Queensland Health

Regulation of Assisted Reproductive Technology Services

NOT GOVERNMENT POLICY

Consultation Paper | February 2024

Queensland Government

Interpreter accessibility The Queensland Government is committed to providing accessible services to Queenslanders from all culturally and linguistically diverse backgrounds. If you have difficulty in understanding this document, you can free call 13 QGOV (13 74 68) and we will arrange an interpreter to communicate the report to you. www.qld.gov.au/languages

Regulation of Assisted Reproductive Technology Services Consultation Paper 2024

For more information contact

System Policy Branch, Strategy, Policy and Reform Division, Queensland Health, GPO Box 48, Brisbane QLD 4001

Email: ART@health.qld.gov.au

Disclaimer:

The content presented in this publication is distributed by the Queensland Government as an information source only. The State of Queensland makes no statements, representations or warranties about the accuracy, completeness or reliability of any information contained in this publication. The State of Queensland disclaims all responsibility and all liability (including without limitation for liability in negligence) for all expenses, losses, damages and costs you might incur as a result of the information being inaccurate or incomplete in any way, and for any reason reliance was placed on such information.

Acknowledgement of Country

The Department of Health acknowledges the Traditional Owners and Custodians of the lands, waters and seas across Queensland.

We pay our respects to Elders past and present, while recognising the role of current and emerging leaders in shaping a better health system.

The Department acknowledges the First Nations peoples in Queensland are both Aboriginal peoples and Torres Strait Islander peoples, and supports the cultural knowledge, determination and commitment of Aboriginal and Torres Strait Islander communities in caring for their health and wellbeing.

Contents

Purpose

This paper is designed to help inform considerations for regulating assisted reproductive technology (ART) services in Queensland. It sets out the key issues that need to be considered, including:

- requirements that should be satisfied before a person accesses ART treatment;
- how gametes and embryos should be used and stored;
- the introduction of a licensing system for ART providers; and
- how information relating to ART should be collected and kept.

Regulating ART services in Queensland has the potential to be a significant change, and it is critical that this is informed by the views of those who will be affected. This paper provides a framework for key stakeholders, including ART providers, consumers, peak and representative bodies and clinicians to articulate and share their views.

Each section of the paper includes questions that we encourage responses to. We also welcome feedback about whether there are issues associated with ART that we have not addressed. Some issues are out of scope – these are outlined below.

This paper is for consultation purposes and is not Queensland Government policy.

Opportunity to have your say

Feedback is sought from all Queenslanders, and particularly people seeking/using ART treatment, donor-conceived people, gamete donors and ART providers. Queensland Health is also seeking the views of national bodies, consumer representative groups, advocacy groups, our non-government organisation partners, including peak bodies, professional groups and colleges from within the Queensland Government.

You can have your say to inform the development of regulation of ART services, by providing a written submission, responding to the questions in this consultation paper, by **email**: ART@health.qld.gov.au

More information is available on the Queensland Government website.

The closing date for feedback is: **25 February 2024.**

Terminology

Table 1 provides a high-level overview of terminology used in this consultation paper.

Table 1: ART terminology

Term	Meaning
Assisted reproductive technology (ART)	The application of laboratory or clinical techniques to gametes and/or embryos for the purposes of reproduction.
ART provider	A facility that provides ART services. These facilities are accredited by RTAC.
ART service	Includes ART treatment, storage of gametes and embryos for use in ART treatment, a procedure to obtain a gamete from a gamete provider for use in ART treatment or for research about ART.
Donor	A person who gives sperm, egg(s) or embryo(s) for use by a person other than their spouse or partner in a reproductive procedure.
Donor-conceived people/person	A person conceived using donor gametes.
Donor conception register	A register of information that may facilitate the sharing of information on genetic heritage, for donor-conceived people, intended parents and donors.
Donated gametes	Sperm or egg(s) given to an individual or couple for their reproductive use. The term is also used when gametes are donated for use in research, training or quality assurance activities.
Gamete	A human sperm or egg (ovum or oocyte). Includes any cell that has resulted from a process of meiosis, or tissue containing such cells (also referred to as gonadal tissue).
Gamete provider	Refers to the persons whose sperm and egg were used (or are to be used) to create an embryo. This could be a donor or a person who is using their own gamete in an ART treatment.
Intending/ intended parent(s)	The individual or couple who seeks to have a child using ART services.
NHMRC	The National Health and Medical Research Council.
RTAC	The Reproductive Technology Accreditation Committee of the Fertility Society of Australia and New Zealand.

Overview

ART gives people the chance to have children they may not otherwise have been able to. The Australian Institute of Health and Welfare (AIHW) has reported that 7.1 per cent (4296) of the 60,451 people who gave birth in Queensland in 2022 became pregnant as a result of ART.[i]

ART helps those with fertility issues, genetic risks and those who identify as LGBTIQ+ to have children. Nowadays many aspects of ART are part of normal medical practice. But, use of ART services prompts distinctive social, ethical and legal considerations, including about the level of regulation, when ART should be used and how gametes and embryos should be managed.

There are 24 accredited ART units in Queensland.[ii]

Current regulatory framework

There is no Commonwealth legislation in place regulating ART services in Australia. However, the following national professional accreditation framework and guidelines govern ART services:

- National Health and Medical Research Council (NHMRC) *Ethical Guidelines on the Use of Reproductive Technology in Clinical Practice and Research* (Guidelines)
- Reproductive Technology Accreditation Committee (RTAC) of the Fertility Society of Australia *Code of Practice for Assisted Reproductive Technology Units* (Code of Practice).

The Guidelines provide an overarching framework for the conduct of ART in clinical practice and research. The Guidelines were intended to be read in conjunction with federal and state or territory legislation to create a robust framework for the conduct of ART in Australia.[iii] The NHMRC Guidelines address a range of matters relating to the clinical practice of ART, including:

- the provision of information and counselling to patients
- consent
- use of donated gametes, including consideration of family limits and exchange of information
- storage of gametes
- ART services requiring specific ethical guidance, such as sex selection, surrogacy, preimplantation genetic testing and posthumous collection and use of gametes
- record keeping and data reporting.

The Code of Practice provides a framework and sets criteria against which ART providers are audited, in order to maintain their accreditation with RTAC. ART providers are audited annually for critical criteria and every three years for good practice criteria. RTAC accreditation is required to obtain Medicare rebates for ART services and medications for any patient attending an ART service.

Compliance with these documents is an accreditation requirement, not a legal requirement, and there are no robust enforcement mechanisms in place.

Victoria (Vic), New South Wales (NSW), Western Australia (WA) and South Australia (SA) have state-based ART legislation in place. The Australian Capital Territory (ACT) introduced a Bill to regulate ART in November 2023.

There is currently no dedicated legislation in Queensland regulating ART services. Queensland ART providers have self-regulated via the national framework to date. This approach leaves Queensland Health with no oversight or enforcement powers should a provider fail to meet their requirements.

Other Commonwealth and Queensland legislation relevant to ART providers includes:

- *Medicines and Poisons Act 2019*
- *Surrogacy Act 2010*
- *Health Practitioner Regulation National Law Act 2009 (Cth)*
- *Public Health Act 2005*
- *Research Involving Human Embryos and Prohibition of Human Cloning for Reproduction Act 2003*
- *Research Involving Human Embryos Act 2002* (Cth)
- *Private Health Facilities Act 1999*
- *Status of Children Act 1978.*

There have recently been several high-profile instances of regulatory failure regarding ART services in Queensland, including the alleged use of incorrect donor gametes, and the alleged use of a donor's sperm to create families that exceed the family limit as discussed in the NHMRC Guidelines.

In November 2023 the Minister for Health, Mental Health and Ambulance Services and Minister for Women publicly committed to regulating the ART industry by 2024.

The Minister also directed the Health Ombudsman, under section 81 of the *Health Ombudsman Act 2013*, to investigate health services provided by ART providers in Queensland. Recommendations from this investigation are expected to inform the development of a legislative framework.

Proposed approach

It is proposed to progress an Act to regulate ART services. This would provide a state-based framework to oversee ART providers, complementing the existing national framework and enabling Queensland Health to introduce additional requirements as necessary to regulate the industry. 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.

Queensland Health will seek to design legislation that balances an appropriate level of regulation on providers with robust protections for Queenslanders. It is also proposed that the legislative framework be designed to be flexible and 'future proofed' to the extent possible given the rapidly evolving nature of the ART industry.

As the findings of the Health Ombudsman's investigation and this consultation process are expected to inform the development of legislation, the proposed approach to issues outlined below, is subject to change.

Establishment of a donor conception register

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

As outlined below in Information requirements, it is proposed to include requirements in the ART Act for ART providers to collect and keep information relating to ART treatments, including donor information. This will support the establishment of a donor conception register.

Out of scope

This paper is intended to seek feedback on the regulation of ART services in Queensland.

Table 2 outlines the items that are out of scope for the purposes of this consultation paper and corresponding regulatory design process:

Table 2: Items out of scope

Issue	Reason
Surrogacy	Surrogacy policies and procedures are regulated by the *Surrogacy Act 2010*.
Research	Research is covered by the *Research Involving Human Embryos and Prohibition of Human Cloning for Reproduction Act 2003*.
Affordability and accessibility of ART services	ART services are provided by private providers in Queensland. The cost and accessibility of services is not in scope for regulation. The Queensland Government is developing a Queensland Women and Girls' Health Strategy 2032 with a strong focus on increasing access to health services for women and girls.
National regulation and national donor conception register	This is a matter for the Commonwealth Government's consideration and is not in scope for the ART Act.
Regulation of donor websites, groups, apps and other informal arrangements	Queensland Health is aware of the issues regarding informal arrangements. The focus of this paper and potential legislation is on accredited ART providers.

A Queensland ART Act

Overview

There is no dedicated legislation in Queensland regulating ART services. Queensland relies solely on self-regulation via the national framework.

Jurisdictional overview

Most states and territories have implemented or are progressing legislation to regulate ART services above the national framework. While regulatory models differ to some degree between jurisdictions, they consist of primary legislation, supported by subordinate legislation and/or conditions.

Purpose

The purpose of ART legislation in states and territories is generally to protect the welfare and interests of those involved in ART, regulate provision of ART services and research, provide greater oversight, transparency and safeguards and prohibit unacceptable ART procedures such as the commercialisation of human reproduction.

Principles

Some jurisdictions have incorporated principles of the NHMRC Guidelines in the guiding principles of their legislation.

These include ensuring the welfare and interests of the person born are paramount, the protection of the health and wellbeing of all involved, informed consent, prevention of discrimination and respect of differing ethical, spiritual and cultural perspectives.

Proposed approach

If Queensland was to take a similar approach to most other jurisdictions and introduce ART legislation, guiding principles of the legislation could include a focus on:

- the health and wellbeing of people accessing ART;
- the rights of donor-conceived people;
- ensuring the preservation of human rights of people involved in ART; and
- prohibiting exploitation of ART services for commercial gain.

While ART services are available for women seeking support for treatments or procedures that address fertility, ART services are equally available for any other person or couple seeking such treatment or procedures. This includes, but is not limited to men, transgender people and gender diverse people.

Questions
1. **If ART legislation is introduced in Queensland, what should the Act's guiding principles be?**
2. **How can the Act ensure that the health and wellbeing of people accessing ART and donor-conceived people are at its centre?**
3. **How could an ART Act support the culture, values and beliefs of all Queenslanders?**
4. **What are the benefits and/or risks of introducing ART legislation in Queensland?**

Accessing ART services

Overview

Accessing ART services can be a significant undertaking for many reasons. For people receiving ART treatment, it can bring about life-changing benefits associated with starting a family or preserving a person's ability to start a family. For donors, it can provide significant satisfaction with helping other people to start their family.

However, ART treatment can be costly and time consuming, and success is not guaranteed. There are many things that people need to consider before accessing treatment. Similarly, while in the past people may have donated sperm on the basis of remaining anonymous, times have changed. DNA testing is readily available, and in other jurisdictions donor-conceived people have a right to access information about their genetic origins.

People will also have their own personal values and ethical factors to consider, and there are a wide range of views in the community.

It is therefore important that people make a properly informed choice. Both the NHMRC Guidelines and other jurisdictions' legislation set out requirements that must be met before a person can access ART treatment or to donate material for use in ART. This can include requirements about the provision of information and counselling, and consent requirements. Some also regulate access to ART treatment from a clinical perspective.

Jurisdictional overview

Eligibility for ART treatment

In some jurisdictions, people are only able to access ART treatment if they meet criteria specified in legislation. This is typically focused on the person being unlikely or unable to become pregnant, carry a pregnancy or give birth other than with the assistance of ART treatment; if there is a medical risk (such as the risk of transmitting a genetic condition or abnormality if a child is conceived naturally); or if the treatment is part of a lawful surrogacy arrangement.

The NHMRC Guidelines state that processes and policies for determining an individual or couple's eligibility to access ART services must be just, equitable, transparent and respectful of human dignity and the natural human rights of all persons, including the right to not be unlawfully or unreasonably discriminated against.

The NHMRC Guidelines also emphasise the importance of clinical practice that is supported by evidence, and minimising the use of procedures not supported by evidence of successful clinical outcomes. The NHMRC Guidelines state that clinics should have specific policies about access to and eligibility for treatment, but do not discuss what potential factors should be considered in determining eligibility.

Provision of information

The NHMRC Guidelines set out a range of requirements for clinics to provide and discuss information with individuals and couples considering involvement in ART services. Some of

the information that should be discussed, at a minimum, includes the nature of the treatment; the experience of the clinic and clinician with the treatment; costs for all parties; privacy and record keeping policies; and participation in research.

The NHMRC Guidelines also set out specific information that should be given to people in different circumstances, namely individuals and couples:

- undergoing ART
- involved in donor conception programs
- seeking to store gametes or embryos
- seeking ART overseas.

With the exception of South Australia, all other jurisdictions that regulate ART have specific provisions about the giving of information to people prior to their involvement in ART services, with content broadly similar to the NHMRC Guidelines. Jurisdictions with donor registers include specific requirements to provide information about the register to people access donor conception services. Some jurisdictions include all requirements in primary legislation, and some include a mix of requirements in primary and subordinate legislation.

There are a range of genetic tests available for some common inherited conditions, such as Fragile X Syndrome; Spinal Muscular Atrophy and Cystic Fibrosis. In donor conception programs, consideration could be given to whether the outcomes of any such tests performed on the donor be required to be communicated to the person undergoing treatment.

Counselling

In addition to the provision of information, the availability of counselling is an important feature of most people's ART experience. ART involves significant and complex decisions, and professional counsellors can help to support people in their decision-making process.

The NHMRC Guidelines require clinics to provide accessible counselling services and actively encourage participation. Counselling should be provided by professionals with appropriate training, skills, experience and competency. Generally, the NHMRC Guidelines provide that counselling should provide an opportunity to discuss and explore issues; explore personal and social implications for the individual, couple and person to be born; provide personal and emotional support and advice about additional supports. They also provide unique considerations relating to counselling for individuals and couples involved in donor conception programs.

The need for counselling to be available features in all jurisdictions that regulate ART, with the exception of South Australia. Jurisdictions differ in their approaches to whether counselling is mandatory. In New South Wales, the legislation explicitly does not require people to undergo counselling, but it must be made available. Matters to be discussed in counselling are often prescribed in subordinate legislation and include similar matters to those considered in the NHMRC guidelines.

Consent

Given the significance of a person's involvement in ART treatment or donor conception programs and the potential outcomes, the need for that person to give their proper and informed consent is well-recognised.

The NHMRC Guidelines state that 'the process of obtaining consent for ART activities is ongoing and not a single event'. The NHMRC Guidelines focus on the person's capacity to consent; ensuring the absence of undue pressure; ensuring information and counselling requirements have been met; and the consent being specific to the treatment or procedure. For individuals and couples in donor conception programs, the NHMRC Guidelines require consent to include a range of extra factors including specific consent from the donor for information to be made available to the recipients and any person born as a result of the donation and acknowledgement of the decision-making responsibilities of each party. The NHMRC Guidelines also expressly recognise that individuals and couples have the right to withdraw or vary their consent for ART activities.

Most jurisdictions regulate consent to a relatively high level of detail, covering factors such as the person to whom consent is given; requirements for the form of consent (for example, in writing); and what must be included in the consent, such as the number of families donated gametes will be used for; verifying the identity of the person giving consent; and record-keeping obligations for consent documents. Most also have specific provisions about the modification or withdrawal of consent.

Proposed approach

A Queensland Act will likely include requirements for providers to meet before lawfully being able to provide ART services to a person or allow a person to participate in any donor conception program. It is expected that these requirements would be broadly consistent with practices in other jurisdictions and cover matters like consent; provision of information and counselling.

At this early stage, Queensland Health has not identified any compelling reasons to regulate eligibility for ART treatment beyond what is already accepted clinical practice. Given the barriers to accessing ART services such as cost, it is unlikely that people would seek to access ART in lieu of other methods of starting a family.

Questions
5. Is there a need for Queensland to provide criteria for ART eligibility in legislation?
6. Should counselling before receiving ART treatment be mandatory in Queensland?
7. Should counselling before being involved in donor conception practices be mandatory in Queensland?
8. Are there any other things that should be required before a person accesses ART treatment or participates in a donor conception program?

Use of gametes and embryos

Overview

The gametes used in ART treatment can either be provided by the person receiving treatment, their spouse or partner, or provided by a donor or donors.

Regulating the use of gametes and embryos ensures clinical best practice is maintained and the rights of donors, people accessing ART and donor-conceived persons are upheld in ART treatments. Regulation can also provide greater oversight, transparency and safeguards for the management of any issues or adverse events that may occur.

Queensland legislation already prohibits several practices that involve gametes and embryos more broadly such as prohibiting:

- creating a human embryo by fertilisation that contains genetic material provided by more than 2 persons;
- commercial trading in eggs, sperm or embryos; and
- embryos being developed outside a person's body for more than 14 days.

Jurisdictional overview

The NHMRC Guidelines outline ethical standards and procedures for using gametes and embryos in ART services. This includes ensuring the donor's wishes are respected when using their donated gametes, that the impacts on the parties involved in ART services are considered when using gametes and embryos, as well as storage, transferals and disposal of gametes and embryos.

Most jurisdictions have enshrined the clinical and ethical best practice requirements for using gametes and embryos in legislation. Table 3 provides more detail.

Table 3: Jurisdictional overview regarding use of gametes and embryos

Key provisions adopted by other jurisdictions	
Prohibited uses of gametes and embryos	• ART providers must not provide treatment to a child or obtain a gamete from a child (except for certain exceptional circumstances such as preserving the future fertility of a child). • ART providers cannot create embryos from gametes derived from close family relatives. • Gametes cannot be donated anonymously. • Commercial trading of gametes and embryos is prohibited.[1] • Sex selection is prohibited in ART services (except for certain exceptional circumstances such as avoiding risk of transmission of a genetic abnormality or disease). • Procedures are prohibited where sperm is produced by more than one person or eggs produced by more than one person.[2] This is to prevent gametes being mixed in a way that allows the genetic origins of the person born to be uncertain.

[1] *Research Involving Human Embryos and Prohibition of Human Cloning for Reproduction Act 2003*, section 17 prohibits commercial trading of human eggs and embryos.

[2] *Research Involving Human Embryos and Prohibition of Human Cloning for Reproduction Act 2003, section 9* prohibits the use of gametes by more than two persons in fertilisation procedures.

	• Embryos cannot be created outside a body of a person without the donor's approval.[3] • ART providers must not use donated gametes obtained more than five years before the ART treatment unless reasonable steps have been taken to determine if donor is still alive. • Some jurisdictions require the ART provider to obtain written approval from the Director-General of the health department to use donated gametes and embryos that were obtained more than 15 years before the ART treatment occurs.
Family limit on donated gametes	• Since the NHMRC Guidelines were developed in 2004, there has been a limit how many families could be created from the same donor. While the NHMRC Guidelines do not set an exact limit, they note that clinics must take all reasonable steps to minimise the number of families created through donated gamete treatment programs and lists a range of factors to be considered by ART providers when deciding what an appropriate family limit is. • All jurisdictions that regulate ART specify family limits by either the number of families created from the same donor or the number of people having children from the same donor. This distinction is relevant given the different outcomes it creates in some situations. For example, a same-sex couple who are both birth parents in a family unit using a sperm donor would constitute one family unit. If the same couple have a child each to the same donor, this will count as two people, if the people limit is used. • Jurisdictions have the following family limits: – Vic prohibits ART providers from performing a procedure if they know it may result in more than 10 people having children who are genetic siblings. – NSW prohibits ART providers conducting ART treatments if it is likely to result in offspring to more than five people. – ACT's Bill prohibits ART providers conducting ART treatments if five or more families will be created in the ACT or 10 or more families created in Australia to the same donor. – In SA, it is a condition of registration that ART providers must ensure the numbers of families created from a single donor is limited to 10. – In WA, ART providers must ensure there are no more than five recipient families for each donor that they know of unless approved by the Reproductive Technology Council. This includes people outside of WA.
Storage - time limits, export and removal	• ART providers may store gametes and embryos only with written consent of the gamete provider(s). Consent addresses storage duration, use, and disposal in the case of death, loss of capacity, withdrawal of consent, and lack of further instructions at storage expiration. • Regulation regarding storage time limits varies between jurisdictions, from: – 5-15 years for embryos for later transfer

[3] *Research Involving Human Embryos and Prohibition of Human Cloning for Reproduction Act 2003* section 10 prohibits the development of an embryo outside the body of a person for more than 14 days.

  - 10-15 years for gametes
  - 20 years or until the person becomes and adult and provides instructions, for gametes obtained from a child for exceptional circumstances such as for the purposes of fertility preservation.
- Some jurisdictions include the ability to apply for storage extensions of gametes and embryos to a Board, panel, secretary or Director-General. What is eligible for an extension varies between jurisdictions from donated gametes and embryos or just embryos or eggs undergoing fertilisation.
- A gamete or embryo cannot be exported from its original jurisdiction without the gamete provider's consent.
- Some jurisdictions legislate that gametes and embryos can only be removed from storage to be used in a treatment procedure or with the consent of all those involved. ART providers disposing of gametes or embryos without consent must make reasonable attempts to notify all responsible parties.
- ART providers must keep records on storage, including consent, duration, removal, storage vessel age as well as donor identities, biological parentage (for embryos), and ultimate recipients.

Proposed approach

A Queensland ART Act will likely include requirements for how gametes and embryos may be used in ART services. It is expected that these requirements would be broadly consistent with practices in other jurisdictions as outlined above.

It is not proposed to duplicate existing provisions under the *Research Involving Human Embryos and Prohibition of Human Cloning for Reproduction Act 2003* that regulate the use of gametes and embryos more broadly.

Questions

9. **Are there any concerns with Queensland adopting similar requirements to other jurisdictions about how gametes and embryos may be used?**
10. **Should the family limit in Queensland be regulated by family or by person? What should that limit be?**
11. **What should the storage time limit be for gametes and embryos? What other requirements should be included in relation to storage?**
12. **Are there any other requirements that should be included in legislation?**

Posthumous and ante-mortem retrieval and use of gametes

Overview

Some couples face the extremely challenging situation where one person dies unexpectedly before the couple have had the opportunity to have children. ART services have the potential

to provide significant benefits in these situations. Gametes that are retrieved from a deceased or dying person in a timely manner can be used in ART procedures to assist the surviving partner to become pregnant; to form an embryo (for example, for later implantation in a surrogate) or for storage.

This is a complex area with significant ethical issues that need to be considered.

In Queensland, the *Transplantation and Anatomy Act 1979* allows for the posthumous retrieval of tissue, including gametes. Part 3 of the Act requires that the next of kin of the deceased person consent to the removal of tissue from the deceased person's body for transplanting into the body of a living person or for other therapeutic purposes, medical or scientific purposes; and it appears to a designated officer for the hospital, after making reasonable inquiries, that the deceased person had not expressed an objection to the removal after death. These provisions cover all types of tissue and are not specific to gametes.

The Transplantation and Anatomy Act also allows for donations of regenerative tissue by living donors. It specifically excludes foetal tissue, spermatozoa and ova, and requires the donor to give consent in writing in the presence of a designated officer. This precludes the retrieval of gametes from an unresponsive person before they die (referred to as ante-mortem retrieval).

Jurisdictional overview

The NHMRC Guidelines state that clinics may facilitate the collection of gametes from a person who is dying if the person has the capacity to provide valid consent, and consents to the storage of their gametes after death.

The NHMRC Guidelines also state that due to the ethical considerations involved, retrieval of gametes from a person who is deceased or dying and lacks the capacity to provide valid consent needs court authority. With appropriate legal authority, a clinic could proceed if the request to do so is from the spouse or partner of the person and the gametes are for their use for reproduction; and that there is evidence that the person would have supported the posthumous use of their gametes (or at least there is no evidence that they were against it).

The NHMRC Guidelines also advise that clinics should not attempt conception or a pregnancy using the gametes or embryos unless:

- sufficient time has passed so that grief does not interfere with decision-making;
- the surviving parent receives sufficient information to facilitate an accurate understanding of the potential implications for the person born;
- the surviving parent receives counselling; and
- an independent body has reviewed the circumstances and supports the proposed use.

Finally, the NHMRC Guidelines provide that gametes collected from a child or young person for fertility preservation should only be used posthumously if the person reached adulthood before their death.

Other Australian jurisdictions have similar provisions to Queensland's Transplantation and Anatomy Act in their respective legislation. However, the regulatory approach to the posthumous use of gametes is not uniform.. WA has a blanket ban on the posthumous use of

gametes, and SA's Act only allows for use when the semen was collected before the person died. It does not contemplate the use of material other than semen.

In the other jurisdictions that allow posthumous use, the requirements are broadly consistent with the NHMRC Guidelines. The consent of the person to the use after their death is a consistent requirement. In some jurisdictions a court order can be obtained to use gametes in the absence of prior consent from the deceased person. Counselling requirements also feature in some jurisdictions – in Victoria, the woman receiving the gametes must undergo counselling about the grieving process and the possible impact on the child to be born prior to receiving treatment. Some jurisdictions also require the approval of an expert panel or advisory group.

Ante-mortem retrieval of gametes from an unresponsive person is not specifically covered by any jurisdictions' legislation.

Proposed approach

Queensland's legislation already allows for the retrieval of tissue from a person who has died. There may, however, be benefit in providing for specific requirements regarding the postmoretem retrivial of gametes and the postmortem use of when the tissue to be retrieved is intended to be used in ART treatment. This could include more specific provisions regarding the consent or wishes of the person before their death; the consent of the person receiving ART treatment; or the need for counselling. This would potentially ensure greater certainty for people during a very challenging period, and ensure that any issues or adverse events are minimised.

The retrieval of gametes from a person who is unresponsive and who has not consented to the retrieval at an earlier date is not something that is currently provided for in Queensland's legislation. While these situations are relatively rare, there may be benefit in providing for a process for this to occur.

Questions

13. **Are the existing provisions for posthumous retrieval of tissue in the *Transplantation and Anatomy Act 1978* adequate? Should there be specific provision regarding posthumous retrieval of gametes in any new ART legislation?**
14. **How should the posthumous use of a person's gametes be regulated?**
15. **Should any new ART legislation provide for the ante-mortem retrieval of gametes from an unresponsive person?**

Licensing of ART providers

Overview

As outlined above, ART providers are required to be accredited by RTAC and comply with the Code of Practice and NHMRC Guidelines, but compliance with these documents is not required by law. The NHMRC Guidelines provide an overarching framework for the conduct of

ART in clinical practice and research and were intended to be read in conjunction with federal and state or territory legislation. The Code of Practice provides a framework and sets criteria against which ART providers are audited.

Queensland does not currently regulate ART services or providers. This means that there is limited transparency about whether providers are complying with the NHMRC Guidelines and Code of Practice and no ability for Queensland Health to ensure compliance. An additional requirement for ART providers to comply with state-based legislation, and particularly a licensing requirement, would ensure that Queensland Health has the mechanisms available to regulate ART services, providing greater oversight, transparency and safeguards for the management of any issues or adverse events that may occur and giving ART patients and the community confidence in Queensland's ART industry.

Jurisdictional overview

A key feature of the ART legislation in other jurisdictions is a registration or licensing scheme. In each jurisdiction, it is an offence to provide ART services without being a registered ART provider. Significant penalties apply for breaching this requirement, including imprisonment and substantial fines. Some of the key features of the registration or licensing schemes in other jurisdictions are outlined below.

Table 4: Jurisdictional overview of the registration of ART providers

Jurisdictional overview of ART registration and licensing schemes	
Eligibility	• To be eligible for a licence or registration as an ART provider, each jurisdiction requires the applicant to be accredited by RTAC. Some jurisdictions also require the applicant to have not been convicted of any offences under ART legislation and not have been prohibited from providing ART services, or require the decision maker to be satisfied that the applicant is a fit and proper person.
Application process	• To provide ART services, an application must be made by an ART provider to the Director-General, Minister or relevant statutory authority. • Some jurisdictions provide that if an application is in the correct form and the person meets the eligibility requirements, the application must be approved. WA's Act provides that an application is to be dealt with on its merits and may be refused or granted. • In some jurisdictions, the term of registration is five years, while in others there is no specific term or the registration or licence continues unless terminated or suspended. • The Acts in most jurisdictions provide for a fee to be prescribed for an application. In NSW, the application fee for registration is currently $3207 and the annual renewal fee is $2270.
Conditions	• Requiring ART providers to be licensed at the state or territory level allows for the imposition of conditions on the licence to ensure that the provision of ART services is carried out with appropriate oversight. All jurisdictions that regulate ART provide for the ability to impose conditions, except for NSW. • General conditions imposed by other jurisdictions include that ART providers must have RTAC accreditation, comply with ART legislation and all other applicable state or territory and Commonwealth laws, provide information and documents as necessary, maintain appropriate records,

	allow authorised officers to enter premises to carry out inspections, and provide written notice of incidents (for example, Victoria requires providers to give written notice to the relevant statutory authority of any actual or potential contravention of the legislation, actual or potential breach of the conditions, any incident reported to RTAC and any contravention of the Act's guiding principles). • Some jurisdictions also provide for specific conditions to be imposed on a particular provider (for example, to limit the scope of services a provider may offer).
Consequences of contravention	• Where an ART provider contravenes a condition of their registration or licence, a range of consequences can apply, ranging from varying conditions, issuing an improvement notice, to suspension or cancellation of the licence or registration. • Some jurisdictions also allow the Director-General to prohibit a person from carrying on a business that provides ART services where there are reasonable grounds to do so, for example where the person has contravened the Act or had their RTAC accreditation refused or cancelled. • In a number of jurisdictions, a decision in relation to an ART provider's application or licence/registration may be reviewed by the relevant state or territory administrative tribunal or appealed to the Supreme Court.
Notification requirements	• A number of jurisdictions require ART providers to notify the relevant authority of particular events, including the provider no longer holding RTAC accreditation, ceasing to provide ART services or changing premises. Failure to notify the relevant authority is an offence.
Register of ART providers	• A register of ART providers is required to be kept (by the Department of Health, Minister or relevant statutory authority) in most jurisdictions. The register is required to be available for inspection by the public.
Inspector powers	• Inspectors can be appointed in other jurisdictions to support their registration and licensing schemes. • These inspectors have a range of powers to maintain oversight of ART providers and support compliance with the legislation, including powers to enter and inspect premises, take and remove things for analysis, inspect and make copies of records, and require persons to answer questions. • In each jurisdiction, offence provisions are included to ensure that appropriate records are kept and that inspectors are not hindered in undertaking their compliance role. This includes offences for destruction or falsification of ART records or documents, obstructing or hindering an inspector, or making false or misleading representations.

Proposed approach

It is proposed to establish a licensing scheme for ART providers in Queensland, requiring providers to be licensed with the Director-General of Queensland Health. This would ensure improved protections for Queenslanders by providing a state-based framework to oversee ART providers that would complement the existing national framework and providing greater transparency and safeguards. Providing for the licensing scheme to be administered by the Director-General of Queensland Health is consistent with the approach taken in several jurisdictions that regulate ART. Queensland Health is already responsible for managing

compliance with a number of licensing schemes, including under the *Tobacco and Other Smoking Products Act 1998*, *Radiation Safety Act 1999* and *Private Health Facilities Act 1999*.

To be eligible as a licensed ART provider, it should be a requirement that the provider is accredited with RTAC. It could additionally be required that the provider has not been convicted or found guilty of an offence against ART legislation or that the Director-General considers them a fit and proper provider for the purposes of the Act.

An application fee would likely be imposed to assist with cost recovery for administering the scheme. The fees will need to be considered further, but would likely be in line with the fees prescribed in other jurisdictions and for other licensing schemes.

Similar to other jurisdictions, the Act could provide the Director-General with the ability to impose conditions on an ART provider's licence. This could include general conditions such as compliance with ART legislation and other applicable state and Commonwealth laws, maintaining RTAC accreditation, and requirements for ART providers to provide information to the Director-General as required and to give written notice of incidents. The Act could also enable the Director-General to impose further specific conditions if deemed necessary, for example, to mitigate particular risks or where there are health and safety concerns with a particular provider.

To ensure compliance with the conditions of the licence and other requirements under the Act, the Act could provide for a range of measures including variation of conditions, the issuing of improvement notices, or suspension or cancellation of a licence where necessary. Further consideration will be given to these measures, and to an appropriate mechanism for an applicant or licence holder to seek a review of a decision.

A requirement could be included for ART providers to notify the Director-General of particular events, including ceasing to hold RTAC accreditation, ceasing to provide ART services and changing premises. This would ensure that Queensland Health is notified in a timely fashion of key events. The Act could also provide for a register of ART providers to be kept by the Director-General and made available for inspection by the public.

The legislation could include the ability for the Director-General to appoint inspectors to monitor and enforce compliance with the Act, including by providing them with powers to enter and inspect premises where ART services are being carried out. This would be consistent with a range of other legislation administered by Queensland Health. Offence provisions could be included in the Act to ensure that appropriate records are kept by providers and that inspectors are not hindered in undertaking their compliance role. This could include offences for destruction or falsification of ART records or documents, obstructing or hindering an inspector, and making false or misleading representations.

Questions

16. **Do you think a state-based licensing system is needed? Why or why not?**
17. **Are there particular features of registration or licensing schemes in other jurisdictions that Queensland should adopt or avoid?**
18. **What do you anticipate will be the impact on ART providers of a new licensing system?**

Information requirements

Overview

ART providers are an important repository of information about ART treatments, patients and results. This includes but is not limited to information relating to donor conception arrangements.

The NHMRC Guidelines note that record-keeping and data reporting are an integral part of the clinical practice of ART and that clinics have a duty of care to all parties to ensure appropriate maintenance of records and data. The NHMRC Guidelines set out requirements for the maintenance of records, including that clinics must have appropriate policies and procedures for the collection, storage and release of data related to ART activities; procedures for record keeping; and the minimum information that should be recorded for each ART activity.

The NHMRC Guidelines also specifically address the exchange of information between parties where donated gametes have been used. The NHMRC Guidelines provide that donor-conceived people are entitled to know the details of their genetic origins and prohibit ART providers from using gametes in reproductive procedures unless the donor has consented to the release of their identifying information to any person born as a result of their donation. This prohibition has been in place since 2004.

Jurisdictional overview

As noted above, some jurisdictions that regulate ART include conditions on an ART provider's licence or registration, including that relevant information or documents be provided to the relevant authority and that appropriate records be maintained. In each jurisdiction, there are offence provisions such as destruction or falsification of ART records or documents, obstructing or hindering an inspector, and making false or misleading representations, to ensure that appropriate records are kept.

Donor conception registers have been established in other jurisdictions to provide donor-conceived people with the right to access information about their donor and genetic origins. To support the register, provisions are included in the ART legislation in these jurisdictions about collection of and access to information.

Proposed approach

To ensure appropriate information is collected and kept by ART providers and to support the establishment of a donor conception register in Queensland, the Act should include the information requirements set out in Table 5.

Queensland has committed to the establishment of a donor conception register and it is likely that requirements to provide information to that register will form part of the Act's information requirements.

Table 5: Jurisdictional overview of information requirements

Jurisdictional overview of information requirements	
Collection of information by ART providers	• Requirement for ART providers to collect information about gamete providers, including full name, contact details, and date of birth. For donated gametes, further information must be collected such as the donor's place of birth and relevant medical history. This information must be collected before the gamete is used or an embryo created from the gamete. • Requirement for ART providers to collect information about a person undergoing ART treatment, including full name, contact details and date of birth. • For ART treatment involving use of donated gametes, additional requirement for ART provider to take reasonable steps to ascertain whether a pregnancy and/or birth resulted from the treatment. If a child was born as a result of an ART treatment using a donated gamete, the ART provider must also take reasonable steps to ascertain the child's full name, sex and date of birth. • Failure to comply with these requirements will be an offence.
Retention of information by ART providers	• Requirement for ART providers to keep records, including relating to each gamete or embryo in its possession, each person who receives ART treatment from the ART provider, and each person born as a result of ART treatment provided. • ART providers should be required to keep ART records for a defined number of years. In other jurisdictions, the retention period ranges from 50 to 99 years. • Requirement for retention of pre-commencement records. This will ensure that ART providers are required to retain records about ART services that occurred before Queensland's ART legislation commences. • Requirement for an ART provider to transfer records to another registered ART provider if intending to cease operating. • Failure to comply with these requirements will be an offence.
Destruction of records	• Offence to knowingly falsify or destroy a record, including records required to be kept under the Act and pre-commencement records.
Disclosure of medical information if necessary	• Provision allowing ART providers to disclose medical information about a donor or a donor-conceived person if a registered medical practitioner has certified in writing that it is necessary to make the disclosure to prevent or reduce a serious risk to someone's life or health or to warn about the existence of a medical condition that may be harmful.
Information sharing	• Provisions should be included relating to information sharing between ART providers and information sharing between relevant government agencies.

Questions
19. Are there particular information requirements you think should or should not be included in the Act? Why?

Thank you

We would like to acknowledge and thank you for your time in considering this consultation paper and for your advice. Your views and input will help us to develop an Act that provides greater oversight of the ART industry, ensuring transparency and appropriate safeguards are in place for the protection of Queenslanders.

The key themes raised through this consultation may be referred to in a deidentified way in material provided to Government in considering the proposal and, if legislative amendments are progressed, included in Explanatory Notes for the Bill or material provided to a Parliamentary Committee.

Reference list

The following jurisdictional legislation and National Guidelines and Codes of Practice were drawn on extensively to inform this paper:

Assisted Reproductive Technology Bill 2023 (ACT)

Assisted Reproductive Technology Act 2007 (NSW)

Assisted Reproductive Treatment Act 1988 (SA)

Assisted Reproductive Treatment Act 2008 (Vic)

Human Reproductive Technology Act 1991 (WA)

Fertility society of Australia and New Zealand. (2021). *Code of Practice for Assisted Reproductive Technology Units.* https://www.fertilitysociety.com.au/code-of-practice/#copanz

National Health and Medical Research Council (NHMRC). (2017). *Ethical guidelines on the use of assisted reproductive technology in clinical practice and research 2017.* *https://www.nhmrc.gov.au/about-us/publications/art*

---

[i] Australian Institute of Health and Welfare (AIHW). (2022). *Preliminary data tables: National Perinatal Data Collection annual update 2022.* *https://www.aihw.gov.au/reports-data/population-groups/mothers-babies/data*

[ii] Fertility Society of Australia and New Zealand. (2023). *RTAC CoP.* https://www.fertilitysociety.com.au/code-of-practice/

[iii] National Health and Medical Research Council. (2023). *Ethical guidelines on the use of assisted reproductive technology in clinical practice and research 2017.*