

Review of assisted reproductive treatment

Consultation paper – Mr Michael Gorton AM

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Foreword

It is 40 years since the first in vitro fertilisation (IVF) child, Louise Brown, was born in the United Kingdom. Victoria followed two years later with the birth of Candice Reed, the first Australian IVF child, born in Melbourne.

Victoria created its ‘first in the world’ legislation regulating assisted reproductive treatment in 1984, with substantial revisions to the legislation in 1995 and 2008.

It is now a decade on since the last significant review of assisted reproductive treatment regulation in Victoria, and it is timely to reflect on the significant changes that have occurred since then, including:

- changes to the number, ownership and management of assisted reproductive treatment clinics from the clinician-owned and led clinics originally established in Victoria
- great advances in treatments and technology for IVF and related procedures
- changes to social values and opinions, including changes to legislative rights and responsibilities, changes to the *Marriage Act* for same-sex marriage and other changes dealing with gender and sexuality.

I acknowledge that many Victorians have been assisted by assisted reproductive treatment to have families, and the great joy it brings.

Assisted reproductive treatment offers many benefits, and it is important that it is not inappropriately limited by people’s ability to pay or by where they live, nor affected by inadequate knowledge or information, or by discrimination according to gender, sexuality, identity, race or other attributes.

It is also important to provide choice for those seeking or needing assisted reproductive treatment to commence or continue a family – but choices should be based on clear, honest information about risks, chances of success and cost.

This review offers the opportunity to consider the issues and the challenges affecting the assisted reproductive treatment industry in Victoria and, hopefully, to suggest changes to improve services for the benefit of all Victorians who may need assisted reproductive treatment in the future.

This review is reaching out to the community, to those who have used assisted reproductive treatment, or those who have specialist knowledge, to suggest changes and recommend improvements. I invite all interested Victorians to provide information on their experience and share their views on future changes.

I am delighted to be conducting this review, and look forward to engaging with the Victorian community in relation to these important issues.

Michael Gorton AM

The review team

The review is being conducted by Michael Gorton AM, a former Chair of the Victorian Assisted Reproductive Treatment Authority and Patient Review Panel under the current assisted reproductive treatment legislation. He is a lawyer and a former Chair of the Victorian Equal Opportunity and Human Rights Commission and Chair of the Victorian Biotechnology Ethics Advisory Committee. He is currently the Chair of Alfred Health, the Chair of the Australian Health Practitioner Regulation Agency and a Board member of Ambulance Victoria and the Australasian College for Emergency Medicine.

Michael is being assisted by Emma Turner. Other members of the Review team include:

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Introduction

Victoria has long led the way in the practice and regulation of assisted reproductive treatment. Australia's first in vitro fertilisation (IVF) baby, and the world's third, was born at Melbourne's Royal Women's Hospital in 1980. In 1984, Victoria became the first jurisdiction in the world to enact legislation regulating assisted reproductive treatment.

Much has changed in the assisted reproductive field since those pioneering days. Now more than 12,000 people undertake some form of assisted reproductive treatment each year, and by 2016, 3.8 per cent of all babies born in Victoria were conceived after some form of assisted reproductive treatment (Victorian Assisted Reproductive Treatment Authority 2017; Australian Institute of Health and Welfare 2018). That first piece of legislation – the *Infertility (Medical Procedures) Act 1984* – was replaced in 1995 with the *Infertility Treatment Act*, which itself was replaced by the *Assisted Reproductive Treatment Act* in 2008. The 2008 Act was most significant in removing legal barriers to access to same-sex and unmarried couples. In 2016, amendments to the Act enshrined the right of all donor-conceived people in Victoria to access available identifying information about their donors without the necessity for donor consent.

With these amendments, the *Assisted Reproductive Treatment Act 2008* (the Act) remains in force today. While the Act has been amended to reflect particular policy directions, the legislation that establishes the regulatory framework for assisted reproductive treatment has not been substantially reviewed for over a decade.

Over that time, social attitudes to sexuality, gender and family issues have changed in significant ways, culminating symbolically in the Commonwealth Parliament legislating marriage equality in the *Marriage Amendment (Definition and Religious Freedoms) Act 2017*. The number of people using assisted reproductive treatment services in Victoria has grown by more than 30 per cent over eight years from the introduction of the Act to 2016–17 (Victorian Assisted Reproductive Treatment Authority 2017), and there have been significant advances in clinical practice and the patterns of service use – for example, growth in the number of people opting to freeze eggs to preserve fertility.

Alongside these developments, some concerns have been raised. Despite its many successes, many people undergoing costly assisted reproductive treatment never give birth to a child. The efficacy of some treatments has been challenged, and the appropriateness of providing treatment to women aged over 40 despite a low probability of success has been called into question. Many families have experienced the joy of a child conceived through in vitro fertilisation, but many others have suffered the pain, grief and enduring consequences of unsuccessful assisted reproductive treatment. Questions have also been asked about the impact of the increased commercialisation of the assisted reproductive treatment industry on patient care.

It is now timely to consider whether the Act, together with the broader regulatory framework for the provision of assisted reproductive treatment in Victoria, remains appropriate and fit for purpose given the substantial changes that have occurred in the last 10 years. In recognition of this, the Minister for Health announced on 6 April 2018 that there was to be a 12-month review of assisted reproductive treatment.

What is assisted reproductive treatment?

Assisted reproductive treatment covers a wide range of treatments used to help people to conceive a child.

This can include simple, minimally invasive techniques such as ovulation induction, or intrauterine insemination (IUI), as well as more complex treatments such as in vitro fertilisation (IVF), intracytoplasmic sperm injection (ICSI) and preimplantation genetic testing (PGT).

Assisted reproductive treatment procedures may make use of donor sperm, eggs or embryos, and can involve the use of a surrogate where necessary. See the glossary for explanations of these treatments.

People seek and make use of assisted reproductive treatment for a range of reasons, including because they are unable for any reason to conceive, carry a baby in pregnancy, or give birth without treatment, or to reduce the chance of a child inheriting a genetic condition.

Assisted reproductive treatment services are used by a diverse range of people, with a variety of sexualities, gender identities and relationship statuses.

Scope and purpose of the review

The aim of the review is to strengthen current laws to provide more safeguards and support to people accessing assisted reproductive treatment services. The full terms of reference for the review are included in Appendix 1. The review will consider if people have access to adequate information to facilitate informed choices, and as well as whether the current Victorian regulatory framework for assisted reproductive treatment:

- creates or enables unnecessary barriers to access
- contains adequate safeguards to protect people using or intending to use assisted reproductive treatment services
- remains appropriate, given the changing nature of the sector and market drivers of demand
- affects access and affordability of services.

The terms of reference note that, in the context of the *Marriage Amendment (Definition and Religious Freedoms) Act 2017*, it is timely to reconsider whether the Act creates or enables unnecessary barriers to access for LGBTI people.

Reference to these legislative reforms is not interpreted as restricting consideration of issues for LGBTI people to those affecting same-sex couples, nor to discrimination on the basis of sexuality. It is intended that the review will consider any issues of access or discrimination experienced by people with a diverse range of characteristics, including sexual orientation, gender identity and intersex status. These issues may include gendered language, awareness of LGBTI family forms and issues, and the availability of donors and/or surrogates.

While the terms of reference allow for the review to consider a range of matters that are related to those outlined above, some issues have been identified as out of scope, given the timeframe for the review or recent reforms. These matters include:

- the prohibition on selling gametes, sex selection or mixing gametes from multiple parties
- consent requirements in the Act – including safety screening requirements for those people seeking to undergo assisted reproductive treatment
- the role of the Patient Review Panel
- changes made by the *Assisted Reproductive Treatment Amendment Act 2016* that introduced the right for donor-conceived Victorians to access available identifying information about their donors, regardless of when the donation was made.

Approach and purpose of this paper

The findings and recommendations of the review will be informed by relevant data and literature, consideration of approaches in other Australian and international jurisdictions, and, most importantly through consultation with key stakeholders and interested members of the public.

This paper seeks the views of anyone with ideas, knowledge or experience relevant to the review. We want to hear about issues related to access to and the delivery of services, and how the current regulatory framework for assisted reproductive treatment can be improved.

We want to hear from experts in the field and a wide range of health practitioners – those working within registered assisted reproductive clinics and those in other areas of practice. Most of all, we want to hear from people with lived experience of assisted reproductive treatment. We want to hear from donors and surrogates. We want to hear from people who have had children through the process, and from those who have not.

This paper is intended to provide context for the review, and to encourage consideration of the broad range of issues the review might address. It does not discuss some legal, technical and medical issues in depth. Some possible reforms are mentioned to prompt discussion. They do not necessarily reflect the direction the recommendations of the review will ultimately take.

How to have your say

You can have your say by:

- completing an [online survey <https://engage.vic.gov.au/>](https://engage.vic.gov.au/) that addresses key themes of the review. The survey also includes an option to anonymously tell your personal story of your experience with assisted reproductive treatment if you wish
- making a formal submission addressing any or all of the questions posed in this paper. Submissions can be lodged via the [Engage Victoria website <https://engage.vic.gov.au/>](https://engage.vic.gov.au/) or by emailing the [review team <ART.Review@dhhs.vic.gov.au>](mailto:ART.Review@dhhs.vic.gov.au).

If you make a formal submission, please indicate if your submission is confidential and whether or not you are prepared to have your submission quoted within a report to the Minister for Health. (The report may, at the discretion of the Minister, be publicly released and/or may be subject to disclosure through freedom of information processes.)

You are welcome both to answer the survey and make a submission if you wish.

All survey responses and formal submissions must be received no later than 21 September 2018, to ensure your feedback can be considered by the review team before the interim report in October 2018.

There will be a second phase of consultation early in 2019 before the final report is delivered in April 2019.

Context of the review

This review is taking place at a time of rapid change and growth in assisted reproductive treatment service provision in Victoria, and the rest of the world.

Assisted reproductive treatment in Victoria – growth since the Act was introduced

Then (2008)	Now (2018)
6 providers across 13 locations	9 providers across 19 locations
Then (2008–09)	Now (2016–17)
17,687 treatment cycles	22,963 treatment cycles (29% increase)
Then (2008–09)	Now (2016–17)
9,262 patients treated	12,495 patients treated (35% increase)

Far from being cutting edge experimental technology, assisted reproductive treatments are now viewed as mainstream health services, with ever increasing numbers of people making use of them.

Some of this growth has been driven by changing social behaviour. People frequently opt to have children later in life, and community attitudes have evolved to recognise that children can be born into and raised in a greater diversity of family types. Some of these issues are currently being considered by the [review of the family law system](https://www.alrc.gov.au/inquiries/family-law-system) <<https://www.alrc.gov.au/inquiries/family-law-system>> being undertaken by the Australian Law Reform Commission.

The assisted reproductive treatment industry has transformed since the Act was introduced. Globally, it has been estimated that assisted reproductive treatment is now worth in excess of \$4 billion annually (Weule 2018). The market in Victoria continues to grow, with two new providers registered within the last year. Providers are looking for new opportunities to compete and expand the services they offer, and to maintain or increase their market share. Most of the registered providers in Victoria have national or global interests, and are either privately operated or publicly listed companies (Blakely et al. 2017).¹

Scientific and technical advances continue to influence and shape service provision and help drive demand further. For example, improvements in egg and embryo freezing technologies have expanded the range of treatments available and the likely success of those treatments. The effectiveness of preimplantation genetic diagnosis (PGD) and the number of genetic conditions that can be diagnosed for also continues to evolve (Victorian Assisted Reproductive Treatment Authority 2014a). In the UK, mitochondrial replacement therapy (which offers a way to ensure that children do not inherit disorders caused by mutations in mitochondria) has recently been permitted.²

Australia is among the world leaders in reducing the multiple birth rate associated with IVF treatment, while continuing to achieve improved success rates. This is recognised as an important development in

¹ In 2014, two major players in the Australian IVF market were floated on the stock market; they each raised more than \$300 million.

² This process involves replacement of the mother's mitochondrial DNA with healthy mitochondria from a donor woman during the IVF process. The resulting baby has DNA from three people – the vast majority from its parents and a very small percentage from the donor. See [Human Fertilisation and Embryology \(Mitochondrial Donation\) Regulations 2015 \(UK\)](https://www.legislation.gov.uk/ukdsi/2015/9780111125816/contents) <<https://www.legislation.gov.uk/ukdsi/2015/9780111125816/contents>>.

the safe delivery of assisted reproductive treatment (University of New South Wales 2017; Fitzgerald et al. 2017).

Yet even with all these advances, a significant proportion of individuals and couples who undergo assisted reproductive treatment will never achieve the birth of a baby (Chambers et al. 2017).

Targeting Zero, the review of hospital safety and quality assurance in Victoria, highlighted the importance of appropriate oversight and governance to support safety and quality in health service provision. Government, regulators and providers continue to seek ways to protect the health and wellbeing of service users.

This review offers an opportunity to draw on 40 years of accumulated knowledge about the effectiveness of assisted reproductive treatment, its risks and benefits, as well as the health, social and emotional consequences for participants, to ensure that the approaches to services delivery and regulation remain appropriate and responsive to the changing context.

Regulation of assisted reproductive treatment

Assisted reproductive treatment occurs within a complex and multilayered regulatory environment. Since Victoria introduced the first ever legislation to regulate assisted reproductive treatment, responsibility for the oversight of these services has shifted towards a national self-regulating accreditation model, with the states retaining specific oversight of some matters.³ Both state-based and national legislation is relevant, and a broad range of regulators and oversight bodies is involved.

Legislation

The Assisted Reproductive Treatment Act 2008

The primary legislation that regulates assisted reproductive treatment in Victoria is the *Assisted Reproductive Treatment Act 2008* (the Act). The Act establishes the Victorian Assisted Reproductive Treatment Authority (VARTA). It sets out requirements in relation to the use of assisted reproductive treatment and artificial insemination; and the keeping of records, and access to information, about treatment procedures carried out under the Act.

The Act promotes research into the incidence, causes and prevention of infertility and makes provision with respect to the use of donated gametes and surrogacy arrangements.

The Act provides for the *Assisted Reproductive Treatment Regulations 2009*, that outline requirements for counselling, consent, reimbursement of surrogates, and information that must be recorded by clinics and with donor registers.

VARTA is a statutory authority responsible for:

- registration of assisted reproductive treatment clinics
- public education about treatment procedures and the best interests of children born as a result of treatment procedures
- management of the donor conception registers and the provision of support and advice to people applying to the registers and those contacted as a result of an application
- provision of donor-linking services to consenting donor-conceived people, donors, descendants of donor-conceived people, recipients of donor treatment and relatives
- facilitation of information exchange or correspondence and assisting contact between consenting parties
- community consultation about matters relevant to the Act
- monitoring of developments, trends and activities relating to the causes and prevention of infertility and in the assisted reproductive treatment industry in Victoria, Australia and internationally
- promotion of research into the causes and prevention of infertility
- approval of the import and export of donated eggs, sperm and embryos formed from donor gametes in and out of Victoria, and to provide for the exemption from particular provisions
- any other functions conferred on it by or under this or any other Act.

³ Appendix 2 provides a detailed history of the development of state and national regulation of ART.

Other relevant Victorian legislation

The *Status of Children Act 1974* outlines provision for parentage in relation to the use of donor treatment, surrogacy and the posthumous use of gametes. The *Births, Deaths and Marriages Registration Act 1996* outlines the requirements for birth registration of a child conceived as the result of a donor treatment procedure or surrogacy arrangements. The *Human Tissue Act 1982* prohibits unauthorised buying or selling of human tissue, this includes eggs, sperm and embryos.

Assisted reproductive treatment research in Victoria is regulated by:

- the *Research Involving Human Embryos Act 2008*, which regulates the use of embryos for research purposes and licensing of embryo research
- the *Prohibition of Human Cloning for Reproduction Act 2008*, which outlines practices that are completely prohibited in Victoria (such as commercial trading in human eggs, human sperm or human embryos); and that are prohibited unless authorised by a licence.

In addition, the *Equal Opportunity Act 2010* is relevant to discrimination against people seeking to use services. The *Health Practitioner Regulation National Law (Victoria) 2009* and the *Health Complaints Act 2016* are also relevant where there are concerns about services provided by registered practitioners or health service providers.

Relevant Commonwealth legislation

The two Victorian Acts that regulate assisted reproductive treatment research mirror Commonwealth Acts of the same name. In addition, the *Family Law Act 1975* (Cth) is the Commonwealth legislation relating to parentage of children born of donor procedures or through surrogacy arrangements.

The *Sex Discrimination Act 1984* (Cth) is relevant to discrimination in the provision of services. The *Australian Citizenship Act 2007* (Cth) may be relevant to Victorians entering into overseas surrogacy arrangements; and the *Competition and Consumer Act 2010* (Cth), in particular the Australian Consumer Law, is relevant to the advertising and promotion of assisted reproductive treatment services.

Guidelines and code of practice

The National Health and Medical Research Council (NHMRC) develops guidelines that form the basis of the regulation of assisted reproductive treatment at a national level. The guidelines – the *Ethical guidelines on the use of assisted reproductive technology in clinical practice and research* – were most recently updated in 2017 (NHMRC 2017).

The Reproductive Technology Accreditation Committee (RTAC), established by the Fertility Society of Australia,⁴ issues the *Code of Practice for assisted reproductive technology units* (RTAC 2017). This is the standard against which assisted reproductive treatment units in Australia and New Zealand are audited. The code was most recently updated in 2017.

Accreditation and registration of providers

Australian providers of assisted reproductive treatment operate within a national self-regulatory scheme to ensure appropriate clinical and commercial practices are adhered to.

Accreditation by RTAC is required for assisted reproductive treatment clinical practice in Australia. Accreditation requires clinics to comply with relevant state and national laws, the NHMRC guidelines and the RTAC *Code of Practice*. Accreditation assessment is undertaken by accredited certification bodies.

Under the Act, in order to provide assisted reproductive treatment in Victoria, a provider must be registered by VARTA. VARTA is required by the Act to grant an application for registration to a person who holds RTAC accreditation. VARTA may impose conditions on that registration if they are not

⁴ The Fertility Society of Australia is the peak body representing scientists, doctors, researchers, nurses, consumers and counsellors in reproductive medicine in Australia and New Zealand.

consistent with the RTAC accreditation, and VARTA considers it in the public interest to do so (ss. 74–75).

Relevant regulators and other organisations

In addition to VARTA and RTAC, a range of other bodies play a role in relation to the regulation or oversight of assisted reproductive treatment. These include:

- the Patient Review Panel, established under s. 82 of the Act to consider applications by people who wish to access assisted reproductive treatment where the Act requires they have permission to do so. This includes hearing applications in relation to surrogacy arrangements, posthumous use of gametes and embryos, issues related to the ongoing storage of gametes and embryos, the use of PGD for the purpose of sex selection, and where there is a presumption against treatment on the basis of the results of a criminal record check or a child protection check
- the Australian Health Practitioner Regulation Agency (AHPRA) and national boards that are responsible for registering health practitioners, managing notifications (complaints) about practitioners and taking disciplinary action to protect the public when required
- the Health Complaints Commissioner, who, under the *Health Complaints Act 2016*, is responsible for receiving, resolving and investigating complaints about health services, including health service providers not required to be registered under the Health Practitioner Regulation National Law
- the Australian Competition and Consumer Commission (ACCC) and Consumer Affairs Victoria (CAV). These organisations have a role to play investigating breaches of the national consumer law, including matters related to false or misleading representation.

Resourcing of assisted reproductive treatment

In Australia, assisted reproductive treatment is almost exclusively provided on a private basis. In contrast, a number of European countries provide assisted reproductive treatment either exclusively or in part through public clinics (Keene et al. 2017).

There is, however, subsidy available through Medicare. Medicare rebates are payable, to eligible persons, to cover part of the costs associated with a range of assisted reproductive treatments. The costs associated with most significant treatments, such as IVF, will mean that a person reaches the threshold for the Extended Medicare Safety Net, so becomes eligible for higher reimbursements for second and subsequent cycles within a given calendar year. However, there is a cap on the rebate that can be paid for IVF services under the safety net.

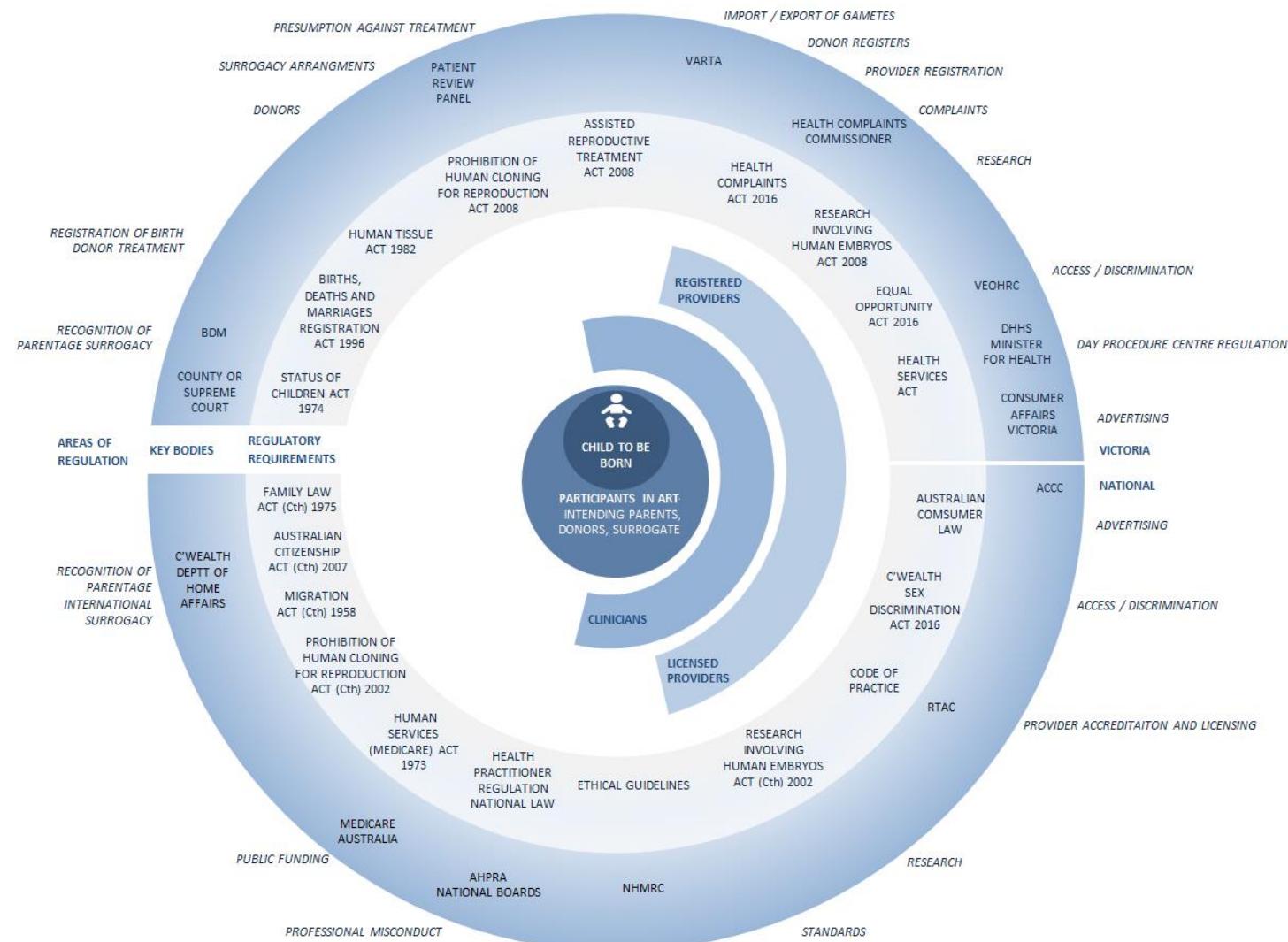
Eligibility for Medicare rebates is restricted to people who have a diagnosis of medical infertility. Without such a diagnosis, the cost of treatment is not eligible for any public reimbursement and the person receiving treatment must pay all expenses out of pocket. For those requiring donor treatment, Medicare rebates are payable, for example, for services associated with the donation of ova only if there is an identified infertile recipient.

Medicare does not in any way subsidise surrogacy.

Private health insurance coverage can also make a contribution to the cost of some aspects of treatment, for example day surgery fees associated with egg collection, anaesthetist fees or medication not covered by the Pharmaceutical Benefits Scheme (PBS).

Figure 1, over page, depicts the regulatory environment in which assisted reproductive treatment occurs in Victoria.

Figure 1: Regulatory environment for assisted reproductive treatment in Victoria



Principles and objectives

The terms of reference for the review require that the guiding principles of the Act be observed in the conduct of the review.

Guiding principles of the Act (s. 5)

- (a) the welfare and interests of persons born or to be born as a result of treatment procedures are paramount;
- (b) at no time should the use of treatment procedures be for the purpose of exploiting, in trade or otherwise—
 - (i) the reproductive capabilities of men and women; or
 - (ii) children born as a result of treatment procedures;
- (c) children born as the result of the use of donated gametes have a right to information about their genetic parents;
- (d) the health and wellbeing of persons undergoing treatment procedures must be protected at all times;
- (e) persons seeking to undergo treatment procedures must not be discriminated against on the basis of their sexual orientation, marital status, race or religion.

Building on these, and reflecting the context and purpose of the review, the following core objectives for the regulatory framework for assisted reproductive treatment have been identified. These objectives will inform consideration of issues, the findings of the review and its recommendations:

- Objective 1: Consistent with the guiding principles of the Act, **the welfare and interests of persons born or to be born as a result of assisted reproductive treatments must be paramount.**
- Objective 2: Access to, and the provision of, assisted reproductive treatment should be **fair and free from discrimination.**
- Objective 3: The regulatory framework should **protect the health and wellbeing of all participants** and guard against the exploitation of any person in assisted reproductive treatment processes.
- Objective 4: The regulatory framework for assisted reproductive treatment should **promote safe, high-quality service provision** that minimises avoidable harm to all participants.
- Objective 5: To the extent it is consistent with the other objectives, the regulatory framework for assisted reproductive treatment should be **sufficiently flexible to allow for innovation** and advances that will benefit those needing assistance to conceive a child.

The review will consider the extent to which the regulatory framework for assisted reproductive treatment supports these objectives, and whether the approach continues to be relevant and appropriate given the changing context in which service provision occurs.

Your views on the objectives of regulation for assisted reproductive treatment in Victoria

Q1. Do the objectives of the regulation for assisted reproductive treatment remain relevant to the delivery of assisted reproductive treatment in Victoria, today and into the future?

Q2. Are the interests of all participants appropriately balanced/reflected in current objectives?

Q3. Do we need more or less regulation? Why? How?

Issues for consideration

The review will consider a broad range of in-scope issues. To prompt discussion and to elicit feedback on other concerns and ideas for reform, this section outlines some of these issues and some possible approaches to address them under the broad headings of:

- access to treatment
- cost, affordability and effectiveness of assisted reproductive treatment
- access to donors and surrogates
- making informed decisions
- support during treatment and if something goes wrong.

Access to assisted reproductive treatment

Who accesses assisted reproductive treatment?

In 2016–17 a total of 12,495 patients were treated by registered assisted reproductive treatment clinics in Victoria.

Access to assisted reproductive treatment is not uniform across the community:

- there is evidence that the rate of utilisation of assisted reproductive treatment is significantly skewed towards those in higher socioeconomic groups (Harris et al. 2016)
- women in metropolitan areas of Australia have been found to use assisted reproductive treatment services 12.3 per cent more than their counterparts in regional and remote areas after other factors have been controlled for (Harris et al. 2016).

In 2016–17, 37 per cent of the women treated were aged under 35 years, 37.7 per cent were aged 35–39 years, and 25.3 per cent were over 40 years of age. This age profile has remained reasonably consistent over the last eight years.

There has been significant growth in same-sex couples accessing assisted reproductive treatment following the introduction of the Act in 2008 which removed the earlier statutory requirement that women be married or in a de facto relationship with a male to access assisted reproductive treatment in Victoria. However, reliable data in relation to the impact of this change is not readily available.

Legal rights of access

Under the Commonwealth *Sex Discrimination Act 1984* and the Victorian *Equal Opportunity Act 2010*, it is unlawful to discriminate against a person in the provision of services on the basis of sex, gender identity, intersex status, sexual orientation, marital or relationship status. This includes the provision of assisted reproductive treatment services.

The introduction of the *Assisted Reproductive Treatment Act* in 2008 removed the legal barrier to access for single women and people in same-sex relationships. However, the Act, like those at the national level and in other jurisdictions, employs terminology that reflects the time of introduction. Social attitudes and understanding of the diversity of individuals and families who may seek assisted reproductive treatment have evolved greatly over the last decade. It is, therefore, timely to consider if any terms or provisions of the legislation inadvertently discriminate against certain groups in the community.

For example:

- Section 46 of the Act allows for the posthumous use of gametes or embryos in specific circumstances where ‘the treatment procedure is carried out on (i) the deceased person’s partner; or (ii) in the case of a deceased woman by the woman’s male partner commissioning a surrogacy arrangement in accordance with Part 4’. This appears to restrict the posthumous use of gametes by people in same-sex relationships and by single women who may require a surrogate because they are unable to carry a baby themselves. It may be timely to consider whether there is an appropriate rationale for such a restriction.
- Section 10 of the Act provides that a woman may only undergo a treatment procedure if the woman and her partner, if any, have consented. The definition of partner in the Act may result in an interpretation that in the case of a couple who have separated but not yet divorced, the woman requires the consent of her estranged husband to proceed with treatment.

Social or cultural barriers to access

Just as some language and assumptions of the Act reflect attitudes and norms that may now be out of date, so too clinical practice and processes may not always have kept pace with social change. It may be that the experience of accessing services, the marketing used and the approach of staff does not align with current awareness of gender and sexual diversity, the changes in patterns of family formation and parenting, or the needs of people from diverse cultural backgrounds. For some people this could mean that, even where there are no regulatory barriers to access, the experience of approaching services may actively discourage them from making use of assisted reproductive treatment.

Ensuring fair and equal access to services requires that they be both universally welcoming and respond to individual needs or preferences. People must feel safe accessing services and efforts must be taken to ensure that any language, communication, social, cultural or physical barriers can be addressed.

A review of provider websites shows that some have made efforts to be more accessible to culturally and linguistically diverse groups through measures such as translated websites and resource materials.

Geographical barriers to access

Assisted reproductive treatment providers are predominantly located in metropolitan Melbourne.

However, there are providers based in the major regional centres of Geelong and Ballarat. Over recent years, satellite clinics have been established in a number of other areas and there are now service locations in Bendigo, Geelong, Sale and Mildura.

While these developments support access for many in rural and regional areas, there remain many people in the state who reside in areas a long way from treatment providers. This has inevitable implications for access.

Statutory restrictions

The Act also includes restrictions on people accessing assisted reproductive treatment. The Act requires that all persons seeking treatment consent to safety screening checks. There is a presumption against treatment if a person seeking treatment or their partner has been convicted of a sexual offence or a violent offence, or if a child protection order has been made in respect of them.⁵ These provisions are

⁵ The Act requires that anyone having ART procedures must undergo a criminal record check with Victoria Police (s. 11) and a child protection order check (s. 12) before they can be treated by an ART provider. If a criminal record check specifies that (i) charges have been proven against a woman or her partner for a sexual offence referred to in clause 1 of Schedule 1 to the *Sentencing Act 1991*; or (ii) the woman or her partner has been convicted of a violent offence referred to in clause 2 of Schedule 1 to the *Sentencing Act 1991* or a child protection order check specifies that a child protection order has been made removing a child from the custody or guardianship of the woman or her partner then a ‘presumption against treatment’ applies and the woman must not be provided treatment by a clinic (s. 14). In such cases, a person may apply to the Patient Review Panel for a

intended to protect the welfare and interests of a child to be born. Although the requirements for these checks is outside the scope of this review, it is timely to consider whether the offences that give rise to the presumption remain appropriate and whether there might be other indicators, such as family violence orders, that might also be important warning signs that a child to be born may be at risk.

Where there is a presumption against treatment, an application may be made to the Patient Review Panel, seeking permission to proceed with treatment. The role of the panel is to determine if there is a barrier to treatment. In doing so, the panel considers whether granting access to assisted reproductive treatment would be in the best interest of the child to be born. This deliberation can be based on any information before the panel – not just the information that gave rise to the presumption against treatment.

Your views on access to assisted reproductive treatment

Q4. What are the most significant barriers to access to assisted reproductive treatment?

Q5. What should be done to address these barriers?

Q6. Does the current regulatory environment unfairly limit access to assisted reproductive treatment by any particular group or groups of people?

Q7. Do any aspects of the regulatory environment or access to assisted reproductive treatment services need to change in response to changes in social attitudes?

review (s. 15). The Patient Review Panel may decide that there is no barrier to the person undergoing treatment procedures generally or a treatment procedure of a specified kind.

Costs, affordability and effectiveness of assisted reproductive treatment

Cost and affordability

Assisted reproductive treatment is a high-cost service. A single cycle of IVF treatment can cost well in excess of \$8,000. Costs can quickly add up where multiple cycles of treatment are required. For some people, these costs may present an insurmountable barrier to accessing treatment. For people in rural or remote areas of the state who must travel significant distances to attend treatment, costs can become even more prohibitive.

The healthcare costs of assisted reproductive treatment are reduced by the provision of public subsidies through Medicare rebates. If the person receiving the treatment has a diagnosis of medical infertility, Medicare will rebate approximately \$3,700 for the initial cycle, and then \$4,250 for all cycles once the Medicare safety net has been reached (Commonwealth Government 2018).

Most countries offer some form of public subsidy for assisted reproductive treatment, whether through a rebate (such as Medicare) or through direct public provision. An international comparison using 2006 data found that the average cost of assisted reproductive treatment as a percentage of annual disposable income – after allowing for public subsidies – was 44 per cent in the USA, 12 per cent in the United Kingdom, 11 per cent in Scandinavia and 6 per cent in Australia (Chamber et al. 2009). Australia is one of a small number of countries that places no limit on the number of treatment cycles that can be publicly subsidised. In addition, some private health insurance policies cover some additional costs of treatment.

While bulk-billing and low-cost services provide an affordable treatment option for some clients, there have been reports of increasing costs of assisted reproductive treatment in recent years, and the use of premium services for some clients. Tests, add-on treatments, legal fees and associated services can also significantly add to the overall cost of various forms of assisted reproductive treatment. In addition, the Medicare rebate is only available for patients with medical infertility issues.

Australian research has found that affordability is a key factor in differing access to services on the basis of socioeconomic group. Some of this difference is explained by the finding that women in higher income brackets are more likely to delay child bearing, and therefore to be at risk of age-related infertility issues. However, even when confounding factors such as these are controlled for there is still a significant difference between the most disadvantaged and most advantaged groups in terms of service use (Harris et al. 2016).

Affordability of services matters, not only because of its direct impact on access, but also because there is also some evidence that affordability of services can impact on practice. For example, jurisdictions where assisted reproductive treatment is relatively more expensive have been shown to have higher average numbers of embryos transferred. This suggests that clinicians and patients may accept less safe practice in order to reduce the number of treatments required and therefore costs (Keane et al. 2017).

Effectiveness of treatment

Worldwide, it is estimated that one in six couples experience some form of infertility at least once during their lifetime. Medical infertility can be explained in between 20 and 30 per cent of cases by physiological causes in men, in 20 to 35 per cent of cases by physiological causes in women, and in 25 to 40 per cent of cases by problems with both partners. Between 10 and 20 per cent of cases have no cause found (Keane et al. 2017).

A range of responses to infertility or delays in treatment are possible, ranging from expectant management, to intrauterine insemination to full IVF. There is considerable discussion within the clinical community on the approach to be taken to different forms of treatment and different fertility problems.

Some clinicians advocate use of lower cost treatments such as intrauterine insemination, but the choice of effective treatments depends on many factors including patient preferences and the age at which they are receiving treatment. Clinical guidance, such as England's National Institute for Health and Care Excellence (NICE) publication *Fertility problems: assessment and treatment* (NICE 2017), generally provide advice on the chances of conceiving through natural conception or other means given the specific issues facing the patient.

Live birth rates for assisted reproductive treatment vary between countries, and reflect varying medical practices. In 2015, approximately 18 per cent of initiated treatment cycles resulted in a live birth (Fitzgerald 2017). Most women undertake three or fewer cycles. Some countries, such as the USA, report higher live birth rates, but as a result of higher rates of multiple embryo transfers that carry significantly greater risk of multiple births and associated health problems.

The chance of success with IVF declines significantly with age of the woman, as does general fertility. For these reasons many countries place limits on accessing publicly subsidised assisted reproductive treatment above a certain age.

Nevertheless, assisted reproductive treatment offers cost-effective responses to a wide range of infertility issues that have enabled many families to have children.

The practice of upselling complementary therapies or 'add-ons' in assisted reproductive treatment has also been the subject of recent attention. Providers are increasingly offering a range of optional treatments in addition to standard IVF treatments. These treatments can be costly, and while some show advantages for some people, in other cases there is limited evidence of benefit.

Despite a lack of clear evidence, use of these add-ons is on the rise. It is unclear if this increase is driven by service providers seeking to upsell clients, by clinicians seeking to do all they can for their patients, or by the clients themselves hearing of treatments and imploring their doctor to provide them. Regardless of the source of the increase, this trend has clear implications for affordability and value.

Approaches to addressing issues of affordability

The commercialisation and expansion of the assisted reproductive treatment industry in Victoria has increased competition and seen the development of new 'low-cost centres'. These centres advertise out of pocket expenses from \$600 to \$1,500 after the Medicare rebate. They indicate that these savings are achieved through bulk-billing any eligible services, standardising treatment, and operating on a model where patients do not see an individual doctor throughout their treatment, but rather see a doctor on duty on a rotational basis. It also appears that these clinics may not treat more complicated cases of infertility.

Other clinics are now offering delayed payment plans. This has the benefit of allowing treatment to commence more quickly and reducing the time between payment of fees to clinics and receiving the Medicare rebate.

Some people access unsecured loans to cover the cost of fertility treatments, and individuals are increasingly seeking to fund assisted reproductive treatment by accessing the superannuation early on compassionate grounds. Early release of superannuation nationally has grown from \$42 million in 2000–01 to \$290 million in 2016–17. Reportedly, IVF treatment is the second most common reason (following bariatric surgery) for accessing this funding (Griffiths 2018).

Public financial support for assisted reproductive treatment

An international review of approaches to public funding mechanisms for assisted reproductive treatment undertaken in 2017 (Keane et al. 2017) found that since 2008, the number of countries providing public funding for assisted reproductive technologies has increased.

This public funding ranges from partial payments (like Australia's Medicare system) to the availability of full public funding as is the case in a number of European countries as well Ontario in Canada, Israel and

New Zealand. Where public funding or partial funding is available, the number of cycles varies from just one cycle in Ukraine to a limitless number of cycles in a handful of countries, including Australia.

Approaches to eligibility for public funding assisted reproductive treatment also varies across jurisdictions. For example, the public subsidy in Japan is means tested; in Denmark the subsidy is available only for the first child. A number of jurisdictions restrict public funding to women under 40 years of age.

Within Australia, the issue of cost has been addressed through new models of service delivery involving public support. Sydney's Royal Prince Alfred Hospital has established a fertility unit as a collaboration between the public health sector and a private provider to offer more affordable treatment.

Your views on cost, affordability and effectiveness of assisted reproductive treatment

Q8. Is affordability a barrier to accessing assisted reproductive treatment?

Q9. Has competition improved the efficiency and affordability of assisted reproductive treatment in Victoria?

Q10. What can be done to improve the affordability of assisted reproductive treatment?

Access to donors and surrogates

For those who require donation of gametes or the use of a surrogate in order to conceive, access can be significantly limited by supply. Demand for donated gametes and embryos continues to rise, without a corresponding increase in the supply of donors (Victorian Assisted Reproductive Treatment Authority 2014b). This has resulted in shortages of donor gametes and increasing pressure on clinics to source donor sperm, eggs and embryos. These shortages may be even more acute for people from diverse ethnic groups, who seek to source gametes/embryos from donors with a shared ethnic background.

In 2016–17, a total of 1,785 recipients were treated with donor gametes⁶ or embryos, resulting in 672 clinical pregnancies. This compares with 1,121 recipients and 440 clinical pregnancies in 2011–12 (a nearly 60 per cent increase in recipients and a more than 50 per cent increase in clinical pregnancies from donations over a five-year period).

In 2016–17, donations used came from 837 individual donors recruited by individuals or clinics:

- the vast majority of egg donors were recruited by the recipient (266 compared with nine recruited by clinics)
- significantly more embryo donors were also recruited by individuals (76 recipient-recruited donors compared with 31 clinic-recruited donors)
- sperm donations were more commonly recruited by clinics (346 donors compared with 109 recruited by recipients).

All surrogacy arrangements where the treatment is to occur in Victoria must be considered by the Patient Review Panel (ss. 39–45 of the Act). Between 2010 and 2016, the Patient Review Panel received 118 applications in relation to surrogacy arrangements. The annual numbers of applications, although still low, have grown considerably over this period.

Finding donors and surrogates

The regulatory framework for assisted reproductive treatment contains a range of provisions aimed at protecting donors, surrogates and any child to be born as a result of these procedures.

Advertising for donations of eggs and embryos is strictly regulated. Ministerial approval is required before a person may advertise for a donor (s. 40 of the *Human Tissue Act 1982*).

Donations may be made to an individual directly or to a clinic. Although the law prohibits discrimination or denial of access to services on the basis of race, religion, sexuality and gender identity, there have been reports of donors agreeing to donate only if they are guaranteed that the recipient will be of a particular religious or cultural background or in a heterosexual relationship.

Advertising in any way for a surrogate, or indicating that a person may be willing to enter into a surrogacy arrangement, is strictly prohibited in Victoria (s. 45 of the Act).

Anecdotally, it has been suggested that these restrictions, designed to protect people from exploitation, may have the effect of leading people to make arrangements outside the regulatory framework and therefore without support. It is understood that unmoderated online forums and discussion groups connecting potential donors and surrogates with intended parents have become common over recent years. There is significant but undocumented use of these forums that may bypass the legislated restrictions on advertising.

⁶ This includes 551 recipients treated using eggs that may be donor eggs or their partner's eggs (Victorian Assisted Reproductive Treatment Authority 2017).

Compensation for donors and surrogates

Under Victorian legislation,⁷ donations and surrogacy arrangements must be altruistic, and not commercial in nature. These provisions are to prevent the risk of exploitation of persons who donate gametes, act as surrogates or are recipients. Under the relevant laws, there can be no commercial incentive or reward for donation or for acting as a surrogate. The laws do, however, allow for the reimbursement of reasonable expenses.⁸

It has been suggested that there may be some lack of clarity about what constitutes reasonable expenses for donations. This lack of clarity has resulted in different interpretations and different levels of compensation paid by different clinics within Victoria. This could act as a disincentive to those who may otherwise be interested in participating on an altruistic basis or result in donors ‘shopping around’ between clinics to receive the highest level of compensation.

To access reimbursements donors are required to produce evidence of expenses, which is perceived by some as an additional burden and a disincentive to participate. Some Australian assisted reproductive treatment clinics have considered making available a predetermined payment to all donors, rather than requiring the production of evidence of expenses incurred. However, the NHMRC reportedly wrote to clinics in 2016 advising that ‘without any consideration of individual circumstances’, such an approach ‘may constitute valuable consideration if the amount exceeds the reasonable expenses incurred by the individual during the donation process’ and as such would be inconsistent with the law (Marriner 2016).

Victoria has among the most restrictive rules in Australia in relation to reimbursement of surrogates. Unlike New South Wales, Queensland and Tasmania, for example, the Victorian regime does not allow for any additional insurance expenses incurred by a surrogate to be met by the intended parent, nor is there provision for lost income as a result of leave taken during pregnancy.

Internationally, other jurisdictions, for example Canada and the United Kingdom, offer more generous approaches to compensation of donors and surrogates while still retaining an altruistic model.

Approaches taken include a global payment that reflects the expenses likely to be incurred by a person making a donation (rather than requiring individual receipts to prove expenses incurred) and a broader range of compensable matters (for example, compensation for annual leave or sick leave used).

Going overseas

In some cases, clinics and individuals have sought to address the shortage of donors through the import of gametes from overseas. Under the Act, any such importation must be approved by VARTA and the donation must be consistent with Victorian law – including that the donation must not have been made on a commercial basis and that identifying information about the donor must be available for inclusion on the donor registers.

VARTA may grant approval in relation to a particular case or for a class application made by clinics on behalf of a group of recipients. In 2016–17, approval was granted for five class applications to import sperm, up from three the previous year. There were also five class applications to import eggs from a number of donors (four received approval with the fifth pending at the time of reporting). This was the first time VARTA had considered a class application in relation to eggs (Victorian Assisted Reproductive Treatment Authority 2017).

⁷ Under ss. 32 and 39 of the *Human Tissue Act 1982*, it is an offence to buy (penalty 100 penalty units or six months imprisonment or both) or sell (50 penalty units) human tissue including eggs, sperm or embryos (this excludes reasonable expenses as allowable under the *Prohibition of Human Cloning for Reproduction Act 2008*). Under s. 17 of the Prohibition on Human Cloning for Reproduction Act, it is an offence for a person to give or receive valuable consideration to another person for the supply of a human egg, human sperm or human embryo – penalty 15 years imprisonment). Under s. 44 of the Act, it is an offence (penalty 240 penalty units or two years imprisonment or both) for a surrogate mother to receive any material benefit or advantage as a result of a surrogacy arrangement.

⁸ The Assisted Reproductive Treatment Regulations 2009 set out the costs that, if incurred, may be reimbursed to a surrogate. These are: (a) any reasonable medical expenses associated with the pregnancy or birth that are not recoverable under Medicare, health insurance or another scheme; (b) any legal advice obtained for the purposes of s. 43(c) of the Act; (c) travel costs related to the pregnancy or birth.

There are controls on where donated gametes come from when they are imported for use in treatment in Victoria, but these do not apply if people seek to travel overseas for treatment. Although numbers are not available, it is known that people do travel to a range of countries seeking donations. Often this occurs in jurisdictions where there are fewer screening processes in place, where donors receive payments above the level of expenses reimbursement, and where there are no requirements for donors to provide identifying information. This has potentially serious consequences for any child born as a result of the donation.

The difficulties in finding a surrogate lead some people to seek surrogates outside Australia. Unlike a number of other Australian jurisdictions,⁹ Victorian law does not prohibit people from entering into surrogacy arrangements overseas.

A 2016 Commonwealth Parliament inquiry into the regulatory and legislative aspects of surrogacy heard that the then Department of Immigration and Border Protection estimated that it dealt with approximately 250 offshore surrogacy cases each year, and that this number had increased steadily over the preceding years. It also heard that in most cases, these overseas arrangements are commercial rather than altruistic in nature (Parliament of the Commonwealth of Australia 2016). Australians seeking overseas surrogates do so in the United States, Canada, Nepal, Laos, Greece and Kenya. Recent regulatory changes in Thailand and Mexico have meant that these destinations are no longer frequented by Australians looking for surrogates (Millban 2017).

There can be complex legal issues associated with overseas surrogacy, depending on the nature of the agreements entered into and the laws of the country in which the surrogacy arrangement occurs (s. 29 of the Act). Many countries where Australians may pursue surrogacy arrangements have little regulatory oversight or protection for surrogates or intending parents. Reportedly, there is a rising trend towards multinational commercial surrogacy operations, with major players responding to tightening restrictions in one country by moving to another less regulated country.

Recent high-profile media reports have highlighted some of the risks associated with overseas surrogacy arrangements in lightly regulated countries.¹⁰

There are risks for the child to be born. Unethical surrogacy agencies do not put the rights and interests of children to be born first. Non-existent or inconsistent record keeping means that children born of surrogacy arrangements using donated gametes are unlikely to have access to information about their genetic history.

For the surrogate, a lack of regulation can increase the risk of exploitation. Health risks associated with pregnancy can be exacerbated through pressure to agree to risky procedures such as multiple embryo transfers or deliveries timed to meet the schedule of the intended parent.

Finally, poorly regulated countries may also expose intending parents to risk of exploitation. People may pay high sums of money and, if promised services are not delivered, there may be little opportunity for recompense.

Restrictions on the use of donated gametes

To mitigate against the risk of donor-conceived people unknowingly forming consanguineous relationships,¹¹ the Act imposes an upper limit of 10 women having children using gametes (or embryos

⁹ The *Surrogacy Act 2010* (NSW), the *Parentage Act 2004* (ACT) and the *Surrogacy Act 2010* (Qld) all make it an offence for residents in these jurisdictions to enter into commercial surrogacy arrangements overseas, with penalties of up to between one and three years imprisonment.

¹⁰ For example, the case of baby Gammy, in which a twin baby was born with Down syndrome to a surrogate in Thailand. The recipient parent took the twin sister back to Australia, leaving Gammy with the surrogate to raise (SBS News 2014); and the case of parents unable to bring their babies home after a court ban on commercial surrogacy in Nepal (Arlington 2015).

¹¹ ‘Consanguineous relationships’ refers to a romantic relationship or marriage between two genetically related individuals. Consanguineous relationships can increase the risks of serious genetic disease in any children born to the two genetically related people. There is also significant stigma that attaches consanguineous relationships, so there may also be social or personal consequences to any inadvertent formation of such relationships.

formed from gametes) from the same donor (s. 29 of the Act).¹² This limit has implications for donor availability, and may have particularly significant consequences for women in same-sex relationships who may seek to each conceive a child and wish to ensure that the children are genetically related by using gametes from the same donor.

Most jurisdictions impose some limit on the use of gametes from the same donor. In Western Australia, there is a limit of donations being used to five families. The New South Wales legislation imposes a limit of five women; however, the limit does not apply if the woman, or the spouse of the woman, is the parent of a child born as a result of treatment using a donated gamete from the same donor. All other Australian jurisdictions rely on the NHMRC guidelines in relation to limits on the use of a donor's gametes. The guidelines state that 'gametes from a single donor must be used to create only a limited number of families' (National Health and Medical Research Council 2017, section 5.3.2).

The guidelines recommend that, in the absence of specific state regulation, clinicians should consider:

- 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.

RTAC has advised in a technical bulletin issued in 2011, that 'a maximum of 10 donor families per sperm donor' is acceptable (Reproductive Technology Accreditation Committee 2011).

Approaches to increasing access to donors and surrogates

A range of options to improve access to, and meet the growing demand for, donor gametes and surrogates are being considered. These range from allowing greater flexibility to reimburse donors or surrogates for a wider range of expenses, to the establishment of a brokerage service or clearing house to link potential donors and donor gamete recipients. It has been suggested that a clearing house of this type would assist in ensuring that access to donations is fair, and that participants can be adequately supported.

The establishment of a Victorian egg bank, similar to models that already exist overseas, has also been proposed. A number of models are in place internationally, including the World Egg Bank in Arizona and the First Egg Bank in Europe, however careful consideration of how this would work in the Victorian context would be required.

Some organisations have proposed community education and awareness campaigns to promote higher rates of donation of gametes and altruistic surrogacy in Australia.

Your views on access to donors and surrogates

Q11. Does the current regulatory environment sufficiently protect donors and surrogates participating in assisted reproductive treatment?

Q12. Are there changes that could be made to improve access to donors and/or surrogates?

Q13. Does the current regulatory environment unfairly limit access to assisted reproductive treatment by any particular group or groups of people?

¹² Note that a donor may specify a smaller number of women.

LGBTI Victorians' access to and experience of assisted reproductive treatment

The terms of reference for the review specifically include consideration of any barriers to access for LGBTI people.

The 2008 Act removed the legal restrictions that had meant only people in a heterosexual relationship could access assisted reproductive treatment. It has been suggested, however, that impediments remain to the full and fair access to assisted reproductive treatment by the LGBTI community. We now have 10 years' experience of LGBTI Victorians accessing assisted reproductive treatment and it is timely to consider whether further changes are required to the regulation of assisted reproductive treatment or related legislative frameworks, such as those regarding the recognition of legal parentage.

Limitations of the regulatory framework

As outlined earlier in this paper, the language of the Act reflects the social attitudes and understanding of diversity that existed at the time it was drafted. Over the last decade attitudes and recognition of the rights and needs of LGBTI people have evolved dramatically, and LGBTI people are increasingly making use of assisted reproductive treatment services. Seen through today's lens some of the provisions of the Act appear outdated at best and at worst discriminatory.

One example of this is s. 46 of the Act, which allows for the posthumous use of gametes or embryos only if 'the treatment procedure is carried out on:

- the deceased person's partner (which precludes a man using his deceased partner's sperm in a surrogacy arrangement); or
- in the case of a deceased woman by the woman's male partner commissioning a surrogacy arrangement (which would prevent a woman who had been in a same-sex relationship using her deceased partner's egg or an embryo created using that egg in a treatment process).

It has also been noted that the Act's guiding principles state that "persons seeking to undergo treatment procedures must not be discriminated against on the basis of their sexual orientation, marital status, race or religion". It is timely to consider if this is sufficiently inclusive or whether it should, for example, also extend to discrimination on the basis of gender identity and/or intersex status.

More broadly, it has been suggested that the family law system that applies in Victoria is also out of step with the evolving understanding of different family formations. In 2013, the Family Law Council considered the parentage provisions of the Family Law Act and found that the legal framework did not 'reflect the reality of parenting and family life for many children in Australia'¹³. These issues are currently also being considered in an Australian Law Reform Commissioner review of the family law system which has noted that 'recognition of same-sex parenthood is complex and will depend on whether a child was conceived using reproductive technology and the circumstances in which this occurred'¹⁴.

Other access issues

Even where there is no legislated barrier to access, LGBTI people may experience discriminatory practice or a lack of understanding or sensitivity to their needs and circumstances. One Victorian assisted reproductive treatment provider has sought to address this through the establishment of the "rainbow fertility" centre, a dedicated fertility service catering exclusively for the LGBTI community. This service states that staff have been specifically trained to better appreciate and respond to the diverse and unique needs of LGBTI families.

¹³ Family Law Council, Report on Parentage and the Family Law Act (2013) 31

¹⁴ Australian Law Reform Commissioner (2018) *Issues Paper – Review of the Family Law System*, (March 2018)

Affordability can be another impediment to access for services for LGBTI people in Victoria. The restrictions on access to Medicare payments for assisted reproductive treatment to those with “medical infertility” means that many LGBTI people may not be eligible for a rebate.

The issues outlined in this paper relation to access to donors and surrogates are also particularly critical for the LGBTI community and shortages can significantly curtail access to treatment.

Your views on LGBTI Victorians' access to and experience of assisted reproductive treatment

Q14. What are the most significant barriers to access to treatment for LGBTI people?

Q15. How can these barriers be addressed?

Q16. What can be done to ensure that practice of assisted reproductive treatment is more inclusive of LGBTI people and their families?

Q17. Are there related issues (e.g. family law issues) that need to be considered in the regulation of assisted reproductive treatment?

Making informed decisions

People often access assisted reproductive treatment at a time of high emotions and at a point in their lives when they may be quite vulnerable. Together with the high financial costs of services, these circumstances mean it is critical that people have access to the right information to make informed and considered choices.

Information on fertility and treatment options

While assisted reproductive treatment offers some hope for people who are unable to conceive naturally, it is not always successful, particularly if treatment is sought later in life.

Recent research has indicated that people's knowledge about the causes of infertility, and in particular the age at which fertility begins to decline, is not strong (Prior et al. 2018).

A key approach to both managing demand for assisted reproductive treatment, and better supporting people to achieve their aim of starting a family, must include information to ensure people understand how age and other factors affect fertility.

This information is critical for young people who may be making decisions about delaying starting a family, and for those who may be concerned about their fertility and considering accessing treatment.

There have been some notable efforts made to improve information provided to people about fertility matters. For example, VARTA, in conjunction with Andrology Australia, Jean Hailes Research Unit and the Robinson Research Institute, has established Your Fertility, a national public education program funded by the Australian and Victorian Governments.

As noted in relation to the costs of treatment, there is some evidence to suggest that people facing fertility challenges often commence IVF treatment as a first response. In many cases, this will be clinically appropriate, however there may be instances where other less invasive approaches may be successful.

People approaching assisted reproductive treatment services should have access to a wide range of information about treatment options and about steps they might take to help manage their own fertility – for example information about the impact of weight, smoking and alcohol consumption on fertility and the time it takes to conceive.

Information about success rates

In 2016, the ACCC undertook an investigation of the claims made by assisted reproductive treatment services about their rates of success. The investigation found that some clinics made claims and comparisons without adequate disclosure, or explanation of the data, and that some used technical terms which may be misleading to consumers.

The ACCC cited for example, the use of 'clinical pregnancy rate' data to compare success rates. 'Clinical pregnancy' data reflects a clinic's success in achieving a pregnancy, regardless of length, rather than achieving a live birth. The ACCC noted that this data was frequently accompanied by photographs of newborn babies, which it considered was likely to lead potential clients to form an inaccurate impression about the rate of successful pregnancies achieved by the clinic.

A number of steps have been taken by regulators to improve the information available to the public.

Outcomes of assisted reproductive treatment in 2015¹⁵

77,721 initiated cycles, resulting in:

17,726 clinical pregnancies (22.8 per cent of initiated cycles), and

14,040 live births (18.1 per cent of initiated cycles)

The revised RTAC *Code of Practice*, issued in 2017, includes criteria related to public information. It specifies that such information must be in language that can be understood by the lay public, and ensure the overall conclusion is not misleading in any way. Specific requirements for the information – including that it be divided by age, specify live birth rates, and be accompanied by qualifying statement of broad factors that affect success rates – are set out in the *Code of Practice*. RTAC has also issued a technical bulletin on [public information, communication and advertising for Australian clinics](#).

<<https://www.fertilitysociety.com.au/wp-content/uploads/20170420-RTAC-Technical-Bulletin-Number-7.pdf>>.

VARTA has also produced materials on [understanding success rates](#)

<[https://www.varta.org.au/sites/varta/files/Understanding IVF success rates - April 2016.pdf](https://www.varta.org.au/sites/varta/files/Understanding%20IVF%20success%20rates%20-%20April%202016.pdf)>.

While these developments may help to ensure that public-facing information is not misleading, providers are not required to publish their success rates, and it is not possible for those seeking to access treatment to easily compare outcomes between providers.

Registered clinics are required, as a condition of registration, to provide data to the Australian and New Zealand Assisted Reproduction Database (ANZARD), and there have been some recent calls to improve public access to data, including comparable success rates, such as through the development of a searchable online database (Siagian 2018). Others have, however, expressed concern that this sort of ‘league table’ may result in unfair comparisons between services, with those treating higher risk populations appearing to be less successful than those servicing people whose personal circumstances mean they are easier to treat.

It has also been suggested that the imperative to compare favourably with competitors could affect clinical decisions. For example, providers may feel compelled to transfer multiple embryos to increase the likelihood of pregnancy, which could reverse Australia’s positive trend of reducing multiple births.

An alternative proposal is that providers be required to provide each person considering treatment with realistic likelihoods of success based on their personal circumstances and factors such as age, health, obesity status and previous pregnancies and the treatments being considered. Such information could also help inform people about whether high intervention services such as IVF are right for them, or whether less intrusive and less costly options, such as losing weight or ovarian stimulation, might be worth trying first. It has been reported that the Fertility Society is working to progress a tool that could provide such predictions, with a view to it being made public within the next 18 months (Siagian 2018).

Consideration may be given both to what information should be available, and the appropriate mechanisms to ensure it can be accessed.

Information about costs

Just as information about success rates can be confusing, so too can disclosures about the costs of treatment.

¹⁵ Clinical pregnancy refers to an early pregnancy, whether ongoing or not at the time of confirmation. Live delivery refers to the delivery of one or more live born infants. Statistics from Fitzgerald et al. 2017.

While most providers include cost information on their websites, there is little consistency in how this information is presented, and often it is not clear what additional out of pocket expenses a person may face.

A recent development in the UK has seen a clinic offering a fixed price up-front fee for unlimited treatment over a two-year period, with the promise of a refund if a baby is not conceived. Critics of this approach have noted the high up-front cost for those who need one or two cycles of treatment to conceive. Others have warned of a dangerous incentive for people to proceed with as many treatment cycles as they can within the time period, which may result in unnecessary physical and emotional burden.

Information about the efficacy of add-on treatments

As noted earlier in this paper, the use of adjuvants or add-on treatments in assisted reproductive treatments is on the rise. While some of these treatments may be effective, in other cases there is no evidence that they improve success rates. It has also been suggested that some treatments may even expose patients or their unborn baby to unnecessary risks (Rombauts 2017; Mottram et al. 2017).

Access to transparent, easily understood information for patients about the impact, risks and evidence for adjuvants is critical to support informed consent.

In response to concerns about the growing use of adjuvants, the Human Fertilisation and Embryology Authority (HFEA), the regulator of assisted reproductive services in the UK has made available an [online tool](https://www.hfea.gov.uk/treatments/explore-all-treatments/treatment-add-ons/) <<https://www.hfea.gov.uk/treatments/explore-all-treatments/treatment-add-ons/>> to inform people about the possible benefits or otherwise of commonly used adjuvants. VARTA has included a requirement that patients be given information about the evidence behind treatment procedures as a condition of registration, and has recently included a requirement that providers advise VARTA of the list of adjuvants being used by clinicians within a program of IVF treatments.

Your views on information to make informed choices

Q18. How should regulators and assisted reproductive treatment clinics better inform the public (especially women of child bearing age) of risk to fertility and effectiveness of assisted reproductive treatment compared to less invasive, cheaper alternatives?

Q19. Should more be done to ensure people have access to accurate information about likely outcomes and costs of assisted reproductive treatment?

Q20. How can information best be provided?

Support before, during and after treatment

The experience of assisted reproductive treatment is a highly emotional one for all concerned, and treatments can be physically and emotionally difficult. It is, therefore, critical that the provision of service is supportive, responds to individual needs and circumstances, and seeks to protect the health and wellbeing of all involved.

Counselling requirements

The Act mandates certain requirements for counselling of participants prior to involvement in assisted reproductive treatment processes.

The Assisted Reproductive Treatment Regulations 2009 set out matters that must be covered in counselling prior to commencing a treatment procedure, making a donation, entering into a surrogacy arrangement, or making posthumous use of gametes or embryos.

While all providers must meet these counselling requirements, it appears there may be a range of approaches to ensuring compliance, with some providers offering group counselling in addition to or in place of some individual counselling sessions.

While counselling prior to the commencement of treatment is mandated, there are no such requirements for the end of treatment. Where treatment has been unsuccessful, individuals are often faced with difficult decisions about discontinuing treatment and must readjust their expectations of becoming parents.

People who have completed their families but have additional embryos or gametes in storage may also face difficult decisions regarding their fate.

Inclusive practice

The experience of assisted reproductive treatment is strongly influenced by interactions with clinicians and staff. Sensitive, patient-centred care is critical for all participants. It has however, been suggested that some providers may be less equipped to provide this sort of care.

People from culturally or linguistically diverse backgrounds or particular religious faiths may have specific needs, and it is important that services are aware and mindful of these in their interactions.

Similarly, a lack of awareness of issues related to sexuality or gender identity may result in unintended discrimination or discomfort for some individuals.

While these may not be issues best addressed through regulatory change, this review does offer an opportunity to understand how current practice affects the diverse range of people who use assisted reproductive treatment, and to consider how the experience can be improved for all.

Your views on support before, during and after treatment

Q21. What more can be done to support the health and wellbeing of people before, during and after assisted reproductive treatment?

Q22. Are current requirements regarding counselling sufficient?

Q23. Should more be done to ensure that services are inclusive and sensitive to individual needs?

Q24. Should there be additional obligations on health practitioners or clinics to provide support to people following unsuccessful treatment?

Oversight of quality and safety

Targeting Zero, the 2016 review of hospital safety and quality assurance in Victoria (Duckett et al. 2016), highlighted the importance of robust systems of oversight and monitoring, clear lines of accountability and strong clinical governance in ensuring safety, and driving quality improvements, in healthcare.

As outlined earlier in this paper, a range of bodies have a role to play in the regulation and oversight of assisted reproductive treatment in Victoria. This system has evolved over time to reflect a national approach to the self-regulated accreditation of services.

This multi-regulator approach allows for more diverse oversight, and it appropriately positions assisted reproductive treatment regulation within a national framework. It is important, however, to consider if the correct balance has been struck, or if the system has resulted in unnecessary duplication or gaps in oversight. It is also important to consider whether any additional systems are required to improve quality and safety of assisted reproductive treatment services other than self-regulated accreditation.

The other risk of a complex regulatory system is that it becomes difficult to navigate. It is important that potential and current patients, donors or surrogates, as well as those working in the system and registered providers, are able to understand the roles and responsibilities of all involved and how to access support if required.

Finally, it is vital that the complexity of the regulatory system does not result in the fragmentation of critical information to the extent that it is impossible to obtain true picture of the state of the industry or any systemic risks within it.

Role of the state-based regulator

VARTA comprises a seven-member board appointed by the Governor-in-Council on nomination by the Minister for Health. A chief executive officer reports to the board and is supported by a small staff.

Licensing and registration

VARTA was established with the commencement of the Act in 2008, and replaced the Infertility Treatment Authority. The Infertility Treatment Authority had been responsible for the licensing of clinics in Victoria and approval of practitioners working in those clinics (including doctors, counsellors and clinical and research scientists).

The system now relies primarily on self-regulation. While the Act includes a requirement for registration of providers to operate in Victoria, VARTA is obliged to register clinics in Victoria when they have received RTAC accreditation (s. 74 of the Act). RTAC is a committee set up by the Fertility Society of Australia – the peak body representing clinicians practicing in the area of fertility. Registration granted by VARTA can include conditions on the registration insofar as these conditions are not inconsistent with a condition imposed on the provider's RTAC accreditation, and VARTA considers them to be necessary in the public interest (s. 75 of the Act).

VARTA has no role in the approval or credentialing of individual practitioners.

The result of this change is that many of the functions that would previously have been carried out by the state-based regulator are now the responsibility of RTAC and the approved agencies who undertake accreditation against the *Code of Practice* on behalf of RTAC.

Requirements regarding practitioners within registered clinics are set out in the *Code of Practice*, which includes the professional requirements of key staff – including the medical director, scientific director, nurse manager and senior counsellor (Item 1.4).

Monitoring of compliance

VARTA has broad responsibility to monitor programs and activities carried out under the Act (s. 100(1)(d)).

To support VARTA's regulatory role the Act confers powers to enter the premises of a provider and inspect documents, for the purpose of determining compliance with a registration under the Act (Duckett et al. 2016).

Sanctions

The Act provides for VARTA to impose conditions on registration specific to an individual provider. This power has been used to require providers to address specific issues of noncompliance with the Act or registration requirements.

VARTA also has powers to suspend the registration of a provider if it reasonably believes there has been a contravention of the conditions of registration, or if it otherwise believes the suspension is warranted.

VARTA is required to advise the Minister of any contravention of the Act or regulations or any contravention of a provider's registration.

Other roles

VARTA also has functions related to the administration of donor registers, including support and advice to people applying for access to information, provision of donor-linking services and facilitation of information exchange between consenting donors and donor-conceived persons. This is in addition to a public education and consultation role; promotion of research into the causes and prevention of infertility; and the approval of import and export of gametes and embryos.

VARTA is required to advise the Minister of significant developments in Victoria or elsewhere related to infertility research or treatment.

Promoting safety, quality improvement and strong clinical governance

The RTAC *Code of Practice* includes requirements for units to have in place 'a management system allowing planned, implemented, coordinated, and appropriate service delivery that meets the needs of all stakeholders'. This includes requirements for a quality management policy and review processes.

It has been suggested that stronger requirements in relation to clinical governance and quality improvement processes may be warranted. *Targeting Zero* highlighted the risks in relying on accreditation systems as the primary means of ensuring quality and safety (Duckett et al. 2016). In response to *Targeting Zero*, a range of mechanisms have been put into place to drive quality and safety improvements and strengthen clinical governance and oversight.

Safer Care Victoria has been established as the state's healthcare quality and safety improvement agency. Safer Care Victoria has the purpose of enabling health services to deliver safe, high-quality care and experiences for patients, carers and staff. As part of this work, Safer Care Victoria has developed a new framework for clinical governance. This framework stresses that 'clinical governance is not about compliance' (Safer Care Victoria 2017) and emphasises the importance of leadership, culture and improvement to the provision of high-quality care.

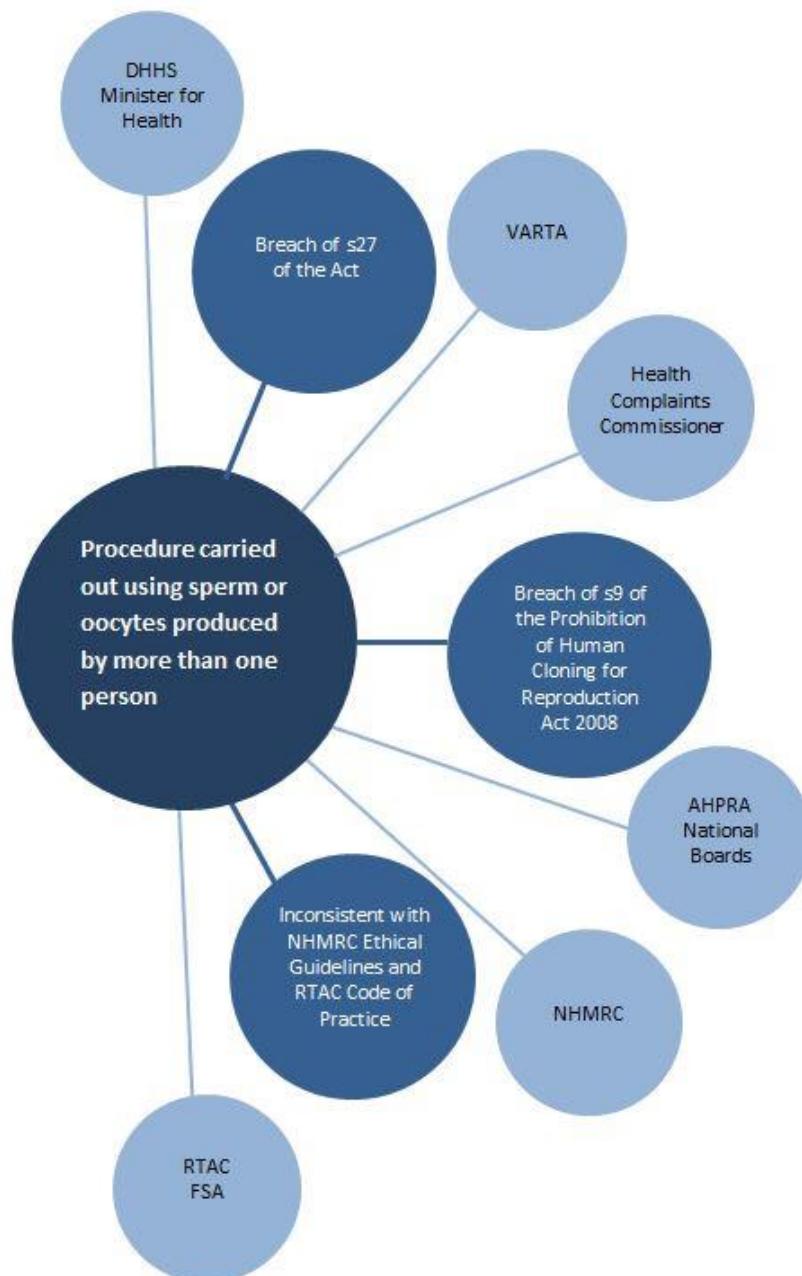
Recent reforms in Victoria have also increased the emphasis on clinical governance and clinical oversight in relation to private hospitals and day procedure centres. This has included amending the Health Services (Private Hospital and Day Procedure Centres) Regulations 2018 to include new requirements for quality and safety review data. These requirements cover regular quality and safety reviews, collection and reporting of patient experience data and staff safety culture survey data. These regulations also include stronger requirements about appointments to senior positions. While assisted reproductive treatment services will access day procedure centres for certain procedures, only two

registered providers currently operate their own day procedure centres to which these regulations would apply.

Identification of concerns and risks

Practice that may affect patient safety or the quality of care provided may come to light through a range of channels. Such practice may be inconsistent with relevant legislation, the NHMRC Ethical Guidelines, the RTAC *Code of Practice* or professional codes or guidelines. They may come to the attention through notifications to the Australian Health Practitioner Registration Authority, complaints to the Health Complaints Commissioner, reports to VARTA, matters raised with the NHMRC or the Fertility Society of Australia. Other issues may be raised directly with the Department of Health and Human Services or the Minister for Health. Matters relating to misleading advertising may be raised with the ACCC or CAV. As illustrated below, a single issue might represent a contravention of a range of Acts or regulatory instruments and may trigger action by a broad range of bodies.

Figure 2: Regulatory activities in response to a single practice issue



While it is understood that these regulators routinely refer complaints and notifications to the most appropriate agency, it is unclear the extent to which current legislation allows for information sharing to support the identification or risk.

A number of recent legislative reforms in Victoria have sought to improve the flow of information between relevant bodies with responsibility for different aspects of the oversight of health or human services.¹⁶

It may be that similar provisions could assist in strengthening the oversight of assisted reproductive treatment and ensuring that learnings about quality and safety can be shared.

Your views on oversight of services

Q25. How effective is the current self-regulatory model for oversight of assisted reproductive treatment?

Q26. Are the functions and powers of VARTA appropriate to provide oversight of Victorian assisted reproductive treatment services?

Q27. How could the mechanisms for safety and quality assurance be improved?

Q28. Are there overlaps or gaps in the existing regulatory model?

Q29. How can we improve information sharing between regulators responsible for oversight of assisted reproductive treatment?

Q30. What other measures could be taken to address any perceived differences in the current regulation?

¹⁶ See for example, information sharing provisions of the *Health Complaints Act 2016* which provided for enhanced sharing of information between the health Complaints Commissioner, AHPRA and the Department of Health and Human Services; or the *Family Violence Protection Act 2008* which provides for the authorisation of prescribed sharing entities to share information between themselves for family violence risk assessment and risk management.

Glossary and abbreviations

ACCC

Australian Competition and Consumer Commission – the ACCC is the independent Commonwealth statutory authority whose role is to enforce the *Competition and Consumer Act 2010*.

AHPRA

Australian Health Practitioner Regulation Agency – AHPRA is the organisation responsible for the implementation of the National Health Practitioner Registration and Accreditation Scheme. AHPRA works in partnership with national boards for 15 registered health professions. National boards set standards and codes of conduct for the professions. AHPRA receives and investigates notifications about individual practitioners in relation to unprofessional conduct, unsatisfactory professional performance and about impairment where this is placing the public at risk. AHPRA presents their findings in relation to these matters to the relevant national board for consideration and appropriate action.

ANZARD

Australia and New Zealand Assisted Reproduction Database – ANZARD is a collaborative effort between the National Perinatal Epidemiology and Statistics Unit, the Fertility Society of Australia (FSA) and the fertility centres in Australia and New Zealand. Data for ANZARD is provided by fertility centres in Australia and New Zealand. The purpose of the ANZARD collection is to monitor the perinatal outcomes of assisted reproduction and to assess the effectiveness of assisted reproductive treatment treatments.

Assisted Reproductive Treatment

A range of treatments used to help people to conceive a child.

BDM

Registry of Births, Deaths and Marriages Victoria – BDM is responsible for recording all births, adoptions, marriages and deaths in Victoria. Since 2010, when a birth registration indicated that a child was conceived through donor treatment, those who apply for a copy of their birth certificate when they are 16 years of age or older, will have an addendum attached to their birth certificate. That addendum will inform them that additional information about their birth is available from the Registrar of Births Deaths and Marriages. If they make further inquiries, the Registrar of Births Deaths and Marriages will inform them that the register indicates they are donor conceived and that they can apply to the Central Register for more information. In the case of surrogacy arrangements, the birth is registered by the surrogate mother. The commissioning parent(s) then apply to the court for a substitute parentage order. If this is granted, the commissioning parent(s) then apply to register the birth. BDM will close the original birth record and create a new one showing the commissioning parent(s) as the child's parent(s).

CAV

Consumer Affairs Victoria – CAV is the consumer regulator for Victoria. Along with the ACCC, CAV enforces the national consumer law.

Donor conception

A conception that takes place through the use of donated gametes (egg, sperm or embryo).

DHHS

Department of Health and Human Services (Victoria).

FSA

Fertility Society of Australia – FSA is the peak body representing scientists, doctors, researchers, nurses, consumers and counsellors in reproductive medicine in Australia & New Zealand.

Gamete

An oocyte (egg) or sperm.

HCC

Health Complaints Commissioner – the HCC is an independent statutory body established under the *Health Complaints Act 2016*. The HCC provides complaints resolution processes for health service complaints. The HCC also issues complaints handling standards for health service providers. The Health Complaints Act includes a statutory code of conduct for unregistered health service providers and provides the Commissioner with powers to investigate and make recommendations.

HFEA

Human Fertilisation and Embryology Authority – the HFEA is the independent regulator of fertility treatment and research using human embryos in the United Kingdom.

ICSI

Intracytoplasmic sperm injection – ICSI is a technique where a single sperm is injected into the inner cellular structure of an egg to achieve fertilisation.

IUI

Intrauterine insemination – IUI is a relatively simple assisted reproductive treatment procedure in which a sperm sample is deposited directly into the uterus with the aim of achieving fertilisation and pregnancy.

IVF

In vitro fertilisation – IVF is a procedure in which sperm are placed with an unfertilised egg in a dish to achieve fertilisation. The embryo is then transferred into the uterus to begin a pregnancy or cryopreserved (frozen) for future use.

LGBTI

Lesbian, gay, bisexual, trans and gender diverse and intersex. This widely used acronym describes the lesbian, gay, bisexual, transgender and intersex community, and is also sometimes written as GLBTI or LGBTIQA (including queer and asexual) among other variations.

NICE

National Institute for Health and Care Excellence – NICE is a body, established under legislation with responsibility for developing guidance and quality standards in social care in England.

NHMRC

National Health and Medical Research – the NHMRC is a statutory authority established by the *National Health and Medical Research Council Act 1992* (Cth) to:

- raise the standard of individual and public health throughout Australia
- foster the development of consistent health standards between the various states and territories
- foster medical research and training and public health research and training throughout Australia
- foster consideration of ethical issues relating to health.

The NHMRC develops guidelines that form the basis of the regulation of assisted reproductive treatment at a national level.

PBS

Pharmaceutical Benefits Scheme – the PBS is a national program that provides subsidised prescription drugs to residents of Australia.

PGD

Preimplantation genetic diagnosis – PGD involves preimplantation genetic testing (PGT) to assess whether an embryo is likely to be affected by a specific genetic abnormality, where there is an increased risk of having a child with a genetic condition, to reduce the risk of that condition being passed on.

PGT

Preimplantation genetic testing – PGT is a technique used to help select embryos that appear genetically normal for transfer. A small number of cells are removed from an embryo in vitro and tested. PGT techniques can be used for PGD to identify specific abnormalities and to screen for chromosome abnormalities.

PRP

Patient Review Panel – the PRP is an independent statutory body established under the Act to consider applications relating to:

- surrogacy arrangements where treatment is to occur in Victoria
- presumptions against treatment due to the results of a criminal record check or a child protection order check
- posthumous use of gametes and embryos
- cases where a registered provider or doctor reasonably believes that a child that may be born would be at risk of abuse or neglect
- cases where an applicant does not meet the criteria for treatment under the Act
- requests for an extensions 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.

RTAC

Reproductive Technology Accreditation Committee – RTAC is a subcommittee of the Board of the Fertility Society of Australia and reports directly to that board. RTAC sets standards for the performance of assisted reproductive treatment through an audited *Code of Practice* and grants licences to practice assisted reproductive treatment within Australia.

Safer Care Victoria

Victoria's healthcare quality and safety improvement agency.

Surrogate

A surrogate is a woman who becomes pregnant and agrees, prior to conception, to permanently surrender the child to another person or couple who will be the child's parent or parents. In Australia, a person may only be a surrogate for altruistic reasons. Commercial surrogacy, undertaken for financial gain, is unlawful in Australia.

VARTA

Victorian Assisted Reproductive Treatment Authority – VARTA is a statutory authority established under the Act. VARTA is responsible for:

- registration of assisted reproductive treatment clinics
- public education about treatment procedures and the best interests of children born as a result of treatment procedures

- management of the donor conception registers and the provision of support and advice to people applying to the registers and those contacted as a result of an application
- provision of donor-linking services to consenting donor-conceived people, donors, descendants of donor-conceived people, recipients of donor treatment and relatives
- facilitation of information exchange or correspondence and assisting contact between consenting parties
- community consultation about matters relevant to the Act
- monitoring of developments, trends and activities relating to the causes and prevention of infertility and in the assisted reproductive treatment industry in Victoria, Australia and internationally
- promotion of research into the causes and prevention of infertility
- approval of the import and export of donated eggs, sperm and embryos formed from donor gametes in and out of Victoria, and to provide for the exemption from particular provisions
- any other functions conferred on it by or under this or any other Act.

VEOHRC

Victorian Equal Opportunity and Human Rights Commission – VEOHRC is an independent statutory body with responsibilities under the *Equal Opportunity Act 2010* and the *Racial and Religious Tolerance Act 2001*. The Commission helps people resolve complaints of discrimination, sexual harassment, victimisation and racial or religious vilification.

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Appendix 1: Terms of reference

Background

The last comprehensive review of the laws governing access to assisted reproductive treatment in Victoria was published in 2007 by the Victorian Law Reform Commission. Since the passage of the *Assisted Reproductive Treatment Act 2008*, which reflected recommendations from the Commission's review, assisted reproductive technology, community attitudes and the nature of supply and demand in the market have evolved significantly.

The assisted reproductive treatment industry is now highly competitive and highly commercialised. The market continues to grow, with new providers entering the market, some providers operating within a global context, and providers seeking to identify new opportunities to increase their range of services.

As well as the changing nature of market providers, demand for reproductive services has increased following legislative changes that resulted in a more inclusive approach to the provision of assisted reproductive treatment services in Victoria. Changing community attitudes, such as individuals choosing to have children later in life or to freeze their eggs as a result of changing societal expectations and cultural norms, and technological advances have also influenced the industry and the profile of services offered.

In 2016, the Australian Competition and Consumer Commission investigated claims of 'success rates' by IVF clinics and found that some clinics made success-rate comparisons without adequate disclosure, or qualification of, the nature of data or graphics used to make the claim, and some used technical terms which may be misleading to consumers without further clarification or explanation.

Additionally, while one of the guiding principles of the Act includes that people seeking to undergo assisted reproductive treatment should not be discriminated against on the basis of sexual orientation or marital status it is timely to again assess whether the Act may affect LGBTI people differently, particularly in the context of the *Marriage Amendment (Definition and Religious Freedoms) Act 2017*.

It is timely to review existing regulatory arrangements to ensure the current framework adequately accounts for the evolving nature of the assisted reproductive treatment market.

Purpose

To review Victoria's regulatory framework for assisted reproductive treatment to assess if it creates or enables unnecessary barriers to access, particularly in light of the *Marriage Amendment (Definition and Religious Freedoms) Act 2017* (Cth), if consumers have access to adequate information to facilitate informed choices, and if the regulatory framework remains appropriate given the changing nature of the market.

Guiding principles

The guiding principles of the *Assisted Reproductive Treatment Act 2008* will apply in conducting the review. These are that:

- The welfare and interests of persons born or to be born as a result of treatment procedures are paramount.
- At no time should the use of treatment procedures be for the purpose of exploiting, in trade or otherwise –
 - the reproductive capabilities of men or women, or
 - children born as a result of treatment procedures.

- Children born as the result of the use of donated gametes have a right to information about their genetic parents.
- The health and wellbeing of persons undergoing treatment procedures must be protected at all times.
- Persons seeking to undergo treatment procedures must not be discriminated against on the basis of their sexual orientation, marital status, race or religion.

Scope

To conduct a concise review into Victoria's assisted reproductive treatment regulatory framework to assess, report on, and present any findings, recommendations or options to government in relation to the matters specified below.

- Whether the framework creates or enables unnecessary barriers to access for LGBTI people, particularly in light of the *Marriage Amendment (Definition and Religious Freedoms) Act 2017*.
- Whether in the context of the recent Australian Competition and Consumer Commission investigation into claims of 'success rates' by IVF clinics in 2016, the regulatory framework for assisted reproductive treatment contains adequate safeguards to protect consumers using or intending to use assisted reproductive treatment services in Victoria.
- If the framework remains appropriate in the context of the evolving market for assisted reproductive treatment, in particular in relation to changing drivers for demand and the corporatisation of market providers.
- Whether the evolving market and regulatory framework has implications for access and affordability of assisted reproductive treatment services.
- Any other matter reasonably considered incidental to these above matters.

The review is to investigate the above matters and options for reform. It will provide an interim report to the Minister for Health within six months and a final report making recommendations to the Minister for Health within twelve months of the review commencing.

A number of regulatory issues related to individuals are out of scope as they could not be adequately considered within the timeframe for the review. These matters include for example:

- The prohibition on selling gametes, prohibitions on sex selection or mixing gametes from multiple parties, requirements for those people seeking to undergo child protection order checks, consent requirements and the Patient Review Panel.
- Changes made by the Assisted Reproductive Treatment Amendment Act 2016 that provided all donor-conceived Victorians access to available identifying information about their donors, which commenced on 1 March 2017.

<p>The terms of reference are published on the department's website <https://www2.health.vic.gov.au/hospitals-and-health-services/patient-care/perinatal-reproductive/assisted-reproduction/regulatory-review>.</p>
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Appendix 2: History of assisted reproductive treatment regulation in Victoria

