Theme 1: Appropriate collection, storage, identification and distribution of gametes and embryos

This theme explored whether there are appropriate protocols and practices to ensure that gametes and embryos, where applicable, were appropriately collected (primarily relating to sperm), stored, identified and provided to consumers for purposes of ART so that consumers are assured that they are being provided with the intended gametes and embryos.

Background

Overview of relevant requirements in the NHMRC Guidelines and the RTAC Code of Practice

In order to meet RTAC's accreditation requirements, Queensland ART providers are required to operate in accordance with the NHMRC Guidelines.[85,86]

Chapter 5 of the NHMRC Guidelines makes provision for the use of donated gametes in ART activities. Gametes may be donated to a specific recipient who is known to the donor (known donation) or to anyone who is receiving ART treatment (clinic recruited donor).

Chapter 7 of the NHMRC Guidelines makes provision for the responsibilities of the ART provider for the use, continued storage or discarding of stored gametes and embryos. ART providers must have obtained valid consent for the storage of gametes and embryos.

ART providers must have procedures in place to ensure all reasonable efforts are made to maintain the safe storage and accurate identification of all gametes and embryos with all procedures consistent with current best practice.

ART providers must also ensure that all reasonable efforts[87] are made to keep gametes and embryos in safe storage for the period of storage specified in the consent form. After this time, if the individual or couple responsible for the stored gametes and embryos cannot be contacted to provide further direction and consent, the ART provider may discard the gametes or embryos in accordance with the ART provider's policy.

The suitability of gametes or embryos for continued storage is a clinical determination. However, if there is no evidence of deterioration, decisions about the continued storage of gametes or embryos may depend entirely on the preferences of the responsible parties.[88]

The Code of Practice also provides that the ART provider must ensure that gametes, embryos and consumers are correctly identified and matched at all times and, in particular, ensure that anyone

[85] The NHMRC Guidelines, in some form, and based upon the provisions of the *National Health and Medical Research Council Act 1992* (Cwlth), have been in place since 1996. The guidelines were heavily revised and reissued in 2004 to continue to promote ethical practice in ART with respect to clinical practice and with respect to research. The guidelines were also revised and reissued in 2007, 2017 and 2023.

[86] The original set of standards promoted by the Fertility Society of Australia, known as the 'Guidelines for Centres using Assisted Reproductive Technology (ART) in Australia and New Zealand' was first introduced in 1986. In 1987, RTAC was established and added explanatory notes to many of the original standards drawn up by the FSA. This initial code was revised in 1992, 1997, 2001 and 2005. It was fully rewritten in 2008 with revisions in 2010, 2014, 2017 and 2021.

[87] The NHMRC Guidelines define Reasonable effort(s) as implying 'that what can be done should be done, given the particular circumstances' and that what 'is reasonable in the circumstances will depend on the context'.

[88] Responsible parties may include male and female gamete donors, donor recipients and ART providers.

providing a semen sample confirm in writing on each occasion that the sample is theirs.[89] Further, the ART unit must provide evidence of the implementation and review of:

- the process that constitutes the traceability of gametes and embryos at all stages of the treatment cycle and associated digital and manual records, including where transport is involved
- regular (at least annual) audit of the patient, gamete and embryo identification process and associated digital and manual records.

In terms of cryostorage of gametes and embryos, the Code of Practice stipulates that the ART unit must provide evidence of implementation and review of policies and procedures to ensure the safe management of cryopreserved gametes, embryos and tissues. These records must include, but are not limited to, clear identification of the storage container in a form that is resistant to degradation during cryostorage, and the location of the container in the storage vessel. It is appropriate to note that advancements in technology have seen developments in this area over the years, as the means for identification at this point in the process have not always been resistant to degradation. Records must be kept of temperature variations within the vessel that may affect the viability of any stored biological material. There must also be a policy covering the temperature monitoring of storage vessels.[90]

Investigation findings

Theme 1 is the most predominant theme identified in the OHO investigation, accounting for 28% of all OHO issues (Table 4) and 40% of all ART provider complaint data (Table 7), where issues with identification and traceability are among the most serious the OHO has examined. Theme 1 also featured dominantly in audit data (relating to a non-conformity or improvement request) and adverse events data.

Allegations raised with the OHO included:

- use of sperm stored for more than a 10-year period
- misplacement of a vial of donor sperm
- use of an embryo without the donor's consent
- loss of last sample of consumer's sperm
- malfunction of temperature gauge during transportation of embryo, resulting in unviable embryo
- incorrect embryo used during an embryo transfer
- mixing of eggs with sperm from incorrect donor.[91]

RTAC data (Table 12 in Appendix 3D: RTAC data) reveals that Queensland ART providers have the highest national rate of non-conformities related to identification and traceability (42% as compared with the next highest, Victoria, with 20%), where this category (identification and traceability) represents nearly one-third of all Queensland non-conformities (Table 11 in Appendix 3D: RTAC data).

[89] Code of Practice, s 2.6.

[90] Code of Practice, s 2.9.

[91] These allegations have been made to OHO via complaints and the Health Ombudsman may not have made a decision on the outcome of the matter/s.

It is unsurprising that consumers are motivated to complain about such incidents given the severity of outcomes if processes are not adhered to during the early stages of fertility treatment. Any failings in this regard may mean that treatment cannot take place, is delayed, or severely confounded.

In complaints to the OHO made in the last three years, concerns have included misplacement of donor sperm; breakage of a sperm vial and subsequent loss of a gamete sample;[92] a provider using a donor embryo for a recipient, which the donor had not consented to; and the incorrect selection of an embryo. A particularly concerning matter relates to the alleged mix-up of donor sperm, resulting in children within a particular family unit having potentially different biological fathers / paternal origins (Case Study 1). It must be emphasised that findings have not yet been made on these allegations but it is clear that the concerns raised have a significant impact on the consumers involved.

Case Study 1

A couple undertook ART treatment from a provider resulting in three children. The couple intended for all three children to be biologically related using a single sperm donor of their choice. Following private genetic testing undertaken by the couple, they learned that their two younger children were not biologically related to the oldest child, although the two younger children are full siblings. One of the younger children also has significant disabilities which may have been inherited from the unintended sperm donor. The provider maintains that the same donor sperm was used to produce all three children.

Note: This matter had not been concluded at the time of publication of this systemic investigation report and no findings had been made.

The impact on consumers and the donor-conceived children in cases of gamete mix-ups cannot be underestimated. The trauma and distress associated with these cases has been evident in the complaints made to the OHO. These incidents (whether ultimately established to have occurred or not) must be thoroughly investigated, with the consumer and their family involved throughout the process, via open disclosure. Appropriate counselling should be offered by ART providers to ensure that consumers and their families are given appropriate support to manage the emotional turmoil created with uncertainty about paternity and genetic origins. The implications for families from such errors are life-long.

In Case Study 2, below, the implications are far reaching for the patient as well as her former partner. It raises issues of patient consent, where the patient did not consent to the transfer of an embryo generated from a cycle undertaken with her former partner (using donor sperm). In addition, the former partner did not consent to the use of the embryo from a cycle he had previously undertaken. This is a highly sensitive matter which was identified from the adverse event reports provided to the OHO. It is outlined in Case Study 2 to illustrate the significant issues that can occur in matters involving errors in embryo identification and the need for oversight and safeguards for these treatments, and associated disclosure processes. It also raises significant questions about patient rights in these circumstances.

[92] In a letter from FSANZ-RTAC to the OHO dated 4 March 2024, it is stated: 'Cryogenic storage containers are inherently fragile due to the extreme environment they are kept in, some loss is inevitable and RTAC is aware that patients are advised of this risk. Again, technology has improved, and losses are less today but only if the newer technology is used as a storage solution. A vial frozen 20 years ago and thawed today has a fragility associated with that older technology and with the longer storage period.'

Case Study 2

A provider used the incorrect embryo for transfer. A patient undertook two cycles, both of which generated embryos which were stored: (1) with her partner, using her (the patient's) eggs and donor sperm; (2) as a single woman using her own eggs and the same donor sperm, following separation from her partner. While the patient requested an embryo from cycle 2 to be transferred, an embryo from cycle 1 was erroneously transferred instead.

This error was identified by the provider shortly after transfer of the embryo. At a management meeting, a decision was made not to inform the patient at that stage, on the basis that this was not in the best interests of the patient physically or emotionally. More than a week later, the patient had a positive pregnancy test. Fourteen days after the error was identified, the Clinic Ethics Committee was convened, and a decision was made to inform the patient. During this period, the patient underwent a viability scan, unaware of the issues with her treatment. A file note was made approximately three weeks after the Committee meeting to confirm that the patient was going to be informed, but it is unclear if or when this occurred.

The total delay between the identification of the incident and the date it was intended the patient would be informed was almost six weeks.

Record keeping (also addressed in Theme 3) has relevance to the appropriate collection, storage, identification and distribution of gametes and embryos. The OHO identified issues with potential misidentification of gametes where poor record keeping appears to have been a factor. Lack of accurate records can also result in difficulties with investigating allegations in complaints made to the OHO. Good record keeping is a fundamental element of healthcare and is of pivotal importance when dealing with family creation. It is recognised that while some issues with record keeping by ART providers reflect historical practices, these issues may still be relevant if donor sperm is still in use many years after donation.

The OHO was advised that Provider E undertook an audit of sperm samples due to risks in being able to prove seamless end-to-end double witnessing of donor sperm samples when assessed against evidence that linked the initial material to the frozen sample. It was found that thousands of samples, frozen before 2020, were determined to be high risk because they did not comply with double witnessing. It was noted that for donors frozen after 2021, 96% of vials were rated as low risk; however, this still leaves 4% of vials that were deemed to be medium or high risk.

While it is acknowledged that human error and mistakes can occur in any environment, the trend apparent from complaints is that collection, storage, identification and distribution of gametes and embryos is an ongoing issue despite advances in technology and regulatory guidelines. This risk was highlighted within the Gorton review, where it is stated*, 'ART relies heavily on the skills and expertise of people working within clinic laboratories. There are extensive risks associated with the collection, storage and use of genetic materials. There is a low but serious risk that genetic material collected may be inaccurately identified, for example, if the identity of a donor is not accurately recorded'.*[93] This suggests that there should be stricter compliance with basic procedures. It is also noted that one facility had not undertaken an identification and traceability internal audit within the last 12 months. This indicates that this particular facility may not recognise

[93] Independent Review of Assisted Reproductive Treatment, May 2019, Michael Gorton.

the value of internal auditing in identifying and addressing important process issues. FSANZ-RTAC maintains that:

> *While the case studies cited, and other historical events reviewed, offer guidance these are not representative of current practice and protocols in contemporary clinic and laboratory operation. Indeed, the improved current practice is an example of how the collegiate model fostered through RTAC's work has encouraged clinics to be rapid adopters of advancing technology and improved protocols. Adoption of proscriptive standards or processes based on historical case studies may result in slowing the rate at which clinics could or would adopt future available improvements.*[94]

Further, FSANZ-RTAC has added:

> *1. Separation of Historical and Contemporary Practices: It is essential to acknowledge that contemporary ART practices are highly reliable. The risk of identification errors, which was a concern in historical contexts, is now minimal due to the implementation of sophisticated identification and tracking systems.*
>
> *2. Disposal of Non-Conforming Donor Material: RTAC recommends that all stored donor material not meeting current identification standards be disposed of. This step will ensure that the only remaining risk pertains to materials already used, thereby safeguarding future procedures. However, we recognize that this recommendation may face significant pushback from recipients who are unable to complete their families with the existing donor material. The emotional and psychological impact on these individuals and families must not be underestimated. To address these concerns, it is essential to implement comprehensive support mechanisms, including counselling and clear communication, to help affected recipients navigate this challenging transition. Balancing the need for stringent safety standards with empathy and support for those impacted is crucial in maintaining trust and confidence in ART services.*
>
> *3. Australia and NZ-Wide Implementation: This recommendation should be adopted across Australia and New Zealand to ensure a uniform standard of safety and reliability in ART practices.*[95]

The OHO considers that the evidence reviewed during the investigation indicates that issues in respect to the appropriate collection, storage, identification and distribution of gametes and embryos, including compliance with standard procedures, continue to persist. Table 5 provides clear evidence that complainant concerns regarding Theme 1 are ongoing and do relate to recent treatment. The OHO received 9 complaints relating to Theme 1 where the treatment took place in the last 1 – 3 years, representing 36% of the total complaints for this theme. A continuous improvement culture is critical to achieving standards and compliance with the NHMRC Guidelines and RTAC Code of Practice. Given that ART providers are managing biological (genetic) material and the creation of families, any systemic breakdown has the potential to have a significant impact on consumers and their children.

Given FSANZ-RTAC's position on the disposal of stored donor material not meeting the current identification standards, the OHO considers that this should be enforced by FSANZ-RTAC and reviewed as part of their auditing process. A recommendation is made by the OHO to ensure that FSANZ-RTAC implement this requirement across all providers.

[94] Letter from FSANZ-RTAC to the OHO dated 4 March 2024.

[95] Letter from FSANZ-RTAC to the OHO dated 14 June 2024.

Consumer perspective

In a response to the OHO consumer survey a consumer has commented:

> *The policies and procedures need to be fixed when a donor has donated, double checking the labels, not having donors donate on the same day (may help with mislabelling). The donor list I have of the siblings is incorrect now.*

Site visits

Site visits undertaken by the OHO confirmed that:

- Many providers now use RI Witness,[96] or similar system, which is a system to minimise human error, especially in light of global incidents prompting heightened vigilance.
- At every stage, two independent individuals witness movements of gametes, ensuring three points of identification, typically name, date of birth, and a unique identifier at every interaction.
- Providers are constantly adapting to technological advancements in the field, such as the transition from manual processes to commercial products.
- There have been improvements in the ART process over the past decade, highlighting digitisation, reduced paperwork, increased professionalism, and enhanced accreditation standards as notable developments.

Expert opinion

Mr Barry has commented on the appropriate collection, storage, identification and distribution of gametes and embryos:

> *The mixing of gametes/ embryos in human IVF is an uncommon event. (Rasouli MA, et al 2021)[97] Embryologists and scientists handling gametes and embryos are diligent and follow procedures to ensure such events do not happen. However there have been documented incidents where a mix up has occurred.*
>
> *When mixes up have taken place it usually points to:*
>
> - *Insufficient work instructions and protocols*
> - *No or incomplete chain of custody systems and/or protocols.*
> - *overtasked employees*
> - *inadequately trained or an under qualified employee.*
> - *Insufficient staff present to manage the immediate tasks.*
> - *time pressures from clinical staff. (Sakkas D, et al. 2015)[98]*

[96] RI Witness is an electronic system used in laboratories which monitors sample movement. RI Witness identifies any mismatches between the sample being reviewed and the records and will sound an alarm if this occurs.

[97] Rasouli MA, Moutos CP & Phelps JY (2021), 'Liability for embryo mix-ups in fertility practices in the USA', *Journal of Assisted Reproduction and Genetics*, 38(5), 1101–1107, https://doi.org/10.1007/s10815-021-02108-1

[98] Sakkas D, Pool TB, Barrett CB, 'Analyzing IVF laboratory error rates: highlight or hide?', *Reprod Biomed Online,* 2015 Oct;31(4):447-8, doi: 10.1016/j.rbmo.2015.08.006. Epub 2015 Aug 14. PMID: 26433559.

The processes needed to reduce the risk of a mix up pivot around clinical and laboratory protocols and work practices.

- *treat each patient independently whilst conducting laboratory and clinical treatment.*
- *record clear and legible laboratory documentation for each patient treatment cycle.*
- *use clear and legibly labelled laboratory disposables in the treatment of patients.*
- *have a system of double witnessing all clinical and laboratory procedures by a second staff member or an electronic witnessing system.*
- *implement a protocolised chain of custody for each treatment type conducted by the laboratory and clinical staff.*
- *ensure the fertility clinic has competently trained staff.*

Conclusions

The ART providers were transparent and open during the site visits about the historical challenges with record keeping. RI Witness and other technological advances make a considerable difference to accuracy of record keeping and reducing risks of human error. The OHO was reassured by the information obtained during the site visits of examples of good record keeping practices and an expressed commitment by the ART providers to maintaining these practices. However, given the evidence of the continuing issues and risks in respect of the appropriate collection, storage, identification and distribution of gametes and embryos, it is important that these risks are considered in proposed legislation and regulations and the practices adopted by ART providers.

Recommendations

To the Minister:

1. It is recommended that the issues and risks identified in respect of the collection, storage, identification and distribution of gametes and embryos are considered in the proposed legislation or associated regulations. This could include requirements for ART providers to use a standardised suite of processes and documents to ensure consistent record keeping and adverse event reporting, with codified information to aid in standardisation of reporting.

For FSANZ-RTAC:

2. It is recommended that FSANZ-RTAC ensure that all ART providers dispose of stored donor material not meeting current identification standards, and compliance is a requirement of the audit process.

For ART providers:

3. It is recommended that any and all incidents related to the collection, storage, identification and distribution of gametes and embryos are comprehensively documented by the ART provider, timeously reported to RTAC as an adverse event (as per the current RTAC Code of Practice) and recorded as such in the ART providers' risk management system.

Theme 2: Screening of gametes and donors used in Queensland

This theme explored the extent to which screening undertaken on donors and gametes was appropriate to ensure, as far as possible, that any relevant medical concerns were identified prior to undertaking ART to ensure the safety of ART for consumers.

Background

Overview of relevant requirements in the NHMRC Guidelines and the RTAC Code of Practice and screening/testing provided by ART providers

Egg donation

Unknown donors are screened by the ART provider which receives the donations. On its website, FSANZ explains the different types of donor programs throughout Australia and New Zealand, which require donors to comply with certain standards.[99] For example, to be accepted as a donor, it is explained that egg donors:

- must have reached the legal age of adulthood (preferably between 21 and 35) and preferably have completed their own family. A donor can be older than 35 if donating to a friend or family member but the recipient needs to fully understand the impact of the donor's age on pregnancy rates
- should be able to provide their full medical history. Donors are required to complete a questionnaire about their family history (including disease), sexual/reproductive history, substance use/abuse history, and psychological history
- will have to be screened (with their partner if they have one) for a range of infectious diseases, including syphilis, hepatitis B and C, HIV, and HTLV 1 and 2, as well as cystic fibrosis, karyotype, their blood group and any genetic conditions prevalent in their racial group
- will have to repeat blood tests for infectious diseases three to six months after the first screening tests
- will have to attend sessions with a fertility specialist to review their history, i.e. an IVF nurse and a counsellor
- will need to provide informed consent for egg donation treatment and to their fertility clinic to (i) store identifying and non-identifying details about them in their donor register; (ii) contact other fertility centres to verify their donation history if they have one; and (iii) release their identifying information to the donor-conceived person when they reach 18 years of age.[100]

Sperm donation

To be accepted as a donor, sperm donors:

- must have reached the legal age of adulthood, preferably between 21 and 50
- should produce semen with characteristics that fall within normal ranges, and they should be willing to produce several semen samples if needed
- should be able to give a full medical history and know their own biological origins and complete a questionnaire on lifestyle, family, and medical history

[99] While the FSANZ website explains different types of donor programs, these are not set standards that clinics are required to operate under – they are examples.

[100] https://www.fertilitysociety.com.au/donor-programme-australia-new-zealand/#egg-donation, accessed on 13 December 2023.

- will have to be screened for a range of infectious diseases, including syphilis, gonorrhoea, hepatitis B and C, HIV, and HTLV 1 and 2, as well as cystic fibrosis, karyotype, blood group and any genetic conditions prevalent in their racial group; and will have to repeat the blood tests for infectious diseases three to six months after the first screening tests
- will have to attend a consultation with a fertility doctor (for review of their history), an IVF nurse and a counsellor who is a member of the Australian and New Zealand Infertility Counsellors Association
- need to give informed consent for sperm donation treatment, which includes providing consent for the fertility clinic to (i) store identifying and non-identifying information details about them in a donor register; (ii) contact other fertility centres to verify their donation history; and (iii) release their identifying information to the donor-conceived person when they reach 18 years of age.[101,102]

In addition to medical screening, ART providers also provide genetic testing. This includes screening of consumers/donors (carrier screening), embryos (PGT), and foetuses (prenatal testing by way of non-invasive prenatal test (NIPT)).

- One provider offers genetic carrier screening tests – a saliva test available to everyone, which screens a person for their genetic carrier status of certain conditions (autosomal recessive and/or X-linked), allowing a person to choose between a three gene panel or a 400+ gene panel; NIPT – testing of foetal cell-free circulating DNA for certain chromosomal conditions by way of a blood sample from the person carrying a pregnancy; and preimplantation genetic testing (PGT) of embryos for single-gene conditions and/or aneuploidy (large chromosomal imbalances).

Since the NHMRC Guidelines were developed in 2004, updates to the guidelines have included references to the undertaking of preimplantation testing (PGT – testing of human embryos for genetic conditions). The 2017 NHMRC Guidelines refer to PGT, which comprises preimplantation genetic testing for monogenic conditions (PGT-M), preimplantation genetic testing for chromosomal aneuploidies (imbalances) (PGT-A), and preimplantation genetic testing for structural rearrangements (PGT-SR).

PGT makes use of cells obtained from embryos created by ART in an embryology laboratory, by way of biopsy. The biopsied cells contain the DNA of the embryo, which can be used for PGT to identify the presence of particular genetic mutations and/or chromosome abnormalities that are associated with genetic conditions and/or risk of miscarriage. PGT therefore aims to identify embryos with a low risk of genetic abnormalities, which are then deemed suitable to transfer to a consumer for the purposes of ART.

Chapter 8 of the NHMRC Guidelines outlines the only circumstances in which PGT may be used by an ART provider, the criteria to be considered when clinicians assess the ethical acceptability of the use of PGT, and the requirement for ART providers to maintain appropriate policies and associated record keeping. The NHMRC Guidelines state that PGT may only be used to:

- select against genetic conditions, diseases or abnormalities that would severely limit the quality of life of the person who would be born

[101] https://www.fertilitysociety.com.au/donor-programme-australia-new-zealand/#:~:text=As%20part%20of%20a%20sperm,prevalent%20in%20their%20racial%20group, accessed on 13 December 2023.

[102] The information contained on the Fertility Society website contains the caveat: 'Regulations are subject to regional variations. Your fertility specialist will inform you about the regulations that apply in your State/Territory or about variations between Australian and New Zealand regulations. The information below serves as a summary of regulations that may apply in your area. These need to be verified by your fertility specialist in the context of your place of residence and/or the location of your treatment centre.'

- select an embryo with compatible tissue for subsequent stem cell therapy intended for a parent, sibling or other relative
- increase the likelihood of a live birth.

Moreover, the NHMRC Guidelines state that the term 'sex selection' refers to the selection and transfer of an embryo on the basis of genetic sex, where 'sex selection techniques may not be used unless it is to reduce the risk of transmission of a genetic condition, disease or abnormality that would severely limit the quality of life of the person who would be born'.

Investigation findings

Theme 2 constituted the third largest number of OHO issues (16%) (Table 4) and the fourth largest number of ART provider complaints (13%) (Table 7).

Some of the alleged issues raised included:

- inadequate donor profiling
- failure to appropriately disclose medical information regarding a donor
- failure to undertake appropriate testing of eggs and sperm before use
- failure to undertake appropriate testing, resulting in stillbirth of child with considerable birth abnormalities
- inappropriate information provided regarding the viability of donor eggs.

Within the data assessed by the OHO, the overwhelming majority of allegations related to inadequacies of the extent to which sperm donor personal and family histories were obtained, recorded and provided to prospective consumers/recipients, by ART providers (who run in-house donor programs). These allegations arose predominantly as a result of donor-conceived children developing clinical symptoms of conditions with a genetic (heritable) component, thus implicating the donor as the source of the condition. Most complaints were from treatments that occurred at least five years ago. This accords with expectations given that donor-conceived children have commenced or will be commencing school, and possible disabilities or medical conditions may be more apparent. Understanding whether an affected child's medical condition is genetic and of paternal origin is also a significant consideration for consumers seeking to expand their family using the same sperm donor. It is also of note that in some cases the complaints made to the OHO are made for altruistic reasons, to ensure that if there is a potentially heritable genetic condition present in the donor, other families can be alerted, and donor sperm withdrawn from availability. This relates to Theme 2, which involves the provision of such information (the possibility of risk) to both other families who have made use of, are currently making use of, or are considering use of a donor of concern; and to the donor themselves (who may or may not be aware of the potential risk).

Also contained within this theme, and related to the above, are issues raised around the extent to which donors are screened for genetic conditions. Information obtained for this OHO investigation has revealed that screening donors for certain genetic conditions (via karyotyping [chromosome screening] and molecular testing for carrier status of conditions such as cystic fibrosis) are commonly undertaken on sperm donors. However, the extent of screening for other conditions (such as other common autosomal recessive conditions via carrier screening) is called into question by consumers. FSANZ-RTAC has commented on genetic testing, explaining that:

> *As genetic testing options continue to expand, clinics are broadening their standard genetic tests and may offer extended genetic carrier screening options to patients. However, it's impractical and costly for donors and patients to undergo every available*

> *genetic test. Instead, clinics prioritize testing based on factors such as health records, ethnic background, geographical location, and social history. Expanded genetic panel testing may be warranted when specific risks are identified, but overall, testing decisions should be guided by established protocols and individual circumstances.*[103]

FSANZ-RTAC has added:

> *The minimum standard for screening donor gametes, which was included in the 2002 version of the Code of Practice on page 35, was removed to move away from a prescriptive approach in the COP. RTAC plans to call for the reintroduction the concept of minimum standards to ensure the safety and quality of donor gametes.*[104]

The OHO notes the steps being taken by FSANZ-RTAC to reintroduce minimum standards to address some of the issues identified within Theme 2. In reviewing the available data from complaints and adverse events, the OHO identified examples where some providers have managed potential genetic concerns proactively. For example, at Provider A, a chromosome issue was identified in a child using donor sperm. The donor was withdrawn from availability while further investigations were undertaken, and contact appeared to be made with a pregnant donor recipient and another consumer who had reserved the sperm. In contrast, the OHO identified other matters where providers have not managed consumer concerns as proactively, which is of particular concern where there have been 'clusters' of complaints around certain donors where conditions with a potential genetic basis are evident. The OHO expects to see providers demonstrate an open, transparent and proactive approach to these complaints, especially when concerns involve the screening of donors.

ART providers require sperm and egg donors to complete health and lifestyle questionnaires when they first commence donating, and at regular periodic intervals thereafter. The NHMRC Guidelines impose an obligation on ART providers to inform potential gamete donors that it is a donor's ethical responsibility to disclose any changes to their health (i.e. medical conditions that arise) that may be relevant to any person born using the donor's sperm and/or recipient families of their donations.[105] The OHO's review of information currently required by ART providers from donors indicates that the donor's answers to these questions are considered to be sufficient, rather than requiring an independent medical review or assessment by a medical practitioner or other suitably qualified healthcare professionals (such as genetic counsellors). While there is no evidence to suggest that any donors have been deceptive, there is still considerable risk that donors may not be aware of conditions or symptoms that may be an indicator of a potentially genetic condition. There are some complaints received by the OHO that include allegations of significant medical conditions that have potentially been inherited from the donor. The OHO's review of those matters revealed that in some cases the questionnaire was completed when the donor was in their late teens on initial donation with the potential for missed disclosure of conditions. Additionally, the donor themselves may have reduced understanding of the need to disclose certain elements of medical history.

The issues raised in complaints support the view that the disclosure of medical conditions should not be solely managed by an individual, non-medical person, to determine inclusion. Provider C has raised issues with how this process would be managed and who would be involved (for example, whether it would include the donor's family).[106] Provider E supports in principle the independent confirmation of a donor's medical history, but they raise the following concerns:

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[103] Letter from FSANZ-RTAC to the OHO dated 4 March 2024.

[104] Letter from FSANZ-RTAC to the OHO dated 14 June 2024.

[105] NHMRC Guidelines (2023), para 5.8.1.

[106] Letter from Provider C to the OHO dated 7 March 2024.

... there is no definition or parameter of what constitutes an independent medical practitioner; the information provided by a potential donor in the medical screening forms and questionnaire, is more likely than not to be the same as that provided by a donor to an independent medical practitioner; dissuading of potential donors; increased costs of semen donation, which will be passed on to patients; overall reduction in donor semen availability, and increase of costs of ART services, disproportionately affecting same sex female couples, females and infertile men.[107]

It is acknowledged that there may be additional costs with the proposed process but given the concerns raised in complaints about the accuracy of the medical information collected from the donor, this independent check should provide consumers with the reassurance that they are seeking. Notwithstanding potential complexities with the process for accurate capture of medical history of the donor, the identified potential deficits in screening processes should be considered as part of the legislative requirements to provide additional safeguards for the medical screening of donors.

Site visits

Site visits undertaken by the OHO provided evidence that:

- Extensive testing of donors is undertaken for communicable diseases. The precise specifications of genetic testing may vary depending on the provider but across the sector is extremely comprehensive. One provider screens donors for 176 different conditions, which are the most common life threatening or life limiting conditions.
- Donors are asked to provide detailed medical histories, including family history for multiple generations when possible. One provider attempts to verify the accuracy of the medical history provided by donors, requesting official diagnoses where possible. Geneticists may assist in verifying medical information.
- Some providers have procedures when notified by a donor of a change in their medical history or information is received from a donor recipient regarding a donor-conceived child's medical condition. Another provider appeared to have a more ad hoc approach to management of disclosure of medical information.

Recommendations

To the Minister:

4. It is recommended that consideration is given to including a requirement for more extensive screening of donors, in terms of (1) personal and family medical histories and potential genetic conditions by personnel appropriately trained in genetics (e.g. clinical geneticists, genetic counsellors); (2) wider screening of donors to include carrier status of common (autosomal recessive) genetic conditions such as those compensable by Medicare.
5. It is recommended that consideration is given to requiring registered healthcare practitioners to provide independent confirmation of a donor's medical history.

[107] Letter from Provider E to the OHO dated 15 March 2024, 21 June 2024

Theme 3: Record keeping and provision of information

This theme explored whether information of any type relating to consumers (inclusive of donors) was managed, recorded and shared appropriately, particularly with donor recipients, including the collection and utilisation of medical information.

Background

Overview of relevant requirements in the NHMRC Guidelines, the RTAC Code of Practice and considerations of the Parliamentary Inquiry[108]

In order to meet RTAC's accreditation requirements, Queensland ART providers are required to operate in accordance with the NHMRC Guidelines and the Code of Practice. However, as will be discussed below, these Guidelines and the Code do not cover the full range of issues and considerations with respect to the management of information and records relating to consumers, donors and donor recipients.

The Health Sector (Clinical Records) Retention and Disposal Schedule,[109] relevant to the retention and disposal of clinical records created or received by Queensland Health requires that IVF/AI[110], and Donor Records (including consents), must be retained. It is expected that all ART providers comply with this.

Patient record retention periods relevant to health records within the Queensland public sector are as follows:

- gynaecology adult – 10 years after the last patient service provision
- gynaecology minor – 10 years after the patient reaching 18 years of age
- obstetrics – 10 years from child reaching 18 years of age
- obstetrics ART origin and clinical ART – 10 years from child reaching 18 years of age
- gamete and embryo donation records – permanently.

The storage and retention of health records created and received by private health service providers in Australia may be governed by applicable legislation (as exists in New South Wales, Victoria and the ACT). Queensland does not have legislation which applies specifically to the storage of medical records by private medical providers. If a health service provider holds information, that provider will need to comply with Australia's privacy laws under the *Privacy Act 1988* (Cwlth).

Avant, Australia's largest medical indemnity insurer, recommends that all doctors retain the complete medical record of an adult patient for at least seven years from the date of last entry in the record. With respect to obstetric records, Avant recommends that medical records be retained for 25 years from the birth of the child.[111]

Section 4.2.4 of the NHMRC Guidelines provides that potential gamete or embryo recipients need information about the potential gamete donor (or gamete providers in the case of donor embryos) that is relevant to the care of the person who would be born. Clinics must allow recipients of

[108] Parliamentary Inquiry into matters relating to donor conception information – Report No. 33, 57th Parliament. See https://www.parliament.qld.gov.au/Work-of-Committees/Committees/Committee-Details?cid=0&id=4150.

[109] https://www.forgov.qld.gov.au/__data/assets/pdf_file/0019/203581/Health-Sector-Clinical-Records-Retention-and-Disposal-Schedule.pdf

[110] In vitro fertilisation / artificial insemination.

[111] https://avant.org.au/resources/medical-records-the-essentials

donated gametes or embryos access, through either a medical practitioner or an appropriately qualified health professional, to at least the following information about gamete donors:

- medical history, family history and any existing genetic test results that are relevant to the future health of the person who would be born (or any subsequent offspring of that person) or the recipient of the donation
- details of the physical characteristics of the gamete donor
- the number, age and sex of persons already born from the gametes provided by the same gamete donor and the number of families involved. (The guidelines do not outline how such information is to be obtained and shared between clinics – whether across Australian jurisdictions or overseas – where gamete donors have made donations in more than one clinic in Australia or overseas).

While the NHMRC Guidelines impose these requirements upon ART providers, in the absence of Queensland legislation enforcing the terms of the guidelines, there is no legal force requiring adherence to these guidelines.

Further, at section 5.8.1, the NHMRC Guidelines provide that ART providers should inform potential gamete donors that it is a donor's ethical responsibility to keep the provider/clinic informed about any changes to their health that may be relevant to any person born or the recipients of their donation and about changes to their contact details.

Prior to the introduction of the 2004 edition of the NHMRC Guidelines, in jurisdictions with no legislation at that time, donations were mainly provided throughout Australia on the condition of donor anonymity. That is, a donor could participate in a gamete donation program requesting that their identifying information was not released at any time to a recipient of donor gametes, or a child born from donated gametes. However, the importance of a person born from donated gametes knowing their genetic origins has since been realised. The 2004 edition of the NHMRC Guidelines acknowledged the right of a person to know the details of their genetic origins, i.e. genetic parents and siblings. This edition of the NHMRC Guidelines, and subsequent editions, outlined that ART providers must not use donated gametes/embryos unless the donor/s consented to the release of their identifying information to the persons conceived from the donated gametes upon reaching the age of 18 years, or if less than 18, when that person has acquired sufficient maturity. 'Identifying information' is not defined in the NHMRC Guidelines. However, information which may be disclosed to a donor-conceived person upon request is outlined above in the previous paragraphs.

Section 5.13 of the NHMRC Guidelines outlines the minimum conditions of use of gametes collected before 2004 and section 5.15 stipulates that clinics must ensure that all existing information about parties involved in donor conception programs prior to the introduction of the 2004 edition of the NHMRC Guidelines is maintained appropriately, in accordance with the provisions of section 9.2.

The NHMRC Guidelines do not specifically address the rights of pre-2004 donor-conceived persons to be provided with identifying information about their donor upon reaching the age of 18 years, or if younger than 18 and determined to be sufficiently mature.

In February 2022, Queensland's legislative assembly agreed that the Parliament's Legal Affairs and Safety Committee (the committee) would enquire into and report to the Legislative Assembly on issues relating to access to donor conception information, including:

- rights of donor-conceived persons, including to know their genetic origins
- access to historical clinical records and implications of retrospectivity
- access to support and counselling for donor-conceived persons and donors

- whether a register should be established
- benefits, risks and implications on donor conception practices arising from any recommendations.

The Committee's Inquiry into matters relating to donor conception information, finalised in August 2022, has recommended that all identifying information about donors, including their medical history, be made available on request to all donor-conceived persons when they reach 18 years of age, regardless of when they were born.[112] Queensland has committed to the establishment of a donor conception register and it is envisaged that requirements for ART services to provide information to that register will form part of proposed legislation to regulate ART services at a future time.

Investigation findings

Record keeping and provision of information was raised in 15% of issues reported to the OHO by consumers (Table 4) and 3% of complaints to ART providers (Table 7). The majority of the complaints to the OHO and to ART providers relating to this theme involved issues regarding the provision of information about donors and siblings. It is recognised that there are limits to the information that providers can supply to donor recipients and their children, and many of these complaints are likely to be resolved in the future through the proposed introduction of a central donor register.

Some of the alleged issues raised include:

- inappropriate record keeping
- failure to maintain and appropriately disclose information about siblings born from the same donor
- issues with disclosure where the individual seeking the information is the donor-conceived child and not the recipient of treatment
- failure to maintain accurate contact details for donors
- failure to use a donor who had consented to identification.

The OHO has noted through the assessment and investigation of complaints received that there are issues with maintenance of records, particularly where there are historical issues in respect of the treatment. For example, issues have been encountered because the:

- managing doctor has retired
- managing doctor is deceased
- a natural disaster has destroyed the records.

Given that some donor-conceived children may not discover the circumstances of their conception until later in life, perhaps when exploring their family heritage, it is of paramount importance that records are retained and maintained to enable those individuals to obtain information about their genetic background. As raised by Provider E, it is noted that:

> *Fertility Specialists, who manage the patient's clinical fertility treatment, are individual/independent and operate their own practice, separate from Provider E including maintaining their own clinical records.*[113]

[112] Parliamentary Inquiry into matters relating to donor conception information – Report No. 33, 57th Parliament. See https://www.parliament.qld.gov.au/Work-of-Committees/Committees/Committee-Details?cid=0&id=4150.

[113] Letter to from Provider E to the OHO dated 21 June 2024.

This will need to be considered within any legislation relating to the retention of records.

The OHO notes that the Victorian *Assisted Reproductive Treatment Act 2008* provides for records identifying donor treatment participants to be kept for a period of at least 99 years after creation of the record.[114]

Further consideration has been given to hard copy records and digital records. Provider E has noted that:

> *Historically, our client's records were held in hard copy which are held in secure archives. Our client recognises that ideally these records ought to be transferred to a digital format for long term preservation. Our client's hard copy records are voluminous, and transfer to digital format would be a vast undertaking. Our client is presently working through the transfer of records to digital format, however, recognises that this is a long process.*[115]

The OHO is pleased to note that the transition to a digital format has commenced at Provider E.

Provider C has urged the OHO

> *to consider the potential consequences of a cyber breach where providers are obliged by legislators to digitise paper records that may not have been otherwise available to threat actors.*[116]

The OHO acknowledges that cyber security is a paramount consideration for all health records, and that the risk of deterioration or loss of paper records also needs to be considered. The issues identified in this investigation support the view that similar provisions to those in Victoria should be considered for inclusion in proposed legislation for the regulation of ART services in Queensland. Such legislation should also include provisions which manage the retention of records if an ART provider (whether healthcare practitioner or organisation) ceases to practise.

The OHO has witnessed the distress experienced by consumers and donor-conceived children when they receive information that their records have been destroyed or cannot be located, which denies them the opportunity to explore the origins of their family. To avoid this situation, the OHO has identified the potential need for mandating requirements for providers to maintain digital versions of any hard copy records relating to donor treatment procedures. Such requirements would need to be applied retrospectively to ensure that donor-conceived children are assured that the records are available if they want to obtain information about their paternal (or maternal, in the case of egg donor-conceived children) origins and family history. It is beyond the OHO's remit to make recommendations on whether the legislation should apply retrospectively – this is a decision for the Government, given that pre-2004 donors donated under strict conditions of anonymity. The OHO's recommendation in respect to records is made to ensure that all records are maintained and accessible so that the donor recipient and donor-conceived child can be provided with the information that they are entitled to (which may be limited due to provisions relating to anonymity).

Through the examination of various types of records obtained for this investigation and individual complaints, the OHO considered the quality of records that have been completed by ART providers. Records were found to be inconsistent across different ART providers, and even within the same ART provider (i.e. the same company across different clinics and locations). While record keeping has improved over time, particularly with the introduction of electronic records and radio

[114] Assisted Reproductive Treatment Act 2008, section 121A.

[115] Letter from Provider E to the OHO dated 15 March 2024.

[116] Letter from Provider C to the OHO dated 7 March 2024, 21 June 2024

frequency identification, poor record keeping has significant implications for families when an incident occurs.

The record keeping issues identified in this investigation support a case for standardisation of key documents and records across services. It is appreciated that this is difficult across independent ART providers but may be achieved with an appropriate regulatory body developing a suite of documents. This may include a statewide standard for storage audit procedure, i.e. standardised processes and documents for registering tank counts and the collection of all necessary information related to stored samples (donor number, batch number, count, etc). Most importantly, providers should be rigorous in documentation audits, completing these regularly, identifying recurring issues and taking remedial action as required. Staff training is also key to consistent record keeping. Consideration of such practices also needs to include the reduction in handling of stored biological samples to minimise temperature fluctuations and risks to the integrity of samples. The OHO notes the support expressed by Provider E in relation to standardisation of documents across the industry and their willingness to engage with Queensland Health in developing relevant forms. Provider E also expressed an interest in working with Queensland Health to develop audit procedures that do not risk compromising consumer outcomes, given risks to the integrity of samples that may be associated with carrying out such audits.[117]

FSANZ-RTAC has provided commentary on the management, utilisation and availability of donor and birth records, noting that:

> *This shift in community attitudes and the request of those born through donor gamete procedures has seen progressive changes to the practices in recording and making available donor information and more recently in some jurisdictions, progeny information to donors. This is a complicated area which needs to recognise and balance the rights and obligations of donors, progeny, birth parents and social parents.*[118]

FSANZ-RTAC caution that:

> *Incorporating diverse perspectives within the community, including patients, donors, donor offspring, counsellors, and clinicians, into anticipated legislation will be a complex task requiring careful consideration rather than hastiness.*[119]

Further FSANZ-RTAC submit that:

> *Contemporary record-keeping practices in ART are robust and satisfactory, addressing many of the deficiencies observed in historical practices. …*
>
> *Prior to 2004, donors were often completely anonymous, and while historical record-keeping was sometimes deficient, contemporary practices ensure that donors' rights are protected. …*
>
> *RTAC emphasises that donor rights are paramount and must be respected alongside recipient and offspring rights. Any policy or practice changes should carefully consider and balance the rights and interests of all parties involved.*[120]

[117] Letter from Provider E to the OHO dated 15 March 2024.

[118] Letter from FSANZ-RTAC to the OHO dated 4 March 2024.

[119] Letter from FSANZ-RTAC to the OHO dated 4 March 2024.

[120] Letter from FSANZ-RTAC to the OHO dated 14 June 2024.

The OHO considers that establishment of a central donor register would address many of the issues raised by donor-conceived individuals regarding access to information about their donor parent and genetic origins. While the OHO notes concerns raised by FSANZ-RTAC in relation to the balancing of rights of the different parties involved, donor registers have been established in Victoria, South Australia, Western Australia, New South Wales and now the Australian Capital Territory with a range of safeguards aimed at balancing and protecting these rights. Legislation which provides clear requirements for the provision of information to donor recipients and donor conceived children will ensure that there is a consistent approach, rather than disclosure being managed by individual ART providers.

There is still a current need for providers to address and respond to the issues regarding the provision of information about donors and siblings. Complainants have highlighted to the OHO concerns about ART providers not maintaining regular communication with donors, which could cause difficulties for donor-conceived children seeking to initiate contact with the donor upon reaching the age of 18. It is appreciated that it can be problematic for ART providers if the donor is not willing to engage with the service and would present challenges to enforce. However, it is important that providers meet their obligations in this regard and use their best efforts to ensure that this information is available for donor-conceived children.

The OHO has noted that some complainants are being provided with unclear or inconsistent information about donor siblings and the number of families created from a single donor. The ability to correctly record this information links with the maintenance of family limits and this issue is addressed in the following section.

The issues raised in complaints about the provision of information to donor recipients or donor-conceived children predominantly involve:

- the ART provider's alleged failure to share information with donor siblings regarding potential medical issues, possibly inherited from the donor
- concerns regarding inaccurate information provided about the number of donor siblings and families
- the ART provider's alleged failure to maintain contact with donors to ensure that contact can be made once donor-conceived children reach the age of 18.

These issues will be addressed within the individual investigations of those complaints which have informed this investigation's consideration of systemic issues and recommendations.

Early awareness of potential medical issues is very important to donor-conceived children, and with some conditions, prompt treatment can be key to successful management or improved outcomes. It is appreciated that this is a sensitive issue for which ART providers will need to consider a threshold for disclosure.

If an ART provider is informed of a medical condition in a donor-conceived child, or a donor provides this information in an update, it potentially raises the following issues:

- whether the information should be shared with other donor-conceived children/siblings; other families/individuals who have donor-created embryos in storage; other families/individuals who have reserved the donor sperm for planned ART use; and/or those who intend to expand their existing family
- whether the ART provider should remove the donor sperm from use altogether.

How this situation is managed is crucial to maintaining public confidence in ART services and the safety of using donor sperm. It has also been suggested that there are opportunities for the regulator to work with the treating clinic in assessment and communicating with families, utilising medical and specialist input.

The OHO's review of complaints indicates that in some instances, ART providers may not be appropriately managing these issues. Three complaints made to the OHO relating to this theme are outlined in Case Study 3.

Case Study 3

The OHO received separate complaints from three individual complainants who had each used the same donor sperm from a provider. Of the four children conceived to the three families, three children had significant medical issues and confirmed clinical diagnoses. One of the families contacted the provider alerting them to the potential medical risk related to the donor sperm. It is not clear that this information was acted upon promptly by the provider, to ensure that individuals who had reserved the sperm for use for starting a family, or extending a family, were made aware of the change in medical information relating to this donor.

Note: These matters had not been concluded at the time of publication of this systemic investigation report and no findings had been made.

Professor Norman commented on the issue of medical information relating to donors or donor-conceived children.

There needs to be full disclosure to the donor and recipients past and present. The donor should be offered a full clinical and genetic counselling, and the stored sperm should not be used until clarity surrounding the conditions obtained. The recipients require similar counselling and investigation.

Factors to be considered should include: Open disclosure, involvement of all parties, full investigation as desired by the donor and recipient. Previously conceived families from the same donor should be informed and counselled. There should be policy and procedures regarding concerns about heritable conditions related to donor and children.

When asked about recommendations that could be made and improvements to processes around the disclosure of medical information, Professor Norman opined:

I agree that clinics and organisations should continue to be educated on medical and genetic implications of questions arising from use of donor sperm. Internal and transparent policies should inform staff of how to respond in various circumstances.

These issues point to the need for ART providers to be required to have a policy which outlines requirements when significant medical history is disclosed relating to donor-conceived child and donor, addressing:

- mandatory list of disclosure requirements to other families with the same donor
- parameters for withdrawing the donor gamete from further use
- documented consultation required between two geneticists when a decision is made to not disclose.

Provider E has noted that:

> *The OHO has recommended that there be documented consultation between two geneticists when a decision is made not to disclose a medical condition. Provider E submits that this process would be unduly onerous, expensive, and unnecessary, particularly if mandatory disclosure requirements and other parameters are in place in relation to disclosable conditions.*[121]

While the OHO notes these concerns, it is pertinent that this proposal relates to the decision to not disclose significant medical history which is currently not subject to any mandatory requirements. The OHO is also of the view that further consideration of the parameters and requirements for such decision making should be addressed through the inclusion of obligations of ART providers with respect to disclosures in the proposed legislation to regulate ART providers.

Consumer perspective

Consumers have commented on their experiences of medical disclosure, sharing of information and record keeping:

I was told that other families were notified of all concerns I had passed along, the other families I've spoken to were never notified of health issues, health issues from other families weren't passed on to me either. … I've spent approximately 3 years trying to get basic health issues and diagnosis of my son passed along to other families so their children can access early intervention if necessary… .The clinic is not interested.

I was assured at the time that they facilitated contact between donor families as soon as the parents were ready to connect. That they kept a spread sheet of all donor groups and as soon as there were families seeking contact they would arrange a counselling session then connect those families. [This] turned out to be false.

I was … assured repeatedly that any health issues, no matter how small in the donor or other children would be shared with me as soon as it was reported to the clinic… . [This] turned out to be false.

Donor profiles should be dated with the date of donation, then updates added as they become available by adding a new date underneath with the change / addition of new information.

Donor profiles should be updated with crucial information regarding health status of children born to those particular donors.

[121] Letter from Provider E to the OHO dated 15 March 2024.

I think there needs to be a middle ground between providing patients with information on the gametes they have purchased that are going into their body, and privacy of the donor.

No meaningful improvements will be possible until records are fully and reliably maintained. This will have to involve significant consequences for failure to keep these.

Site visits

Site visits undertaken by the OHO provided evidence that:

- There are different approaches by providers in relation to maintaining contact with the donor. For example, one provider contacts donors every three years for updated contact information. Another provider stated that donors are responsible for updating medical information, but the clinic provides resources and support. There is no systematic contact with donors unless they report changes.
- Some providers do not provide a donor linking or recipient/family linking service. They will inform parents of a donor-conceived child how many siblings they have, the year of birth and the sex, but they do not link the families.
- One provider involves a geneticist if a donor recipient reports that a child has a potentially genetic health condition. They will consider whether it is necessary to remove the donor from availability until further enquiries are made. This may also mean that use of an embryo is put on hold. Counselling will be offered to consumers in these circumstances. Donor recipients may be notified if there are implications for the health of their children. Another provider has a Medical Advisory Committee to review cases involving donor-conceived children with medical conditions to decide on further use of the donor's sperm. Decisions regarding disclosure and further action involve geneticists' input to assess risks and determine appropriate measures.
- Providers were supportive of a donor conception register.

During the site visits it became apparent that not all ART providers keep in regular contact with donors, whether that be in relation to checking donor's contact information or seeking updated medical information. The OHO considers that this is an important element of managing ART services, particularly when there is no donor registry in place. It should not be left to the donor to initiate contact when their circumstances change. ART providers should also have a policy and procedure if they are unable to locate a donor.

Recommendations

For ART providers:

6. It is recommended that all ART providers have a schedule of contact with the donor for updated contact details and medical information. The OHO proposes that contact is made with donors every two years. ART providers should have a policy and procedure if they are unable to locate a donor.
7. It is recommended that ART providers must have a policy and procedure for situations that arise where a significant medical event is evident in a donor-conceived individual or a gamete donor and is disclosed to an ART provider, where there is implied potential medical risk to children conceived from that donor and/or risk for the gamete donor. The policy and procedure should include:
    a. how the information is recorded and decisions are documented

b. who has responsibility for investigating the medical disclosure

c. who has responsibility for decision making regarding medical disclosure

d. timeframes within which the medical disclosure should be considered and acted upon

e. mandatory list of disclosure requirements to other families with the same donor

f. parameters for withdrawing donor gametes from further use

g. if appropriate, a documented consultation required between the ART provider Medical Director and a Clinical Geneticist when a decision is made to not disclose.

8. It is recommended that ART providers are required to transfer any hard copy records relating to donor treatment procedures to digital format where they are currently retained in hard copy only.

To the Minister:

9. It is recommended that consideration is given to the inclusion of obligations of ART providers with respect to disclosure of a significant medical history relating to donor-conceived child and donor through, for instance, the proposed central register and legislation with respect to access to information for donor-conceived children.

10. It is recommended that the legislation defines the period of time for retention of records relating to donor ART procedures, and backups (including hard and soft copies) of such documents to mitigate loss.

11. It is recommended that the time period defined in section 121A of the *Assisted Reproductive Treatment Act 2008* (Vic) that identifying records must be kept for at least 99 years after creation of the record be used.

12. It is recommended that legislation should incorporate requirements for maintenance of records if an ART provider ceases to practise.

Theme 4: Maximum family limits of donor gametes within Queensland and Australia

This theme explored donor usage limitations to assess whether they were being appropriately practised for the creation of donor-conceived families to mitigate (as far as possible) the risks associated with consanguinity.[122]

Background

Overview of relevant requirements in the NHMRC Guidelines and the RTAC Code of Practice

In order to meet RTAC's accreditation requirements, Queensland ART providers are required to operate in accordance with the NHMRC Guidelines and the RTAC Code of Practice. The NHMRC Guidelines are, however, recommendations which refer to 'reasonable steps' to be taken by the clinic/provider which are not defined.

Only altruistic gamete and embryo donation is permissible in Australia. Apart from the payment of expenses incurred as a result of donating gametes or embryos, a donor cannot receive any payment or other inducement.[123]

[122] Relationship by descent from the same ancestor; blood relationship (Collins English Dictionary).

[123] NHMRC Guidelines, section 5.4.

At section 5.3, the NHMRC Guidelines state as follows in relation to limits on the number of families created from a single donor:

- 5.3 Limit the number of families created from a single donor
- 5.3.1 Clinics must take all reasonable steps to minimise the number of families created through donated gamete treatment programs.
- 5.3.2 Gametes from a single donor must be used to create only a limited number of families. In the absence of specific state or territory legislation, clinics must take account of the following factors when deciding on an appropriate number of families to be created:
  - the number of persons already born from the donor's gametes
  - the risk of a person born from donor gametes inadvertently having a sexual relationship with a close genetic relative (with particular reference to the population and ethnic group in which the donation will be used)
  - any limitations on the number of families expressed as part of the consent of the donor
  - whether the donor has already donated gametes at another clinic.
- 5.3.3 In the absence of a national registry for gamete donation, to encourage disclosure of multiple donations at multiple clinics, potential gamete donors should be reminded of the importance of limiting the number of families created from a single donor. Prior to donation, clinics must:
  - ask potential donors whether they have donated at other clinics
  - obtain consent from potential donors to contact other clinics about any previous donations.[124]

RTAC's Technical Bulletin 3, issued in May 2011, titled *Donor Issues*, states that where state legislation does not apply, a maximum of 10 donor families per sperm donor is acceptable. This refers to all families wherever the donor's sperm is used, not just the number of families from one ART provider, in one city or in one country.[125] However, as outlined previously in this report, the information in RTAC's Technical Bulletins is not enforceable (unless it is incorporated into the RTAC Code of Practice).

The RTAC Code of Practice also requires that in the absence of state legislation, the ART provider must provide evidence that it complies with the recommendation of the NHMRC Guidelines for family limits.[126] Outside of Queensland, the Australian Capital Territory, Western Australia, New South Wales and Victoria have enacted family limits through legislation. In the Australian Capital Territory it is an offence for ART providers to use donated gametes or embryos for '5 or more families' within the Australian Capital Territory, and '10 or more families' Australia-wide.[127] Western Australia limits the number of 'recipient families' of donated gametes or embryos to five.[128] New South Wales has imposed a limit of five families with reference to the number of 'women' rather than families.[129]

[124] Previous editions of the NHMRC Guidelines have also commented on ART providers taking all reasonable steps to ensure that gametes from one donor are used in a limited number of families.

[125] 20110506-technical-bulletin-number-3.pdf (fertilitysociety.com.au)

[126] Code of Practice, s 2.8(d).

[127] *Assisted Reproductive Technology Act 2024* (ACT) s 40.

[128] *Surrogacy Amendment Regulations 2021* (WA) r 8.1.

[129] Assisted Reproductive Technology Act 2007 (NSW) s 27.

Victoria similarly references 'women' in family limits; however, differs in that Victoria imposes a limit of 10 families.[130]

Investigation findings

The OHO has received three complaints (issues) relating to Theme 4, all of which relate to ART services provided more than 10 years ago (Table 5). Complaints received by ART providers that relate to family limits were very low (one instance reported) (Table 7). It is difficult to predict whether this theme will become more significant as children conceived through ART reach 18 years of age and seek familial connections via genetic ancestry databases. Equally, it is possible that ART providers have been adhering to the 2011 RTAC Technical Bulletin on family limits.[131]

The OHO has noted that adherence to the family limit is also referenced when consumers complain about ART providers not agreeing to transfer of donor sperm between providers. In these cases, the providers acquiesced to transfer following the complaint. It is unclear what impact these practices may have on the compliance of ART providers with the maximum family limit or whether adequate safeguards are in place when these transfers occur.

Some of the alleged issues raised included:

- failure to maintain appropriate family limits for use of donor sperm
- concerns regarding the number of families created from one donor.

Case Study 4 is an OHO complaint which involves consideration of the family limit.

Case Study 4

The patient commenced fertility treatment in early 2000s with a provider, using donor sperm. After successful treatment, the patient later found out that the donor she used had donated sperm on more than 200 occasions at the same clinic. The patient had concerns about the reasons for the collection of such a large number of donations and wanted to know whether this resulted in the creation of an excessive number of families (the 10-family limit guideline was not in force at that time).

Note: This matter had not been concluded at the time of publication of this systemic investigation report and no findings had been made.

Professor Norman has considered the issue of family limits in a matter brought to OHO's attention. The matter involves the creation of more than 20 families that appear to be created by the same donor prior to the introduction of family limit obligations on providers to 'take reasonable steps' in the NHMRC Guidelines and the 'maximum of 10 donor families' in RTAC's Technical Bulletin.

Even in this period [2002], this practice would have been seen to be very ethically dubious and with little concern for the welfare of the offspring. This practice would seem to be contrary to the NHMRC guideline, FSA and RTAC expectations and possibly without recipient knowledge and informed consent.

[130] Assisted Reproductive Treatment Act 2008 (Vic) s 29.

[131] RTAC Technical Bulletin 3, issued in May 2011, titled Donor Issues.

Definitions of what constitutes a 'family' vary across ART providers. For example, there are varying practices as to whether other consumers who have not had families yet using donations from that donor, but have reserved semen of that donor, or have frozen embryos created from donations from that donor, are included in the family limit. Moreover, it is also uncertain whether donations of gametes that are transported interstate are monitored and recorded by ART providers and included in the 10-family limit for a particular donor. Some ART providers do have agreements in place that the receiving clinic must consent to disclose birth outcomes of donor sperm transferred before the sperm is transferred.

Recording of offspring created by donated gametes also relies on the consumer notifying the ART provider of the birth outcomes for pregnancies of donated embryos or semen. In instances where the consumer does not report birth outcomes to the ART provider, or where the ART provider is unable to contact the consumer to ascertain the birth outcomes, it is unknown whether each ART provider includes these instances as counting towards the family limit for that donation.

The definition of 'family' also varies across different ART providers concerning same-sex couples. In one occurrence a female consumer in a same-sex relationship whose female partner had a donor-conceived child while in a previous relationship requested to use the same donor to conceive. The consumer was initially refused on the basis that the donor had already reached the family limit and the use of the donor sperm on this occasion would constitute a *new* family. However, after the consumer queried the decision, the ART provider reversed their decision and permitted the consumer use of the donated sperm. Subsequently, another consumer who was in the same situation was refused by the same ART provider on the basis that the use of the donated sperm would constitute a new family.

Maintaining the family limit requires clear guidelines on what constitutes a 'family' and to avoid inconsistencies across ART providers and across the state. Provider E has confirmed agreement with the need to ensure that a 'family' is clearly defined in legislation to avoid doubt and misinterpretation.[132] The OHO has considered the UK's HFEA[133] Code of Practice (2022), which defines a family as a unit consisting of the patient, their partner (if present) and any existing children of either partner, including children born to a same-sex partner within the same family unit.

> **11.57** For the purpose of this guidance, a 'family' is defined as the patient to be treated and their partner (if they have one) and any existing legal child or children of either partner. Any donor-conceived child born from future treatment at any UK licensed centre will form part of the same family provided the child is a genetic sibling or half sibling of any existing donor-conceived child, and shares at least one legal parent with the existing donor-conceived child.
>
> **11.58** Where a woman has treatment resulting in the birth of a donor-conceived child and her same sex partner subsequently has treatment using the same donor, any child born will form part of the existing family and not a new family.
>
> **11.59** If a couple with a donor-conceived child separates and one or both former partners subsequently return for treatment either alone or with a new partner and uses gametes from the same donor, any child that is born will form part of the existing family, not a new family. This is provided that the child born from the treatment shares at least one legal parent with the existing donor-conceived child.

[132] Letter from Provider E to the OHO dated 15 March 2024.

[133] Human Fertilisation and Embryology Authority (HFEA).

Professor Norman has also commented on the complexities of defining family limits:

> *The view on family will vary between societies and ethnic groups and a universal Australian opinion may prove controversial. In New South Wales, 4 families and the donor's own family are allowable. In Victoria and South Australia 10 are allowable. There does not appear to be any attempt to extend these definitions outside of the state legislation. If there were many sperm donors available and donation was more widely accepted, it makes sense to limit the number of families significantly. This is not the case using Australian recruited donors and hence there will be pressure to allow a larger number of families. Another issue is the size of families which is falling in Australia. It could be argued that 20 children from 10 families is equivalent to 20 children from 5 families and therefore the number of children is as important as the number of families. The situation is enormously complicated by sharing sperm across states and the purchase of sperm from international companies who may sell the product from one individual to several states and countries, thereby complicating the ascertainment of the number of families. ANZICA, the national infertility counsellor organisation, prefers harmonisation of donor family limits to 5 families per donor world-wide but accepts current legislation make this difficult. They consider 10 families world-wide to be the absolute limit. They do recognise a potential exception might be people from a particular ethnic background.*

FSANZ-RTAC comment on the issue of the family limit as follows:

> *While clinics can set limits on donor families, privacy laws hinder their ability to cross-reference donors across providers to effectively manage these limits. Despite consistent recommendations on family limits from the RTAC code of practice and NHMRC guidelines, disparities exist within state legislation and regulations. A fundamental issue faced by clinics is the inability to ascertain whether a donor has made donations elsewhere. Additionally, the lack of coordination between different jurisdictions and state registries exacerbates this challenge.*[134]

FSANZ-RTAC also submit that:

> *Approximately 90% of donors have historically produced fewer than 10 families, even before the limit was imposed.*
>
> *… The primary issue is not the family limit itself but the ability of donors to donate at multiple sites or through black-market channels. This problem persists despite existing legislation and donor registers … . RTAC recommends updating the COP to include a clear family limit, reflecting contemporary practices and data. This will provide a consistent standard across clinics and enhance the integrity of ART practices.*[135]

The OHO notes that it would be helpful to consumers, donors and donor conceived people if the rates of family creation by donors, as submitted by FSANZ-RTAC, could be verified and made available.

[134] Letter from FSANZ-RTAC to the OHO dated 4 March 2024.

[135] Letter from FSANZ-RTAC to the OHO dated 14 June 2024.

Given current legislative considerations in relation to the creation of a donor registry, it is relevant to note FSANZ-RTAC's position:

> *Both FSANZ and RTAC endorse the idea of housing these records within the Queensland Registry of Births, Deaths and Marriages. This arrangement offers a safeguard in case clinic records are lost or compromised, as the government-owned registry would securely preserve the information. Ideally, a national database would be preferred for identity protection and to ensure donor family limits remain intact despite cross-border donations. FSANZ advocates for the inclusion of ART regulation that establishes a national donor-conceived database. Such a database would enhance transparency and uphold ethical standards while promoting patient centred care, which tailor's [sic] treatments to individual preferences and needs, enhancing the quality and ethical delivery of ART services.*[136]

As mentioned above, some providers are inconsistent in their listing of sibling information, and on individual matters, the OHO has had difficulty on occasions establishing the number of families created and the number of siblings a donor-conceived child has. It is recognised that accurate record keeping relating to the creation of donor families is also problematic for providers, given that there is no enforceable requirement for consumers to report on pregnancy outcomes. The implementation of a donor conception register would accord with the findings of the Inquiry into matters relating to the donor conception information[137] and go some way to address the issues raised with the OHO and enable ease of access to sibling information. In the submissions to the OHO, ART providers expressed broad support for the proposed establishment of a donor conception register.

Allegations of excessive use of donor gametes (specifically sperm) is a recurrent observation in this investigation, where such practices can pose harm to donors and donor-conceived families by way of increasing risk of consanguineous relationships between donor-conceived individuals. It is noted that there can be significant distress and mental health impacts related to the discovery of a high number of relatives for donor-conceived persons and their parents, and donors and their families.

Consumer perspective

In a survey response to the OHO a consumer raised the following concern:

> *There needs to be more communication between clinics to prevent donors from donating to multiple clinics and especially to prevent donors who donate under an alias.*

Site visits

Information was obtained by the OHO during site visits:

- All providers do enforce a 10-family limit from one donor. This does not include families outside the state.
- Providers reported difficulties in obtaining accurate information from donor recipients – consumers are not always compliant with the requirement that they inform the provider of the birth of a child.

[136] Letter from FSANZ-RTAC to the OHO dated 4 March 2024.

[137] Inquiry into matters relating to donor conception information, Report No. 33, 57th Parliament Legal Affairs and Safety Committee, August 2022.

- All providers agreed that a national consensus on a family limit should be reached and a definition of 'family' should be included in legislation.

Recommendation

To the Minister:

13. It is recommended that a gamete donor family limit is clearly defined within legislation, including a definition of what constitutes a 'family'. Consideration may also need to be given to a 'person' limit. Furthermore, consideration of limits needs to extend to both Queensland and Australia.

Theme 5: Provision of information and informed consent

Within complaints to the OHO and ART providers, concerns have been raised about whether consumers are provided with sufficient information to give their informed consent to treatment, and fully understand the treatment options open to them. For example, the use of ICSI is, in some contexts, considered an 'add-on' to fertility treatment and is not performed as standard. There may be reasons why ICSI is appropriate for the consumer, but care must be taken to ensure that the consumer is informed about why the treatment is required, and the risks that are associated with pursuing this treatment option (explored further in Theme 6).

It is noted that fertility specialists are not employed by, but are affiliated with, particular ART providers. The fertility specialist has overall responsibility for the consumer and manages the initial treatment pathway. The ART provider will follow the plan which has been developed between the consumer and the fertility specialist. In terms of the consenting process, this is undertaken by the ART provider (once the plan has been agreed to). The difficulty with the process appears to be that the ART provider's fertility nurse provides the consumer with consent forms, and only escalates to the fertility specialist if the consumer has questions about their plan or does not understand the treatment being provided. It is recognised that there needs to be clarity and a shared understanding of the respective roles and responsibilities of the ART provider, including the role of the fertility nurse and the fertility specialist in these circumstances, to ensure that the consumer is able to provide their informed consent to treatment.

Background

Overview of relevant requirements in the NHMRC Guidelines and the RTAC Code of Practice and screening/testing provided by ART providers

The RTAC Code of Practice requires that ART providers obtain valid consent to treatment. This is included within section 2.3 Valid consent (Critical Criterion 5) of the Code of Practice, as follows:

The ART provider must:

- ensure that treatment only occurs with valid consent, as defined by the NHMRC Guidelines
- ensure that consent is written, signed and dated. Documentation must include a signed statement by the treating clinician confirming that all relevant provision of information and counselling requirements have been satisfied
- have a process whereby clinical staff ensure that valid consent is obtained from all consumers, donors and/or surrogates (and, where relevant, their spouses or partners) before treatment commences.

Consent, as defined in the Code of Practice (and reflective of the NHMRC Guidelines), is only valid if:

- the person giving consent is considered to have the capacity to provide consent
- the decision to consent to the treatment or procedure is made without undue pressure
- all relevant requirements regarding the provision of information and counselling requirements in Chapter 4 of the NHMRC Guidelines are satisfied
- the consent is specific and is effective only to the treatment or procedure for which information has been given.

The NHMRC Guidelines include within their guiding principles that: '*Decision-making in the clinical practice of ART must recognise and respect the autonomy of all relevant parties, promoting and supporting the notion of valid consent as a fundamental condition of the use of ART*.'[138] The NHMRC Guidelines recognise that: '*Central to the provision of valid consent for ART activities is informed decision-making which involves provision of accurate and contemporary information relevant to the circumstances. Decision-making must be supported by the provision of access to counselling by a professional with the appropriate training, skills, experience and competency to counsel in reproduction.*'[139]

Relevantly, under section 4 the NHMRC Guidelines, clinics must ensure that information is discussed with consumers (at a minimum), including:

- whether the proposed procedure or treatment is accepted practice or an innovative practice, acknowledging areas of uncertainty (4.1.2)
- the experience of the clinic and the clinician with the procedure, any clinically relevant outcomes and success rates and, where applicable, an explanation that certain procedures may be undertaken by persons other than the individual's or couple's treating clinician (4.1.2)
- the provision of accurate and contemporary information to individuals and couples undergoing ART activities is ongoing and not a single event prior to the commencement of treatment; and clinics should document the information provided in relation to paragraph 4.2.1 and reassess the accuracy of the information before the commencement of a new cycle, or following any clinically significant change in circumstances (4.2.2)
- the survival rate and suitability for transfer of gametes and embryos after freezing and thawing for the particular clinic (4.2.6).

Investigation findings

This was one of the largest themes within the OHO matters (28%) (Table 4) and the second largest of the ART provider complaints (20%) (Table 7).

Complaints

The list below (which is not exhaustive) highlights some of the issues which have been raised by consumers in complaints or enquiries made to the OHO:

- failure to advise the consumer prior to commencing IVF treatment that endometritis was present, despite a prior hysteroscopy indicating this

[138] NHMRC Guidelines, Guiding Principles, 2017, updated 2023.

[139] NHMRC Guidelines, Guiding Principles, 2017, updated 2023.

- use of ICSI (with suitable fresh sperm) despite the consumer expressly requesting it be documented on their file that ICSI was only to be used for egg fertilisation if the fresh semen sample was not suitable for IVF
- failure to provide consumers with sufficient time to process the extensive information provided to them to enable them to make an informed decision about their medical treatment
- failure to disclose to the consumer prior to treatment concerns about the results of tests for Thyroid Stimulating Hormone (TSH) levels (indicating hypothyroidism). The consumer would not have proceeded with treatment if she had known.

Complaints made to the OHO raised a range of issues relating to consent for ART treatments. Case Study 5 is a good example of when issues with consent can arise, even when there are seemingly robust processes in place. One provider's response to the incident demonstrates a willingness to improve processes to ensure that the scientist, fertility specialist and, most importantly, the consumer understand what has been consented to and what will be occurring.

Case Study 5

The patient underwent fertility treatment. She provided instructions that ICSI was only to be used if the fresh sperm sample was not suitable for IVF. The patient's request was included on the consent form. In error, on the day of treatment a fertility specialist confirmed to the provider that ICSI should be performed, which was contrary to the patient's wishes. The provider subsequently reviewed this event and it was noted that a Team Timeout should occur immediately prior to egg pick up to enable a discussion with the fertility specialist and the patient to ensure that the correct method is being used. The provider also determined that the wording of the consent form be reviewed to make it clearer if a patient does not want to use ICSI and if it needs to be used due to unforeseen circumstances.

Case Study 6 highlights the complexities of the consenting process. In this case, the complainant and his partner were very clear that they did not want to use ICSI, but allegedly still signed their consent for 'IVF + ICSI'. This example demonstrates that the consent forms can be confusing, even when a consumer is very clear about their wishes.

Case Study 6

The complainant raised concerns with the OHO about the treatment that his partner had received. The complainant advised that he and his partner did not consent to the use of ICSI because his semen test had shown that the sperm was of high quality and ICSI can compromise the integrity of the eggs. The provider noted that the complainant and his partner verbally informed the nurse that they did not want to use ICSI. The complainant maintains that consent was not provided to ICSI in the consent forms. The provider asserted that when consent forms were then completed the complainant and his partner inadvertently consented to ICSI, selecting Consent to IVF + ICSI, however, did not select type of egg insemination ICSI. ICSI was used to fertilise the eggs, despite the complainant's wishes.

It is crucial that consumers are fully advised about the processes, but it is recognised that this can be overwhelming. This reinforces the importance of a discussion around consent, to ensure that all parties know what has been consented to.

Although consent is standard practice and part of business as usual, Case Study 7 shows how issues can be encountered. Each consent process needs to be carefully considered in the context of whether it complies with the required standards.

Case Study 7

The complainant and his partner attended a provider to undergo ART. The complainant stated that two hours after his surgery to retrieve sperm, the provider emailed consent forms requesting that they be signed. The complainant stated that neither he nor his partner could understand parts of the form so made a note on those parts of the form. The complainant stated that they signed the form because they were under the belief that the treatment would not go ahead if the form was not signed. It was acknowledged by the provider that the consent form should not have been sent to the complainant two hours after administration of a general anaesthetic and an apology was provided.

Audits and adverse events

Consent is one of the cornerstones of health service delivery. It is critical that the patient (as a consumer of healthcare services) understands what they are consenting to and that the consenting process is revisited should the treatment pathway change. This is particularly important for ART treatments given the specialist and technical nature of the treatments, the evidence base for different treatments, and the emotional significance of decisions being made by consumers. The importance of valid informed consent from all parties for each specific procedure or treatment was discussed in the Gorton Review of Assisted Reproductive Treatment in Victoria.[140] In particular, the review noted the 'rapid evolution of science in ART, along with an increasingly corporate and competitive approach to service provision' requiring a clear and consistent process for informed consent. Despite this, a number of issues were identified with the consenting processes being undertaken in the provision of ART treatments.

Key incidents listed in audits and adverse events included:

- consent process had not been adhered to where there was a change in treatment plan
- consent had not been obtained prior to taking an egg donor to theatre for egg collection, despite being highlighted as required multiple times. Staff raised this several times; however, the treatment appeared to be completed with the full knowledge that formal consent had not been taken
- several occasions where consents were not signed by the doctor
- a donor withdrew consent in 2020 but in 2021 the donor was still considered to be available at the ART provider (albeit had not been used since withdrawing consent)
- the consumer had to consent/sign on the day of ovum pick up while recovering from sedation
- consumer who had erroneously been consented for IVF instead of ICSI
- a consumer undertook IVF without a valid signed consent form

[140] Review of assisted reproductive treatment: Final Report May 2019, Michael Gorton.

- consent process was being reviewed because consent forms were not being signed by clinicians
- doctors were signing consent forms prior to the consumers signing.

Information provided to consumers should also include the complications that can arise from treatment to ensure that consumers understand the issues that can occur as a result. Consumers do not always have the medical literacy to connect a medical issue as a complication of ART.

The OHO considers that consumers would benefit from an information pack which contains information about their treatment, to enable them to provide their informed consent, as well as information about possible complications from treatment so that the materials can be reviewed should issues arise. The information obtained to date in this investigation indicates that the amount and timing of the provision of such information about treatment is variable across providers and units. The OHO considers that ART providers should be taking a rigorous approach to obtaining consent from consumers, with attention given to improving quality assurance in relation to the consenting process. While the quality of information provided to consumers is critical, it is also recognised that the consumer's fertility journey can be overwhelming, and they may not be able to absorb information contained in voluminous documentation. The consent form completion should be discussed with the consumer, with a suitably qualified person, at the time of signing to ensure that there are no misunderstandings about what the consumer is consenting to.

It is important to note that registered practitioners have an obligation under their professional standards and codes of practice to obtain informed consent from consumers, including financial consent. The potential for ART providers supplying misleading information was highlighted within the Gorton Review[141] where it is stated that: '*The Review has found that there is a significant risk that people seeking treatment to form a family may be misled by providers who charge considerable sums for ART services and may not adequately communicate to patients the efficacy of treatment and the likelihood of successful treatment.*' While the OHO's investigation did not identify examples of ART providers supplying misleading information, the issues identified in relation to consenting processes support the view that the regulation of ART should include requirements regarding evidence-based information in advertising.

Consumer perspectives

A number of consumers raised concerns regarding consenting processes when responding to the OHO's survey:

> *Doctors need to be aware that normal people don't know what IVF is and likely don't know anyone who has been through IVF. When I originally agreed to IVF … . I had to find out from a YouTube. It felt like they were purposely omitting traumatic information so that women would be in too deep with a particular procedure or plan (IUI/IVF) to back out.*
>
> *ICSI … should never have been recommended to us, since donor sperm should be motile and healthy. The doctor never gave us … options..*

Site visits

The OHO obtained information from ART providers at site visits:

[141] Independent Review of Assisted Reproductive Treatment, May 2019, Michael Gorton.

- Providers agreed that consumer consent is key to the choice of ART.
- A provider explained that consumers are informed about the risks and benefits of each ART procedure, including the risk of multiple pregnancies, ovarian hyperstimulation and the use of human serum albumin in embryo culture.
- Providers were consistent in confirming that consumers are advised that sperm quality may be a factor in their choice of procedure.
- One provider commented that regarding the importance of consumer consent in the choice of ART, Provider E does try and offer consumers choice with IVF, IUI and ICSI with frozen sperm; however, sometimes the post thaw quality of the sperm can mean that this is not practical.

Expert opinions

Professor Norman has commented on the provision of information to consumers when they are considering fertility treatment.

He opined that:

There is so much to discuss medically as well as the practical aspects … . Almost everyone would agree there is not enough adequately funded time spent with patients to get sufficient informed consent in all areas.

Reasons for limited time spent discussing aspects of IVF for true informed consent include;

1. *Inadequate remuneration for time spent due to Medicare funding bias towards interventions rather than discussion.*
2. *Heavy work loads for clinicians with many patients, operating schedules and administrative burden.*
3. *Limited current knowledge of all aspects relevant to fertility treatment and outcomes by some clinicians with inadequate or inappropriate training.*
4. *Inadequacy of prognostic models to assist staff and patients in prediction of outcomes of treatment or waiting longer.*
5. *Hesitancy by many medical staff to discuss all financial aspects of treatment, given the complexity of Medicare reimbursement, company charges for gap funding and uncertainty of treatment outcomes.*

Clinicians and organisations attempt to manage this issue in various ways:

1. *Relying on written and digital resources to provide detailed knowledge prior to consent. There are several national and international resources available as well as clinic derived information. Those provided by independently funded organisations tend to be more balanced and cautious with examples including those from VARTA, ESHRE, ASRM and other international bodies.*
2. *Use of other clinical staff including counsellors, nurses, administrative officers and specialists including genetic counsellors and clinical geneticists. This is usually in addition to the information from the medical doctor looking after the patient.*
3. *Use of complex and comprehensive consent forms to cover all medical risk contingencies. ….*

Improvements could be better addressed by:

1. *Expectations that clinicians will spend more time on information giving and consent (with adequate funding to make this worthwhile)*
2. *Better training of clinicians, (currently improving through REI training from RANZCOG)*
3. *National, independent, easily accessible information on all aspects of fertility options*
4. *Establishment of national evidence-based guidelines for fertility investigation and treatment (note an Australian guideline for unexplained infertility is currently being reviewed by NHMRC and approval expected within the month).*
5. *Reinforcing the authority and surveillance power of RTAC, the current accreditation organisation of FSANZ, in ensuring adequate consenting processes are practised.*

Dr Hammarberg also provided opinion on the issue of provision of information to consumers and consent:

Based on research I have been involved in I believe that information on clinic websites is inadequate. While patients may get more comprehensive information in their consultations with their specialist and the clinic, as their first point of information is the clinic website more balanced information which includes potential drawbacks of different options would benefit patients. Evidence also suggests that women are inadequately informed about the benefits and risks of add-ons and of the chance of having a baby with ART. ...

Transparent, comprehensive and evidence-based information is essential for informed decision making. Written material on clinic websites is clearly skewed towards describing benefits of various ART options. More engagement with potential risks or drawbacks would improve the quality of information. I also think that using short animated videos to explain treatments and their pros and cons would be helpful for those with poor literacy and those who don't speak English.

Recommendations

To FSANZ-RTAC:

14. It is recommended that consideration be given to the establishment of national evidence-based guidelines for fertility investigation and treatment which will assist treating practitioners in determining what information should be provided and consistency of information provided to patients when obtaining their informed consent to treatment.

For ART providers:

15. It is recommended that ART providers should review the adequacy of information provided to patients and, in consultation with stakeholders, consider (if not already in place):

a. development of detailed information materials for patients and/or other means of providing sufficient information to patients for them to make informed decisions, for purposes of information sharing and obtaining informed consent

b. provision of an information package (if not already provided to patients) containing:

   i. detailed information materials, which include potential complications of treatment

   ii. a copy of the consent form signed by the patient confirming the information has been explained to them

c. processes for confirming the patient's understanding of the information provided.

16. It is recommended that ART providers should consider consent forms which:

    a. require a suitably trained person to explain the process to the patient at the time of obtaining their signed consent, e.g. completion of the consent form with sections confirming that information has been provided and explained to the patient about ICSI, including: 1) the nature of the procedure, 2) the risks and benefits, and 3) the availability of alternative treatment (including no treatment) and the risks and benefits thereof; and specific treatment options that have been explained to the patient.

17. It is recommended that informed consent from consumers to be subject to internal audit processes, and regulatory scheme annual audits. This should include consideration of:

    a. information provided to consumers and whether this is understandable to a consumer

    b. timing of obtaining consent

    c. forms which are simple to understand and complete and avoid accidental consent / box ticking.

18. It is recommended that ART providers should consider undertaking regular surveys of consumers to establish the adequacy of information provided and whether consumers do understand what treatment they have consented to.

19. It is recommended that ART providers review their induction and training materials for staff, including clinical, counselling and administrative staff, involved in consenting of consumers and consider whether it is adequate to enable informed consent. This should include consideration of training staff on the need for timely communication to patients, and in how to take into account the emotive context of decision making on ART treatments and its impact on patient understanding and information processing.

To the Minister:

20. It is recommended that consideration is given to whether requirements for informed consent be included in proposed legislation or associated regulations.

21. It is recommended that consideration is given to including requirements in legislation to ensure that the information provided by ART providers to consumers in advertising and consent processes is evidence-based, accurate and clinically relevant.

Theme 6: Sperm quality and ART options

When consumers are using clinic recruited donated sperm, there is an expectation that the sperm will be of good quality and accord with the WHO laboratory manual for the examination and processing of human semen (the WHO Manual).[142] The WHO Manual provides parameters on volume, count, motility and morphology of sperm.

[142] WHO laboratory manual for the examination and processing of human semen, sixth edition, 2021.

The use of poor-quality donor sperm may also impact on the consumer's choice of ART procedure. If there are issues with the sperm, ICSI may be the only option, but may also carry a concurrent risk of passing on genetic causes of infertility.

Background

Sperm donation in Australia and Queensland

In Australia, sperm banks play a crucial role in facilitating artificial insemination and assisted reproductive technologies for individuals and couples facing infertility or seeking alternative family-building options. These banks collect, store and distribute donor sperm for use in fertility treatments.

Donor gamete banks in Australia operate under strict regulations to ensure the safety and ethical use of donor gametes:

- Donors are typically required to undergo thorough medical and genetic screening, as well as counselling, to assess their suitability and ensure the quality of the donated gametes (primarily sperm).
- ART providers are required to ensure that gametes are safe for donation, and must provide evidence that:
  - it will obtain a declaration from the recipient patient/couple before the initiation of the treatment cycle saying that the recipient patient/couple will provide information about the treatment cycle outcome
  - counselling has been undertaken by a counsellor who is eligible for membership of ANZICA.[143]
- Clinics must meet regulatory requirements and have policies and procedures in place to minimise transmission of infectious diseases from the donor to the recipient or the person who would be born.[144]

Individuals or couples seeking donor sperm can choose from a variety of donors based on characteristics such as physical appearance, educational background, and medical history, often with the option of accessing basic information or extended profiles of donors.

Moreover, sperm banks in Australia adhere to guidelines regarding donor anonymity and disclosure, with regulations varying across different states and territories. Access by donor-conceived individuals to information about their donors varies across jurisdictions. In states, including Queensland, that do not have legislation establishing a central donor register, access to donor information will depend on clinic cooperation and skills in locating and seeking contemporaneous information from the donor (or consent from the donor, if it was an early donation prior to use of identity release donors). Use of an overseas donor may also require sophisticated search methods not readily available to the clinic.

The gametes used in ART activities can either be provided by the person receiving treatment (autologous use), their spouse or partner (autologous use), or provided by a donor or donors.[145] Gametes may be donated to a specific recipient who is known to the donor ('known' donation) or to anyone who is receiving ART treatment ('unknown' donation).[146]

[143] Australian and New Zealand Infertility Counsellors' Association, a subcommittee of the Fertility Society of Australia and New Zealand.

[144] https://www.fertilitysociety.com.au/donor-programme-australia-new-zealand/

[145] *WHO laboratory manual for the examination and processing of human semen*, sixth edition, 2021.

[146] *WHO laboratory manual for the examination and processing of human semen*, sixth edition, 2021.

The current situation in Australia is that gamete donation must be altruistic, and that commercial trading in human gametes or the use of direct or indirect inducements is prohibited by legislation.[147]

Key points from section 5 of the NHMRC Guidelines 2017 (updated 2023) on the Use of Donated Gametes in ART Activities, include:

- Consideration of Well-being:
  - Clinics must consider the physical, psychological, and social well-being of all parties involved when accepting or allocating gamete donations.
- Exchange of Information:
  - There should be voluntary exchange of information between donors, recipients, and persons born from donated gametes, respecting privacy laws and consent.
- Right to Know Genetic Origins:
  - Persons born from donated gametes have the right to know their genetic origins, and clinics must ensure donors consent to the release of identifying information.
  - Clinics must not mix gametes to obscure genetic origins.
  - Section 5.6.3 of the NHMRC Guidelines specifically state that:
  - 5.6.3 Clinics must:
    - encourage gamete recipients to disclose to their children their genetic origins
    - provide ongoing support to parents, to help them to understand the potential significance of the biological connection and the benefits of early disclosure
    - assist parents to find effective ways of disclosing to their children their genetic origins
    - provide persons born from donated gametes with a supportive environment within which to explore the possibility of meeting with the donor(s) and/or siblings.
- Providing Information to Donors:
  - Gamete donors are entitled to non-identifying information about persons born from their donation.
  - Clinics should encourage donors to update relevant health information.
- Responsibility for Gametes:
  - Clear procedures should be in place regarding decision making about the use, storage, and discard of donated gametes, respecting the donor's right to withdraw consent.
- Handling Pre-2004 Donations:
  - Gametes collected before 2004 should not be used without the donor's consent for release of identifying information, except in specific circumstances.

These guidelines aim to ensure ethical and responsible practices in the use of donated gametes in ART, protecting the rights and wellbeing of all involved parties.

[147] https://www.fertilitysociety.com.au/donor-programme-australia-new-zealand/

Donor banks[148]

A number of prominent Queensland-based ART providers have internal donor programs, particularly for unknown sperm donors.

Several Australian ART providers also utilise international sperm and egg banks[149,150,151,152,153,154] to supplement their donor programs. These international banks often work with Australian ART providers to provide donors that meet the specific needs and preferences of consumers. These external donor banks must comply with the guidelines set forth by the NHMRC Guidelines and the RTAC Code of Practice.

Sperm donor supply in Australia

The donor sperm supply and demand in Australia reflects a situation of high demand and a carefully managed supply. Demand for donor sperm is substantial, with most consumers seeking specific donor characteristics, such as hair and eye colour (and other physical characteristics often associated with certain ethnicities), height, education level, and interests. This specificity presents challenges in finding suitable donors to meet consumers' preferences.

To meet demand, Australian ART providers sometimes work with international gamete banks, such as the World Egg & Sperm Bank, based in the United States. These partnerships allow clinics to access a broader pool of donors and provide additional options to consumers.

Despite efforts to manage the supply, challenges persist in meeting the diverse demands of consumers. The process involves careful screening of donors for medical history, genetic conditions, and semen quality to ensure compliance with Australian standards. Additionally, legislative changes and the need for a national regulatory framework to govern donor conception practices are areas of ongoing consideration within the industry.

The shortage of sperm donors in Australia is highlighted by several sources, including academic reports, ART providers, and media coverage:

- Goedeke et al. (2021):[155] This academic research discusses fertility stakeholders' concerns regarding payment for egg and sperm donation in New Zealand and Australia. While the specific details of the sperm donor shortage may not be outlined in this summary, the study provides insights into the challenges and implications of the shortage based on stakeholder perspectives.
- HCF:[156] This source discusses how the shortage of donated sperm is adversely affecting Australians who aspire to become parents. It provides anecdotal evidence or interviews with individuals impacted by the shortage, shedding light on the personal struggles and challenges they face due to the unavailability of sperm donors.

[148] Information obtained via OHO research and subject to accessible information (and transparency/clarity therein) contained on public websites.

[149] https://au.seattlespermbank.com/

[150] https://www.cryobankaustralia.com/

[151] https://www.theworldeggandspermbank.com/intended-parent/getting-started/australian-recipients/

[152] https://eggandspermcentre.com.au/

[153] https://www.cryosinternational.com/

[154] https://centralivf.com/australian-partner-clinics/?utm_source=Google+Ads&utm_medium=PPC&utm_campaign=Paradox+-+Performance+Max&gad_source=1&gclid=CjwKCAjwtqmwBhBVEiwAL-WAYY10QCoBPNbEDnBG57En0QkcxEofs09heIRPkjaRurgkPul0IfqmFBoCICwQAvD_BwE

[155] https://doi.org/10.1016/j.rbms.2021.07.006

[156] How A Shortage Of Donated Sperm Is Hurting Aussies Who Dream Of Being Parents

- FertileMinds (Virtus Health):[157] This source directly addresses the issue of the sperm donor shortage in Australia, indicating that only 20% of men are aware of it. It provides statistics and insights into the factors contributing to the shortage and its impact on fertility treatments.

Overall, these sources collectively emphasise the severity and multifaceted nature of the sperm donor shortage in Australia, highlighting its impact on individuals, families and the broader healthcare system. The use of international donor banks to alleviate the donor shortage in Australia is accompanied by concerns which are briefly addressed in this report under 'Additional issues'.

Professor Norman has commented on current demand and supply of sperm:

> *Anecdotally, I hear some clinics are very successful at donor recruitment locally and offer substantial choice. Others are very dependent on overseas sperm banks exporting to Australia. All clinics must follow NHMRC, RTAC and state rules on donor identity and registration, where present. It takes a lot of effort and expense to recruit donors and counsel, test and inform them before they are available for donation.*
>
> *I do not expect it to be different in Queensland as most of the national fertility commercial companies have clinics in the state and can access donors nationally.*
>
> *Demand seems to be growing …*

Dr Hammarberg has commented:

> *Both sperm and egg donation depend on altruism in Australia and the lack of compensation might be a barrier. Also, most people are unaware of the need for donor gametes so may not have considered it for that reason. ...*
>
> *As people currently go overseas for gamete donation due to the shortage of donor eggs and sperm in Australia I believe we need a national conversation about offering reasonable compensation to donors as has been done in the UK...*

Sperm quality

The WHO Laboratory Manual for the Examination and Processing of Human Semen[158] (the WHO Manual) provides the benchmark for assessing the quality of semen. The key elements of assessment of sperm quality are motility and morphology. This Manual further provides threshold cutoff values for both qualitative and quantitative quality metrics in sperm analysis. These metrics include:

Qualitative metrics:

- Motility: (1) Progressive motility (PR): ≥32%; (2) Non-progressive motility (NP) and immotility (IM): No specific cutoff values provided, but these categories are essential for assessing overall motility.

[157] There's a sperm donor shortage in Australia – but only 20% of men know about it

[158] *WHO Laboratory Manual for the Examination and Processing of Human Semen*. 6th ed. Geneva: World Health Organization, 2021; Cooper TG et al. 'WHO reference values for human semen characteristics'. *Hum Reprod Update*. 2010; 16: 231-45;.Agarwal A et al. 'Male infertility'. *Lancet*. 2021 397: 319-33; Gupta S et al. 'A Comprehensive Guide to Sperm Recovery in Infertile Men with Retrograde Ejaculation'. *World J Mens Health*. 2022; 40: 208-16;.*Manual for the Laboratory Examination and Processing of Human Semen*, 6th Edition; https://www.nice.org.uk/guidance/qs73/chapter/quality-statement-4-semen-analysis

- Morphology: Normal forms: ≥4% normal forms based on strict criteria[159] or ≥ 15% normal forms based on less strict criteria (WHO criteria).

Quantitative metrics:

- Concentration: Normal sperm concentration: ≥15 million spermatozoa per millilitre (mL) of semen.
- Total Sperm Count: Normal total sperm count: ≥39 million spermatozoa in the entire ejaculate.
- Viability: No specific threshold provided in the WHO manual; however, viability is typically assessed qualitatively, with a higher percentage of live sperm indicating better fertility potential.

It is important to note that these cutoff values are guidelines, and individual laboratories may have slightly different reference ranges based on their specific methodologies and equipment.

In relation to sperm quality, Professor Norman has commented:

> *The criteria generally used to define normal semen analysis parameters are those defined by the updated WHO laboratory manual (2021) which details information on many parameters used by clinical laboratories to define normal sperm … . It should be noted that an Australian study has shown that only a small percentage of men fulfil all the criteria (volume, count, motility, morphology) in their entirety and clinicians recognise that mild variations outside of the WHO criteria are compatible with normal fertility potential.*

These metrics and cutoff values help categorise semen samples into different quality classes; aid in assessing male fertility; and provide clinical information that may guide clinical management (ART options and choices) of consumers.

Sperm quality and ART options

Conventional semen analyses (including quality parameters of sperm count, motility and morphology) and related clinical studies have provided important insights into the threshold values that are commonly applied in clinical practice, albeit to varying degrees. It is therefore generally considered to be important to consider sperm quality, as it may influence the choice of ART.

For example, while the number of progressively motile sperm detected in fresh ejaculates may not provide a reliable predictor of pregnancy outcome in IUI, evidence suggest that it can be a reliable indicator for the discrimination of whether to refer a couple for IUI or IVF (using a threshold of one million progressively motile sperm).[160]

In some instances, consumers are referred for IVF (an arguably more invasive and costly procedure as compared to IUI) regardless of sperm quality parameters. Nevertheless, due to the nature of IVF – where sperm are placed together with an egg in culture medium to allow quasi-natural fertilisation to occur – greater emphasis is generally placed on sperm motility (where sperm motility higher than 30% and progressive motility higher than 15% is recommended for IVF opt in[161]).

[159] Kruger strict morphology.

[160] Villani et al (2021), 'Are sperm parameters able to predict the success of assisted reproductive technology? A retrospective analysis of over 22,000 assisted reproductive technology cycles', *Andrology* 10:310–321.

[161] Michelmann HW, 'Minimal criteria of sperm quality for insemination and IVF therapy', *Int J Androl*. 1995 Dec;18 Suppl 2:81-7. PMID: 8719866.

Additionally, it has been observed that sperm motility in IVF is correlated with increased fertilisation rates.[162]

With respect to ICSI, it was noted that the use of non-motile spermatozoa appears to negatively impact fertilisation outcome, despite the direct microinjection of a single sperm into the egg,[163] and found that sperm concentration is directly correlated with ICSI fertilisation rates in addition to sperm morphology.[164]

While it is reasonable to assume that sperm quality parameters, such as progressive motility, are important considerations for guiding the choice of ART and subsequent pregnancy success rates, current literature is conflicted, with some studies suggesting a strong correlation, and others not.[165] In a more recent study, it has been observed that a direct correlation between fertilisation rate and semen parameters (sperm count, motility and morphology) is evident in both ICSI and IVF cycles[166] with the authors stating that: 'These predictors are extremely interesting, suggesting and confirming the difference between the two ART methods, as well as the different male contributions to the ART according to the technique applied.'

In summary, semen quality parameters in the ART setting are clinically relevant – where sperm motility is an important factor in IVF and sperm morphology an important factor in ICSI[167] – as these appear to influence fertilisation rates. As such, these parameters can aid on the choice of the best ART approach to be undertaken.

Association of sperm defects with potentially heritable genetic issues

The advent of ICSI has significantly advanced the ability of men with severely low sperm count (oligozoospermia) to produce genetically own offspring. Moreover, ICSI has been demonstrated to be associated with higher fertilisation, pregnancy and/or live birth rates as compared to IVF, albeit at an incremental cost due to the increased time and resource requirements related to ICSI.

Despite the evident advantages of ICSI, it does pose potential issues of concern. As summarised by Villani et al (2021)[168] several studies have suggested a higher risk of chromosomal abnormalities, epigenetic modifications, imprinting disorders, autism, intellectual disability, hospitalisation at neonatal intensive care units, and congenital disorders in ICSI as compared to IVF cycles. Men with azoospermia (absence of motile sperm in the semen) are at the highest risk of being carriers of genetic anomalies (25%), and this risk progressively decreases with increasing sperm output.[169] In the era of ARTs, such as ICSI, in which natural barriers to egg fertilisation are removed, genetic causes of infertility have an obvious clinical significance as it could have implications for the reproductive health and the general health of the consumer and their children, where such genetic anomalies could be inherited. Furthermore, ICSI to treat male factor infertility

[162] Villani et al (2021), 'Are sperm parameters able to predict the success of assisted reproductive technology? A retrospective analysis of over 22,000 assisted reproductive technology cycles', *Andrology* 10:310–321.

[163] Dcunha R, Hussein RS, Ananda H, 'Current insights and latest updates in sperm motility and associated applications in assisted reproduction', *Reprod Sci*. 2020: 1-19. https://doi.org/10.1007/s43032-020-00408-y

[164] Villani et al (2021), 'Are sperm parameters able to predict the success of assisted reproductive technology? A retrospective analysis of over 22,000 assisted reproductive technology cycles', *Andrology* 10:310–321.

[165] Villani et al (2021), 'Are sperm parameters able to predict the success of assisted reproductive technology? A retrospective analysis of over 22,000 assisted reproductive technology cycles', *Andrology* 10:310–321.

[166] Villani et al (2021), 'Are sperm parameters able to predict the success of assisted reproductive technology? A retrospective analysis of over 22,000 assisted reproductive technology cycles', *Andrology* 10:310–321.

[167] Villani et al (2021), 'Are sperm parameters able to predict the success of assisted reproductive technology? A retrospective analysis of over 22,000 assisted reproductive technology cycles', *Andrology* 10:310–321.

[168] Villani et al (2021), 'Are sperm parameters able to predict the success of assisted reproductive technology? A retrospective analysis of over 22,000 assisted reproductive technology cycles', *Andrology* 10:310–321.

[169] Krausz and Riera-Escamilla (2018), 'Genetics of male infertility', *Urology* 15:369-384.

(e.g. azoospermia, oligozoopspermia) has been associated with higher rates of chromosomally abnormal embryos.[170]

Professor Norman has commented:

> *There is significant literature to suggest the use of ICSI is related to an increased risk of congenital anomalies even when the sperm count is normal. This comes from case series as well as data-linkage studies in Australia and internationally.*
>
> *I think there should be greater awareness of the relative disadvantages of ICSI in terms of congenital anomalies, the increased cost, likelihood of failed fertilisation and potential for avoidance of ICSI even with relatively poor-quality sperm.*

Based on the above, sperm quality parameters (e.g. morphology) and potential for increased risk of genetically abnormal embryos and potentially heritable conditions should be considered in ART and discussed with consumers to the extent required for them to make an informed decision about treatment.

In relation to possible genetic conditions, Professor Norman has commented:

> *A normal semen analysis does not exclude the possibility of a genetic condition, but severely abnormal sperm counts may indicate an underlying genetic problem. Complete absence of sperm (azoospermia) is associated with a higher chance of chromosomal dysfunction (e.g. Klinefelter's syndrome) or genetic microdeletions, particularly of the Y chromosome. ...*
>
> *Low quality sperm is hard to define precisely. If all parameters are significantly deviated from the*
>
> *WHO criteria, sperm is impaired with respect to fertility and potential to fertilise an egg. The more that sperm deviates from normal criteria, the more likely there will be problems with fertility, but much depends on the clinical background. For instance, a man with 'poor' semen parameters but with a proven fertility history may arguably indicate a potential for use as a donor sperm participant. … there is no absolute boundary between normal and abnormal sperm with respect to fertility, offspring health or transmission of adverse genetic tendencies..*

Investigation findings

Complaints

Concerns about the availability and quality of donor sperm were evident in a number of the complaints to ART providers. It is acknowledged that this is a challenge across the industry, and it appears inevitable that establishing sufficient supply to meet demand requires the use of international sperm banks. International importation of sperm is outside the scope of this report.

Concerns about the quality of sperm was raised in one complaint made to the OHO. The conduct raised in this complaint related to an alleged failure to provide sperm of the recommended quality

[170] Greco E, Litwicka K, Minasi MG, Cursio E, Greco PF, Barillari P, 'Preimplantation Genetic Testing: Where We Are Today', *International Journal of Molecular Sciences*. 2020; 21(12):4381. https://doi.org/10.3390/ijms21124381

for an IUI procedure. The donor selected by the consumer had been 'regraded' and deemed no longer suitable for IUI. The consumer raised concerns about the accuracy and reliability of the information provided.

Anecdotally, the OHO recognises that some ART providers face difficulties in meeting the high expectations of consumers in terms of the physical attributes of donors. Some work may be required by ART providers in managing the consumer's desire, say, for a donor with specific height and athletic qualities.

Consumers' expectations in terms of sperm quality are reasonable and appropriate, given that they are paying for a service and want to ensure that the treatment has the highest prospects of success. This is very different to that of a person seeking treatment due to fertility issues, who is using their own sperm. Despite the reasonable expectation of quality sperm, the OHO has noted concerns raised by consumers.

Case Study 8 provides an example of the use of apparently poor-quality sperm for ICSI, with a negative outcome for the patient. This raised considerable concerns for the patient and managing gynaecologist, to the extent that an investigation was undertaken.

Case Study 8

A gynaecologist complained to a provider on behalf of a patient who was a single woman using donor sperm to conceive. Following collection of 13 eggs, they were fertilised using donor sperm, via ICSI. No eggs fertilised. The laboratory informed the patient's gynaecologist that the sperm was very poor quality, and would have rated the sperm as having 0% motility and the team struggled to find any normal sperm for use with ICSI. The provider investigated the complaint and determined:

- Cycle 1: Cycle was planned for IVF but converted to ICSI based on poor motility of the sperm. The sperm had been frozen in 2008 and there was a notable reduction in quality post-thaw, at 12% progressive motility.
- Cycle 2: Poor motility noted by the ICSI scientist.

It was concluded that there appeared to be a significant reduction in the quality of frozen sperm over time (original semen analysis was at 70% motility).

The patient was particularly upset because the quality of the sperm was not discussed with her and so was not given the option to change donors before attempts were made to fertilise her eggs.

As a result of the investigation, it was recommended that a requirement be introduced to the donor program that sperm stored over a timeframe should be thawed and tested before use (or not offered for use). It is not known whether the provider implemented this recommendation.

Another similar complaint was made to an ART provider regarding poor-quality sperm in 2022. The consumer maintained that when she reserved the sperm it was graded for use in IVF and IUI, but at the time of using the sperm, she was advised that the sperm motility was low and that ICSI was required. The consumer was advised that the freezing process did create a risk of issues with the sperm and that assessment could only be made once the semen was thawed.

The issue is not limited to one ART provider. Case Study 9 is a consumer complaint regarding poor-quality sperm.

Case Study 9

The patient raised concerns about the failure of her two IVF cycles. Upon seeking to transfer to a new ART provider, the patient obtained her records and discovered the donor sperm used for her two cycles was extremely poor quality. It is noted that the patient was informed of the requirement to use ICSI with the donor chosen; however, the patient alleged that she was not aware of the extent of the quality issues. Frozen sperm in 2020 was recorded as having overall motility of 6%, with 94% immotile and only 2% with progressive motility. In 2022, 99% of the sperm was recorded as immotile and 1% had progressive motility.

It is not evident from the information examined for this investigation that consumers fully understand why ICSI is recommended, and the extent to which they are informed of the poor quality of the semen they have reserved for use. Consumers do appear to recognise that there is limited availability of donor sperm, but equally, they are paying for a service for which they want to maximise the chances of success (a positive pregnancy outcome). It is acknowledged that if a consumer has selected a specific sperm donor, they may be willing to use the sperm regardless of the quality (particularly if they have a previous child born using that sperm donor). Ensuring that consumers are fully informed of the quality of donor sperm and why an ART option (such as ICSI) may be recommended are important considerations.

Audits and adverse events

There were no issues identified during audit or in adverse events that related to sperm quality.

Consumer perspective

A consumer responding to the OHO's survey made the following comment:

The clinics have a financial investment in upselling … interventions to patients.

Site visits

The OHO obtained information from site visits as follows:

Sperm quality

Providers reported that:

- There can be issues with demand for donated sperm, and consumers may have expectations about the physical features of the donor.
- Providers now operate separate organisations, such as Sperm Donors Australia, and utilise websites and apps for donor recruitment, increasing accessibility and professionalism.
- One provider reported that there has been a shift in societal acceptance, with women now openly discussing and even celebrating the use of donor sperm, marking a more transparent and open industry. Consequently, donor numbers have increased significantly over the past decade, with clinics processing a much larger pool of donors compared to before.
- Another provider commented on a general national decline in local donor availability since anonymity laws changed, causing donors to decrease. Lack of compensation was also cited as a factor in this decrease. Despite an overall decline in donors, they have seen an upturn in

local donor recruitment for their in-house donor program following advertising efforts, but demand remains high, especially among single women and same-sex couples.

Additional commentary from providers and FSANZ-RTAC

In correspondence to the OHO, Provider E has commented:

> *Provider E recognises the importance of preserving sperm quality and has stringent protocols for the collection, analysis, storage and handling of sperm samples to ensure that the reproductive potential is maximised, and risks associated with compromised sperm quality are reduced. From the outset Provider E wishes to make clear that just because sperm may be below the recommended reference value, this is not an indication of its fitness for purpose. Given that only one motile sperm is needed for procedures such as ICSI, many of the other sperm quality parameters are of lesser relevance. Provider E submits that the quality of sperm can also be measured by the outcome of a positive fertilisation.*[171]

Provider C has commented:

> *While it is true that injection of non-motile spermatozoa is less likely to lead to normal fertilisation, it is also important to recognise that this potential is non-zero. Indeed, in these cases, what is more important is the viability of the spermatozoa, i.e. whether the spermatozoon is alive. There are multiple methods for assessing viability of non-motile spermatozoa and, hence, the legislation should be careful to not prohibit the use of nonmotile spermatozoa.*[172]

In correspondence to the OHO, FSANZ-RTAC has stated:

> *Techniques such as IVF and ICSI enable the use of donor samples that would otherwise not be acceptable for insemination procedures. Additionally, these methods allow for more dilute samples to be used, thereby making more efficient use of a rare resource compared to insemination procedures… . It is a misconception that sperm quality, as defined by the WHO manual, directly relates to the fertilization capacity of sperm when using IVF and ICSI. The WHO manual defines sperm quality parameters applicable only to natural intercourse. ART procedures make these categories irrelevant.*[173]

The OHO notes the comments from the ART providers, particularly in relation to the use of sperm that is below the recommended reference values. The OHO appreciates that this sperm can be used for fertility treatments, but it is crucial that consumers are appropriately advised of their options for ART procedures and whether the quality of the donor sperm selected impacts on their choices. This is captured in the OHO's recommendations.

Choice of ART

Providers reported that:

- The decision between IUI, IVF or ICSI depends on various factors, including sperm quality, consumer preference, and the clinician's recommendation. Each procedure has its advantages and disadvantages, which consumers are informed about.

[171] Letter from Provider E to the OHO dated 10 May 2024.

[172] Letter from Provider C to the OHO dated 14 June 2024.

[173] Letter from FSANZ-RTAC to the OHO dated 14 June 2024.

- ICSI may be used for donor sperm with poor quality if there is a demand for specific genetic traits, although it is less common.
- ICSI involves a higher success rate but also carries risks, such as potential trauma to the egg and a small percentage of embryo degeneration, but live birth outcomes are generally comparable to other ART methods.
- The decision about the type of ART service remains with the consumer, informed by the treating doctor, rather than made by the clinic. IUI has a very low success rate (a 94–96% failure rate), but with donor insemination the rate is slightly higher because the sperm is usually good quality.

Expert opinions

Professor Norman has commented on the use of poor-quality sperm:

> *Poor motility and immotile sperm are associated with a higher risk of failed fertilisation, certainly for IVF and possibly for ICSI when few motile sperm are available. Immotile sperm may be associated with non-viability and failed fertilisation, even with ICSI.*

Professor Norman has noted that changes can occur between donations, but this can be a flag in terms of an underlying issue:

> *All parameters can change significantly between donations, particularly with respect to count. This is normal physiological variation although dramatic changes from normal to severely abnormal are unusual in the absence of known predisposing factors. ...*
>
> *If a sperm donor had repeated poor results, they should not be used unless there are other considerations (e.g. donation to a family member or to help someone complete a family having used the same donor previously). Poor results should indicate counselling of the donor on potential underlying causes, (including genetic and lifestyle factors), as well as long term consequences (potential increased metabolic sequelae).*

Professor Norman also notes:

> *Shortage of sperm donors influences clinical decisions, including higher use of ICSI instead of IVF or IUI. Inferior quality sperm may be used more frequently especially if it is hard to attract and retain suitable donors.*

Mr Barry has added:

> *NHMRC make recommendations regarding the storage of gametes and embryos. (Section 7. Ethical guidelines on the use of assisted reproductive technology in clinical practice and research 2017 (updated 2023)). The storage time for gametes should be specified by the fertility clinic and accompanied with a risk assessment.*
>
> *Current best practice protocols for the freezing, storage, and use of frozen donate sperm will ensure continued sperm quality. Each fertility unit must determine how this occurs by referencing up to date articles, publication and in house experience.*

Conclusion

The information examined for this investigation highlights that the use of semen with low sperm count or complete absence of sperm may carry the risk of possible inherent genetic issues present in the sperm donor. In some cases, when sperm are present (albeit at low counts), possible genetic issues present in the donor (and their sperm) can be inherited by embryos the sperm is used to create. It is clear that the use of ICSI (particularly for sperm indicated to be for 'ICSI use only') should be accompanied by patient counselling to inform consumers of particular potential risks (including the possible increased risk of foetal abnormalities).

Recommendations

The following recommendations are linked with Theme 5, Provision of informed consent.

For ART providers:

22. It is recommended that steps are taken to ensure that patients are fully informed about:
    a. the quality of sperm to be used for ART, including any potential issues with concentration, motility, morphology or viability
    b. the approaches taken to inform the choice of ART (which may include quality, cost and other medical considerations)
    c. the advantages and disadvantages of each ART procedure, considering factors such as success rates, cost, and potential risks
    d. the reasons for recommending specific ART procedures based on sperm quality and the likelihood of success
    e. the importance of genetic screening and counselling for patients considering ART.
23. It is recommended that ART providers should ensure compliance with NHMRC Guidelines and the RTAC Code of Practice when selecting donors (particularly those from international banks).
24. It is recommended that ART providers should consider the genetic implications of sperm quality, particularly in cases of severe abnormalities or azoospermia, which may indicate underlying genetic conditions.

Theme 7: Sex selection

Sex selection is the selection and transfer of an embryo on the basis of genetic sex.[174] The investigation explored whether sex selection is occurring and whether this requires more robust regulation.

Background

Preimplantation Genetic Testing

Preimplantation Genetic Testing (PGT) is a molecular genetics technique that tests genetic material (DNA) of embryos. In order to access this genetic material, embryos are generated outside the body in an embryology laboratory by way of IVF or ICSI. While embryos are in culture (growing in the laboratory), a trained embryologist removes a cell or number of cells from each embryo, called a biopsy. The biopsied cells contain the genetic information of the embryo, which can be extracted for genetic testing. As such, biopsied cells are sent to specialist genetics

[174] Ethical guidelines on the use of assisted reproductive technology in clinical practice and research, NHMRC, 2017.

laboratories for PGT testing, facilities which may be in-house or outsourced to a third-party provider.

PGT is comprised of two primary forms:

- **Preimplantation Genetic Testing for Aneuploidy (PGT-A).**
  Formally known as Preimplantation Genetic Screening (PGS), PGT-A screens embryos for chromosomal abnormalities. Incorrect numbers of chromosomes can lead to failure of the embryo to implant into the uterine wall, miscarriage, or genetic conditions like Down syndrome.

  Thus, the purpose of PGT-A is to identify chromosomally normal embryos, to prioritise for transfer to a patient's uterus. This process potentially improves chances of pregnancy, and reduces risk of miscarriage and certain genetic conditions. The risk of chromosomally abnormal embryos is generally associated with advancing maternal age. Additionally, while embryonic chromosomal abnormalities mainly arise from maternal origins (the egg), some can be derived from paternal origins (the sperm).

  Due to the inherent nature of PGT-A to screen all chromosomes, in conjunction with the fact that sex is chromosomally determined, PGT-A is able to identify the genetic sex of each embryo.

  PGT-A is therefore a technique used in conjunction with IVF/ICSI to screen embryos for chromosomal abnormalities, allowing for the selection of chromosomally normal embryos which have the highest chance of implantation and a successful pregnancy outcome. However, it is essential to consider the limitations and ethical implications associated with this technology.

- **Preimplantation Genetic Testing for Monogenic conditions (PGT-M).**
  Formally known as Preimplantation Genetic Diagnosis (PGD), PGT-M tests embryos for the presence of single-gene conditions (such as cystic fibrosis, spinal muscular atrophy, thalassaemias). The process of PGT-M is identical from an embryology point of view to that of PGT-A, where embryos are generated outside the body, biopsied and sent to a genetics laboratory for testing. The difference between PGT-M and PGT-A is the testing approach, where PGT-M assesses individual and specific genes, as opposed to whole chromosomes (PGT-A).

Overall, PGT is used to avoid or significantly reduce as far as possible the risk of passing on genetic and/or chromosomal conditions to embryos. Clinical indications for PGT therefore include (but are not limited to)[175]: (1) Advanced Maternal Age (AMA), (2) recurrent pregnancy loss, (3) recurrent implantation failure, (4) male factor infertility and (5) consumers who carry or are affected by a single-gene condition.

Use of PGT for sex selection

The clinical utility for PGT has driven global demand and the availability of such technologies, as an adjuvant treatment to standard fertility treatment. The rapid advancements of PGT-A have raised numerous concerns regarding the ethical acceptability of some of its potential applications. Among these is the use of PGT-A for sex selection.

While the majority of single-gene conditions do not involve the sex chromosomes (X and Y), there are a considerable number that do. Some examples include: red-green colour blindness, haemophilia A, Duchenne muscular dystrophy, Alport syndrome, Fabry disease, and Charcot-

[175] Greco E, Litwicka K, Minasi MG, Cursio E, Greco PF, Barillari P, 'Preimplantation Genetic Testing: Where We Are Today', *International Journal of Molecular Sciences*, 2020; 21(12):4381. https://doi.org/10.3390/ijms21124381

Marie Tooth syndrome. While PGT-M has the ability to test specifically for individual genetic conditions (specific genes), it is generally significantly more expensive and complex to design, as compared with PGT-A. As such, considering that sex-linked conditions are associated with the sex chromosomes, screening embryos by way of PGT-A and preferentially selecting for embryos of a certain sex can be used to avoid sex-linked conditions.

Sex selection can be used in the context of a medical indication to reduce the risk of sex-chromosome linked single-gene conditions, and for non-medical indications. The preeminent ethical considerations that support consumer choice of sex selection for non-medical reasons are consumer autonomy and reproductive liberty.[176] Reasons for seeking non-medical sex selection may include wishes to have the experience of raising children of both sexes, which is especially strong for individuals/couples who have more than one child of a particular sex. The desire to create genetic sex diversity among children within a family unit by way of sex selection is often referred to as 'family balancing'. Primary arguments against sex selection for non-medical reasons includes harm to offspring, harm to women (and also to men), misuse of medical resources for non-medical purposes, and risks of discrimination and perpetuation of social injustice.[177] This is of particular concern in countries where there is a preference for a particular sex, where arguments are made about the potential to skew population sex ratios.[178]

Regulation of sex selection

In the context of ART, the term 'sex selection' refers to the selection and transfer of an embryo on the basis of genetic sex (biologically speaking, males typically being chromosomally XY and females typically being chromosomally XX). Intended parents seeking to select the sex of an embryo may have genetic (medical) or non-medical reasons for doing so. The NHMRC guidelines have long considered that the use of sex selection techniques may be ethically acceptable when used to reduce the risk of transmission of a serious genetic condition, disease or abnormality.'… despite AHEC's majority view that there may be some circumstances where there is no ethical barrier to the use of sex selection for non-medical purposes, paragraph 8.14 applies until such time that wider public debate occurs and/or state and territory legislation addresses the practice.'

> *8.14 Sex selection for non-medical purposes is not currently supported*
> *8.14.1 Sex selection techniques may not be used unless it is to reduce the risk of transmission of a genetic condition, disease or abnormality that would severely limit the quality of life of the person who would be born (see paragraph 8.13).*

At the time of publication of the NHMRC Guidelines (2017), four Australian jurisdictions (South Australia, New South Wales, Victoria and Western Australia) had legislation regulating the clinical practice of ART. Legislation in Victoria[179] and Western Australia[180] establishes eligibility criteria, typically limiting ART services only to individuals where it is medically necessary. Consequently, it is unlikely that individuals seeking ART solely for the purposes of non-medical sex selection would fulfil the eligibility requirements in these jurisdictions.

Outside of eligibility criteria, Victoria is the only jurisdiction which expressly prohibits the use of gametes or embryos for the purpose of sex selection where it is not necessary to avoid the transmission of a genetic disease or abnormality. Furthermore, the Victorian legislation also

[176] Ethics Committee of the American Society for Reproductive Medicine (2022), 'Use of reproductive technology for sex selection for nonmedical reasons: an Ethics Committee opinion', *Fertility and Sterility* 17:720-6.

[177] Ethics Committee of the American Society for Reproductive Medicine (2022), 'Use of reproductive technology for sex selection for nonmedical reasons: an Ethics Committee opinion', *Fertility and Sterility* 17:720-6.

[178] Tafuro and Guilmoto (2020), 'Skewed sex ratios at birth: A review of global trends', *Early Human Development* 141: 104868 https://www.sciencedirect.com/science/article/pii/S0378378219305225

[179] Section 10, Assisted Reproductive Treatment Act 2008 (Vic).

[180] Section 23, Human Reproductive Technology Act 1991 (WA).

provides an avenue for individuals to bypass the legislative prohibition on sex selection for non-medical purposes and the limitations imposed by the statutory eligibility criteria by allowing individuals to apply to the independent Patient Review Panel[181] for approval.

Victoria – Assisted Reproductive Treatment Act 2008

> Section 28 Ban on sex selection
>
> (1) A person carrying out a treatment procedure must not use gametes or an embryo, or perform the procedure in a particular way, with the purpose or a purpose of producing or attempting to produce a child of a particular sex.
>
> Penalty: 240 penalty units or 2 years imprisonment or both.
>
> (2) Subsection (1) does not apply if—
>
> (a) it is necessary for the child to be of a particular sex so as to avoid the risk of transmission of a genetic abnormality or a genetic disease to the child; or
>
> (b) the Patient Review Panel has otherwise approved the use of the gametes or embryo for the purpose or a purpose of producing or attempting to produce a child of a particular sex.

RTAC and NHMRC

NHMRC Guidelines define sex selection as 'the selection and transfer of an embryo on the basis of genetic sex.'

> Sex selection to reduce risk of transmission of a genetic condition, disease or abnormality
>
> 8.13 Assess the ethical acceptability of selecting the sex of a human embryo to reduce the risk of transmission of a genetic condition, disease or abnormality.
>
> 8.13.1 Sex selection techniques may be used to reduce the risk of transmission of a genetic condition, disease or abnormality that would severely limit the quality of life of the person who would be born, when there is evidence to support:
>
> - claims that the condition, disease or abnormality affects one sex significantly more than the other (see paragraph 8.16)
> - that the risk of transmission is greater than the general risk of the condition, disease or abnormality occurring within the general population.
>
> 8.13.2 Sex selection techniques may not be used unless the intended parent(s) have been provided with relevant information and counselling, in accordance with paragraph 8.18.
>
> 8.14 Sex selection for non-medical purposes is not currently supported
>
> 8.14.1 Sex selection techniques may not be used unless it is to reduce the risk of transmission of a genetic condition, disease or abnormality that would severely limit the quality of life of the person who would be born (see paragraph 8.13).

The RTAC Code of Practice does not specifically address sex selection, only to say that providers must be compliant with the NHMRC guidelines.

[181] Victoria has an independent Patient Review Panel established under the Assisted Reproductive Treatment Act 2008 (Vic). Its role is to consider applications relating to several issues, including the use of preimplantation genetic diagnosis for the purpose of sex selection.

Investigation findings

Complaints

A complaint to the OHO regarding allegations of sex selection highlighted the importance of considering the issues under this theme and whether current guidelines need to be strengthened by regulation. At the time of publication of this report no findings had been made in relation to this matter.

The OHO did not identify any other issues raised with individual providers during the review of adverse events and audit reports, which is unsurprising (given the ethical and regulatory sensitivity of this practice). While the data is limited on the ongoing use of sex selection, it remains an issue which should be considered as part of regulation and legislation around the provision of ART.

Audits and adverse events

There were no issues identified during audit or in adverse events that related to sex selection.

Site visits

Information was obtained from providers during site visits:

- Providers all acknowledged the restrictions on sex selection under the NHMRC Guidelines.
- PGT is offered to consumers, particularly older fertility consumers and those with recurrent implantation failure or multiple miscarriages.
- Consumers *may* be able to choose which embryos to implant based on quality and other factors, but decisions are guided by medical advice and ethical considerations.
- One provider acknowledged that there can be pressure to undertake sex selection from consumers. This provider changed its policy on testing because occasionally scientists were being put under pressure by the consumer to select a particular sex of embryo for transfer. Testing of sex is now performed externally, and the result is not released unless the external geneticist and the provider's geneticist agree that there is a sex-linked disorder.
- Another provider commented that for the majority of the consumers, genetic reports would not include gender. There are exceptional circumstances where this is taken to the Medical Research Committee for approval for the gender to be released.
- At one provider, requests for gender selection undergo review by the Queensland Medical Advisory Committee to ensure compliance with NHMRC guidelines. This provider ensures compliance by requiring documentation or a letter from a geneticist justifying the need for sex selection based on medical grounds. The clinic also maintains transparency by not disclosing the sex of embryos to embryologists, except when medically indicated.

Additional commentary from providers

Provider C put forward that:

> *... if there is a review of the [NHMRC] stance on sex selection that this is then reflected in any Qld legislation.*
>
> *Provider C recommends that the legislation recognises that 'sex selection for family balancing reasons is not currently explicitly legislated against, but rather regulated against in line with NHMRC guidelines.*

The provision of services by ART providers in QLD must remain in line with NHMRC guidelines with respect to sex selection of embryos.' Inclusion of such a clause, or similar, will allow the legislation to be more agile in response to changes that might occur in the NHMRC guidelines.[182]

Expert opinions

Professor Norman has commented on the selection of embryos based on sex:

> *NHMRC will allow embryo sex selection for certain sex-linked diseases and there is also a tendency to allow selection of female embryos where autism is seen to be a problem in a family (this condition is more common among males). My impression is most clinics will not allow sex selection even when preimplantation genetic testing for aneuploidy (PGT-A) is widely practiced. PGT-A will reveal the sex of the embryo but most clinics will not tell this to patients unless medically indicated. I cannot exclude the possibility that some clinics may give patients all the chromosomal information obtained and succumb to pressure to replace certain embryos of a chosen sex. …*
>
> *I think sex selection is a big issue for ART providers, especially with the changing ethnic composition of the Australian population, the attitude of some patients that they are entitled to choose, international opportunities for this option and the threat to go to another clinic (local or international) if the service is not provided. The risks of breaking the law are likely to restrain the large corporations from allowing any deviation from NHMRC standards but that may not apply to smaller, stand-alone organisations that are under lesser governance.*

In relation to the current guidelines on sex selection and the need to consider future developments, Professor Norman has commented:

> *With respect to compliance with the NHMRC guideline, I would expect clinics to obey the requirement that they do not provide the patient with information on the sex of the embryo undergoing PGT-A (or by any other indirect method), that they choose the embryo for transfer based on scientific and embryology parameters that exclude chromosomal sex and that the scientific and medical directors sign a statutory declaration annually at the time of RTAC inspection that they are fully complying with NHMRC guidelines and the relevant law.*
>
> *There should also be a recommendation that the clinic does not refer patients who are seeking sex selection to overseas organisations offering this service. I expect in time it will be possible to separate human sperm into X and Y carrying components allowing fertilisation with favoured sperm to produce a desired gender. This will challenge existing regulations and community attitudes and should be anticipated in any future regulations.*

[182] Letter from Provider C to the OHO dated 14 June 2024.

Recommendation

To the Minister:

25. Based on the NHMRC Guidelines, it is recommended that state-specific legislation explicitly affirms the position on the practice of non-medical sex selection in Queensland.

Theme 8: Discarding of gametes and/or embryos (genetic or biological material)

Decisions to discard or destroy gametes and/or embryos have particular importance and emotional significance for consumers. For some consumers the decision to discard gametes and/or embryos is multifaceted and highly sensitive.

This section applies to the disposal of the consumers' gametes and/or embryos, rather than donor sperm and donor gametes.

ART providers have a responsibility to manage this process efficiently, effectively and with sensitivity and awareness of the impact on consumers. The NHMRC Guidelines set out key requirements for ART providers in respect of the discard of gametes or embryos as set out below.

Background

The NHMRC Guidelines include sections on the discard of gametes or embryos, including:

> 3.9 Clinics must maintain policies for each treatment and procedure available at the clinic. These policies must identify the line of responsibility in each circumstance. For example, specific policies should be developed and implemented in relation to:
>
> - … use, storage and discard of gametes and embryos
>
> 4.1.2 Clinics must ensure that the following information is discussed, at a minimum:
>
> - … options for the use or discard of gametes or embryos, including options that are legal, but may not be offered at the particular clinic
>
> 5.11 Ensure that all parties are aware of who is responsible for decision making about the use, storage and discard of donated gametes
>
> 7.1.2 Clinics must ensure that all reasonable efforts are made to keep gametes and embryos in safe storage for the period of storage specified in the consent form. After this time, if the individual or couple responsible for the stored gametes and embryos cannot be contacted to provide further direction and consent, clinics may discard the gametes or embryos, in accordance with the clinic's policy.

Investigation findings

Complaints

ART providers may have policies in place for the disposal of gametes, embryos or other biological material. Based on the information considered for this investigation, the OHO is concerned that a patient-centric approach was not demonstrated by all providers.

The list below highlights issues raised by consumers in complaints to the OHO:

- continued charges for storage of embryos when the consumer ceased the relationship with the provider and had understood the embryos had been discarded
- failure to confirm that embryos had been discarded

- refusal of the provider to dispose of semen samples.

Case studies 10 to 13 describe situations where consumers provided signed confirmation of their wishes and consent to discard embryos and/or ovarian tissue, only to find out that the disposal process was still in progress or only completed many months (in some cases, years) after providing signed consent. This resulted in significant emotional distress to these consumers. The impact of unexpected delays or lengthy turnaround times for the disposal of embryos and other biological material, and the impact that this can have on consumers, should not be underestimated. ART providers also need to be cognisant of the impact on their staff of managing consumers who are distressed or experiencing trauma. It is recommended that staff should be appropriately trained to support the consumer and signpost support services, as well as ensuring that the staff's own wellbeing is considered given the nature of the contact with consumers.

In some cases, there is concern that the ART provider has treated the disposal of biological material as a transactional process, which can be considered to be wholly inappropriate in this sector, given the emotional nature of ART for consumers.

Case Study 10

The patient had sent a completed embryo disposal form to a provider in 2017. A staff member called the patient five months later to obtain verbal consent, as per the provider's process. The patient was extremely distressed to receive the call, so long after she had sent back the disposal form. The complaint describes the patient as feeling an 'immense lack of care' and 'emotionally broken'. It is not clear how this complaint was resolved other than the staff member providing a verbal apology and assurances that the patient's feedback would be passed on.

Case Study 11

The patient had given a provider with her consent to dispose of her ovarian tissue but was not contacted until six months later for verbal confirmation of her consent to disposal. The patient expressed her anger about the delay in contact with her. The patient expressed considerable disappointment in her care.

The complaint records note that the disposal was finally actioned over a year later, and that timeframes around disposal consent times were being reviewed, with the aim of making contact within two weeks of receiving written notice of consent. It is not clear whether this has been achieved.

Case Study 12

The patient provided consent to dispose of her embryos. She was contacted by the provider approximately 18 months later to obtain her verbal consent for disposal. The complaint records that the patient was extremely upset and angry that it had been 18 months since she had signed the original consent. The patient said that the contact from the provider had been very traumatic.

This was followed up by the facility and the complaint documentation records: 'Speaking to clinic coordinators, chasing embryo disposal verbal consents is often put aside for other more time-critical work, when clinics are busy. Everyone is clear on what the process is.'

In Case Study 12 the statement from the provider that the following-up of verbal consents is put aside for other work raises concerns that the staff are not appropriately trained and/or possibly appreciative of the significant emotional element associated with a consumer's decision to dispose of their embryo or other biological material. It should be recognised that this is often an extremely difficult decision for consumers to make and when that decision is finally reached, it should be acted upon swiftly to avoid any risk of retraumatising consumers. For some consumers, the destruction of biological material represents the end of an unsuccessful fertility journey.

Case Study 13

The patient provided consent to dispose of their final embryo. Approximately three years later she was contacted by the provider enquiring what the patient would like to do with their final embryo. The patient called the provider but did not hear anything for a further four weeks when she followed up again, explaining how distressing that she was finding this process. She confirmed that she had previously signed a consent form for disposal. The embryo was finally disposed of nearly four years after consent was provided. The OHO is informed that the provider undertook an investigation into what had occurred and determined that the disposal consent was sent to an individual scientist rather than a general inbox and had been missed. It is noted that at the time of the original consent, the provider was transitioning from a paper-based records system to a paperless system.

Audits and adverse events

Key findings from audits and adverse events identified:

- At one provider there was a backlog in the disposal of biological material. In order to address this issue, it was noted that approval was obtained to take on additional staff for a six-month period to audit the tanks and address the outstanding disposal.
- At another provider, the waiting period following obtaining the consumer's consent to dispose had been reduced to 60 days. Following this period, the material should be discarded any time after 60 days, with a maximum timeframe of 90 days.

Site visits

The OHO obtained information during site visits:

- Two of the providers had no backlog with disposals.
- Providers have a cooling off period between consent to dispose and the disposal. One provider has a cooling off period of 60 days, with disposal occurring no later than 90 days following receipt of a patient's request to dispose. Another provider allows one month between consent to destruction and the actual disposal.
- During one site visit the OHO was informed that due to resourcing issues, there was a backlog in managing the disposal of biological material. It was also noted that historically, the provider has a cautious approach to disposal of material and that has contributed to the issue. It was identified that there were challenges in processing the disposals given that skilled scientists were required to manage the day-to-day processes of ART, which understandably took priority.
- One provider reconsidered their processes for discards given consumer feedback about the process. A verbal consent following written consent is no longer required and the scientists can rely upon the written consent only.

Additional commentary from providers

Provider E has commented in correspondence to the OHO that if recommendations are made regarding disposal of genetic material:

> *a reasonable transition period will be required for compliance with any new requirements, noting the significant volume of historical bio items in storage … . Whilst Provider E agrees in principle with the OHO's recommendations including the appropriate resourcing of laboratories to ensure disposal of biological material is conducted in an appropriate, effective and patient centric approach, it acknowledges that the scarcity of resources and cost are also contributing factors to implementing this recommendation. Further, Provider E submits that the competing demands of timely disposal of biological materials needs to be balanced with prioritising time-critical aspects of treatment for patients pursuing ART. Nevertheless, Provider E is content for specific timeframes for disposal of biological materials to be considered at a legislative level.* [183]

Provider E further submits that:

> *'legislation should provide authority for ART providers to dispose biological material where consent has expired and further consent not able to be obtained'.*[184]

The OHO notes the ART provider's concerns regarding the imposition of legislative requirements for the disposal of 'genetic material'. Legislation and any unpinning regulations will need to appropriately meet the needs of the consumers while taking into consideration what can reasonably be achieved by ART providers – consultation on timeframes with relevant stakeholders is likely to be key.

Expert opinion

Mr Barry has commented on the discarding of gametes and/or embryos:

> *The discarding of gametes and embryos is normally protocolised and the NHMRC gives guidance on this matter (section 7.6 Ethical guidelines on the use of assisted reproductive technology in clinical practice and research 2017 (updated 2023)).*
>
> *This usually involves double checking details, cooling off periods, time to allow for the embryo to succumb etc.*
>
> *There is not a standard protocol, but it generally follows the process of*
>
> - patient consenting,
> - a cooling off period,
> - double checking of items to dispose.
> - disposal
> - documentation completion.

[183] Letters from Provider E to the OHO dated 10 May 2024, 21 June 2024

[184] Letter from Provider E to the OHO dated 21 June 2024

The practice of seeking written and verbal consent is not unusual for the disposal of gametes and embryos. Many clinics will only seek written consent with a witness signature.

A cooling off period after receiving consent to dispose is appropriate and necessary. Patients will change their minds. A reasonable cooling off time scale for disposal can range between 4 weeks to 6 months. This would reflect the risk assessed by each clinic. i.e. accommodating the chance of a patient changing their mind. The only challenge for meeting timescales will be the allocation of staffing resources. Often labs are busy places. It is not unusual that the task of discarding is not prioritised.

A mandated time frame through legislation or an industry accreditation body such as RTAC would prioritise the allocation of resources to the task of discarding biological material.

Recommendations

To the Minister:

26. It is recommended that the proposed legislation to regulate the provision of ART services in Queensland include provisions for oversight, safeguards and mandatory requirements for the disposal of biological material.

For ART providers:

27. It is recommended that providers consider appropriate resourcing of laboratories to ensure that disposal of gametes and/or embryos or other genetic material is managed appropriately, effectively and from a patient-centric approach.

28. It is recommended that ART providers review their training to staff to ensure that they are appropriately trained to support consumers in the decision making process in relation to the disposal of gametes and/or embryos or other genetic material and provide information about support services.

Theme 9: ART oversight and regulation in Queensland

Background

In the absence of legislated regulation, the quality and safety of ART services in Queensland rely on the oversight of FSANZ-RTAC which, in principle, should provide the public with reassurance that standards are upheld. The OHO acknowledges the important roles performed by FSANZ as the ART sector's peak body and RTAC as the regulatory mechanism 'to provide clinical guidance and direction to improve the standard of reproductive medical practice in Australia including medical review and quality assurance activities' and 'determine, oversee and improve the standard of fertility service offered in Australia and New Zealand'.

Fulfilment of regulatory functions by RTAC

The OHO has considered the areas which fall within RTAC's remit:

- audits
- management of adverse events
  - adverse events notified direct to RTAC

- adverse events captured within audits
- follow up of adverse events

- receipt of complaints by consumers.

Audits

RTAC commissions the conduct of rigorous audits of clinics, assessing their compliance with national accreditation criteria, and accrediting those that meet the established standards.

RTAC provided the OHO with aggregate data relating to non-compliance of ART providers across Australia. Specifically, the aggregate data and information supplied by RTAC described non-conformities with the RTAC Code of Practice identified and documented during audits[185] of ART providers by Certifying Bodies (auditors) engaged to undertake this task on behalf of RTAC.

The RTAC Scheme defines what constitutes minor and major non-conformities (Table 9, Appendix 3D: RTAC data)[186]

Table 10 in Appendix 3D: RTAC data shows the number of non-conformities for ART providers by year for Australia and New Zealand between September 2019 and end of 2023. In 2020, audits were suspended due to COVID. New unit site audits were also conducted during the period, which may account for some non-conformities. Similarly, Table 11 (in Appendix 3D: RTAC data) records categories of non-conformities which occurred in Queensland ART provider audits between 2020 and 2023.

Section 2.6 of the RTAC Code of Practice relates to identification and traceability of donors, where the Code of Practice states:

> *The ART Unit must ensure that gametes, embryos and patients are correctly identified and matched at all times and, in particular, ensure that men providing a semen sample confirm in writing on each occasion that the sample is theirs.*[187]

Data provided by RTAC[188] showed that the total number of non-conformities for Queensland against section 2.6 of the RTAC Code of Practice is significantly higher than other states/territories and New Zealand (42% or 46 of 109 non-conformities) (Table 12). This is not explained by the number of audits conducted in Queensland, which is around 27% of the total number of audits in the data provided by RTAC (Table 10 and Table 12). Non-conformities relating to section 2.6 of the RTAC Code of Practice (identification and traceability) also represented the highest proportion (30% or 46 of 155) of the total non-conformities found across all audits of Queensland ART providers (Table 11).

At the time of providing this data, RTAC also put forward that:

> *Our view is that the self-regulatory system of professional cooperative improvement is far more responsive and quicker to initiate change than regulators are able. We believe the evidence is clear on this matter when comparing state outcomes.*[189]

[185] Letter to the Health Ombudsman from the Fertility Society of Australia and New Zealand and RTAC, 22 December 2023.

[186] RTAC Scheme, 20 December 2021.

[187] RTAC Code of Practice for Assisted Reproductive Technology Units, 2021.

[188] Letter to the Health Ombudsman from the Fertility Society of Australia and New Zealand and RTAC, 22 December 2023.

[189] Letter from FSANZ-RTAC to OHO dated 18 March 2024.

This statement, however, was difficult to reconcile with the higher number of non-conformities reported in Queensland in relation to section 2.6 of Code of Practice, which deals with the correct identification and matching of gametes, embryos and patients.

RTAC subsequently clarified that:

> *The data provided by RTAC … does not support the claim that Queensland has fewer non-conformities than other more regulated states.* [190]

The evidence examined for this investigation does not substantiate the assertion that Queensland should remain self-regulated but has instead identified gaps and risks in reliance on a self-regulatory regime for ART providers and the need to strengthen the safeguards and protections for Queenslanders. The OHO also notes that any suggestions that regulation will impede innovation in the provision of ART services does not withstand scrutiny given the many examples of innovation in regulated health services.

Investigation findings

Each Certifying Body conducts audits of an ART provider's compliance with the RTAC Code of Practice in conjunction with the RTAC Scheme Rules (which defines the requirements for bodies providing audit and certification to these Codes of Practice), and then records their findings in an audit report. There were some differences in the audit reports by each ART provider because audit reports are specific to each Certifying Body's organisation and auditing methods. Despite the differences, all audits appear to comply with the RTAC requirements for Certifying Bodies and appeared to have been conducted thoroughly. An OHO investigator attended a site audit and observed that the auditor was very rigorous in review of the ART provider.

The OHO observed that while these audits appear to comprehensively address RTAC's auditing criteria, a standardised approach to audit forms (layout and content) used by each Certifying Body would provide an improved reporting tool to identify local issues in relation to individual ART providers and systemic issues across the sector. FSANZ-RTAC has confirmed their agreement with this proposed approach and it is understood that preliminary discussions with Certifying Bodies are underway.[191]

The non-conformities data is summarised as follows:

- Non-conformities overview: A total of 116 audits were assessed, of which 55 have non-conformities. Of these 55 non-conformities, 27 (49%) were in scope.
- Major non-conformities primarily related to inadequate patient identification procedures and infection risks associated with gamete and donor screening processes.
- Minor non-conformities included breaches of chain of custody, historical non-reporting of incidents, mislabelling of ampoules, and failure to meet protocol requirements, albeit with lesser immediate risk compared to major non-conformities.
- Each provider showed varying levels of non-conformities, with some demonstrating positive reporting cultures and timely resolution of issues, while others faced challenges in meeting protocol requirements.
- There were inconsistencies in the classification of non-conformities across different providers, indicating potential gaps in auditing processes and the need for standardisation.

[190] Letter from FSANZ-RTAC to OHO dated 8 April 2024

[191] Letter from FSANZ-RTAC to the OHO dated 4 March 2024.

- Audits highlighted improvement requests and observations regarding identification and traceability issues, suggesting areas for enhancement in protocols and procedures. However, it remains unclear if these requests are reviewed by RTAC.
- Overall, the data underscores the importance of thorough auditing processes, transparency, and continuous improvement in ensuring compliance with standards and protocols in ART units.

Adverse events

Adverse events notified to RTAC within scope of investigation

Adverse events are referred to, described and defined in the RTAC Code of Practice, under section 3.2. As stated, ART providers 'must acknowledge, investigate, report and review any serious adverse events. For the purposes of this investigation the key serious adverse events which related to the scope are those that:

- result in a breach or potential breach of legislation
- arise from a gamete or embryo identification mix-up
- cause a loss of viability of gametes or embryos or suspected deterioration (beyond accepted laboratory standards) that renders them unsuitable for use
- arise from a systematic failure in the validation/verification of a diagnostic test and/or technology that has resulted in misdiagnosis and/or significant potential harm or loss to patients, their gametes or embryos.

With respect to serious adverse events, these must be reported as soon as practical, but no later than six weeks after the provider becomes aware of the incident, within two weeks for a potential or actual breach of legislation and within 48 hours for a sentinel event, e.g. death.

RTAC supplied the OHO with serious adverse event data for Themes 1–4,[192] which had been provided to them by individual ART providers in Queensland. RTAC did not include adverse event notifications that they considered outside the scope of this investigation. The OHO have received multiple adverse events from providers directly, within Themes 1–4, that were not provided by RTAC. It is unclear if this is because RTAC did not consider them in scope on their review, or if the providers never actually provided them to RTAC as required under mandatory reporting requirements.

Overall, 18 adverse event notifications were provided by RTAC (identified as being relevant to the section 81 investigation scope, as determined by RTAC) from all ART providers in Queensland, between 2018 and 2023 (Table 13). Of the 18 adverse events provided by RTAC, 15 related to Theme 1. There were no events relating to Themes 2 to 4.

The majority of the serious adverse events reported to RTAC related to handling errors (11 out of 18 events) (Table 13), where in most cases there was a loss of a gamete due to the related incident. It is of note that Provider C reported the highest number of adverse events while Provider E reported only one adverse event relating to handling errors. It is noted that diligence and openness with reporting may result in a higher number of reported adverse events.

From the review of the documentation on hand, it appears that these incidents have been attributed to a human error or accident such as a culture dish knocked against a microscope. The reports on these adverse events often included an investigation and corrective action plan, and a process for full open disclosure to occur within a timely manner. There are some cases which note

[192] Letter to the Health Ombudsman from the Fertility Society of Australia and New Zealand and RTAC, 22 January 2024.

that either an open disclosure did not occur in a timely manner, or the error was intentionally withheld from the patient entirely or for an unreasonable period of time (Case Study 2 and Case Study 14).

Adverse events identified in audits

The adverse events data is summarised as follows:

- Timeliness of notifications: Most ART providers notified RTAC of adverse events promptly, with one notable exception of a significant delay (nearly one year) in notifying RTAC about an alleged gamete mix-up. This delay raises concerns about compliance and highlights the importance of timely reporting.
- Scope of investigation: A total of approximately 309 adverse events were assessed (Table 8 in Appendix 3C: ART provider data), with 53 (17%) identified to be within the scope of the investigation. Theme 1 (related to gamete and embryo handling) constituted the vast majority (83%) of in-scope adverse events.
- Provider-specific insights:
  - Provider B demonstrated consistency and transparency in reporting adverse events, with most incidents relating to clinical issues like ovarian hyperstimulation syndrome (OHSS).
  - Provider D reported 36 adverse events, mostly related to OHSS hospitalisations. However, some incidents lacked clarity regarding notification to RTAC.
  - Provider C had the highest volume of events reported to RTAC, with adverse events appropriately identified and reported, potentially due to robust reporting systems.
  - Provider A reported 75 adverse events, with sound systems in place for reporting to RTAC and appropriate management of incidents.
  - Provider E's adverse event data was challenging to interpret, with discrepancies between the number of events reported to the OHO and those recorded by the auditor. Some adverse events were not reported to RTAC, raising concerns about oversight.
- Examples of adverse events:
  - Examples include identification mix-ups, loss of viability of gametes or embryos, and suspected deterioration beyond laboratory standards.
  - Some incidents, such as incorrect labelling of frozen semen and unclear labelling of straws, were not reported to RTAC by Provider E, potentially indicating lapses in reporting protocols.
- Limitations and caution:
  - Differences in data provision among providers and sources limit the analysis of adverse events.
  - Adverse event reporting thresholds and systems vary across providers, making it challenging to use the number of events as a sole indicator of service delivery standards.

It is a requirement of the Code of Practice that RTAC is provided with reports of all adverse events by ART providers as soon as practical, but no later than six weeks after the provider becomes aware of the incident. According to the RTAC Code of Practice, if the investigation has not been completed within this timeframe, the notification is still required to be submitted. The OHO's review of the available documentation on adverse events and audits has identified apparent deficits and inconsistencies in the reporting of adverse events to RTAC. The documentation reviewed also suggests that adverse event notifications proactively supplied to RTAC by ART providers is not

cross-checked with the adverse event reports that RTAC identifies during ART provider audits. For example, there were some occasions where the auditor identified an adverse event that met criteria for reporting but had not been reported to RTAC. Despite the recognition from the auditor, and commentary that the adverse event would retrospectively be reported, it is understood that a notification to RTAC did not eventuate. See one such example in Case Study 14 below.

Case Study 14

In an audit, a provider had a minor non-conformance reported which related to a notifiable adverse event that was not reported to RTAC or the Certifying Body. The minor non-conformance was closed after corrective actions were put in place. Notably, there was no mention of the event being reported to RTAC, only that corrective actions were put in place to address the non-compliance of reporting.

Additionally, there were multiple times a sample of adverse events were reviewed within an audit, which included adverse events that met criteria for reporting but no notification (or recommendation for a notification) was made. Some examples include lengthy hospital admission associated with ART related treatment and occasions that resulted in the loss of viability of gametes or embryos or suspected deterioration (beyond accepted laboratory standards) that rendered them unsuitable for use. Under the current regulatory framework for ART services, RTAC has the responsibility to ensure that adverse events are appropriately monitored and addressed. FSANZ-RTAC maintain that this process of cross-checking has been undertaken since October 2021.[193] The documentation reviewed to date for this investigation raises questions about the adequacy of current oversight mechanisms in respect of adverse events which occur in the provision of ART services. It is noted that in Victoria, VARTA requires clinics to dually report adverse events to VARTA as well as to RTAC (and to provide all audit reports) to inform whether follow up or further investigation was required.

Follow-up and investigation of adverse events

Information provided to the OHO by auditors often focuses on the non-compliance of not reporting adverse events. From the OHO's review of these audits, it does not appear that the adverse event itself is always reported and investigated. This has been observed in audits and raises concerns for consumers undertaking ART who are affected by such adverse events. This is demonstrated in Case Study 15.

Case Study 15

A patient made a complaint in 2022 and subsequently two months later to RTAC regarding a serious allegation of a gamete mix-up, allegedly resulting in the incorrect donor sperm being used for the conception. In 2023, RTAC enquired as to why the adverse event had not been reported previously. A minor non-conformance for the significant delay in reporting was noted. The provider formally reported the matter to RTAC in spring 2023 recording this as a 'compliance issue' commenting that they had only been aware of the issue the month prior to the report (10 months after the patient's complaint). As far as the OHO is aware, an adverse event notification has never been made to RTAC or the Certifying Body specifically related to the actual gamete mix-up allegation, only regarding the compliance failure regarding the delayed reporting.

[193] Letter from FSANZ-RTAC to the OHO dated 4 March 2024.

The OHO notes that both RTAC and the auditors are limited in what actions they can take following notification of a serious adverse event. The OHO appreciates that in some cases legal action is underway; however, this should not impede investigation by a regulator into a potential public safety issue. It is crucial that action is taken swiftly to determine whether there is any substance to the complaint and whether other consumers may be impacted.

It is useful to note that oversight provided by VARTA in Victoria adds another layer of protection for consumers undertaking ART services. In VARTA's Annual Report for 2022–23[194] it is noted that:

> *VARTA reviewed adverse incidents, including clinical and scientific incidents, as well as actual or potential breaches of the Act, Regulations and/or Conditions for Registration. VARTA also monitored progress on the implementation of agreed corrective actions.*

Further commentary in the Annual Report notes that:

> *In addition to the general conditions set out in the Conditions for Registration, VARTA reserves the right to enforce additional conditions on the registration of an ART provider if deemed necessary for public interest. VARTA may furthermore suspend (either in whole or in part) an ART provider's registration by written notice to the registered ART provider if VARTA: (1) believes that the ART provider has breached a condition for registration, or (2) is satisfied that there are reasonable grounds for suspension.*

VARTA's capacity to review incidents, together with the ability to suspend a provider's licence, provides important safeguards and independent oversight of the quality and safety of the provision of ART services.

Complaints made to RTAC

While noting that RTAC is not established as a complaint body, the low number of individual consumer complaints (seven) that were received by RTAC from ART providers and provided to the OHO, in comparison to complaints made directly to the OHO in the same period (being 1 January 2018 to 15 December 2023) relating to ART services (154), suggest that there is limited public knowledge of the role that RTAC plays in the oversight and licensing of ART providers.

On the FSANZ website, RTAC encourages consumers to contact them 'if [their] complaint is not adequately resolved [by their treating ART provider/treating unit] and [they] believe that the treating unit might be in breach of the RTAC Code'.

It would appear from this statement that RTAC investigates consumer complaints which indicate potential breaches of the RTAC Code of Practice.[195] Despite the information on the FSANZ website, the steps taken by RTAC appear to be predominantly limited to forwarding the complaint information to the auditor, to consider in the provider's next annual audit. The complaint is then typically resolved by way of a systematic solution (i.e. suggested implementation of a corrective action to operationally address the issue, without necessarily directly addressing the consumer and/or clinical aspect of the issue). While the audit process is important, it is not a substitute for a rigorous investigation of potentially serious breaches of the RTAC Code of Practice at the time of notification. Moreover, it may be some months before an audit is due to take place. Additionally, if

[194] www.varta.org.au/sites/default/files/2023-11/7093_VARTA_AR2023_spreads_web_signed.pdf.

[195] In a letter from FSANZ-RTAC to the OHO dated 4 March 2024, it is stated: 'While it is able to ensure that auditors are aware of complaints relating to potential breaches of the Code of Practice, it is not the role of the RTAC to investigate those complaints. This is indicated on the FSANZ website which encourages patients to contact the appropriate health complaints authority where their complaint has not been resolved with the treating unit directly.'

no regulatory action is taken by RTAC based on audit information, a cycle of inaction potentially perpetuates.

It is acknowledged that some of the complaints relate to historic treatment; however, others relate to potential breaches postdating the introduction of the revised RTAC Code of Practice in 2008. RTAC's limited responses to complaints (i.e. the extent to which they are investigated and resolved, particularly from a consumer perspective) is concerning given that the issues raised include potential mix-ups of donor sperm.[196] While RTAC's responses to complaints may be reflective of the scope of RTAC's role, it is also an indication that more robust regulatory oversight is required with clear pathways for complaints. In one instance, RTAC contacted the ART provider and requested that the provider undertake an investigation. Correspondence was sent on 16 October 2023 to the provider; however, as of 2 February 2024, no follow up had occurred. Following the OHO's query about this matter, RTAC advised that they would contact the provider.

Given RTAC's oversight role of ART providers, the approach in this instance raises concerns. It is recognised that capacity to undertake review of incidents is potentially constrained by a lack of resources. This points to the need for a regulatory body with sufficient resources to immediately investigate notification of potentially serious breaches and to provide robust regulatory oversight.

Independence of FSANZ-RTAC

The OHO acknowledges the willingness of RTAC to share insights from their work and voluntarily provide aggregated data to inform the early stages of this investigation. Through the course of this investigation, the OHO has identified gaps and risks in the level of oversight and independence that RTAC has in the performance of its role as a regulator in the current self-regulatory regime in Queensland.

Concerns regarding the level of independence in RTAC's performance of its regulatory role were identified in a number of responses to notices issued under section 228 of the *Health Ombudsman Act 2013* requiring the provision of:

- all audits for ART providers/organisations in Queensland where there have been identified non-conformities
- all reports of serious adverse events or serious notifiable adverse events
- all current and closed complaints received against ART provider/ organisations or Certifying Bodies.

Despite the notice specifying the powers of section 228 and that: 'You do not require written or verbal consent from anyone else to comply with this notice and give the required information', FSANZ-RTAC responded that FSANZ would be in contact with the individual ART providers in consultation regarding the OHO's section 228 notice. Following further contact and correspondence from the OHO to FSANZ-RTAC providing an explanation of section 228 of the Act and FSANZ's obligations to produce the documents, as directed, under the Act, FSANZ-RTAC provided the adverse events reports (only) to the OHO and was granted an extension to provide the remainder of the documents. When FSANZ-RTAC provided consumer complaint data and audit reports, the OHO noted that audit reports in relation to all but one of the Queensland ART providers were given in full, without audit data content redacted. FSANZ supplied heavily redacted audit data in relation to Provider E on the basis of a 'certificate of agreement' between FSANZ-

[196] In the letter from FSANZ-RTAC to the OHO dated 4 March 2024 it is stated: 'RTAC does not agree with this statement, and it appears that the QOHO is confused about or unaware of the process RTAC follows. In all cases RTAC responds to the complainant. Prior to one audit, information was given to the auditors in relation to complaints received, this information was passed on with the permission of the complainants involved. In all cases RTAC advises the complainant if they have not already contacted the clinic they should do so. RTAC also points out that various state authorities such as the QOHO are a better choice should the complainant not receive an appropriate response from the clinic. RTAC also contacts the clinic concerned if it appears the complainant is not receiving proper attention.'

RTAC and Provider E. This certificate required that Provider E 'and FSANZ mutually commit to uphold the confidentiality of the contents of the audit reports' ensuring that FSANZ-RTAC only provide such versions to the OHO. It was noted that heavily redacted audits were also provided by Provider E in response to a separate section 228 notice issued to them, and that these were identical to those supplied by FSANZ-RTAC.

In response to correspondence from the OHO reminding FSANZ-RTAC of their obligations to comply with the section 228 notice in respect of the audit data in relation to Provider E, FSANZ-RTAC replied 'it would be most appropriate and productive for the OHO to discuss the redactions with Provider E and the FSANZ would accept the outcome of any such discussion.' This response required the OHO to advise FSANZ-RTAC that a confidentiality agreement entered with a provider was not considered to be a reasonable excuse under section 228 not to provide the requested information. Consequently audits with identical revised redactions were provided to the OHO by both FSANZ-RTAC and Provider E. The final provision of this information took almost eight weeks.

The above responses from FSANZ-RTAC in seeking to consult with ART providers before providing information that has been obtained for the purposes of RTAC's regulatory functions, and more importantly entering into an agreement with one provider on the information that would be provided to the OHO, raises significant concerns about the ability of RTAC to provide independent oversight and transparency of the provision of ART services in Queensland. According to RTAC Terms of Reference,[197] RTAC responsibilities include setting of standards for ART providers to encourage adherence to best practice principles and to issue, suspend and withdraw RTAC licences. To perform the functions of a regulator, the responsible body must be accountable and independent. In the current regulatory regime in Queensland, it is critical that the public can have confidence that RTAC will fulfil its obligations with impartiality and ensure that there are no barriers to the effective enforcement of the RTAC Code of Practice. As noted by Michael Gorton: 'A lack of transparency or external accountability in the setting of standards can contribute to a loss of public confidence in a system of regulation … This gives rise to a perceived conflict of interest, with the industry both setting the standards by which it will be judged, and making determinations on whether it meets those standards.'[198] In other states which regulate the provision of ART services, RTAC's role is complemented by statutory requirements and independent regulatory oversight.

In response to the OHO's interim report, FSANZ-RTAC commented that:

> *FSANZ and RTAC accept observations and criticisms may arise which might be helpful and advance clinic standards and patient safety and the efficacy of treatment. However, we will not accept assertions that RTAC … [does] not act independently …*[199]

The issues identified in this investigation, including those summarised above, are instructive in demonstrating the gaps and risks associated with reliance on a self-regulatory regime for ART providers, particularly in terms of transparency of audit results, reported non-conformities and responses to adverse events and complaints. It is noted that FSANZ-RTAC put forward that:

> *Our view is that the self-regulatory system of professional cooperative improvement is far more responsive and quicker to initiate change than regulators are able. We believe the evidence is clear on this matter when comparing state outcomes. Legislative*

[197] The Reproductive Technology Accreditation Committee (RTAC) Terms of Reference, January 2020.

[198] Independent Review of Assisted Reproductive Treatment, May 2019, Michael Gorton.

[199] Letter from FSANZ-RTAC to the OHO dated 4 March 2024.

support and government input into the self-regulatory framework would be a far more effective measure than static and prescriptive imposition.[200]

FSANZ-RTAC added:

RTAC agrees that national regulation is essential to ensure consistent and high standards across Australia and New Zealand. A central donor registry is a crucial component of this regulatory framework, providing comprehensive oversight and improving traceability.[201]

It was beyond the scope of this investigation to examine the assertion that legislative regulatory regimes can impede the speed of improvements in treatments and practices by ART providers.

It is noted that the Gorton review identified concerns with reliance on RTAC's role to ensure the quality and safety of services stating:

The concerns raised with the Review in relation to the RTAC accreditation process mirror the issues raised in the Targeting zero: the review of hospital safety and quality assurance in Victoria (Duckett et al. 2016). Targeting zero called out an overreliance on accreditation as a means of assessing quality and safety risk and cited mixed evidence as to the benefits and effectiveness of accreditation. The report noted that accreditation assesses documentation of processes and functions, rather than quality and effectiveness. Further, it is often experienced as an 'event' for which the agency prepares rather than a driver of ongoing continuous self-assessment and improvement.[202]

The findings and observations of the OHO's investigation, particularly the gravity of adverse events that can occur in the provision of ART treatment indicate a compelling case for the need for proposed legislation to regulate ART providers in Queensland and strengthen the safeguards for consumers, donors and donor-conceived children. Such safeguards could include mandatory reporting requirements of any serious adverse events, similar to the reporting requirements to VARTA under the Victorian legislation or to the reporting of root cause analysis reports to the OHO under section 108 of the *Hospital and Health Boards Act 2011.*

Efficacy of regulation

During the course of this investigation, the OHO identified a very concerning example which involved a significant delay in regulatory action in response to the identification of 'high risk' sperm samples, where there were risks in being able to prove seamless end-to-end double witnessing of donor sperm samples when assessed against evidence that linked the initial material to the frozen sample. The identification of these risks had been prompted by an incident of a gamete mix up. It is not clear whether the provider notified RTAC at the time. The OHO reviewed information that indicated that no action was taken to remove these 'high risk' samples which remained available and used for fertility treatment for at least three years. There are a number of very concerning issues about the adequacy of responses by both the provider and RTAC in addressing the risks associated with these sperm samples, which the OHO will be continuing to investigate. However, it is clear from evidence on historical sperm audits from this provider, which were obtained for one of the individual investigations, that no action was taken either by the provider or RTAC until after an external audit was undertaken three years after the initial discovery. Even without further

[200] Letter from FSANZ-RTAC to the OHO dated 18 March 2024.

[201] Letter from FSANZ-RTAC to the OHO dated 14 June 2024.

[202] Independent Review of Assisted Reproductive Treatment, May 2019, Michael Gorton.

investigation, this example raises further questions about the efficacy of the current self-regulatory scheme, and its associated risk.

FSANZ-RTAC has confirmed to the OHO that:[203]

- They were not informed of the issues by the provider.
- RTAC has not taken any action to date on the issues raised, due to a lack of awareness.

Apparently prompted by the OHO's enquiries, RTAC advised that it planned to:

> *...notify all licensed clinics in Australia and New Zealand about the risks associated with using genetic samples that do not comply with either Technical Bulletin 4 or Section 2.6 d) of the Code of Practice. Specifically, the Code requires a minimum of three forms of identification to ensure traceability of persons and specimens. Additionally, RTAC has requested both Certifying Bodies to closely examine the risk assessments conducted by clinics regarding the use of specimens or samples that do not meet the standards of TB-4 or Section 2.6 d). They are to confirm that these risk assessments have been conducted appropriately.*[204]

This is a key example of the breakdown in the current regulatory system, with areas of concern including:

- failure of the provider to notify FSANZ-RTAC of a high risk issue
- failure of the auditors to identify the high risk issue at any of the audits between 2020 and 2023
- no action taken by FSANZ-RTAC regarding the potential for more widespread issues across multiple service providers until the OHO's intervention.

Site visits

The OHO received the following commentary about regulation of ART services during site visits:

- All providers would like to see legislation in Queensland for the regulation of ART.
- Providers recognise the importance of good regulation in ensuring patient safety, industry accountability and continuity of service across providers. They highlight how regulation, whether self-imposed or legislated, holds practitioners accountable and maintains standards. They see benefits in legislation, particularly in providing clear guidelines and backing for certain practices, such as storage periods.
- There is a need for consistency across the states and territories because it is confusing for both staff and consumers.
- One provider noted that there are considerable risks associated with conflicts of interest within the ART industry. To have an individual who may be part of a regulatory scheme who is also directly involved with their own ART facility raises concerns about whether they could act for the benefit of the industry, rather than as an advocate for their own facility.

Interviews with auditors

The auditors had differing views on the various issues raised. These are captured below and are not intended to be representative of the views of all auditors interviewed.

[203] Letter from FSANZ-RTAC to the OHO dated 19 April 2024.

[204] Letter from FSANZ-RTAC to the OHO dated 19 April 2024.

- It was recognised that an independent body to regulate ART services would be appropriate, such as that in place in Victoria.
- There are no disadvantages with the introduction of legislation, as it enables the provision of clear guidance on the applicable standards.
- Audits should be performed by specialist auditors given the very specific requirements of the industry.
- Certifying Bodies do have the ability to ensure that corrective actions are taken by a provider and if this is not done, this is automatically escalated to the RTAC Chair.
- Auditors reported some inconsistencies in the understanding of providers in what should and should not be reported – the Code of Practice is not always clear.
- In the auditor's experience, ART providers were very good at reporting adverse events. Occasionally, these are missed, but there may be a reason for this.
- It was noted that Technical Bulletins are put out by RTAC to respond to changing situations in the industry and to advise clinics on what would constitute best practice. Until it is enshrined in the Code of Practice, auditors do not have any ability to address those issues with ART providers.

Additional commentary from providers

Provider C commented:

> *Reporting to both RTAC and [relevant oversight agency] or to the Queensland Government would be beneficial if a clinically qualified person uses the data to inform safety initiatives and in turn affords protection to the public. … FSANZ have recently sought Stakeholder feedback to the Comprehensive Review of Governance and Standards in ART/IVF Sector and communicated that there are plans for a national approach and Provider C are supportive of consistency across all Australian states and territories and propose that the Queensland Government delay the implementation of this Bill until a federal decision is made.*[205]

The OHO notes that the timing of the implementation of any legislation is a decision for the Queensland Government, in consultation with relevant stakeholders. The OHO's investigation has however identified gaps and risks in the current self-regulatory regime in Queensland and the need for strengthened safeguards and protections for Queenslanders who use ART services.

Expert opinion

Dr Hammarberg has commented on the regulation of ART providers:

> *Overall, the ART industry in Australia is operating to a high standard. However, there are few mechanisms that I am aware of to stop clinics or individual clinicians who don't perform to the highset standard or who offer treatments that are not based on good evidence and that might have significant risks (including immune therapies). In relation to clinics offering so called add-ons, there may be a place for independent oversight to avoid vulnerable patients paying a lot of money for non-proven therapies.*

[205] Letter from Provider C to the OHO dated 14 June 2024.

Recommendation

To the Minister:

29. It is recommended that legislation is designed to provide robust oversight of ART providers, including the licensing of providers, audits, and investigation of non-conformities and adverse events.

The OHO notes the Queensland Health Commentary in the Regulation of Assisted Reproductive Technology Services Consultation Paper[206] where it is stated:

> *A Queensland ART Act would ensure greater protections for Queenslanders through oversight and safeguards for the management of non-compliance, adverse events and incidents, and transparency of the obligations of providers.*

Theme 10: Open disclosure and adverse events management

Background

Considering the impact on consumers is particularly important when an adverse event occurs, the RTAC Code of Practice requires ART providers to have a policy of open disclosure that is consistent with the Australian Open Disclosure Framework from the Australian Commission on Safety and Quality in Health Care.[207] The OHO has explored how open disclosure is managed by ART providers when an adverse event occurs.

Investigation findings

Despite difficulties in analysing some provider information (given the difference in levels of disclosure to the OHO), the documentation that has been provided indicates that there is clear disparity between how different providers manage complaints and incidents. It is noted that some consumers have complained on multiple occasions to the same providers about the same incident(s) due to their dissatisfaction with the complaints process and/or resolution of the complaint.

Consumers are often going through a difficult fertility journey and when something goes wrong, the response from the ART provider has the potential to compound the consumer's distress and trauma if this process is not managed well. The OHO has heard from some consumers that some ART providers have not been transparent when events have occurred, and this has led to frustration and anguish. Such experiences indicate to the OHO that significant improvements could be made to the management of the open disclosure process.

Public hospitals in Queensland follow the 'Best practice guide to clinical incident management',[208] which provides a consistent approach to clinical incidents. The fundamental principles of clinical incident management include the early identification of the incident, open and transparent investigation, and ensuring that lessons are learned and communicated, to minimise risks of similar incidents occurring. The NSQHS standards also provide clear guidance and expectations for the

[206] Queensland Health Commentary in the Regulation of Assisted Reproductive Technology Services – Consultation Paper, February 2024.

[207] RTAC Code of Practice, 2021, Section 2.2.2.

[208] Best practice guide to clinical incident management, January 2023, Queensland Health.

incident and complaint management systems and responses to adverse events through the Australian Open Disclosure Framework.[209]

In the course of dealing with complaints, the OHO has identified issues in the approaches to complaint management by some providers, which do not demonstrate a patient-centred or transparent approach or commitment to continuous improvement. These matters are still under consideration and will inform future recommendations for improvements in providers' responses to complaints and incidents. The OHO did, however, identify examples of complaint management which entailed continuous improvement processes in the documentation provided by ART providers (highlighted in Case Study 16 and Case Study 17).

Case Study 16

A patient requested another copy of a donor profile, used for her fertility treatment. She was provided with an updated donor profile which disclosed that the donor had a family history of a genetic condition. The patient contacted the clinic raising concerns about this new information. The provider acknowledged that information had been initially missed from the donor profile and confirmed that the donor statement had been updated to offer recipients more visibility. The provider also undertook a review of the relevant policy to ensure that provision was made for retrospective updating of donor profiles and release to donor recipients. While the patient found the news of the genetic condition concerning, she felt that the provider managed the situation with compassion and empathy.

Case Study 17 provides an example of an approach to an incident that was responsive and effective, with a positive consumer experience outcome, despite the occurrence of an error.

Case Study 17

Patients were receiving treatment using donated embryos. They were sent both male and female donor profiles for the donated embryos. After selecting their chosen donor profiles, the patient underwent a frozen embryo transfer and became pregnant. Following the treatment, the couple contacted the clinic to query a disparity in information in the donor profiles. The incident was investigated and it was determined that the information in the male donor profile was incorrect, and the gamete used belonged to another donor profile. The patients were contacted two days later to inform them of the mix-up and were provided a copy of the correct donor profile. They were offered support and counselling, and an opportunity to speak with the clinic management team.

It was identified that the adverse event was caused by a lack of staff training, and a failure of staff to complete appropriate checklist paperwork for donors and follow two-person verification processes. A series of preventative measures were implemented. The patients were also provided with an open disclosure letter detailing the incident that occurred and the corrective actions that had been implemented. The patient acknowledged that the provider was very helpful and transparent throughout the process.

[209] Australian Open Disclosure Framework – Better communication, a better way to care, February 2014.

FSANZ-RTAC has commented that:

> *It is undeniable that mistakes and adverse events can occur within any healthcare setting, including ART services. However, what sets exemplary providers apart is not the absence of errors, but rather their approach to addressing and rectifying such occurrences. Open disclosure, as mandated by the RTAC Code of Practice and consistent with the Australian Open Disclosure Framework, embodies the ethical imperative for honesty, transparency, and accountability in healthcare.*[210]

However, in dealing with complaints about ART services, the OHO has identified issues with providers' communication and disclosure with consumers despite the requirements for open disclosure and the principles of patient-centred care. A theme across many of the complaints is that consumers have raised concerns about their treatment directly with providers but have not been provided with a fulsome response. This theme was consistent with the findings of the Gorton Review: '... the Review has heard repeatedly from recipients of ART that they feel unable to make complaints and/or are unaware of how to raise concerns about services or how to escalate these concerns if they do not feel the response has been adequate.'[211] These themes were also echoed in the HCC inquiry into Assisted Reproductive Treatment Practices in Victoria which focused on consumer experiences of ART services.[212] The consistency of these findings point to the need for dedicated attention to addressing these issues within the provision of ART services.

In some cases, the OHO identified significant issues in the provider's lack of transparency or willingness to engage with the consumer and formed the view that had there been an open dialogue, it is possible that a complaint to the OHO could have been avoided. Some of the matters considered involve allegations which have a significant impact on the and their children, for example, the alleged use of the incorrect sperm which has resulted in children not being biological siblings. For consumers, the discovery that their family is not biologically linked can cause substantial trauma. The Gorton Review recognised the significance of consumer feedback: 'The Review emphasises that the measurement of patient experience ought to contribute to a culture of continuous improvement and increased engagement with patients … Complaints can be another powerful driver of quality and safety improvements in health services.'[213]

FSANZ-RTAC commented:

> *'While it is acknowledged that some providers may face challenges in implementing open disclosure practices consistently, particularly in the context of complaint management, it is imperative that these challenges are addressed swiftly and comprehensively. The goal must be to cultivate a healthcare environment where patients feel heard, respected, and confident in the quality and safety of their care.'*[214]

It is also important that ART providers provide consumers who complain with an escalation pathway if their complaint is not resolved. It is recognised that complaints may not always have a satisfactory outcome and the ability to explore this via an independent organisation, such as the OHO, enables issues to be impartially reviewed. The OHO has made recommendations to providers on approaches to incident management which focus on ensuring that consumers are

[210] Letter from FSANZ-RTAC to the OHO dated 14 June 2024.

[211] Independent Review of Assisted Reproductive Treatment, May 2019, Michael Gorton.

[212] Health Care Complaints Commissioner (Vic), *Inquiry into Assisted Reproductive Treatment Practices in Victoria,* Final Report (2020)

[213] Independent Review of Assisted Reproductive Treatment, May 2019, Michael Gorton.

[214] Letter from FSANZ-RTAC to the OHO dated 14 June 2024.

treated with empathy, respect and openness. Early acknowledgment of incidents also encourages a robust reporting process, with a focus on continuous improvement of services.

Early and timely disclosure of incidents to consumers is also a paramount consideration for ensuring patient-centred care. As referenced in Case Study 2 the records supplied to the OHO indicate that the patient was not informed by a provider that she had had a transfer of an embryo created from a cycle undertaken with her former partner (using donor sperm), rather than the embryo created as a single woman, until at least five weeks and five days after the event, by which time she had undergone a viability scan. To withhold this information from the patient directly impacts on her choices in relation to the pregnancy and indicates a lack of transparency from the provider. It also raises serious questions about patient rights.

It is noted that the Australian Commission on Safety and Quality in Health Care's (the Commission) National Standards[215] (NSQHS Standards) do not directly apply to the provision of ART services unless the 'parent service' is accredited under this scheme. In December 2023, under a new initiative, the Commission introduced the National Safety and Quality Cosmetic Surgery Standards. The OHO considers that there may be some merit in the Commission considering a similar scheme for provision of ART services with particular focus upon the standards relating to clinical governance, partnering with consumers, and communicating for safety. This could go some way to address the OHO's concerns about ART services not always responding appropriately to incidents and complaints and recognising the impact that this has on consumers and would readdress areas that are not covered in the RTAC Code of Practice. It is acknowledged that there is a considerable cost to developing a new set of standards.

As mentioned earlier in this report, Victoria now has some publicly provided ART services, which means that the provider is subject to ART regulation as well as the NSQHS Standards, and presumably any other Victorian Department of Health clinical governance frameworks, providing a suite of safeguards for the service delivery to consumers.

Audits and adverse events

Key findings from audits and adverse events are as follows:

- While a policy and procedure made reference to alignment with the Australian Open Disclosure Framework, staff were unfamiliar with the terminology.
- Some providers are undertaking effective open disclosure processes, often resulting in improvement to practices and attempts to put the consumer back in the position that they would have been in but for the incident.

The OHO continues to see evidence of inconsistencies in the way that open disclosure is managed. The next two case studies (Case Study 18 and Case Study 19) show the diversity of approach, which is a concern and supports the OHO's recommendation that the practice of open disclosure should be a part of the audit process.

[215] Australian Commission on Safety and Quality in Health Care National Safety and Quality Standards, 2021.

Case Study 18

The patient was undertaking ART. They had stored embryos after their first cycle and planned to thaw a single embryo. However, while a trained member of the laboratory team was thawing the embryo, the dish was knocked and the embryo could not be recovered. A second embryo was thawed successfully and the procedure went ahead as planned. Following instructions from the clinician, despite the fact that an embryo was lost due to human error, the patient was informed that two embryos had been thawed with only one surviving. The manner in which the information was provided was considered to be in the patient's best interests (i.e. to not provide fulsome information to them at that time).

Case Study 18 is a concerning example of where the consumer has not been provided with information that is relevant and truthful about their ART treatment and biological material (embryos). It is appreciated that the ART environment is stressful and, at times, distressing for the consumer, but it is important that they are provided with honesty and transparency from the ART provider.

The OHO acknowledges that mistakes (including human error) do occur but also considers that how these incidents are managed can significantly reduce the impact to the consumer and their family. The OHO is reassured that in Case Study 19, the open disclosure framework was used appropriately, ensuring that the consumer was part of the process.

Case Study 19

A patient undertook fertility treatment intending to use embryos created with her partner's eggs. The patient undertaking treatment also had one embryo generated using her own egg, remaining in storage. After completing the treatment, the patient received a patient cycle letter stating that no embryos were remaining in storage, indicating that the patient's last embryo (using her own egg) had been used. The couple subsequently made a complaint to the clinic.

The complaint was investigated by the clinic, and it was determined that the patient's embryo was used in the treatment, instead of the embryo of the patient's partner which the patient expected. The clinic met with the patients and apologised for the error and informed them that an investigation was being conducted. The investigation determined that there was a discrepancy in the information documented in the clinic's patient management system and the specific treatment cycle instructions. The clinic subsequently reviewed the current work process and checklists and implemented several preventative measures. When the investigation was concluded the clinic provided the patients with a detailed letter of the findings of the investigation and preventative measures implemented by the clinic to prevent a similar incident from occurring.

Consumer perspectives

Consumers have commented on their experiences of making complaints to ART providers:

> *It was a very adversarial and stressful experience trying to resolve the issue with the provider. … The way I was spoken to was rude and often patronising and at no stage did anyone ever apologise for any wrongdoing. I was supposed to accept that this was 'the way things were done back then', as though it was the actions of an entirely different business for which they weren't accountable.*
>
> *Complaints should be handled by a government body. The clinics do not engage in open disclosure at all. Many patients are scared to complain because the clinic is still holding their eggs or embryos or sperm.*
>
> *I was told after following up, that they had reviewed my concerns but I was never able to get any comprehensive answers to my questions.*
>
> *With my issue, I would like to have had support, recognition, and acknowledgement that there was an issue.*

Site visits

Interviews were held with staff during site visits with three providers and open disclosure was discussed:

- Staff confirmed that their services had systems and processes for open disclosure following adverse events and incidents.
- They acknowledged that the wellbeing of the consumer is a priority in the open disclosure process.
- One provider indicated that action would be taken regarding an adverse event or incident within 24 hours. The policies and procedures relating to open disclosure are available to all staff. Complaints are logged and investigated, with responses formulated collaboratively and improvements identified. Internal audits are undertaken to ensure compliance with the policies and procedures. The general manager has oversight of all consumer complaints. Complaints are used as an opportunity for continuous improvement and may result in a change to the policy and/or procedure.
- Two of the providers referenced escalation pathways for consumers if they are not satisfied by the outcome of the complaint.
- Another provider noted that any deviation from expected outcomes prompts open and honest communication with consumers as soon as possible.
- Providers referred to training on open disclosure being provided to staff. One provider mentioned that this was part of staff onboarding and ongoing training.

Recommendations

To the Minister:

30. It is recommended that consideration is given to a requirement that licensed ART providers adopt the 'Australian Open Disclosure Framework – Better communication, a better way to care', noting that RTAC's Code of Practice requires ART providers to adopt policies *consistent* with this framework without the detailed guidance.

For ART providers:

31. It is recommended that ART providers ensure that approaches to open disclosure reflect the requirements of the Australian Open Disclosure Framework, and that responses to adverse events and complaints are person centred and trauma informed.
32. It is recommended that ART providers ensure that consumers who complain are provided with an escalation pathway in the event that their complaint is not resolved.

Theme 11: Impacts on consumers

Background

The provision of ART is a stressful and emotionally demanding journey for consumers. The impact is considerable and differs from any other forms of health service provision because it involves creation of a family. The RTAC Code of Practice states 'that patients and their offspring remain the most important consideration in all decisions'[216] and therefore requires ART providers to deliver a patient-centred approach to both treatment and responses to concerns. FSANZ-RTAC has commented to the OHO that:

> *First and foremost, it's crucial to acknowledge that the provision of ART isn't akin to other healthcare services. It involves the profound desire to create a family, with embryos representing not just biological material, but the hopes and dreams of consumers. Recognizing this, every interaction with patients must be approached with the utmost empathy and understanding.*[217]

Investigation findings

Complaints

Appropriate communication with consumers undergoing ART is key. An already stressful process can be made significantly more distressing if ART providers are not cognisant of the impact that poor or inappropriate interactions can have on consumers. This is demonstrated in Case Study 20 below. [218]

Case Study 20

The patient called the provider to ask how her embryos were developing. It is alleged that the patient services officer told her not to worry and that the laboratory would let her know if they 'chuck' them out. The patient found this terminology inconsiderate and upsetting.[218]

It is essential that any discussions about embryos in these circumstances recognise that the embryos are the consumer's genetic material and hopes for a family. These themes were also explored in Theme 8 relating to the disposal and destruction of biological material.

Timing of the delivery of news to consumers is also an important consideration. It is commonly known that the disclosure of sensitive news should be carefully timed to avoid the anniversary of an adverse event, birthdays and festive periods. Case Study 21 serves as an example of this,

[216] RTAC Code of Practice, 2021, Introduction.

[217] Letter from FSANZ-RTAC to the OHO dated 14 June 2024.

[218] The provider maintains that this complaint was investigated but could not be substantiated.

which caused patient distress. This is a relatively simple method to implement to assist with a patient-centred approach.

Case Study 21

The patient was contacted by the provider to request verbal consent to discard embryos. The patient was upset that she was unable to donate the embryos and had been given this news two weeks before a significant festive period. She felt that this information could have been better timed.

It is concerning to note that a provider recorded in their complaints data that they had responded to a complaint using a response formulated through ChatGPT, which was then adapted slightly.[219] While it is acknowledged that the complaint was anonymous, it appeared to provide detailed feedback to the clinic on a variety of issues. Every complaint should be considered and responded to appropriately and professionally; it is not appropriate for any ART provider to respond to a complaint with a generic response given that the consumer has taken the time to contact the clinic with feedback or a concern.

Case Study 22 relates to contact being made with the consumer without checking the records, which led to the patient losing trust in the provider. It is, however, reassuring to see that a new system was promptly implemented following the complaint. Although arranging an appointment would appear to be a straightforward process, this is a good example which demonstrates that ART is considerably different to other areas of health where sensitivities around consumer contact should be considered at every stage of the process.

Case Study 22

The patient received an SMS in 2023 and another four months later, to inform the patient of an embryo transfer appointment when in fact, they had no embryos to transfer due to failed fertilisation. The provider apologised explaining that it was a junior nursing team who were new to IVF. It was human error. The patient felt that the trust in the unit had gone and there was no guarantee that this would not happen again. The provider has now implemented a check point which is colour coded. When the patient is to be booked for embryo transfer, the appointment will be marked as tentative and will be yellow bordered, which will make the nurse check for the cycle status and check the notes by going into the patient file. After that, the appointment will change to blue. A message to the patient will be sent after that.

Patient/person-centred approach

Recommendation 20 of the Gorton Review of Assisted Reproductive Treatment[220] in Victoria proposed that guidelines for person-centred care in ART should be developed by the regulator in collaboration with relevant national and state organisations and with the active involvement of consumers, their families, surrogates, donors and donor-conceived people. This recommendation arose following the recognition of the impact of ART providers' practices on consumer experiences

[219] The provider maintains that 'Chat GPT was only used to help articulate a response. We take all complaints seriously - they are individualised and personalised. We do not respond generically to complaints.'

[220] Independent Review of Assisted Reproductive Treatment, May 2019, Michael Gorton.

and wellbeing, and in 2021 the VARTA Guidance on Person-Centred Care[221] was released. The guidance provides good practice advice for providers that aims to improve consumer understanding, satisfaction, emotional wellbeing and success rates of ART.

The NHMRC Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research touches on elements of patient-centred care such as informed consent and being respectful of human dignity and the autonomy of all relevant parties; however, it does not provide specific guidelines for providing patient-centred care. Providing specific guidance on patient-centred care may improve not only the consumer experience, but ART staff engagement and retention.

Given the concerns highlighted by consumers in this report, it is considered that improvements can be made by ART providers in relation to consumer interactions, ensuring that a patient-centred approach is applied to all aspects of the service, whether that is managing the consenting process, dealing with an adverse event or discarding of embryos.

FSANZ-RTAC has commented on the recommendation proposed by the OHO below as follows:

> *The recommendations put forward, particularly the implementation of guidance on person-centred care, are not arbitrary suggestions. They are essential steps towards ensuring that the ethical and moral obligations of ART providers are upheld. However, it's imperative to extend these guidelines beyond mere recommendations. They should encompass measurable criteria that can be audited to gauge adherence to person-centred principles.*

Recommendation

To the Minister / ART regulator:

33. It is recommended that the proposed regulator of ART provision in Queensland implement guidance on person-centred care, to be utilised by all Queensland ART providers.

Additional issues

Use of international donor banks

ART clinics in Australia also source gametes from international donor banks. In the course of conducting this investigation, concerns were raised by members of the Expert Panel regarding the service level agreements in place between ART clinics and the international donor banks and whether these meet NHMRC Guidelines. Extensive use of overseas donors raises concerns about donor and family limits, where a donor is used internationally and in Australia, as well as the capacity to search for and contact the donor in response to a request from a donor-conceived person. Consideration could therefore be given to the regulation of the importation of gametes to ensure a legislated family limit is maintained, or authority given to the regulator to monitor arrangements between ART clinics and international donor banks.

Recommendation

To the Minister:

34. It is recommended that consideration be given to the options for addressing concerns raised in relation to the use of international donor banks.

[221] VARTA Guidance on Person-Centred Care, Victorian Assisted Reproductive Treatment Authority, Version 01 2021.

Regulation of informal sperm donation

Consideration should be given to the regulation of informal sperm donation. There are a growing number of people seeking sperm donors online through social media groups and mobile applications. This issue was raised by RTAC[222] in respect of the challenges of managing family limits and the accuracy of donor registers. While this method circumvents the need to use licensed ART clinics, and the related costs and administrative and medical processes, it poses significant dangers with risks of consanguinity, transmission of infectious and genetic diseases due to lack of controlled testing and reduced reliability in identifying the donor. There is also a risk that donors to licensed clinics have not also provided gametes privately through an informal process, increasing risks of consanguinity. Informal donation also poses significant safety concerns, with anecdotal reports people seeking informal sperm donors having been pressured towards natural insemination.[223]

Recommendation

To the Minister:

35. It is recommended that consideration be given to the options for addressing concerns raised in relation to informal sperm donation.

Withdrawal of consent

Issues relating to the withdrawal of consent by donors were also identified during the course of this investigation. Section 20(1) of the *Assisted Reproductive Treatment Act 2008* (Vic) (the ART Act Vic) provides that a person who gives consent under section 10(1) or section 16 of the ART Act Vic[224] may withdraw it at any time before the procedure or action consented to is carried out. This provision meant that a donor could withdraw consent for an embryo created with the donor's gametes right up until the point at which it is transferred into a woman. This provision had given the donor significant power to extinguish an embryo that would create a child, even though a donor had no legal obligation in relation to the child that might be created from the donation. This perceived power imbalance was addressed to some extent through the enactment of the *Assisted Reproductive Treatment Amendment Act 2021* (Vic) which came into force on 15 August 2022. This Act introduced a variety of reforms including amendments to sections 17(d) (relating to requirements as to consent) and 20(1) of the ART Act Vic.

Section 20(1A) of the ART Act Vic now provides that a person who gives consent under section 16 of the ART Act Vic may withdraw it in the case of donor gametes, at any time before the earliest of the following occurs: when the gametes are used in a treatment procedure, or if the gametes are earlier used to form an embryo, when the gametes are used to form an embryo.

In practical terms, what this means about consent to use is:

- Donors who donated on or after 15 August 2022 will not be able to withdraw consent to the use of their gametes once the gametes are used in a treatment procedure, such as artificial insemination, or to form an embryo. These changes do not apply retrospectively to donor consents provided before 15 August 2022 unless the donor is counselled and reconsents.
- Donors who donated before 15 August 2022 and who were counselled and consented before 15 August 2022 still have the entitlement to withdraw consent to the use of their gametes or to the use of embryos formed from using their donor gametes up to a point they are used in a

[222] Letter from FSANZ-RTAC to the OHO dated 3 May 2024.

[223] Law must catch up with growing popularity of informal sperm donation | Deakin

[224] These sections refer to required consents for a woman who undergoes a treatment procedure and persons who donate gametes or embryos.

treatment procedure. However, donors in this category may reconsent to the new rules and will then not be able to withdraw their consent to the use of their gametes once an embryo has been formed using their gametes.[225]

Considering the issue of withdrawal of consent, Provider D [226] cautioned that in Victoria the legislation at the relevant time enabled donors to withdraw consent at any time, commenting that:

> *So families that have siblings in a tank, now can't transfer those embryos because the donor said [they] no longer give consent for that to be used.*

Such concerns would need to be considered in the details of proposed recommendations to address the issues of withdrawal of consent by donors.

Recommendation

To the Minister:

36. It is recommended that consideration be given to addressing the issues of withdrawal of consent by donors in proposed legislation to regulate the provision of ART services in Queensland.

Independent review of decisions relating to ART treatments

Background

Victoria has an independent Patient Review Panel established under section 82 of the *Assisted Reproductive Treatment Act 2008* (Vic). Its role is to consider applications relating to:

- surrogacy arrangements where treatment is to occur in Victoria
- posthumous use of gametes and embryos
- where a registered ART provider or doctor reasonably believes that a child that may be born would be at risk of abuse or neglect
- where an applicant does not meet the criteria for treatment
- requests for an extension of storage period of gametes or embryos or the removal of embryos from storage
- the use of preimplantation genetic diagnosis for the purpose of sex selection.

Investigation findings

While the above issues were not examined in detail for this investigation, the issues raised about decision making about ART treatments suggest that there is merit in considering an independent mechanism to review such decisions. If Queensland were to set up a similar panel or mechanism to the Victorian Patient Review Panel, thought should be given to the purpose of the panel and therefore how prescriptive or flexible the legislation ought to be. In Victoria, the Patient Review Panel aims to hear matters as quickly as possible and make swift decisions. As such, the panel is not required to adhere to the rules of evidence and there are no legislated powers for the panel to compel witnesses or documents or to adjourn matters. Complex matters may therefore be more thoroughly handled via the review process in the Victorian Civil and Administrative Tribunal. Thought would also need to be given to the constitution of a panel, were it to be implemented, including whether one or more panel members should have particular qualifications or expertise.

[225] https://www.varta.org.au/regulation/practical-guide-legislation, accessed on 4 April 2024.

[226] Observation made by staff from Provider D at a site visit undertaken by OHO staff on 11 March 2024.

Some concerns have been raised relating to the establishment of an independent mechanism for review of decisions about ART treatments, with Provider C commenting that:

> *ART providers and clinicians alike would have serious concerns about a body compelling them to provide treatment against medical advice, company policies or ethical standards.*[227]

Victorian legislation is silent on how the regulator and panel interact. If implemented in Queensland, it may be appropriate to review how a Queensland panel should report any identified concerns about an ART provider to the regulator. Legislation could address specific issues in consideration of the types of matters a Queensland panel may hear. For example, how long gametes or embryos can be stored, posthumous use of gametes, interstate surrogacy, and how clinics make decisions or risk assessments regarding the safety of a child that may be born.

Recommendation

To the Minister:

37. It is recommended that consideration be given to the establishment of an independent mechanism for review of decisions about ART treatments and posthumous use of gametes and embryos, with functions similar to those performed by the Victorian Patient Review Panel as part of the proposed legislation to regulate the provision of ART services. Such consideration should include clarity on its purpose, powers, interconnection with regulators and reporting obligations.

Use of non-discriminatory forms

Background

Individuals may identify and be recognised as a gender other than the sex that they were assigned at birth and, in line with Australian legal protections[228] against discrimination based on gender identity and intersex status, this should be recognised in their personal records. The Australian Commission on Safety and Quality in Health Care's Australian Charter of Healthcare Rights[229] provides that everyone has the right to have their culture, identity, beliefs and choices recognised and respected. The Australian Government Guidelines on the Recognition of Sex and Gender[230] provides that where sex and/or gender information is collected and recorded in a personal record, individuals should be given the option to select male, female or indeterminate/intersex/unspecified.

Investigation findings

During the OHO investigation, it was noted that various forms provided by ART providers did not provide for the recognition or collection of a patient's gender identity. Providers described to the OHO that forms do not cover situations where, for example, a male who was assigned female at birth attends for assisted reproductive treatments or a woman who was assigned male at birth attends to provide a sperm donation. It is recognised that a patient's sex assigned at birth is often an important factor when considering assisted reproductive treatments; however, it is important to recognise that this may not reflect how the patient identifies themselves. Online resources

[227] Letter from Provider C to the OHO dated 14 June 2024.

[228] Human Rights Act 2019 (Qld); Anti-Discrimination Act 1991 (Qld); Sex Discrimination Act 1984 (Cwlth).

[229] Australian Charter of Health Care Rights - LGBTQI+ | Australian Commission on Safety and Quality in Health Care

[230] Australian Government Guidelines on the Recognition of Sex and Gender (acon.org.au)

document the importance of recording a person's preferred names and pronouns[231] and the harm that can occur from misgendering[232].

Recommendation

To ART providers:

38. It is recommended that ART providers review relevant patient registration forms and include gender identity, to ensure that the forms are non-discriminatory and inclusive of all gender identities.

[231] Medical records — TransHub

[232] Misgendering and experiences of stigma in health care settings for transgender people | The Medical Journal of Australia (mja.com.au)

Overall quality and provision of ART services

While the OHO investigation has identified potential areas of concern within the provision of ART services, it is important to look at the health sector holistically.

ART providers were asked to comment on their successes within the industry.

Provider C:

- Provider C identified pregnancy rates, birth rates, and patient satisfaction as key indicators of success for ART providers. They emphasised the importance of ensuring patients feel supported throughout the process, even if they don't achieve a successful pregnancy.

  'I think … patient satisfaction is a key indicator [of success]. We know that realistically not every patient is [going to] go home with the baby … . And so from my perspective, you know [what] success for those patients looks like … [we want to know that] we've done everything that we could possibly do to help them realise that dream.'

- Provider C expressed deep satisfaction in being able to assist patients in achieving their dream of starting a family through ART. They receive immense fulfilment in providing access to reproductive health services and witnessing the joy of patients who have struggled with infertility.
- Provider C reflected on the successes and achievements of ART providers in Queensland, highlighting the joy of helping families conceive children. They shared heartfelt stories of witnessing the fulfilment of patients' dreams through ART procedures. Additionally, they discussed the importance of posthumous collections and advocate for clearer processes and consent regulations in this area. They expressed pride in the advancements in ART success rates over the years and emphasised the ongoing commitment to improving scientific practices within the industry.

Provider D:

- The key philosophy of Provider D is that the interests of the child are paramount.
- Success is recognised as a live birth. They are trying to ensure doctors recognise that it is not just about achieving pregnancy, but about achieving the birth of a child.
- *'[We] love helping people…'* Staff thought that it was a fantastic industry to be part of.

Provider E:

- *'Patients come to us to get pregnant, so I suppose pregnancy rates are … crucial …'*
- *'… our fundamental reason for being, [is] to get people pregnant'*
- For Provider E their KPIs include ICSI, fertilisation rates, standard IVF fertilisation rates, utilisation rates and egg maturation rates. The data is tracked monthly.

Professor Norman had some valuable commentary in this regard:

The quality of ART in Australia is high compared to most countries in Europe and the Asia Pacific region. This is a function of good ethical practice, adequate regulation, RTAC accreditation, good clinical training and a highly trained embryology profession. There is also a well-developed outcome reporting mechanism through ANZARD and a professional inspection regimen overseen by RTAC and conducted by experienced independent inspectors. …

Australia has one of the highest rates of ART services per capita in the world and the federal government does not impose a limit on the number of cycles offered or indeed the age of the female partner, provided she is before the natural age of menopause. ….

Provision of ART in Australia is underpinned by Medicare funding for a proportion of the cost and is widely available in urban areas where there is significant competition. Regional and remote areas are less well served and access by some groups (e.g. the indigenous population in rural areas) is not yet equitable given travel, access to services and choice of provider. Public service of ART is very limited although Victoria and New South Wales have provided substantial support to widen access to care. South Australia has no support for public services and Western Australia has a limited quota system. I am not aware of the public services in Queensland but understand the high proportion of the community in regional and remote parts of the state make provision of services challenging. My view is there are many groups and communities who cannot afford ART in Australia, and I have advocated that every state should have a high-quality ART service in a public hospital supported by well qualified staff.

In an ideal health care setting, a limited number of ART services should be available free of charge to those who cannot afford it. Introduction of evidence-based guidelines and prognosis-based treatment would be an excellent way of ensuring quality, effective outcomes at a reasonable cost to the state or Federal government..

Recommendations

Theme 1: Appropriate collection, storage, identification and distribution of gametes and embryos

To the Minister:

1. It is recommended that the issues and risks identified in respect of the collection, storage, identification and distribution of gametes and embryos are considered in the proposed legislation or associated regulations. This could include requirements for ART providers to use a standardised suite of processes and documents to ensure consistent record keeping and adverse event reporting, with codified information to aid in standardisation of reporting.

For FSANZ-RTAC:

2. It is recommended that FSANZ-RTAC ensure that all ART providers dispose of stored donor material not meeting current identification standards, and compliance is a requirement of the audit process.

For ART providers:

3. It is recommended that any and all incidents related to the collection, storage, identification and distribution of gametes and embryos are comprehensively documented by the ART provider, timeously reported to RTAC as an adverse event (as per the current RTAC Code of Practice) and recorded as such in the ART providers' risk management system.

Theme 2: Screening of gametes and donors used in Queensland

To the Minister:

4. It is recommended that consideration is given to including a requirement for more extensive screening of donors, in terms of (1) personal and family medical histories and potential genetic conditions by personnel appropriately trained in genetics (e.g. clinical geneticists, genetic counsellors); (2) wider screening of donors to include carrier status of common (autosomal recessive) genetic conditions such as those compensable by Medicare.
5. It is recommended that consideration is given to requiring registered healthcare practitioners to provide independent confirmation of a donor's medical history.

Theme 3: Record keeping and provision of information

For ART providers:

6. It is recommended that all ART providers have a schedule of contact with the donor for updated contact details and medical information. The OHO proposes that contact is made with donors every two years. ART providers should have a policy and procedure if they are unable to locate a donor.
7. It is recommended that ART providers must have a policy and procedure for situations that arise where a significant medical event is evident in a donor-conceived individual or a gamete donor and is disclosed to an ART provider, where there is implied potential medical risk to children conceived from that donor and/or risk for the gamete donor. The policy and procedure should include:
    a. how the information is recorded and decisions are documented
    b. who has responsibility for investigating the medical disclosure
    c. who has responsibility for decision making regarding medical disclosure

d. timeframes within which the medical disclosure should be considered and acted upon

e. mandatory list of disclosure requirements to other families with the same donor

f. parameters for withdrawing donor gametes from further use

g. if appropriate, a documented consultation required between the ART provider Medical Director and a Clinical Geneticist when a decision is made to not disclose.

8. It is recommended that ART providers are required to transfer any hard copy records relating to donor treatment procedures to digital format where they are currently retained in hard copy only.

To the Minister:

9. It is recommended that consideration is given to the inclusion of obligations of ART providers with respect to disclosure of a significant medical history relating to donor-conceived child and donor through, for instance, the proposed central register and legislation with respect to access to information for donor-conceived children.

10. It is recommended that the legislation defines the period of time for retention of records relating to donor ART procedures, and backups (including hard and soft copies) of such documents to mitigate loss.

11. It is recommended that the time period defined in section 121A of the *Assisted Reproductive Treatment Act 2008* (Vic) that identifying records must be kept for at least 99 years after creation of the record be used.

12. It is recommended that legislation should incorporate requirements for maintenance of records if an ART provider ceases to practise.

Theme 4: Maximum family limits of donor gametes within Queensland and Australia

To the Minister:

13. It is recommended that a gamete donor family limit is clearly defined within legislation, including a definition of what constitutes a 'family'. Consideration may also need to be given to a 'person' limit. Furthermore, consideration of limits needs to extend to both Queensland and Australia.

Theme 5: Provision of information and informed consent

For FSANZ-RTAC:

14. It is recommended that consideration be given to the establishment of national evidence-based guidelines for fertility investigation and treatment which will assist treating practitioners in determining what information should be provided and consistency of information provided to patients when obtaining their informed consent to treatment.

For ART providers:

15. It is recommended that ART providers should review the adequacy of information provided to patients and, in consultation with stakeholders, consider (if not already in place):

    a. development of detailed information materials for patients and/or other means of providing sufficient information to patients for them to make informed decisions, for purposes of information sharing and obtaining informed consent

    b. provision of an information package (if not already provided to patients) containing:

        i. detailed information materials, which include potential complications of treatment

ii. a copy of the consent form signed by the patient confirming the information has been explained to them

c. processes for confirming the patient's understanding of the information provided.

16. It is recommended that ART providers should consider consent forms which:

    a. require a suitably trained person to explain the process to the patient at the time of obtaining their signed consent, e.g. completion of the consent form with sections confirming that information has been provided and explained to the patient about ICSI, including: 1) the nature of the procedure, 2) the risks and benefits, and 3) the availability of alternative treatment (including no treatment) and the risks and benefits thereof; and specific treatment options that have been explained to the patient.

17. It is recommended that informed consent from consumers to be subject to internal audit processes, and regulatory scheme annual audits. This should include consideration of:

    a. information provided to consumers and whether this is understandable to a consumer

    b. timing of obtaining consent

    c. forms which are simple to understand and complete and avoid accidental consent / box ticking.

18. It is recommended that ART providers should consider undertaking regular surveys of consumers to establish the adequacy of information provided and whether consumers do understand what treatment they have consented to.

19. It is recommended that ART providers review their induction and training materials for staff, including clinical, counselling and administrative staff, involved in consenting of consumers and consider whether it is adequate to enable informed consent. This should include consideration of training staff on the need for timely communication to patients, and in how to take into account the emotive context of decision making on ART treatments and its impact on patient understanding and information processing.

To the Minister:

20. It is recommended that consideration is given to whether requirements for informed consent be included in proposed legislation or associated regulations.

21. It is recommended that consideration is given to including requirements in legislation to ensure that the information provided by ART providers to consumers in advertising and consent processes is evidence-based, accurate and clinically relevant.

Theme 6: Sperm quality and ART options

For ART providers:

22. It is recommended that steps are taken to ensure that patients are fully informed about:

    a. the quality of sperm to be used for ART, including any potential issues with concentration, motility, morphology or viability

    b. the approaches taken to inform the choice of ART (which may include quality, cost and other medical considerations)

    c. the advantages and disadvantages of each ART procedure, considering factors such as success rates, cost, and potential risks

    d. the reasons for recommending specific ART procedures based on sperm quality and the likelihood of success

e. the importance of genetic screening and counselling for patients considering ART.

23. It is recommended that ART providers should ensure compliance with NHMRC Guidelines and the RTAC Code of Practice when selecting donors (particularly those from international banks).

24. It is recommended that ART providers should consider the genetic implications of sperm quality, particularly in cases of severe abnormalities or azoospermia, which may indicate underlying genetic conditions.

Theme 7: Sex selection

To the Minister:

25. Based on the NHMRC Guidelines, it is recommended that state-specific legislation explicitly affirms the position on the practice of non-medical sex selection in Queensland.

Theme 8: Discarding of gametes and/or embryos

To the Minister:

26. It is recommended that the proposed legislation to regulate the provision of ART services in Queensland include provisions for oversight, safeguards and mandatory requirements for the disposal of biological material.

For ART providers:

27. It is recommended that providers consider appropriate resourcing of laboratories to ensure that disposal of gametes and/or embryos or other genetic material is managed appropriately, effectively and from a patient-centric approach.

28. It is recommended that ART providers review their training to staff to ensure that they are appropriately trained to support consumers in the decision making process in relation to the disposal of gametes and/or embryos or other genetic material and provide information about support services.

Theme 9: ART oversight and regulation in Queensland

To the Minister:

29. It is recommended that legislation is designed to provide robust oversight of ART providers, including the licensing of providers, audits, and investigation of non-conformities and adverse events.

Theme 10: Open disclosure and adverse events management

To the Minister:

30. It is recommended that consideration is given to a requirement that licensed ART providers adopt the 'Australian Open Disclosure Framework – Better communication, a better way to care', noting that RTAC's Code of Practice requires ART providers to adopt policies *consistent* with this framework without the detailed guidance.

For ART providers:

31. It is recommended that ART providers ensure that approaches to open disclosure reflect the requirements of the Australian Open Disclosure Framework, and that responses to adverse events and complaints are person centred and trauma informed.

32. It is recommended that ART providers ensure that consumers who complain are provided with an escalation pathway in the event that their complaint is not resolved.

Theme 11: Impacts on consumers

To the Minister / ART regulator:

33. It is recommended that the proposed regulator of ART provision in Queensland implement guidance on person-centred care, to be utilised by all Queensland ART providers.

Additional issues:

Use of international donor banks

To the Minister:

34. It is recommended that consideration be given to the options for addressing concerns raised in relation to the use of international donor banks.

Regulation of informal sperm donation

To the Minister:

35. It is recommended that consideration be given to the options for addressing concerns raised in relation to informal sperm donation.

Withdrawal of consent

To the Minister:

36. It is recommended that consideration be given to addressing the issues of withdrawal of consent by donors in proposed legislation to regulate the provision of ART services in Queensland.

Independent review of decisions relating to ART treatments

To the Minister:

37. It is recommended that consideration be given to the establishment of an independent mechanism for review of decisions about ART treatments and posthumous use of gametes and embryos, with functions similar to those performed by the Victorian Patient Review Panel as part of the proposed legislation to regulate the provision of ART services. Such consideration should include clarity on its purpose, powers, interconnection with regulators and reporting obligations.

Use of non-discriminatory forms

For ART providers:

38. It is recommended that ART providers review relevant patient registration forms and include gender identity, to ensure that the forms are non-discriminatory and inclusive of all gender identities.

Appendices

Appendix 1: List of ART providers in Queensland

ART providers as at 31 January 2024:

ART provider	RTAC Accredited Provider Number
Care Fertility	425
City Fertility Toowoomba	437
Cairns Fertility Centre	424
City Fertility Centre – Brisbane	401
City Fertility Centre – Sunnybank	427
City Fertility Centre – Gold Coast	418
Coastal IVF	402
Fertility Solutions Sunshine Coast	421
QFG Sunshine Coast	404
Life Fertility Clinic	422
Monash IVF Gold Coast	405
Monash IVF Rockhampton	408
Monash IVF Townsville	420
QFG Cairns	409
QFG Gold Coast/The Fertility Centre Gold Coast[233]	410
QFG Mackay	411
QFG Toowoomba	414
QFG Townsville	415
Queensland Fertility Group	416
The Fertility Centre	429
Fertility Solutions Bundaberg	426
Adora Fertility	436
Monash IVF Brisbane	438
Genea Brisbane	439

[233] One RTAC number is allocated to QFG Gold Coast and The Fertility Centre Gold Coast.

Appendix 2: Expert advisory panel

1. **Professor Robert Norman AO**

   Robert Norman holds a personal chair as Professor for Reproductive and Periconceptual Medicine at the University of Adelaide. He is a specialist reproductive endocrinologist and is a subspecialist in reproductive medicine (CREI) and in endocrine biochemistry (FRCPA).

2. **Michael Barry**

   Michael Barry is the Scientific Director at Flinders Fertility. He is an experienced embryologist and laboratory manager. His embryology career began in 1990 at the Reproductive Medicine Unit of the University of Adelaide. He is a science graduate from the University of Adelaide and completed his Masters in Clinical Embryology at the University of Leeds in 2012. In addition to his role at Flinders Fertility, Michael Barry is an associate lecturer at the University of Adelaide Robinson Institute. He mentors colleagues in Australia and overseas.

3. **Dr Karin Hammarberg**

   Dr Karin Hammarberg is a Senior Research Fellow in the School of Public Health and Preventive Medicine, Monash University. She is a registered nurse with 20 years' experience as clinical coordinator of IVF programs. Her PhD research examined the experience of birth and mothering after assisted conception. She is the senior research officer at the Victorian Assisted Reproductive Treatment (VARTA) and undertakes research at Monash University.

4. **Michael Gorton AM**

   Michael Gorton is an experienced commercial lawyer with a focus on the health sector. His clients benefit from his practical and commercial approach. Through his association with peak industry bodies and his position on numerous boards, he keeps abreast of developments in his area of practice and is often asked to address public and private companies and government and non-government organisations.

5. **Louise Johnson**

   Louise Johnson was recently the CEO of VARTA where she led oversight of the IVF industry in Victoria, collaborating with key stakeholders including the Victorian Health Minister, state and Commonwealth Governments, university institutes, industry representative and accreditation bodies to support quality healthcare and service provision, policy development, and research related to community education or service provision.

Appendix 3: Investigation data

Appendix 3A: Data summary

The OHO assessed over **1,226 data records**, which included OHO matters; complaints (from ART providers provided to the OHO); audits (provided by Certifying Bodies (CBs) and ART providers); and adverse events (from ART providers provided to the OHO) (Table 2).

Of the 116 audits assessed, 55 contained non-conformities (NCRs). As such, a total of 1,147 data records were relevant, of which **242 (21%) were within the scope of this investigation**. As such, approximately 79% of the data obtained by the OHO for this investigation related to themes/topics other than those of Themes 1–11.

The proportion of data that was in scope for each category varied from 17% to 49% (Table 2). An anecdotal insight into the data that fell outside the scope of this investigation included:

1. OHO matters – ART health complaints beyond the scope of this investigation, which included communication issues, incorrect information about medication, billing issues, and clinical issues.
2. ART provider complaints – generally related to interpersonal issues experienced between consumers and ART provider staff, including bedside manner of medical practitioners. Complaints also related to billing issues and difficulties with appointments.
3. Audits – a general spread of non-conformities related to sections of the RTAC Code of Practice which were not within the scope of this investigation (see examples in Table 11, Appendix 3D: RTAC data), including issues related to emergency care, compliance, infection risk, data reporting, internal auditing and key personnel.
4. Adverse events – most of which related to adverse clinical (medical) outcomes for consumers, predominantly OHSS or other hospitalisation post-ART.

Table 2: Summary of investigation data

Category	Total Assessed	Total which were relevant	Total in scope	% in scope
Matters (OHO complaints, enquiries) [Issues: 88]	304	304	76	25%
Complaints (ART providers) [Total received: 863]	479	479	86	18%
Audits (CBs, ART providers) [Total: 116 audits, 55 had NCRs]	116*	55*	27	49%
Adverse events (ART providers)	327	309	53	17%
GRAND TOTAL	1,226	1,147	242	21%

**To accurately reflect the proportion of audits that were in scope, audits which had no non-conformities (NCRs) were removed in the calculation. As such, the 61 audits which had no NCRs were removed, leaving 55 audits with at least one NCR, of which 27 (49%) of audits were in scope.*

Appendix 3B: OHO data

OHO matters (complaints and enquiries)

The OHO raw data[234] identified 304 matters received by the OHO relating to possible ART treatment between 1 July 2014 and 15 May 2024.

While OHO data was analysed quantitively for Themes 1–8, Themes 9–11 (regulation of ART, open disclosure and patient impact) are more appropriate for qualitative analysis and interpretation. As such, they are reflected in various case studies and observations from audits and/or adverse events, rather than being presented by way of a quantitative analysis.

Analysis of the OHO data identified a **total of 76 matters** (Table 3), which related to **88 issues** (Table 4). A total of **47 matters** related to **Themes 1–4** and a total of **29 matters** involved issues or concerns dealing with **Themes 5–8** (Table 3). Of these latter 29 matters related to Themes 5-8, 26 matters are health service complaints, and three matters are enquiries.

Of the total matters relating to Themes 1-4, there are 37 complainants. Six of those complainants made more than one complaint totalling 16 matters. The greatest number of matters raised by a complainant was four (two complainants each raised four matters). One complainant made three complaints about the same provider with the fourth complaint about an individual practitioner and the other complainant made all four complaints against the same provider. Of the total matters relating to Themes 5-8, there are 27 complainants (including 'anonymous' who raised three complaints and an enquiry about the same theme). Four complainants made complaints to the OHO about more than one provider. Apart from 'anonymous', all other complainants raised only one matter (i.e. either a complaint or an enquiry).

Within the period assessed (1 July 2014 – 15 May 2024), Themes 1–4 represented approximately 62% of the total OHO matters and issues; and Themes 5–8 represented approximately 38% of the total OHO matter and issues (Table 3 and Table 4).

In totality (considering quantitatively assessed Themes 1–8 – see Table 4), the predominant themes (as a percentage of total issues) rank as follows:

1. Theme 1: Appropriate collection, storage, identification and distribution of donor gametes and embryos (28%)
2. Theme 5: Provision of information and informed consent (28%)
3. Theme 2: Screening of gametes and donors used in Queensland (16%)
4. Theme 3: Record keeping and provision of information (15%)
5. Theme 7: Sex (gender) selection (5%)
6. Theme 8: Discarding of gametes and/or embryos (3%)
7. Theme 4: Maximum family limits of donor gametes within Queensland and Australia (3%)
8. Theme 6: Sperm quality and ART options (1%).

[234] Raw data was obtained from the OHO's complaints management database (Resolve).

Table 3: Stratification of OHO matters by ART provider and theme (1 July 2014 – 15 May 2024)

ART provider	OHO matters Themes 1–4	OHO matters Themes 5–8	TOTAL
Provider B	1 (2%)	0 (0%)	1 (1%)
Provider C	6 (13%)	3 (10%)	9 (12%)
Provider D	5 (11%)	2 (7%)	7 (9%)
Provider E	33 (70%)	8 (28%)	41 (54%)
Provider F	0 (0%)	1 (3%)	1 (1%)
Provider K	0 (0%)	1 (3%)	1 (1%)
Provider J	0 (0%)	2 (7%)	2 (3%)
Individual practitioners	2 (4%)[235]	12[236] (41%)	14 (18%)
TOTAL	47 (62%)	29 (38%)	76

Theme 1: Appropriate collection, storage, identification and distribution of donor gametes and embryos
Theme 2: Screening of gametes and donors used in Queensland
Theme 3: Record keeping and provision of information
Theme 4: Maximum family limits of donor gametes within Queensland and Australia
Theme 5: Provision of information and informed consent
Theme 6: Sperm quality and ART options
Theme 7: Sex (gender) selection
Theme 8: Discarding of gametes and/or embryos

Table 4: Stratification of OHO issues by ART provider and theme (1 July 2014 – 15 May 2024)

ART provider	Theme 1	Theme 2	Theme 3	Theme 4	Theme 5	Theme 6	Theme 7	Theme 8	TOTAL
Provider B	1	0	0	0	0	0	0	0	1
Provider C	2	2	2	0	3	0	0	0	9
Provider D	4	1	0	0	2	0	0	0	7
Provider E	16	7	11	3	5	1	0	2	45
Provider F	0	0	0	0	1	0	0	0	1
Provider K	0	0	0	0	1	0	0	0	1
Provider J	0	0	0	0	1	0	0	1	2
Individual practitioners	2	4	0	0	12	0	4	0	22
TOTAL	25 (28%)	14 (16%)	13 (15%)	3 (3%)	25 (28%)	1 (1%)	4 (5%)	3 (3%)	88
	55 (63%)				33 (38%)				

Theme 1: Appropriate collection, storage, identification and distribution of donor gametes and embryos
Theme 2: Screening of gametes and donors used in Queensland
Theme 3: Record keeping and provision of information
Theme 4: Maximum family limits of donor gametes within Queensland and Australia
Theme 5: Provision of information and informed consent
Theme 6: Sperm quality and ART options
Theme 7: Sex (gender) selection
Theme 8: Discarding of gametes and/or embryos

[235] Three matters involving individual practitioners also involve an ART organisation and have therefore already been counted with the relevant ART organisation in this table.

[236] Four matters involving individual practitioners also involve an ART organisation and have therefore already been counted with the relevant ART organisation in this table.

Dates of matters and issues

The OHO matters data was organised according to the time period in which treatment was provided (Table 5). This analysis was performed in order to determine whether matters raised by consumers were historical or are of ongoing concern.

Of the matters raised with the OHO in relation to Themes 1–8, 66% pertain to health services (treatment) provided 5–10+ years ago (Table 5: 34% + 32%). Of the remaining 34%, 16% relate to health services provided 3–5 years ago and 17% relate to health services provided 1–3 years ago (Table 5). Furthermore:

- Of those issues relating to health services provided 10+ years ago, the majority relate to Themes 1 and 3 (23% and 46% respectively).
- Of those issues relating to health services provided 5–10 years ago, the majority relate to Themes 1, 2 and 5 (30%, 23% and 37% respectively).
- Of those issues relating to health services provided 3–5 years ago, the majority relate to Themes 5 and 7 (59% and 24% respectively).
- Of those issues relating to health services provided 1–3 years ago, the majority relate to Theme 1 (64%).

The vast majority of Themes 3 (record keeping and provision of information) and Theme 4 (maximum family limits of donor gametes) relate to healthcare services provided over 10 years ago (92% and 100% respectively) (Table 5). Regarding Theme 3, the main issues raised related to the release of donor identifying information or donor-sibling information. It is therefore unsurprising that the majority of issues relate to health services provided 10+ years ago, given that the children involved are reaching, or have now reached, 18 years of age (the age at which the RTAC Code of Practice permits the release of donor identifying information to donor-conceived persons who request this), which prompts enquiries to be made regarding donor identification. Similarly, for Theme 4, donor-conceived families become generally more interested in the number of siblings of their donor-conceived children, if information related to sibling numbers is provided – which consequently raises concerns in some instances, particularly if consumers learn of family limits that have exceeded 10 (which may or may not be in contravention of ART provider policies).

The OHO is aware that some of the issues which have been raised regarding historical treatment may have been rectified with compliance with more recent RTAC guidelines. Significant technological improvements have been made to support integrity of record keeping, for example, digital records and radio frequency identification of samples. Scrutiny of issues relating to treatment which occurred between one and three years ago is important to establish whether there are ongoing issues and the extent to which these are being addressed through RTAC auditing and oversight.

In most cases, the consumers' contact with ART providers has been made in the last two years. However, it is not possible to definitively identify the timing of record keeping deficiencies which have resulted in issues with the release of donor information. The OHO considers that this is reflective of long-term issues with record keeping within the sector, and the focus on initial treatment of the consumer, rather than a holistic approach to ART, where management of information surrounding children's parentage is of significant importance.

Table 5: OHO matters and issues stratified by date period and theme (1 July 2014 – 15 May 2024)

Time period when treatment provided	Number of matters	% of matters	Issues (note: some matters related to multiple issues)																						TOTAL	
			Theme 1			*Theme 2*			*Theme 3*			*Theme 4*			*Theme 5*			*Theme 6*			*Theme 7*			*Theme 8*				
			No.	%T	%P	No.	%T	%P	No.	%T	%P	No.	%T	%P	No.	%T	%P	No.	%T	%P	No.	%T	%P	No.	%T	%P	No.	%P
10 years +	24	32%	6	24%	23%	3	21%	12%	12	92%	46%	3	100%	12%	2	9%	8%	0	0%	0%	0	0%	0%	0	0%	0%	**26**	30%
5–10 years	26	34%	9	36%	30%	7	50%	23%	1	8%	3%	0	0%	0%	11	41%	37%	0	0%	0%	0	0%	0%	2	67%	7%	**30**	34%
3–5 years	12	16%	1	4%	6%	2	14%	12%	0	0%	0%	0	0%	0%	10	41%	59%	0	0%	0%	4	100%	24%	0	0%	0%	**17**	19%
1–3 years	13	17%	9	36%	64%	2	14%	14%	0	0%	0%	0	0%	0%	2	9%	14%	1	100%	7%	0	0%	0%	0	0%	0%	**14**	16%
Unknown	1	1%	0	0%	0%	0	0%	0%	0	0%	0%	0	0%	0%	0	0%	0%	0	0%	0%	0	0%	0%	1	33%	100%	**1**	1%
TOTAL	**76**		**25**			**14**			**13**			**3**			**25**			**1**			**4**			**3**			**88**	

%T = % of Theme %P = % of Period

Theme 1: Appropriate collection, storage, identification and distribution of donor gametes and embryos
Theme 2: Screening of gametes and donors used in Queensland
Theme 3: Record keeping and provision of information
Theme 4: Maximum family limits of donor gametes within Queensland and Australia
Theme 5: Provision of information and informed consent
Theme 6: Sperm quality and ART options
Theme 7: Sex (gender) selection
Theme 8: Discarding of gametes and/or embryos

Appendix 3C: ART provider data

Complaints

RTAC supplied the OHO with consumer complaint data, for all complaints received between 1 January 2018 and 15 December 2023, relating to individuals who have complained directly to RTAC about the treatment that they have received from ART providers in Queensland.[237] Only seven individual complaints were received by RTAC for the period February 2020 to December 2023, with no complaints from January 2018 to January 2020. Two complaints related to Theme 1: Appropriate collection, storage, identification and distribution of gametes and embryos; two complaints related to Theme 2: Screening of gametes and donors used in Queensland; one related to Theme 3: Record keeping and provision of information; and one related to Theme 4: Maximum family limits of donor gametes within Queensland and Australia. Five of the complaints had been lodged with the OHO.

ART providers who had complaints made to the OHO about the treatment they provided supplied the OHO with consumer complaints that they had on record for the period from 1 January 2018 to 15 December 2023.

A total of 863 ART provider complaints were received for the period 1 July 2014 to 20 March 2024. Of the total ART provider complaints, only 56% (479) were randomly assessed due to time constraints – but which was considered a suitably representative sample size. Of those assessed, 18% (86) were in scope of the investigation.

The majority (57%) of in-scope complaints fell within Themes 1–4 and the remainder (43%) in Themes 1–8 (Themes 9–11 would not naturally appear in such complaints and were therefore not explored in this dataset). Themes 1–8 were represented in complaints in the following ranking:

1. Theme 1 (40%)
2. Theme 5 (20%)
3. Theme 8 (17%)
4. Theme 2 (13%)
5. Theme 6 (6%)
6. Theme 3 (3%)
7. Theme 4 (1%)
8. Theme 7 (0%).

A summary of this complaint data is as follows:

1. Quality and Transparency of Complaint Management:
    a. Varying degrees of transparency and effectiveness in handling complaints.
    b. Some providers demonstrate proactive and transparent approaches, promptly addressing issues and engaging with complainants.
2. Patient Communication and Information Provision:

[237] RTAC patient complaint files provided under section 228 notice, 1 February 2024.

a. Concerns regarding inadequate communication with consumers, particularly regarding genetic testing results and storage status of biological material.

b. Instances where consumers were misinformed about the availability of embryos, leading to emotional distress and financial implications.

3. Adherence to Regulatory Guidelines:

   a. Instances of non-compliance with regulatory reporting requirements, such as delayed reporting of serious adverse events to the appropriate authorities.

4. Storage and Record Keeping Practices:

   a. Issues related to storage and record keeping processes, including mismanagement of patient records leading to confusion and emotional distress.

5. Disposal Processes and Communication:

   a. Patient concerns regarding delays and lack of communication regarding the disposal of biological material, causing distress and reopening emotional wounds related to fertility treatments.

6. Donor Screening and Medical Information Management:

   a. Cases highlighting the importance of robust donor screening processes and proactive management of donor medical information to prevent potential risks to patients and offspring.

Considering OHO issue data and ART provider complaint data collectively, Themes 1 and 5 accounted for the highest proportion (58% in total, 34% and 24% respectively) (Table 6).

Table 6: Combined OHO issues and ART provider complaints

Theme	ART provider complaints	OHO issues	Combined
Theme 1	34 (40%)	25 (28%)	59 (34%)
Theme 2	11 (13%)	14 (16%)	25 (14%)
Theme 3	3 (3%)	13 (15%)	16 (9%)
Theme 4	1 (1%)	3 (4%)	4 (2%)
Theme 5	17 (20%)	25 (28%)	42 (24%)
Theme 6	5 (6%)	1 (1%)	6 (3%)
Theme 7	0 (0%)	4 (5%)	4 (2%)
Theme 8	15 (17%)	3 (4%)	18 (10%)
TOTAL	86	88	174

Theme 1: Appropriate collection, storage, identification and distribution of donor gametes and embryos
Theme 2: Screening of gametes and donors used in Queensland
Theme 3: Record keeping and provision of information
Theme 4: Maximum family limits of donor gametes within Queensland and Australia
Theme 5: Provision of information and informed consent
Theme 6: Sperm quality and ART options
Theme 7: Sex (gender) selection
Theme 8: Discarding of gametes and/or embryos

Table 7: ART provider complaints stratified by provider and theme (1 July 2014 – 20 March 2024)

Complaints	Total received	Assessed	Theme 1	Theme 2	Theme 3	Theme 4	Theme 5	Theme 6	Theme 7	Theme 8
Provider C	311	60	5	2	0	0	1	0	0	0
Provider D	239	239	7	2	1	1	2	1	0	1
Provider E	263	130	14	7	0	0	9	4	0	13
Provider A	21	21	7	0	2	0	2	0	0	1
Provider B	21	21	1	0	0	0	2	0	0	0
Provider I	7	7	0	0	0	0	0	0	0	0
Provider F	1	1	0	0	0	0	1	0	0	0
TOTAL	863	479 (56% of total received)	34 (40%)	11 (13%)	3 (3%)	1 (1%)	17 (20%)	5 (6%)	0 (0%)	15 (17%)
			49 (57%)				37 (43%)			
			86 (18% in scope of total assessed)							

Theme 1: Appropriate collection, storage, identification and distribution of donor gametes and embryos
Theme 2: Screening of gametes and donors used in Queensland
Theme 3: Record keeping and provision of information
Theme 4: Maximum family limits of donor gametes within Queensland and Australia
Theme 5: Provision of information and informed consent
Theme 6: Sperm quality and ART options
Theme 7: Sex (gender) selection
Theme 8: Discarding of gamete and/or embryos

Adverse events

Table 8: Adverse event data provided to the OHO

ART provider	No. of adverse events reported*	Theme 1	Theme 2	Theme 3	Theme 4	Theme 5	Total in scope for each provider*
Provider B	16	2	0	0	0	0	2 (4%)
Provider D	36	1	0	0	0	0	1 (2%)
Provider A	75	4	2	0	0	0	6 (11%)
Provider C	98	31	0	0	0	7	38 (72%)
Provider E	84	6	0	0	0	0	6 (11%)
Total (aggregate)	**309**	**44 (83%)**	**2 (4%)**	**0 (0%)**	**0 (0%)**	**7 (13%)**	**53 (17%)**

* Data/information was provided that was deemed to be in scope by each provider. Some providers provided adverse events that were beyond the immediate scope of the investigation, and others aligned more closely to the scope.

Theme 1: Appropriate collection, storage, identification and distribution of gametes and embryos
Theme 2: Screening of gametes and donors used in Queensland
Theme 3: Record keeping and provision of information
Theme 4: Maximum family limits of donor gametes within Queensland and Australia
Theme 5: Provision of information and informed consent
Themes 6-11 did not appear in any adverse events data

Appendix 3D: RTAC data

Table 9: RTAC definitions

Major non-conformity	The requirements of an item in the Code are not met, the outcome is ineffective and there is a patient risk. Several related minor non-conformities may also constitute a major non-conformity.
Minor non-conformity	The requirements of an item in the Code are not met, the outcome is ineffective but there is no patient risk.
The RTAC Code of Practice defines adverse events as follows: Serious adverse event	3.2.2 A serious adverse event includes any event which: a. Causes a significant medical or surgical condition that occurs as a result of the ART treatment (as defined in section 3.2.3 of the Code of Practice and includes ovarian hyperstimulation syndrome) b. Results in the hospitalisation of the patient due to a complication of ART treatment as defined in section 3.2.3 c. Results or may result in the transmission of a communicable disease d. Results in a breach or potential breach of legislation e. Arises from a gamete or embryo identification mix up Causes a loss of viability of gametes or embryos or suspected deterioration (beyond accepted laboratory standards) that renders them unsuitable for use. Arises from a systematic failure in the validation/verification of a diagnostic test and/or technology that has resulted in misdiagnosis and/or significant potential harm or loss to patients, their gametes or embryos.

Table 10: ART provider non-conformities as reported by RTAC

Location	Total audits (Sept 2019 – 2023)*	Total non-conformities	Average non-conformities per audit	Major non-conformities
ACT	10 (3%)	18	1.8	1
NSW	84 (26%)	162	1.93	13
NT	4 (1%)	19	4.75	1
NZ	20 (6%)	158	7.9	5
QLD	85 (27%)	188	2.21	3
SA	13 (4%)	21	1.62	1
TAS	7 (2%)	25	3.57	5
VIC	69 (22%)	158	2.29	11
WA	25 (8%)	13	0.52	0
TOTAL	**317**	**762**	**2.40**	**40**

* Audits suspended in 2020 due to COVID.

Table 11: RTAC Queensland non-conformity categories as they relate to the RTAC Code of Practice sections

RTAC Code of Practice section number	Code of Practice title of section	Critical Criterion (CC) / Good Practice Criterion (GPC)	Number of non-conformities	
1.1	Establishment of an ART unit	N/A	0	0%
1.2	Quality management system (QMS)	GPC1	13	8%
1.3	Compliance	CC1	0	0%
1.4	Personnel	CC2	9	6%
1.5	Stakeholder feedback	GPC2	0	0%
1.6	Disaster management	CC3	2	1%
1.7	Renaming or closure of an ART unit	N/A	0	0%
2.1	Medical management	GPC3	1	1%
2.2	Information	GPC4	0	0%
2.3	Valid consent	CC4	4	3%
2.4	Management of infection risk	CC5	12	8%
2.5	Medication management	GPC5	16	10%
2.6	Identification and traceability	CC6	46	30%
2.7	Emergency care	GPC6	8	5%
2.8	Donor and surrogacy requirements	CC7	9	6%

2.9	Cryostorage of gametes and embryos	CC8	17	11%
3.1	Ovarian hyperstimulation syndrome	GPC7	0	0%
3.2	Adverse events**	CC9	18	12%
3.3	Multiple pregnancies	CC10	0	0%
3.4	Data monitoring	CC11	0	0%
3.5	Data reporting	CC12	0	0%
Total*			**155**	

* Sections of RTAC Code of Practice recorded from 2020, so does not match the total non-conformity rate for Queensland (188 v 155) as data on allocation to RTAC Code of Practice Section was not implemented until 2020 by RTAC data recording practices.

** Adverse events include a range of matters, including ovarian hyperstimulation syndrome, anaphylaxis, endometriosis, infection.[238]

Table 12: RTAC reported non-conformities against section 2.6 (identification and traceability) of the Code of Practice

Location	Total audits (Sept 2019 – 2023)*	Total non-conformities in relation to section 2.6 of Code of Practice	
ACT	5 (4%)	0	0%
NSW	33 (23%)	19	17%
NT	3 (2%)	0	0%
NZ	18 (13%)	20	18%
QLD	40 (28%)	46	42%
SA	4 (3%)	0	0%
TAS	2 (1%)	2	2%
VIC	31 (22%)	22	20%
WA	5 (4%)	0	0%
Total	**141**	**109**	

* Audits suspended in 2020 due to COVID.

**141 audits relating to section 2.6 of the RTAC Code of Practice, rather than the total number of audits completed.

Table 13: Adverse events reported to RTAC that related to section 3.2 of the Code of Practice (2018–2023)

ART provider	No. of adverse events reported to RTAC	Adverse event type	No. of adverse events reported to RTAC
Provider B	2	Handling	11
Provider F	1	Identification	3
Provider D	2	Privacy	1
Provider A	2	Records	2
Provider C	10	Regulatory	1
Provider E	1		
Total	**18**		

[238] Letter to the Health Ombudsman from the Fertility Society of Australia and New Zealand and RTAC, 15 January 2024.