

Helping Victorians create families with assisted reproductive treatment

Interim Report of the Independent Review of Assisted Reproductive Treatment

October 2018

Mr Michael Gorton AM



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Where the term 'Aboriginal' is used it refers to both Aboriginal and Torres Strait Islander people. Indigenous is retained when it is part of the title of a report, program or quotation.

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Foreword

Assisted reproductive treatment is unlike any other medical procedure.

When it succeeds, it creates children and families, and those children grow up to become adults who may need to negotiate new social relationships, such as with their donor-parents and donor-siblings, that were unheard of a generation ago.

When it fails, it can leave deeper scars than any surgery – a lifelong emotional burden of infertility and the grief for a family never born.

The need for assisted reproductive treatment arises not only from medical illness, but also from how we form families and arrange our working lives. While the average age of giving birth has increased for social reasons, the biological facts about the decline of fertility from the early 30s have not changed. More and more women face difficult, expensive choices about using assisted reproductive treatment to create their family.

Assisted reproductive treatments are procedures that are not only undertaken by health practitioners on one living person. They also involve complex medical science forming embryos from the delicate process of fertilisation. The sperm and eggs used in this process may be collected from people other than the intended parents of the child. They may have been collected in another country or stored for decades before use. In cases of surrogacy, another woman carries the pregnancy and is the birth mother of the child.

All of these differences mean that assisted reproductive treatment requires special regulation that is sensitive to the interests of all those involved. Assisted reproductive treatment in Victoria involves many stakeholders – from the hopeful parents to the clinics, with clinicians, scientists, nurses, counsellors and, now, managers and shareholders. The parents and families who receive assisted reproductive treatment are as diverse as our community. The needs and preferences of persons conceived through assisted reproductive treatment – now more than 4 per cent of all children born – are just as diverse.

Striking the right balance for that regulation is challenging since assisted reproductive treatment involves major issues for our society – legal, social, ethical and economic. Victoria is where assisted reproductive treatment began in Australia 38 years ago with the birth of the third IVF child in the world. Victoria was also the first state in the world to regulate assisted reproductive treatment, and some of those early decisions, such as the creation of a central donor register, have been of enduring significance for later generations of children conceived through the use of assisted reproductive treatment.

In 2008, the Victorian Parliament made two major changes that reset the balance of the legal and regulatory framework for assisted reproductive treatment. It removed discrimination against same-sex couples and single people in accessing assisted reproductive treatment. It also reduced the level of detailed regulation and supervision of assisted reproductive treatment services by the Victorian regulator.

Ten years on from the *Assisted Reproductive Treatment Act 2008*, we have seen many changes in our community and assisted reproductive treatment services. Same-sex couples can not only access assisted reproductive treatment, they can marry legally. The understanding of diverse gender and sexual identities among the public and health services has increased markedly. There has been a change in both social attitudes and the law about donor-conceived children accessing information about their genetic heritage. The possibilities of assisted reproductive treatment scientifically and socially have expanded. For example, more women choose to freeze their eggs in anticipation of later

ART. More genetic testing procedures are possible, and debates are emerging on the future uses of DNA testing and gene editing. There are more IVF clinics competing in Victoria, including some relatively low-cost services. Some clinics have moved from being largely clinician owned and led to being publicly listed companies with investors from Australia and overseas. Donor sperm and eggs can be scarce, and some Victorians choose to travel overseas for their fertility treatments.

These changes have exposed some problems with the 2008 Act. As recently as September this year, the Federal Court identified a significant problem with a part of the Act, finding it inconsistent with the Commonwealth Sex Discrimination Act.

This is, therefore, a timely review and it was, and is, important that the whole community has an opportunity to make submissions and give their views. I am grateful to all of those individuals and organisations that have so far participated and given their opinions and, more importantly, shared their stories for this Interim Report.

At the heart of our legislation and this review is the reason for assisted reproductive treatment – the children.

The major guiding principle in our legislation is that:

the welfare and interests of persons born or to be born as a result of treatment procedures are paramount

The first children born using IVF are now in their 30s. The first donor-conceived people are now creating their own families. The complexities of the IVF landscape we have created have shaped and are impacting on these people. In particular, the needs of donor-conceived people are being expressed by them, many for the first time – and it is important that we listen.

I recognise and thank the many people born through assisted reproductive treatment who have shared their personal stories for this Review.

I have also heard from parents and would-be parents – whether using IVF procedures with their own and their partner's gametes, donor procedures or surrogacy. I have heard from patients whose assisted reproductive treatment journey has led to a child, and other patients who have had no success after many rounds of expensive treatment.

The birth of a child brings great joy, and if assisted reproductive treatment can assist that to happen then it should be available equitably to all those who need it to form their family. Assisted reproductive treatment has, overall, had an enormously positive impact in our community. However, some of the stories I have heard from those involved in assisted reproductive treatment and those accessing or wishing to access services have been concerning. These stories have helped to identify areas for improvement.

There are many areas for this Review to consider. Only some of them are addressed in this Interim Report. Some others are identified for ongoing consideration. More consultation with the community and stakeholders will be necessary before I present the Final Report of this review next year.

Michael Gorton AM

The Reviewer

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 Principal at Russell Kennedy, Lawyers 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, Principal at Russell Kennedy, Lawyers.

The Review team

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Executive summary

The scope of this Review is broad ranging. Stakeholder feedback has been substantial, and the Review has benefited greatly from the willingness of so many people to share their stories and expertise.

The Review has held approximately 40 meetings involving more than 120 people. Forty written submissions were received in response to the consultation paper, released in August 2018, and there were 191 responses to the survey.

The feedback given has touched on many facets of the key issues identified in the Review's terms of reference: discrimination, access, affordability, the adequacy of safeguards, and the appropriateness of the regulatory framework.

This Interim Report will present preliminary findings in relation to a number of key policy areas.

In some cases, it has been possible to make clear recommendations at this early stage, in others the Report presents issues that require further exploration before a recommended response can be proposed. Where possible, the Interim Report flags likely directions and/or areas where further targeted consultation will be undertaken over coming months to test ideas with the community or gather further intelligence in order to identify a way forward.

General findings

A number of key themes have emerged through research and consultation undertaken to date.

Many stakeholders spoke positively about their experience of assisted reproductive treatment (ART) in Victoria. Recipients of ART expressed their gratitude for the availability of services and the opportunity to pursue treatment in order to try to expand their families. Victoria compared favourably with the rest of Australian and other parts of the world on a number of key safety indicators.

Nonetheless, the Review has already identified a number of areas where improvements can be made.

Although Victoria has greater regulation of ART than most other Australian jurisdictions, there remain ongoing concerns about the adequacy of oversight of quality and safety, and the impact of increased corporatisation and expansion of the sector. While the Review notes that corporate provision of healthcare is not unique to this setting and does not equate to an unmanageable conflict of interest, the weight of opinion that patient experience is being adversely affected by some business and clinical practices warrants further consideration.

Furthermore, the Review has heard credible and significant evidence that breaches of the Act and risks to patient safety are not always identified and/or appropriately acted upon. The public consultation has raised concerns about patient experience, and that these concerns are not always being adequately attended to by the industry. There is strong support from many stakeholders for a stronger role for a regulator to provide independent oversight of the co-regulatory arrangements in this industry.

While increased competition and the introduction of new players has improved access to some lower cost services, this is not always comprehensive, and cost remains a significant barrier to access and a driver of treatment choices. While some of the potential means of addressing cost are outside the

scope of this Review (i.e. Medicare), a range of approaches have been raised that might have a beneficial impact, including considering public provision of ART services.

Various provisions within the ART Act are discriminatory against particular groups in the community. Furthermore, the Review has heard some evidence of a range of social, cultural and practice barriers to treatment, and a lack of inclusive service provision for particular groups in the community. The experience of LGBTIQ+ (lesbian, gay, bisexual, trans and gender diverse, intersex, queer etc.) people accessing ART services has been a particular focus of the consultation and findings of the Review.

A further barrier to treatment is access to donors and surrogates for those who require them. Consideration of these issues (indeed all of the issues raised by the Review) has been greatly assisted by the feedback received from donor-conceived people who have been generous in sharing their experiences. A range of approaches to increasing access to donors and surrogates has been considered, with particular reference to the concerns raised by donor-conceived people.

Fertility management and preservation has emerged as a significant issue for many stakeholders. In particular the Review was alerted to the sharp increase in the number of people electing to freeze their eggs for later use. The intensive marketing of these services and the fact that these processes are not clearly reflected in the legislation has been raised as an issue.

The Review has heard evidence that recent changes, following the Australian Competition and Consumer Commission (ACCC) investigation of ART units reporting of success rates and the subsequent changes to the Reproductive Technology Accreditation Committee (RTAC) Code of Practice and the Victorian Assisted Reproductive Treatment Authority's (VARTA) conditions of registration, have had positive impacts. Nonetheless, patients continue to report that information provided about their personal likelihood of success, anticipated costs and the evidence base for some treatment remains inadequate, confusing and potentially misleading.

Many recipients of ART report positive personal relationships with their clinicians, nursing staff and/or counsellors, and have expressed gratitude for the opportunity to try to form a family. However, the Review also heard significant concerns about a lack of supportive and patient-centred care within clinics. Overwhelmingly people reported that support drops off throughout treatment and is poor towards the end of treatment – be that because of pregnancy or because ART has been unsuccessful, and/or a decision is being made to discontinue treatment. Supportive counselling was valued by many, but there is a perception that counselling has increasingly shifted from being therapeutic in nature to a 'tick box' compliance exercise with competing interests undermining the supportive purpose.

Recommendations

Although many of the more significant areas of reform likely to be proposed by the Review require further consultation and consideration, this Report does present a number of recommendations. These initial recommendations relate especially to the terms of reference to remove unnecessary or discriminatory barriers to access, especially for the LGBTIQ+ community, the adequacy of safeguards and improving access and affordability more generally. Taken together, these early recommendations are anticipated to remove discriminatory or outdated provisions from the Act and have an immediate impact on:

- strengthening capacity for the timely identification of potential quality and safety risks (Recommendations 1 and 2)
- improving access to low cost services (Recommendation 3)

- reducing unintended discrimination resulting in barriers to access for some women and members of the LGBTIQ+ community (Recommendations 4 to 11)
- improving access to donors and surrogates for those who need them (Recommendations 12 to 17).

In the final report, the Review will consider some broader dimensions of its terms of reference concerning improving access and affordability, the adequacy of safeguards, and the appropriateness of the regulatory framework. The Review's assessment is that ART in Victoria is, and should remain, subject to a co-regulatory framework, but is not making any recommendations on the design of the framework and safeguards at this stage. Similarly, the Review considers access and affordability is likely best improved by targeted public provision of services, and will assess specific options, such as public or public/private IVF clinics or a gametes bank, in its final report.

Summary of recommendations

Recommendation

Recommendation 1 – It is recommended that the Act be amended to include protections for individuals who report, or intend to report, breaches, or possible breaches, of the Act, or non-compliance with the conditions of registration of a provider, to the relevant regulator. It should be an offence for any person to refuse to employ, or dismiss another person, to refuse to treat another person or to subject another person to any detriment because the other person makes such a report to the relevant regulator.

Page 29

Recommendation 2 – It is recommended that legislation be amended to facilitate the sharing of information between relevant regulators and other bodies for the purpose of identifying and responding to concerns about safety and quality in assisted reproductive treatment. This will include sharing of quality and safety information between VARTA, the Patient Review Panel, AHPRA, the Health Complaints Commissioner, Safer Care Victoria, the Department of Health and Human Services and the Minister for Health.

In particular, the Patient Review Panel should be empowered to report instances of potential breaches of the Act to relevant regulators for investigation.

Page 32

Recommendation 3 – It is recommended that s. 8 of the Act be amended such that artificial insemination may be carried out by (i) a doctor; or (ii) by a person acting under the direct or indirect supervision and direction of a doctor who is carrying out artificial insemination on behalf of a registered provider.

Page 42

Background / rationale

The Review has heard from a number of stakeholders (including patients and staff of clinics) that they have been unwilling to report breaches or possible breaches of the Act for fear of adverse repercussions for their employment, future treatment or reputation within the industry. This recommendation will promote patient safety and improve quality of services. These changes should not create any duplication or overlap with health complaints bodies such as the Health Complaints Commissioner.

The Review has heard some evidence that information about incidents or issues arising from assisted reproductive treatment is fragmented, and that without specific legislative mandate this information cannot be shared between relevant regulators.

Prior to the current legislation, artificial insemination was able to be carried out by a person under the direction of a medical practitioner. The Act subsequently tightened restrictions such that only doctors could perform these relatively simple procedures (in contrast, other more complex ART procedures can still be carried out under the supervision of a doctor in a registered clinic). The tight regulation has resulted in increased costs and the closure of at least one rural clinic which was no longer sustainable.

Recommendation

Recommendation 4 – It is recommended that the Act be amended to remove any discrimination against married women who wish to access assisted reproductive treatment following separation. The Act should ensure that where a married couple have separated, the consent of a person who would otherwise meet the definition of a partner is not required to undertake treatment, provided that their gametes are not used without specific consent.

The government should undertake further consultation on the most appropriate way to implement this objective, and any implications for related legislation.

Page 47

Recommendation 5 – It is recommended that the definition of ‘donor’ in the Act be amended, as well as other defined terms which include the word ‘donor’, to make it clear that, regardless of gender, sexuality, gender identity or marital or relationship status, where a person provides gametes for use by their partner in a treatment process, that person is not considered a donor for the purposes of the Act.

Page 49

Background / rationale

A recent Federal Court decision found that s. 10(1)(a) of the Act was invalid in the circumstances of a woman who was estranged from her husband and as a consequence she was not required to obtain her estranged husband’s consent to undergo a treatment procedure under the Act. The Federal Court found that the requirement under s. 10(1)(a) of the Act that the woman must obtain the consent of her estranged husband operated to discriminate against her on the basis of marital or relationship status under the Commonwealth Sex Discrimination Act. The reason that s. 10(1)(a) is discriminatory is that it currently requires a person who is separated from their spouse to wait 12 months to apply for a dissolution of the marriage in order to access treatment without their estranged spouse’s consent. This contrasts to a person who separates from a de facto partner, as they do not have any such waiting period. (Recommendation 6, below, deals with the use of gametes and embryos following the separation of a couple).

The current drafting of the definition of donor does not exclude the provision of gametes by a person for use by their partner in a treatment process from that definition. In practice, clinics do not generally interpret the provisions relating to a ‘donor’ to apply to a person who provides gametes for use by their partner.

The interpretation of the donor provisions in respect of LGBTIQ+ couples is, however, inconsistent and has been interpreted to apply to the practice of egg sharing by women in same-sex relationships.

Stakeholders have indicated that clarity on the matter would be useful.

Recommendation

Recommendation 6 – It is recommended that a new provision be included in the Act to create a presumption that where a person has provided gametes for use by their partner in a treatment procedure, consent is withdrawn in respect of the use of those gametes, or any embryos formed from such gametes, following the separation of the couple.

Page 50

Background / rationale

There is currently no provision in the Act, nor consideration prior to treatment, which addresses the status or use of gametes provided, or embryos created, following the separation of a couple.

It is proposed to amend the Act to create a presumption that the consent of a person who has provided gametes for use by their partner in a treatment procedure is withdrawn following the separation of the couple.

This provision is intended to provide clarity for the clinics regarding the status of gametes and embryos in storage once they are made aware of the separation of a couple. It is not intended that the clinic will need to make enquiries as to the ongoing relationship status of people receiving treatment. The provision will address a gap, where currently the law is silent.

Recommendation 7 – It is recommended that s. 46 of the Act, which relates to posthumous use of gametes and embryos, be amended to provide that where written consent was provided by the deceased person, and appropriate counselling has been undertaken, the Patient Review Panel may approve the use of the deceased person's gametes, or embryos created from a deceased person's gametes:

- in a treatment procedure carried out on the deceased person's partner, or
- by the deceased person's partner in commissioning a surrogacy arrangement (regardless of the gender of the person or their partner).

Additionally, the requirement for written consent might be reconsidered, and the Patient Review Panel may be permitted to approve posthumous use where it is satisfied that the use is not inconsistent with the deceased person's expressed wishes.

Page 52

Section 46 of the Act, which allows for the posthumous use of gametes or embryos in specific circumstances, has been identified as potentially discriminatory. Stakeholders have indicated in particular that the current drafting unreasonably restricts the posthumous use of gametes, in accordance with the deceased partner's wishes, by women or by people who had been in same-sex relationships.

The Review has heard no rationale for the limitations imposed by s. 46 of the Act that restrict posthumous use of gametes in surrogacy arrangements to a woman's male partner. Accordingly, it is proposed that the provision be amended and simplified to remove these discriminatory elements.

Further, it would be appropriate to reconsider the need for written consent in cases involving the posthumous use of gametes. The Patient Review Panel should be authorised to approve posthumous use of a deceased person's gametes, or embryos created from such gametes, where it is satisfied that the use is not inconsistent with the deceased person's expressed wishes.

Recommendation**Background / rationale**

Recommendation 8 – Consistent with the objectives of the Victorian *Equal Opportunity Act 2010* and similar Commonwealth legislation, and recognising the diversity of our people and relationships, it is recommended that the ‘Guiding principles’ of the Act be amended to use non-discriminatory language, including in relation to gender, where appropriate. It is also recommended that the anti-discrimination principle in s. 5(e) be expanded to recognise people who are currently excluded.

Page 58

The current language in the ‘Guiding principles’ of the Act is outdated and does not reflect current standards and law related to anti-discrimination and equal opportunity. The ‘Guiding principles’ also do not protect the diversity of people and relationships identified in this Report.

Recommendation 9 – It is recommended that the Act be amended to remove any language that is potentially discriminatory against, or not inclusive of, particular individuals or groups on the basis of their sexual orientation, marital or relationship status, gender identity or sex characteristics. This will include (but should not be limited to):

- replacing discriminatory terms and using more inclusive language in the Act.
- amending s. 40(1)(a) of the Act so that the Patient Review Panel may approve a surrogacy arrangement if satisfied that there is a medical or social need for the surrogacy arrangement, to remove the requirement for same-sex couples to demonstrate that they are unlikely to become pregnant.

Page 59

There are examples of the Act being discriminatory towards, or not inclusive of, LGBTIQ+ people.

The Act also states that the Patient Review Panel can only approve a surrogacy if a doctor has determined that the intended parents cannot become pregnant. This results in the requirement that two men in a same-sex relationship must have a doctor certify that they cannot become pregnant.

Recommendation 10 – It is recommended that s. 29 of the Act be amended to ensure that the limit on the use of donated gametes applies to ‘families’ rather than ‘women’.

Page 61

The current restriction on donating gametes to more than 10 women discriminates against women in same-sex relationships. The restriction can have the effect of preventing women in same-sex relationships having biologically related children by accessing the same donor’s gametes. By amending the provision to replace the word ‘woman’ with ‘families’ the Act will remove this barrier and recognise women in same sex relationships as a family.

Further consideration will be given to the appropriate limit on the number of families able to use gametes from the same donor.

Recommendation**Background / rationale**

Recommendation 11 – VARTA and the Patient Review Panel should work together with the LGBTIQ+ community to develop embedded, regular inclusive practice and cultural competency training for ART industry members and staff.

VARTA should amend the conditions of registration to require clinics to ensure that all staff involved in patient contact be required to undertake training in LGBTIQ+ inclusive practice.

Page 64

Inclusive practice and cultural competency are integral parts of removing barriers to access for LGBTIQ+ Victorians.

Rainbow Families Victoria indicated in their submission that the most significant, immediate change ART services could make would be education and training of clinics, and all the staff within them, in LGBTIQ+ inclusive practice.

Recommendation 12 – It is recommended that the Act be amended to allow for gamete donors to modify or revoke consent only up until the time the gamete is used, either for insemination or to create an embryo.

Page 79

The proposal aims to bring Victoria into line with interstate practice where withdrawal of consent by a donor is only permitted until the gametes have been used to create an embryo. The amendment will bring greater certainty for intended parents who wish to make independent decisions about the use of embryos created with donor gametes.

Recommendation 13 – It is recommended that the Act be amended to remove requirements for donors to consent to the extension of storage or disposal of embryos formed from donated gametes.

Page 79

Consistent with the amendment proposed above that consent may be modified or revoked by the donor until the donated gamete has been used, the Act should remove the requirements for a donor to consent to the extension of storage or the disposal of any embryos created from donated gametes. The Review considers that decisions relating to the use, storage or disposal of embryos formed from donated gametes are best made by the recipients of the donation.

Recommendation

Recommendation 14 – It is recommended that the Assisted Reproductive Treatment Regulations be amended to allow for the payment or reimbursement of reasonable costs that are incurred by a surrogate where the costs would not have been incurred but for the surrogacy arrangement. It is intended that this should better reflect the actual costs incurred by surrogates as a result of taking on that role. Costs that may be covered should include, but not be limited to:

- medical costs for the birth mother (including costs incurred prior to conception, during pregnancy and after delivery) or a child born as a result of a surrogacy arrangement where these are not payable by Medicare or private health insurance
- a premium payable for health, disability or life insurance that would not otherwise have been obtained
- counselling expenses
- reasonable legal costs for the birth mother and their partner (if any)
- lost earnings because of leave taken— for a period of not more than 2 months during which a birth has happened or was expected to happen; or (ii) for any other period during which the surrogate was unable to work on medical grounds as a result of the surrogacy
- other out of pocket expenses including travel, accommodation and childcare.

The nature of costs agreed by the parties to a surrogacy arrangement should be disclosed to the Patient Review Panel as part of the application for approval of the surrogacy arrangement.

Page 86

Background / rationale

The category of surrogacy expenses currently eligible for reimbursement in Victoria is overly restrictive and inconsistent with the NHMRC Guidelines. It is recommended that Victoria's legislation be brought into line with other jurisdictions, to allow for the payment or reimbursement of reasonable costs that are incurred by a surrogate. It is envisaged that the nature of costs agreed by the parties to a surrogacy arrangement would be disclosed to the Patient Review Panel as part of the application for approval of the surrogacy arrangement. Costs listed on the application could subsequently be amended if gaps were subsequently identified by the parties. The Review will continue to consider issues around the enforceability of surrogacy arrangements to better protect surrogate mothers in respect of costs incurred; and the possible role of a third party intermediary in processing payments between surrogates and intended parents.

Recommendation**Background / rationale**

Recommendation 15 – It is recommended that section 44 of the Act be amended to make it an offence for all parties to enter into, or offer to enter into, a commercial surrogacy arrangement. A surrogate must not receive any material benefit or advantage as a result of the surrogacy arrangement and the intending parents must not provide or offer to provide material benefit or advantage in exchange for the surrogacy arrangement.

Page 86

The current drafting of the Act makes it an offence for a surrogate mother to receive payment but not for commissioning parents to offer such payment. To remedy this oversight, the Review recommends that section 44 of the Act be amended to make it an offence for intended parents, as well as a surrogate, to enter into or offer to enter into a commercial arrangement.

Recommendation 16 – It is recommended that references to “commissioning parents” in the Act be replaced with the term “intended parents”.

Page 87

It would be appropriate for references to ‘commissioning parents’ to be replaced with ‘intended parents’ throughout the Act. The proposal aims to use more sensitive language preferred by parties to a surrogacy arrangement and is consistent with terminology used in a number of other Australian jurisdictions.

Recommendation 17 – It is recommended that the Status of Children Act be amended to remove the now redundant reference in section 23(3). A new provision should allow for parties to a surrogacy arrangement to receive counselling from a counsellor providing services on behalf of a registered ART provider or an independent counsellor who meets specified qualification criteria and has relevant experience and skills.

Page 95

Section 23(3) of the Status of Children Act provides that relevant parties to a surrogacy arrangement must receive counselling from a counsellor within the meaning of section 61(3) of the Assisted Reproductive Treatment Act 2008.

This is an incorrect cross-reference as section 61(3) of the Act has been repealed.

It is proposed that section 23(3) be amended to require that counselling be provided by a counsellor providing services on behalf of a registered ART provider or an independent counsellor who meets specified qualification criteria and has relevant experience and skills.

Key issues for consultation in second stage of Review

Many of the matters raised in this Interim Report require additional information or further consideration before a policy response can be proposed.

The Interim Report presents a range of potential directions that have not yet been sufficiently investigated or canvassed with key stakeholders to enable refinement of proposals, confirmation of likely impact and assurance that no undesirable outcomes will result. These issues will be the focus of consultation in the second stage of the Review. Some of the major proposals to be examined in more depth in the second stage of the Review are:

- **More effective co-regulatory arrangements.** ART in Victoria is, and will remain, subject to a co-regulatory regime. The Review will continue to consider the most appropriate regulatory model to support this, taking account of both specific ART regulation and broader health service regulation. This will include consideration of the most appropriate regulatory approach and the entities that should deliver it. The idea of a regulated code of practice has been considered. This would adopt the RTAC Code of Practice but give it greater standing than a voluntary code, and could additionally address a range of regulatory gaps and issues identified including information provision, counselling, requirements for clinical governance, patient-centred care and inclusive practice. Alternatively, RTAC could initiate changes to its Code of Practice and procedures to address the concerns raised in this Review.
- **Public provision of services.** Two Victorian institutions are considering proposals for the establishment of public health ART services, particularly targeting patients who may not be able to afford private health services. In general, it is likely that the establishment of such public ART services would improve access and affordability of in vitro fertilisation (IVF) services, and offer a model of high-quality care that integrates teaching and research that is common across the health system. The Review will continue to consult and obtain information about these proposals and provide further advice in the Review's final report on the likely impact of such proposals on access, equity, affordability, patient-centred care, the evolving market for ART and the regulatory framework for ART.
- **Support service to connect donors and surrogates.** The establishment of a statewide service to facilitate connections between donors, surrogates and recipients may assist in increasing supply of, and improving equity of access to, donated gametes and altruistic surrogacy. Such a service might also provide a safer option for connection, and better information and education, and thereby reduce the risks of exploitation and misinformation associated with some of the unmoderated online forums currently being used.
- **Sperm/egg bank.** The establishment of a public service that recruited donors of gametes, stored gametes, and made them available fairly to all ART providers would reduce a major access barrier – the shortage of donor eggs and sperm. In addition, it would reduce pressures on Victorians to travel overseas to source donor gametes, provide a supportive framework for altruistic donations, and support the Victorian regulatory framework that provides donor-conceived people a right to know their genetic heritage. Establishment of such a bank raises a number of complex ethical, regulatory and business issues, and the Review will test proposals further with stakeholders.
- **Improving information available to people seeking treatments.** The Review has heard of a number of initiatives that would improve the information available to patients on their individual prospects of having a child through ART. Feedback has also been received about the need to improve information about costs and the efficacy of treatments. The Review will further examine the best means that this information could be provided to patients within an overall model of patient-centred care.

- **Transparent oversight of quality and safety.** The Review has heard that there is scope to strengthen the oversight of quality and safety of ART services and improve clinical governance. The Review will investigate ways to ensure adequate monitoring of services without unnecessarily increasing regulatory burden. To this end, the Review will consider reforms introduced following the *Targeting Zero* review of hospital quality and safety oversight in Victoria, which included expanded and better aligned reporting and clinical governance requirements for public and private health services. The Review will also consider what, if any, role Safer Care Victoria, the state's healthcare quality and safety improvement agency, might play in supporting any proposed changes.
- **Counselling.** Stakeholders have raised a range of issues around counselling, including the mandatory nature of counselling; timing and accessibility of counselling; the scope, quality and format of the counselling provided; and the independence, qualifications and role of counsellors. The Review will explore areas of concern and highlight opportunities to provide more comprehensive, patient-centred care for people accessing ART.

1. Introduction

1.1. Background

The Minister for Health announced the 12-month review of the Victorian regulatory framework for ART in April 2018.

The announcement acknowledged that the last substantive review of the laws governing ART occurred more than 10 years ago and that, since that time, technology, community attitudes and supply and demand for treatment have evolved significantly.

The terms of reference for the Review are included in Appendix 1.

1.2. Public consultation

The interim findings and recommendations presented in this Report have been greatly informed by consultation with key stakeholders and with the public more generally.

To guide the consultation, a paper was released on 22 August 2018 (Gorton 2018). The consultation paper was distributed broadly to service providers, relevant peak bodies, academics, professional groups, consumer organisations, advocates and regulators. Direct emails were sent by the Review team to key stakeholders and the assistance of services and peak bodies was sought to ensure even broader distribution. The consultation paper was also made available to the general public on the Department of Health and Human Services website and the government's Engage Victoria website.

The consultation paper outlined the key issues to be considered by the Review and, in particular sought guidance from stakeholders in relation to:

- the appropriate objectives for the regulation of ART in Victoria
- access to ART
- costs, affordability and effectiveness of treatment
- access to donors and surrogates
- LGBTIQ+ Victorians' access to and experience of ART
- information to enable people to make informed choices about treatment
- support before, during and after treatment
- oversight of services.

Stakeholders were invited to provide a formal response to any, or all, of the questions posed in the consultation paper and/or to complete a short survey on the Engage Victoria website.

To supplement the submission and survey process, approximately 40 meetings were involving more than 120 stakeholders between July and September 2018. This included meetings with both individuals and groups of people with particular relevant knowledge or areas of expertise and attendance by the Review team at standing meetings and forums. Details of these consultation activities are outlined in Appendix 2.

In order to generate awareness of the Review, opportunities to promote it through print media, radio and social media were pursued.

Although timeframes for stakeholder feedback were short, there has been considerable interest in the Review. The Engage Victoria webpage for the Review received over 2,000 visitors, with 211 people making at least one contribution through the site.

A total of 191 survey responses were received. The majority of these (nearly 60 per cent) were people who identified as recipients of ART. A more detailed breakdown of the characteristics of survey respondents is included in Appendix 3. In addition, Rainbow Families Victoria conducted a similar survey of an additional 86 members of its community.

Further, 40 formal submissions were received from service providers, professionals in the field, relevant regulators, recipients of ART, donor-conceived people and other interested stakeholders. A list of submissions received is at Appendix 4.

The consultation feedback received to date has informed this Interim Report and will continue to be considered as future recommendations are developed during the next stage of this project. It is anticipated that further consultation, targeted to particular stakeholder groups or particular issues, will be required prior to finalising the recommendations of the Review.

1.3. Other information considered

The Review examined available data about the use, costs and outcomes of ART and changes over time. Where possible, Victorian data was compared with data from other jurisdictions.

Information about ART providers operating in Victoria has also been reviewed. This includes publicly available information on websites, information provided to patients (where this was made available by clinics) and information regarding the companies providing services, including financial data accessible through annual reports or public announcements, including those lodged with the Australian Stock Exchange.

The Review has also considered the regulatory arrangements for ART in place in other states and territories and in other comparable countries. Lessons learned from evaluation of different approaches have informed the recommendations and directions of the Review.

The findings outlined in this Interim Report also draw on the wide range of relevant inquiries and reviews that have been undertaken into various aspects of ART and its regulation over the last decade, both in Victoria and elsewhere.

Finally, published research related to clinical practice, service management and patient outcomes and experience has been surveyed.

2. Context

As outlined in the consultation paper, this review is taking place at a time of considerable change for the ART industry.

ART in Victoria occurs within a crowded regulatory environment (Figure 1). Relevant legislation exists at both the national and state level and there are statutory and industry-based regulators and oversight bodies involved.

The regulatory landscape today is very different from that which existed in 2008 when the Act was introduced. It was 2010 before the Australian Health Practitioner Regulation Agency (AHPRA) was established and the Health Practitioner Regulation National Law commenced. Significant changes have been made to Victoria's health complaints scheme (2016) and to the quality oversight of health services (2017).

There have also been significant changes in the clinical practices and business environment of ART.

2.1. Overview of ART practice

As many as one in six couples encounter problems with fertility. ART offers these people help with conceiving and ultimately giving birth to a healthy live baby. Fertility treatments are complex and costly, and each assisted reproduction cycle consists of several steps. The stakes are high, because conception may not occur if one of the steps is incorrectly applied.

These steps are outlined in a recent review of Cochrane reviews of ART (Farquhar and Marjoribanks 2018):

- Persons undergoing treatment are prepared through counselling and assessment by doctors, nurses and counsellors.
- Drugs are provided to stimulate growth of multiple ovarian follicles, to suppress the natural menstrual cycle and to down-regulate the pituitary gland.
- After ovarian stimulatory drugs are initiated, monitoring is undertaken at intervals to assess the growth of follicles.
- When the follicles have reached an appropriate size, the next step involves giving a drug to bring about final maturation of the eggs (known as ovulation triggering).
- The next step involves egg (oocyte) collection, usually with the help of an ultrasound probe, in a process known as oocyte pick-up. Sperm are collected through ejaculation or, in some cases, surgical methods of sperm retrieval.
- The fertilisation process itself is usually completed by IVF, with many sperm in a petri dish or by intracytoplasmic sperm injection (ICSI), where a single sperm is injected into the egg.
- Laboratory procedures follow for embryo culture. Issues include differing culture media and oxygen concentrations, and for some, co-culture, assisted hatching and other techniques. The embryo may be cultured for two to three days (cleavage stage) or five to six days (blastocyst stage).
- Some or all of the embryos may then be frozen: in 'fresh' cycles, one or more embryos are used immediately; otherwise embryos are frozen and stored for later use in 'thaw' cycles. Freezing may

be relatively slow or fast in a process known as vitrification.

- Fresh or thawed embryos are then placed into the uterus. Issues of importance at this stage include endometrial preparation, the best timing for embryo transfer, how many embryos to transfer, what type of catheter to use, the use of ultrasound guidance, need for bed rest and so on.
- A range of hormones may then be provided to help establish pregnancy.

All of these procedures may result in a chemical pregnancy (which may last only a few days, and were it to occur through natural conception may not have been noticed), a clinical pregnancy (which may only last months and lead to a miscarriage), or most successfully, a live birth.

It is not the role of this Review to assess the evidence on the clinical effectiveness of various ART procedures. However, a number of important characteristics of this complex set of procedures are important to emphasise when reviewing the regulatory framework for ART.

First, ART is a multidisciplinary practice. The patient may be supported by a fertility specialist (an obstetrician and gynaecologist with subspecialty training), a general practitioner, a fertility nurse and other nursing staff, embryologists and other scientific specialists, fertility counsellors (generally trained psychologists or social workers), counsellors outside the clinic, pharmacists and range of diagnostic professionals. The patient's experience will also be shaped by how these services are marketed and paid for. Regulatory frameworks need to provide oversight of the quality and safety of all parts of this multidisciplinary practice, and ensure they work effectively together.

Second, some of the most critical steps in the ART process are undertaken by embryologists in laboratories, rather than by the treating clinicians. Technical procedures in the laboratory can make a significant difference to ultimate live birth rates. Relatively minor administrative or technical mistakes in the laboratory can lead to catastrophic consequences, such as the use of incorrect genetic material. The quality of the procedures undertaken by embryologists and other technical staff prior to the transfer of the embryo are central to the success of ART, and make for a unique intertwining of medicine and laboratory practice.

Third, ART is a field with ongoing scientific advances that flow through to changes in treatment procedures. For example, in recent years in Australia, in response to improved cryopreservation methods (freezing gametes or embryos), there has also been a shift from the use of fresh embryo transfers to thawed embryo transfers. There has also been a shift towards transfer at a later stage of the embryo's development, from cleavage to blastocyst stage transfers (Fitzgerald et al. 2018). These changes in procedures do make for some complexity – for both regulators and patients – in understanding key outcome measures (such as live birth rates), variations in clinical practice, and the performance of clinics and practitioners.

Fourth, although the science of ART continues to advance, the evidence base for some ART procedures and interventions is patchy. The recently published overview of Cochrane reviews (Farquhar and Marjoribanks 2018) identified 68 Cochrane systematic reviews on various stages of the ART cycle as they related to IVF and ICSI, but not intrauterine insemination (IUI) or ovulation stimulation. It identified 38 interventions that were effective or promising, and 19 interventions that were ineffective or possibly ineffective. For 15 interventions, the reviews were unable to draw conclusions owing to lack of evidence. During the course of this review, consultations have highlighted debates within the clinical community about the overuse of IVF (compared to IUI), concerns with a range of adjuvants that are not supported by a sufficiently robust evidence base, practices such as endometrial scratching and ICSI, and possible risks of preimplantation genetic diagnostic or screening tests. Given the high costs of IVF treatment for both patients and the public (through Medicare rebates), there is a need to ensure that patients are receiving evidence-based medicine, and are aware if treatments they choose to engage with are not yet proven.

Finally, the steps involved in IVF present a very complex array of choices to patients. At times, it can be bewildering and overwhelming. It can be challenging to understand the full implications of treatment – the likely success rates, the health risks, how many cycles of treatment, the range of medications, the benefits of and, importantly, the total cost of the many procedures.

In brief, ART is not just any ordinary medical procedure. It is more than a medical procedure because of the vital importance of high-quality scientific and technical procedures involved in the fertilisation and growth of the embryo. It involves the creation of new life and the formation of families. It responds to both medical issues and the emotional desire of people to have a baby. More than one person is involved in the treatment. It may involve a couple, and also donors and surrogates. All of these differences mean that ART requires special regulation that is sensitive to the interests of all those involved and attentive to the ongoing clinical, scientific and ethical advances in the field.

2.1.1. The evolving market for assisted reproductive treatment in Victoria

The public consultation paper noted that this review is taking place at a time of rapid change and growth in ART service provision in Victoria, and the rest of the world.

It noted the growth in the numbers of people who have been treated in Victoria since the introduction of the current Act in 2008, and the developments in the industry since 2008 with new providers entering the market.

Table 1: 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 (2017–18)
17,687 treatment cycles	23,743 treatment cycles (34% increase)
Then (2008–09)	Now (2017–18)
9,262 patients treated	12,959 patients treated (40% increase)

Source: VARTA 2018

During the course of the public consultation period, three data sources have provided additional data on the trends in the development of the industry over recent years. The Australian and New Zealand Assisted Reproduction Database (ANZARD) published its annual comprehensive publication, including 2016 data for Australia and New Zealand on live birth outcomes. VARTA published its annual report, including treatment services figures for the 2017–18 financial year, and treatment outcome data for all Victorian clinics and treatment sites for the 2016–17 financial year. Finally, the Review analysed publicly available data on use of Medicare ART items.

ANZARD, live birth rates and other outcome data

ANZARD reports the latest aggregated Australian national and New Zealand data on procedures and outcomes but does not publish state level or clinic level data (Fitzgerald et al. 2018).

From 2012 to 2016, the total number of cycles commenced in Australia and New Zealand increased by 16 per cent to 81,062 cycles. The rate of live deliveries per thaw cycle increased by 6.2 per cent to 28.2

per cent or 8,440 live deliveries. In contrast, the rate per fresh embryo transfer remained stable and resulted in 6,075 live deliveries.

During the same period, the percentage of cycles where all of the eggs or embryos produced were frozen for later use increased on average 37.4 per cent per year. This reflects changing clinical practice, including a greater preference for thaw rather than fresh embryo transfer cycles.

The percentage of embryo transfer cycles that used embryos created with ICSI has declined slightly from 64.7 per cent to 62.9 per cent. The majority of embryos are now frozen at the later blastocyst rather than cleavage stage of development as was previous practice – the use of blastocysts has increased by 18.6 per cent to 78.4 per cent of all embryo transfer cycles. Quick freezing using vitrification has also substantially increased by 28 per cent to 83.7 per cent of all embryo transfer cycles.

Consistent with the increasing practice of transferring only a single embryo per cycle, the percentage of multiple deliveries (twins or more babies) continued to decline from 6.5 per cent to 3.8 per cent.

The age groups of women who undertake ART using their own eggs have remained relatively stable between 2012 to 2016. Those in the 35–39-year age group comprise the largest group – in 2016 this was 36.2 per cent followed by 29.0 per cent in the 30–34-year old age group. The women in the age group least likely to achieve success with their own eggs are those between 40–45 years – they comprised 22.7 per cent of the 76,255 women treated.

Victorian clinic treatment data

VARTA publishes data on treatment outcomes and procedures at a Victorian level. Clinics report the same data to VARTA as they do to ANZARD, but on a financial year rather than calendar year basis. VARTA reports total numbers of the various aspects of treatment and outcomes but do not express these as a per capita rate. Apart from multiple pregnancies, VARTA does not publish adverse outcome data.

Table 2: Victorian clinics and treatment sites 2017–18

Treatment site	No. of women treated	No. of cycles included
Ballarat IVF	317	609
City Babies	145	242
City Fertility Centre	855	1,758
Genea	16	22
Melbourne IVF	4,392	8,868
Monash IVF	4,637	7,923
Number 1 Fertility	412	506
Primary IVF	1,211	2320
The Royal Women's Hospital	974	1,495
Aggregated total	12,959	23,743

Source: VARTA 2018

Of particular note is the impact on the market of the recent entrants Primary IVF and Number 1 Fertility. According to VARTA's most recent data, while the volume of services has been relatively stable, there has been increased competition in Victoria with low-cost provider Primary IVF growing to 10 per cent of all women treated in Victoria. Number 1 Fertility was established in 2017–18 by a fertility specialist formerly employed at Monash IVF, and now services in excess of 3 per cent of the market. These market developments have considerably impacted on the market share of Monash IVF, and the likely medium-term trends are difficult to predict.

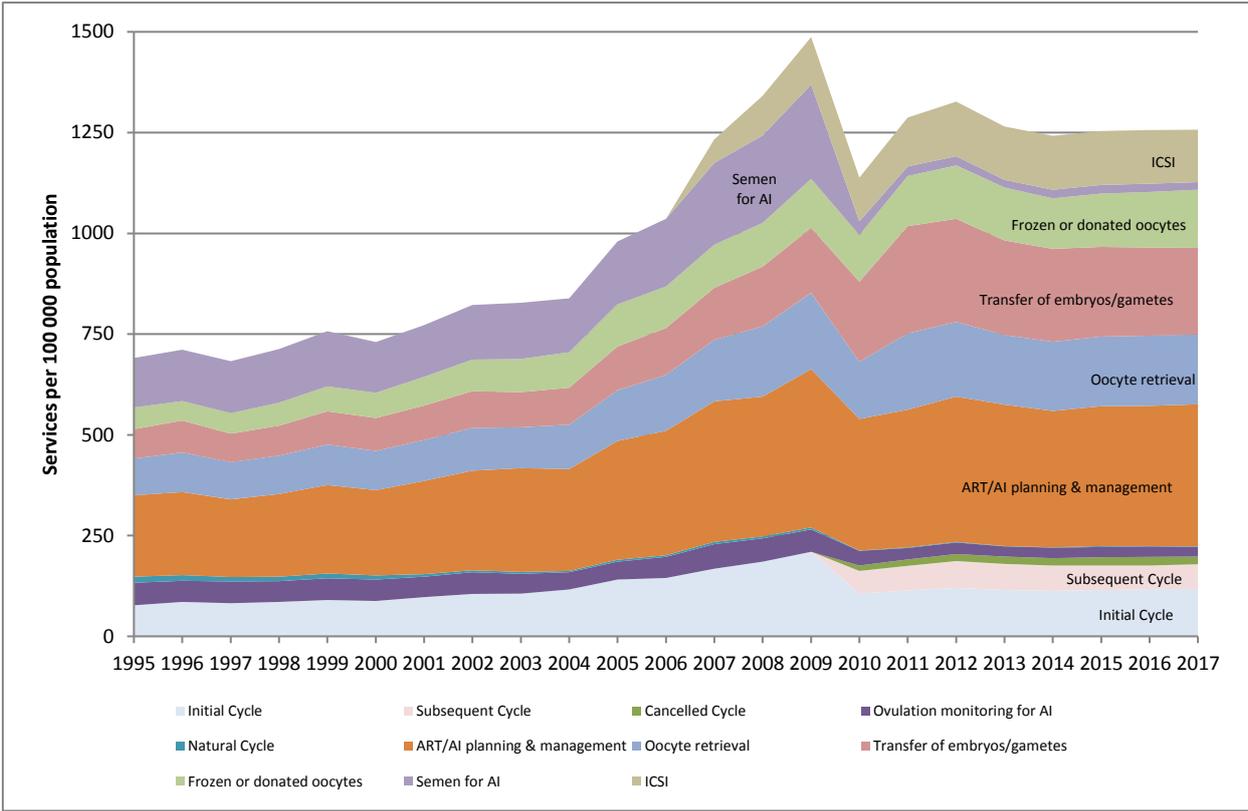
2.1.2. Medicare support of assisted reproductive treatment

Medicare publishes extensive statistics on all Medicare items including counts of services, per capita rates of service use, and total benefits paid by item numbers. This data can be analysed by state and some demographic information is available for item numbers. Of most relevance to ART is the age breakdown of the use of ART services. Medicare data on ART items is available from 1995 to July 2018.

The Medicare data gives the strongest indication of trends over time and allows some comparison of rates of treatment in Victoria compared with other states. The Medicare data, however, does not capture the range of ART services that do not attract rebates. Some people undertaking ART are not eligible for Medicare rebates, most notably people without medically diagnosed infertility – for example, some LGBTIQ+ and single parents by choice accessing ART. However, the difference between ANZARD and Medicare total treatment numbers is not large. In addition, some services – notably elective egg freezing – that have reportedly been growing in recent years are not recorded in Medicare statistics.

MBS data shows that the sector grew considerably from the 1990s to approximately 2010, and has been relatively stable since (Figure 2). It should be noted that there was a significant change to the rules for the Medicare Safety Net in 2010 that led to a change in billing arrangements in 2009. Advice from the Commonwealth Department of Health is that the spike in service numbers in 2009 and fall in 2010 is largely a result of rebates being brought forward into 2009 in anticipation of this change to the Medicare Safety Net rules.

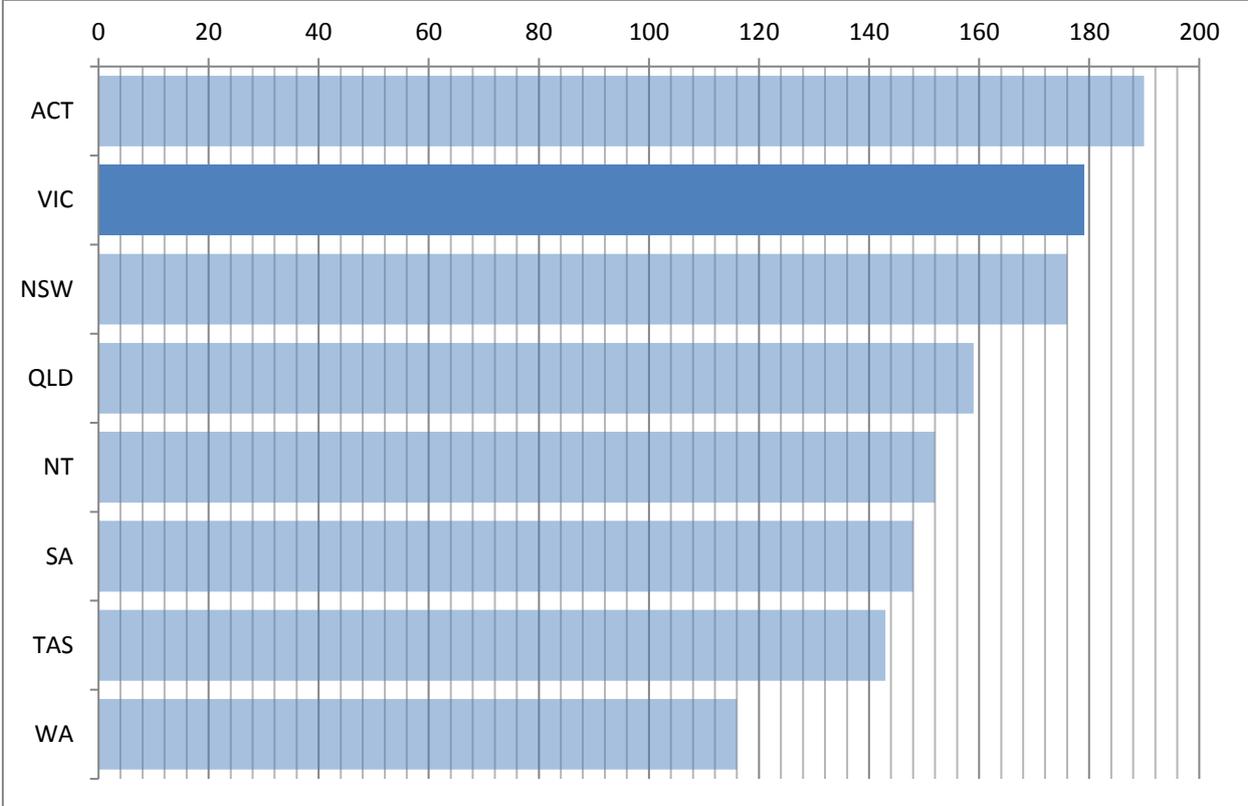
Figure 2: ART Medicare items – Victoria 1995–2017



Source: Australian Medicare Statistics

MBS data also shows Victoria’s relative performance – per capita rates of treatment in Victoria are high compared with other states (Figure 3). While there is considerable debate about the impact of increased regulation in Victoria, it does not appear to have held back the provision of services.

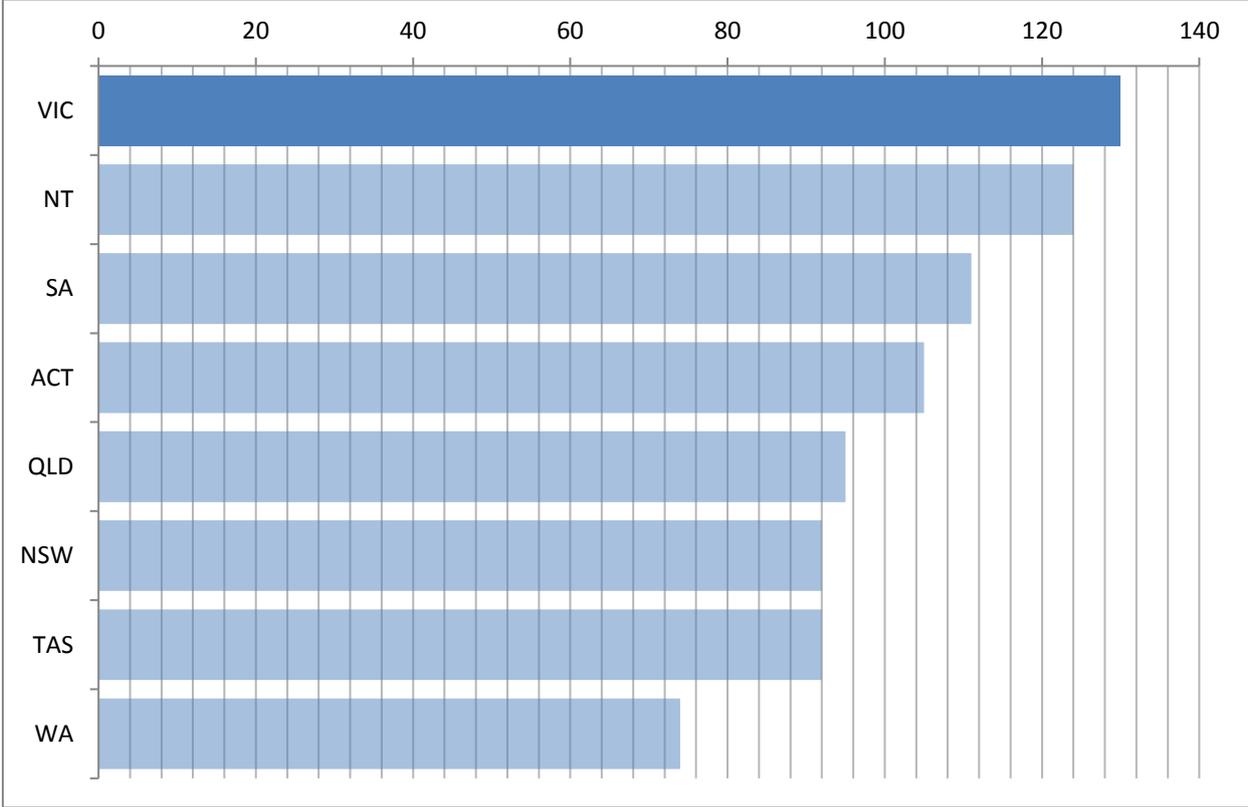
Figure 3: Medicare ART cycles (items 13200 and 13201) per 100,000 people by state and territory



Source: Australian Medicare Statistics

Victoria also has the highest rate of ICSI use of all states and territories and is substantially above other populous states. ICSI is an invasive technique for the egg and is used primarily for male factor infertility and when using previously frozen eggs; there is a lack a robust evidence base for other uses (Farquhar and Marjoribanks 2018). It is not clear why Victoria’s rate is comparatively higher and concerns about this have been expressed during consultations (Figure 4).

Figure 4: Medicare ICSI cycles per 100,000 people by state and territory

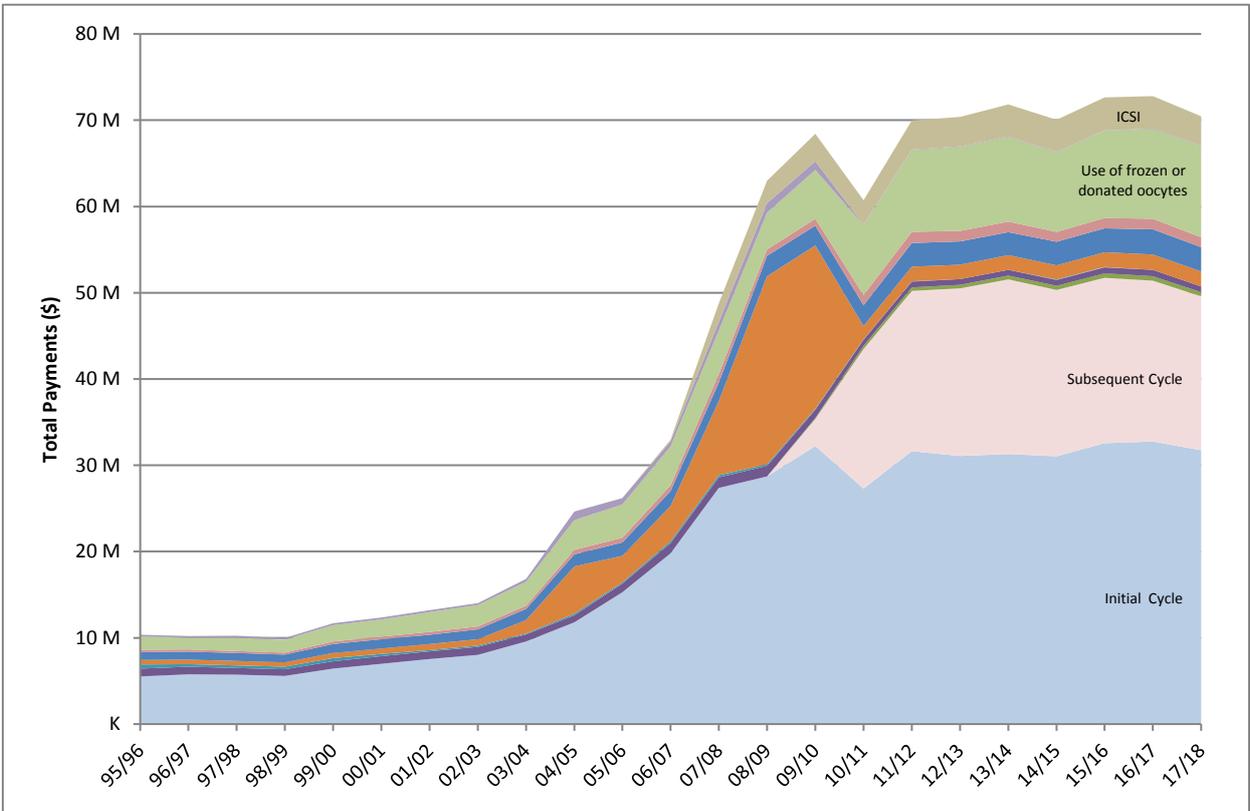


Source: Australian Medicare Statistics

In total, Medicare benefits totalling \$70.5 million were paid to Victorians for ART items in 2017–18 (Figure 5). The largest item numbers in terms of benefits were the two primary item numbers for the management of the initial or subsequent cycle (13200 and 13201) and item number for the use of frozen or donated oocytes in a treatment cycle (13218). This last item number has grown most significantly in recent years, corresponding with reported increases in egg freezing, use of donated eggs among older women and changes in practice in the use of thaw cycles more commonly.

It appears to be an industry that has reached a plateau in expanding access to infertility treatments. This is consistent with the modest projections for growth of the publicly listed firms – Virtus and Monash IVF – which project growth broadly in line with population growth. Significant increases in demand are unlikely without significant changes in technology or the price of services, or other initiatives that would facilitate access to patients who cannot afford the high out-of-pocket expenses of IVF currently or who are ineligible for Medicare rebates.

Figure 5: ART Medicare Benefits – total payments (\$) Victoria 1995–2018



Source: Australian Medicare Statistics

Finally, none of these sources of data provide information on the numbers of Victorians who travel interstate or overseas for ART, especially those persons who travel overseas for donor gametes or surrogacies. This is a common practice, and is motivated by a variety of reasons including difficulties in accessing local donors or surrogates. In some cases, Victorians travel to countries with a poorer safety record on key measures (such as the United States of America with its high multiple pregnancy rate) or to jurisdictions (such as Spain) that have a regime of donor anonymity. The Review will attempt to further explore this issue for its final report, however, estimating the numbers of people who travel overseas for treatment is difficult.

3. Findings and directions

Overview

Reflections on feedback received and how it is understood

The views expressed by respondents to this review are as diverse as the people who make use of ART services, and those who work in and provide those services.

Fertility care occurs in a highly multidisciplinary setting. Clinics employ and/or engage a wide range of professionals including patient liaison staff, clerical officers, health information managers, fertility nurses and embryologists as well as specialist medical practitioners. Each of these groups brings different expertise, interests and perspectives to reflecting on the way that clinics operate, and the care provided to patients. Those in positions of management or corporate governance bring a different set of considerations, while people with lived experience of ART reflect on the service system from another perspective altogether. These varied, and sometimes competing and contested, viewpoints are reflected in the feedback received from stakeholders.

One of the great challenges of this Review is to understand how all these different, but equally legitimate, perspectives should be understood and inform recommendations. In part, this has been guided by the set of core objectives for the regulatory framework for ART that were proposed in the consultation paper.

Respondents were generally supportive of these objectives, and in particular, the ongoing application of the guiding principle of the Act that:

the welfare and interests of persons born or to be born as a result of assisted reproductive treatments must be paramount

Section 5(1)

Some of the most compelling and moving representations made to the Review came from those who are now, as adults, dealing with the consequences of decisions made 20 or 30 years ago that led to their conception. These decisions, made by people with the best of intentions who sought to help those who desperately wanted a child, have had ongoing, and in some cases difficult, impacts on the individuals born as a result of the ART practises of the time.

The feedback from people born as a result of ART is outlined in Chapter 3.1.

Overview of key emerging themes

Despite the many and varied responses received, a number of key themes have emerged that are summarised below and addressed in detail in the following chapters.

- The issues of the adequacy, burden and appropriateness of the current system for oversight of service quality and safety is discussed in Chapter 3.2, this was among the most divisive issue. The

Review heard strongly held views both in favour of more robust oversight and for reducing, or removing, regulatory requirements that are viewed as overly prescriptive or costly to comply with.

- Affordability emerged as a key concern among those seeking to use services and those who support them. Chapter 3.3 discusses the cost of services, the impact on accessibility and proposals for addressing barriers to access arising from affordability. The Review heard that one approach to addressing the issue of affordability, for at least some people who require assistance to form a family, is to ensure that low-cost services are available and accessible where appropriate. Chapter 3.3 also explores opportunities for properly trained nursing staff to undertake artificial insemination under supervision, to improve affordability for those who may benefit from these less invasive procedures access to services.
- The Review has heard that, in addition to concerns about affordability, there remain significant barriers to equity of access arising from the existing legislation. Chapter 3.4 highlights opportunities to remove discrimination against married women who wish to access ART following separation from their spouse and ensuring that the definition of 'donor' clearly excludes the partner of the person seeking treatment. The chapter also considers ways to clarify the use of gametes provided for use by a partner, or embryos created from such gametes, following the separation of a couple or the death of the gamete provider.
- A range of social, cultural and practice issues can prevent equitable access to services or mean that services are not experienced as equally inclusive of all groups in the community. For example, the Review heard that access to ART for Victorians living in rural and regional areas can be difficult and travel expenses and additional time off work can add to costs. Further, notwithstanding legislative changes, there remain cultural and practice issues that are experienced as exclusionary by single people accessing ART services. Accordingly, Chapter 3.5 explores geographic barriers to access, the experience of single people accessing ART, and the extent to which services are inclusive of other groups in the community.
- The terms of reference for the Review specifically ask whether the regulatory framework creates or enables unnecessary barriers to access for LGBTIQ+ people. Chapter 3.6 identifies opportunities to address a range of legislative, social, cultural and practice barriers, to better meet the needs of the LGBTIQ+ community. Some of the key recommendations include updating the 'Guiding principles' of the Act to broaden inclusiveness, removing discriminatory language from the Act, clarifying that the current limit on the use of gametes applies to 'families' rather than 'women', and enhancing clinic staff training in LGBTIQ+ inclusive practice.
- Feedback to the Review indicates that the lack of supply of donor gametes, in particular donor eggs, is leading to an increasing reliance on importation of gametes and to people travelling interstate or overseas to receive treatment. Chapter 3.7 considers ways to improve access to donor gametes and embryos; and enhance support for all individuals involved in donor conception. Some of the key topics explored in this chapter include ways of increasing the number of local donations in Victoria, including through better public education and awareness, improving communication channels between potential donors and recipients, and the establishment of a local donor and sperm bank. The chapter also considers current limits on the number of families formed from gametes donated by the one person, as well as donor control over the use of gametes and the storage of gametes.
- The Review heard that there are a number of areas of the legislation focusing on surrogacy that would benefit from greater clarity and a reconsideration of the most restrictive provisions that hinder access to such arrangements. Feedback highlights that improving the local system will give more opportunities for intended parents to access surrogacy locally rather than travelling interstate or overseas. Chapter 3.8 explores a range of topics to improve access to surrogacy, including current restrictions on reimbursement of reasonable costs incurred by a surrogate and barriers to advertisements and publications concerning surrogacy arrangements. Opportunities to introduce more counselling support for intended parents and surrogates during the pregnancy and following the

birth of a child, and ways to bring traditional surrogacy within a clear and supportive regulatory framework are also considered in this chapter.

- Fertility management and preservation is a significant issue for a number of stakeholders. Chapter 3.9 considers ways to improve fertility education, as well as opportunities to clarify the provision of fertility preservation treatment, including egg freezing, within the legislation. The Review heard concerns about the intensive marketing of egg freezing to women concerned about age-related fertility loss and that the promotion of these services may give women false assurances about their future fertility. Given the high costs of this procedure and the strong social and psychological pressures on women who are making decisions about their fertility, this chapter also considers the need for the practices of clinics in this area to be further regulated, and with a clear ethical framework and evidence-based medicine.
- The Review heard that there is a significant unmet need for comprehensive, accessible and accurate information about treatment options, risks, possible outcomes and costs to enable service users to make informed choices. People need to have the right information at the right time, so they can understand options available to them at all points in their engagement with services. Chapter 3.10 explores the quality and process of information provision about a range of matters including success rates, costs and adjuvants.
- The need for support was a consistent theme in submissions and survey responses from current and past recipients of ART. Many people described experiences of inadequate support. There are concerns in particular that counsellors attached to fertility clinics are not independent and this hinders the counselling process. The role of counsellors to review police checks can also give rise to tension in therapeutic relationships. Chapter 3.11 examines the support offered to people undergoing ART, and proposals for enhancing the availability, timing, format and quality of counselling made available to those seeking ART. The chapter also considers the role and independence of counsellors.
- A range of matters related to the storage of gametes and embryos were raised during consultation and are explored in Chapter 3.12. Key issues considered include the time limits on the storage of gametes and embryos, and the processes for extending storage periods, which are considered to be unnecessarily restrictive. The Chapter also explores the current regulation in relation to research involving stored gametes, and whether this unreasonably restricts the capacity for important research.
- Chapter 4 provides reflection on a range of matters beyond the scope of this Review which nevertheless generated considerable stakeholder feedback. The key topics explored in Chapter 4 include the requirements for police and child protection checks, the role and operation of the PRP, implementation of the *Assisted Reproductive Treatment Amendment Act 2016*, and prohibition on sex selection.
- Many of the matters raised in this Report require additional information or further consideration before a policy response can be proposed. The issues which will be the focus of research and consultation in the next stage of the Review are set out in Chapter 5 of the Report.

3.1. Welfare and interests of persons born as a result of ART

The first guiding principle of the *Assisted Reproductive Treatment Act 2008* (Vic) is that:

the welfare and interests of persons born or to be born as a result of treatment procedures are paramount.

This principle reflects the distinctive character of ART as a medical procedure – when successful, it leads to the creation of new individuals, who must be treated with dignity and respect for their rights not only as children, but as they grow into adulthood.

Effective regulation in the welfare and interests of persons born or to be born as a result of treatment procedures can be challenging. Regulators must pay attention to the developing research on the long-term consequences and health risks of ART. They must also pay attention to the changes in family and other social relationships that support persons born as a result of treatment procedures. Some of these effects may not be known for many years. IVF is only 40 years old, and while most studies suggest no adverse health consequences, research is ongoing to identify any health problems that may only emerge later in life. ICSI is only 25 years old, and the evidence on the balance of health risks and consequences is not yet comprehensively assessed.

Nowhere is this more challenging than in relation to the interests of donor-conceived children. The welfare and interest of donor-conceived children include their relationships with their parents, donors and persons genetically related through both their parents and donors. It is a more complex world for them.

Many of today's donor-conceived adults were born under the earlier regulatory regime of donor anonymity and when it was the accepted norm not to tell donor-conceived children of the full story of their birth origins. Today, social norms promote telling donor-conceived children of their origins in childhood. The regulatory regime now supports the rights of donor-conceived individuals to know their genetic heritage, and provides for both donor-conceived and donors to make contact with each other. Today's donor-conceived adults have had to navigate the emotional highs and lows of these complex social changes. Supporting this process has developed into one of VARTA's most important functions, even though in some respects such a support and counselling role is unusual role for an industry regulator.

The terms of reference for this review excluded consideration of 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. Reflecting this exclusion, the public consultation paper had only a brief discussion of issues of concern for donor-conceived individuals.

What the Review has heard in the public consultations is that there is much to learn from the experiences of now adult donor-conceived children, and that there is great diversity in those experiences. The stories the Review has heard have highlighted the need to be mindful of the potential impacts of decisions on people born as a result of ART, even decades later.

Some survey responses reported a lack of interest from ART clinics in the experiences of donor-conceived persons.

Support services that extend beyond conception and encompass the child would give a better impression that they are interested in providing a service to parents and their children, rather than providing a product/child who is then out of warranty if they ever seek more information about themselves. It has often been my experience that in trying to contact clinics for even basic information, donor-conceived people are treated with disdain and lack of compassion which has lead people like myself to feel commodified and 'less than human'.

Survey response – person born as a result of assisted reproductive treatment

From our experience there was also very little information and support from the clinic with regards to the needs and potential issues faced by donor conceived children regarding stigma and access to biological connections.

Survey response – Rainbow Families Victoria submission

Counselling should address how the child may feel growing up and whether the parent/s are prepared for this. It should cover topics like connecting with half siblings created via donor conception, DNA testing and discovery, family mapping from a child's perspective (such as potentially wanting to call their donor their father). There is a responsibility to ensure donor conceived children grow up in fully aware, informed and supportive environments.

*From our personal experience the clinic provided plenty of support for us focussing on our experience. There needs to be **more focus on the health and wellbeing of the children created** [original emphasis], nothing was mentioned about the potential impact donor conception might have on a child and how to address this. More resources should be provided for parents with regards to this.*

Survey response – Rainbow Families Victoria submission

The donor-conceived people who spoke to the Review expressed a strong preference for greater use of local donors by ART clinics who would be bound by the Victorian rules that provide all donor-conceived Victorians access to available identifying information about their donors. Use of local donors and younger donors makes it more likely that a donor-conceived individual may be able to establish a relationship with their donor in adulthood.

The use of overseas egg and sperm banks were viewed by donor-conceived people as creating practical obstacles for adult donor-conceived individuals to contact their donors.

[M]y heart aches for 'DC' people in the future who will hope to seek out their 'donor' as I have and find that they are overseas, that they speak a language that they do not speak, or even that they'd passed away before the person had even been conceived. ... to allow the use of donor gametes from deceased people, international donors who will be largely inaccessible to DC people for various reasons and the inherent risks associated with overseas donors and sibling limits (or lack thereof) is in my opinion to take a step back toward anonymity and functional secrecy.

Survey response – person born as a result of assisted reproductive treatment

Similarly, donor-conceived people expressed concerns about large family sizes, caused by donors providing gametes for a large or even unlimited number of families. Some people talked of discovering that they had very large numbers of genetically related siblings. While the Review heard stories of powerful and positive relationships formed between donor siblings who met as adults, others talked of

the feeling of being 'cloned' or of constantly looking at people on the street and wondering if they could be related.

It never leaves my mind and I am constantly analysing people in the street comparing features to my own.

Submission – Chloe Allworthy – donor-conceived person

There was a suggestion that the likelihood of having a very high number of donor siblings is exacerbated by the use of less regulated overseas egg and sperm banks.

Overseas egg and sperm banks are often not subject to regulation regarding family limits. They may not keep records of people born because of the donations. It is not unusual for it to be reported that births from a single donor can be from 100–200.

Submission – professional in the field

The law needs to be more child focused, mostly it seems to revolve around the recipients and donors failing to consider the future for the children conceived. It's great that donations are no longer able to be anonymous however anonymous sperm can still be imported and there are no regulations about donor access when it comes to private arrangements and home insemination.

Survey response – Rainbow Families Victoria submission

Donor-conceived people told the Review of the importance of knowing where they come from and the possibility (if all parties wished) of having some connection with genetic relatives. They expressed varied experiences of the impact of their birth origins on their developing identity, making contact with their donors in adulthood, and the impact of these contacts on their other family relationships. In some cases, donors welcome contact and form positive relationships with donor-conceived offspring. In other cases, donors refuse contact or donor-conceived people do not wish to form connections with their donors. Stakeholders advised that with the growth in DNA testing and use of family history databases such as ancestry.com, many people are now discovering their donor-conceived origins or finding their genetic relatives unexpectedly and outside of any regulation or support. The diversity of experiences highlighted the importance of support services for donors and donor-conceived persons to address specific concerns of donor-conceived individuals and to establish the connections that work for them.

A common concern expressed by donor-conceived people was in relation to donor siblings. One survey response urged the government to provide donor-conceived people with identifying information in relation to their donor siblings so that the community does not 'set up the next generation for accidental incest'. A widely reported concern was the possibility that an individual may have multiple half-siblings of a similar age living in the same state, but no way of knowing who they are.

Allow donor-conceived people to outreach to their siblings. Not only is it extremely difficult to ask our donors to do this for us, this is reliant on us actually knowing/locating or having contact with our donors ... discovering my brother changed my life in many positive ways, allowing me a friend to lean on who understands the feelings I may be going through, as he is going through them too. Isolation is a terrible feeling for any human being, and having (now many) siblings, has improved my sense of identity, support and my quality of life.

Submission – Chloe Allworthy – donor-conceived person

I do wonder if the donor registry could be extended to include requests to contact donor siblings. It would be good if siblings could voluntarily seek each other out with assistance from the registry.

Survey response – Rainbow Families Victoria submission

Allowing this to happen would require changing the rules for releasing information related to donors established by the *Assisted Reproductive Treatment (Amendment) Act 2016* (Vic), and is outside the terms of reference. However, some reflections on these matters are made later in this Report.

Most stakeholders expressed support for the ‘Guiding principles’ of the Act, including making the welfare and interests of persons born through ART the paramount concern. However, some legal specialists in the field did express concerns with the clarity and balance of the ‘Guiding principles’ and how they impact on all involved in ART.

Professors Jenni Millbank, Isabel Karpin and Anita Stuhmcke of the University of Technology Sydney argued that:

We do not believe that the current objectives strike the right balance and in particular we do not accept that the first objective ‘the welfare and interests of persons born or to be born as a result of treatment procedures are paramount’ is correct because it misleads clinicians and other health practitioners into a focus on (what they imagine to be) the interest of non-existent persons over and above those of their female patient. Most ART procedures do not result in the birth of a child and the majority of patients undertaking treatment, like all other prospective parents, are better judges of what is in the interest of their putative future child than a stranger is likely to be.

... Assisted reproductive technology (ART) procedures must be conducted in a way that is respectful of all involved. While all persons are affected by these technologies, women more than men are directly and significantly affected by their application and the health and well-being of women must be the central consideration in the application of these technologies. People who seek to undergo assisted reproduction procedures must not be discriminated against, including on the basis of their disability, race, sexual orientation or marital status. Clinical decisions must respect the long-term health and psychosocial welfare of all participants, including gamete donors.

Submission – Professors Millbank, Karpin and Stuhmcke – University of Technology Sydney

Dr Michelle Taylor-Sands of the University of Melbourne argued that there is a lack of clarity around the welfare of the child principle. She commented that the principles/objectives in the ART Act remain relevant and the welfare of the child is an important principle to uphold. However, there is a genuine need for this concept to be more clearly articulated by Parliament in the Act itself.

Rather than viewing the interests of donor-conceived individuals as outweighing all other interests, it is more accurate to view the donor conception scenario as a complex web of interrelated interests that sometimes coincide and sometimes conflict.

Taylor-Sands 2018

These issues of how best to frame the principles of the Act and to balance the interests of donor-conceived individuals with all others involved in ART are complex. It would be desirable for the issues raised here to be clarified in any substantive legislative amendments to the Act that may follow this Review.

However, one clear finding from the public consultation is that there is a need for more research and public education on the experiences of donor-conceived individuals.

There's a fundamental lack of awareness in the community about donor conception, about what it means and why donors should not be fearful or concerned about what DC people might seek in terms of information in the future.

Survey response – person born as a result of assisted reproductive treatment

The voice of donor-conceived people should be strong in that research and public education, and the diverse range of experiences should be represented. The experience of a donor-conceived child growing up today, informed of their birth origins and in contact with their donor siblings, will be very different to the generation who have had to contend with the legacy of donor anonymity. Furthermore, we do not yet know what impact a more globalised market for donation will have on the lives of donor-conceived people. Research and public education can build on work already undertaken by VARTA. There was strong support during the public consultation for VARTA's work in linking donors and donor-conceived persons, and general agreement that it performs this function very well and could expand it for broader public education and research.

The Victorian Government may wish to consider commissioning research on the diverse social and family relationships of donor-conceived children, and that this research informs approaches to implementing the 'Guiding principles' of the Act and linking donor-conceived individuals to their family members.

3.2. Patient safety and effective regulation

Stakeholders expressed a range of, at times conflicting, views about the adequacy and appropriateness of the regulatory regime governing ART in Victoria.

It was argued that Victoria is over-regulated in comparison with other states, and that this has resulted in duplication of effort, an unreasonable burden on providers and a waste of government funding, as well as having a negative impact on access to and affordability of treatments. Many of these concerns relate to the restrictions, such as police checks and mandatory counselling, that flow through to additional costs for patients.

For each additional requirement imposed on the organisation, significant resources and costs are associated with meeting these requirements.

Submission – Monash IVF

It was suggested that this greater level of regulation is unnecessary as there exists a national accreditation scheme used by a number of jurisdictions that have not introduced specific state-based legislation.

The FSA has the view that its longstanding, internationally recognised accreditation process through RTAC provides the appropriate safeguards for those undertaking ART and their offspring.

Submission – Fertility Society of Australia

For example, respondents pointed to Australia's success in reducing the multiple birth rate associated with IVF treatment as a sign that the self-regulatory accreditation model through RTAC is working well and can deliver improved patient safety (University of New South Wales 2017; Fitzgerald et al. 2017).

The RTAC Code of Practice has been responsible for directing changes in the practice of ART Units since 1986 for the good of patients and off-spring, such as the increased use of single embryo transfers to reduce multiple pregnancy rates after IVF.

Submission – RTAC

Adverse outcomes occur in any sphere of health care ... In ART in Australia disastrous outcomes have not occurred. Loss of embryos from freak events, for example, the power cuts in SA or the mishandling of a culture dish by an embryologist will always be a risk whatever legislation or regulation is created. These types of events are rare given the vast number of embryos that clinics deal with.

Submission – RTAC

Conversely, some stakeholders expressed concerns about an over-reliance on an industry-based accreditation system, particularly within an increasingly corporatised and competitive industry. There appears to be a reasonably widespread perception among survey respondents, whether justified or not, that there is a conflict of interest inherent in the self-regulatory approach.

I want to particularly call for attention to any arrangements where organisations effectively monitor and report on themselves without sufficient independent quality assurance and review. The role of VARTA is essential.

Submission – Deb Martindale – recipient of assisted reproductive treatment

... [S]elf-regulation of a multi-million dollar industry clearly poses risks. Private clinics are owned by companies which depend on private investment and report to their shareholders on profit which in turn relates to numbers of patients, cycles and additional tests sold, not the health and wellbeing of those affected by or born of ART.

Submission – VANISH

A small study of perceptions of conflict of interest within the IVF industry found that there were several ways in which commercial interests affect, or have the potential to affect, clinical practice in ART clinics. They linked commercialisation in general (and corporatisation in particular) to significant changes in clinical practice. This was, in turn, linked to physical and psychological harms to women, as well as harms to the taxpayer from exploitation of the Medicare funding model (Blakely et al. 2017).

Furthermore, the Review has heard concerning reports, from both recipients of care and individuals working in the field, that practice inconsistent with the RTAC Code, breaches of the Act and risks to patient safety occur more frequently than is acceptable, and at least some of the time go unreported and unaddressed.

The Review has heard credible evidence, from a person known and respected by the Reviewer and with extensive experience in the industry (name withheld to protect anonymity), about a number of serious incidents of which this person has direct knowledge.

Clinical incidents observed by professional in the field, referred to here as ‘Charlie’¹

Incident 1

During their time working in the field, Charlie observed an incident during which an error in a freezing schedule resulted in the loss of embryos.

It is understood senior management elected not to advise the affected patients and chose not to keep records of the incident.

Incident 2

Charlie reported to the Review an incident where faulty incubators within the laboratory of an assisted reproductive treatment clinic resulted in the loss of a number of embryos. The affected patients were not advised of the equipment failure, but rather were led to believe the embryos had succumbed naturally.

Incident 3

Additionally, Charlie told the Review of an incident in which a scientist was ordered, by a doctor, to load a degenerate embryo into a transfer catheter. Despite this, the doctor told the patient she had a viable embryo and a good chance of success. The doctor then transferred the embryo into the patient.

Charlie advised that the doctor later explained to the scientist that the doctor did not explain to the patient that her embryo had not survived because they did not believe that the patient would understand.

The scientist is understood to have complained to the scientific director but was told scientists cannot override doctors instructions and not to worry about it.

The person who gave this evidence observed that:

Incidents such as these do not get identified in routine audits and the culture of many clinics is that employees are threatened with disciplinary action for speaking out.

Survey response – name withheld – identified known industry professional

Recipients of ART have also shared stories of suboptimal care, including instances where their health was significantly impacted and where they felt the response of the clinic was inadequate. In one case study (see below) there appeared to be a failure to identify the warning signs of a serious adverse event, a lack of communication and inadequate emergency management procedures.

¹ Name changed to protect anonymity.

Case study: patient experience

Celine² had several stimulated cycles of IVF, with each cycle being characterised by increasing nausea, vomiting, headache and weight gain. Celine found communication with the clinic to be frustrating, as a different nurse would eventually ring back each time, and sometimes not at all. This also made it difficult to establish much-needed rapport and obtain consistent advice. Egg pick-ups resulted in excessive deep swelling and bruising. After Celine's first stimulated cycle failed to result in a pregnancy, she was advised by a nurse that it was not necessary to see her doctor until she was five weeks pregnant and that she should go straight on to another stimulated cycle. Celine contacted her doctor herself, who told her that she should not do another stimulated cycle straight away.

There were repeated failures of communication between the clinic and Celine's treating doctor. Egg pick-ups were followed by increasing nausea, vomiting and heavy bleeding – repeated calls to the clinic advised her to 'self-monitor' at home without apparently recognising the potentially serious nature of her condition. Her treating doctor advised her to attend the emergency department for pain relief resulting in prescription of opioid pain killers.

By the third stimulated cycle her increasing symptoms, including abdominal pain, meant that she needed higher amounts of opioid painkillers. After her egg pick-up Celine collapsed at home and had to be revived by the MICA ambulance. Consequently, she spent over two weeks in hospital with fully developed ovarian hyperstimulation syndrome in much pain and with difficulty breathing. The hospital doctors had difficulty obtaining information from the clinic on her prior treatment. Months later, Celine still does not feel fully well and is reticent to return for further fertility treatment given the high chance of recurrence of ovarian hyperstimulation syndrome. Celine is reluctant to complain to the clinic about her treatment as she has embryos remaining in storage.

It appears from the responses received in surveys and submissions that, although perhaps not common, this was not an isolated incident.

In our time there were a couple of concerning errors – lost bloods, temporarily lost sperm, inability to reach urgent on-call medical advice after hours.

Submission – Deb Martindale – recipient of assisted reproductive treatment

I got hyper ovarian stimulation syndrome and found the response from my IVF clinic a little lacking; the women's emergency was much better.

Survey response – Rainbow Families Victoria submission

Troublingly, many of the respondents who reported safety or quality concerns in relation to their treatment told the Review they had not reported their experience nor made a complaint. In some cases, this was because they did not know who to tell; in others it was out of concern about personal repercussions if they were to do so.

² Name and some identifying details that do not impact on the critical details of the case study have been altered to protect anonymity. This case study is from a person who has been identified and has met with the Review team. She has requested that neither her personal details nor the name of the clinic or clinicians involved be disclosed, but the Review is confident that this is a reliable report of her experience.

Concerns have also been raised about the rigour of the accreditation and audit processes currently in place. The Review has been told, by those with experience of the process, that clinics are forewarned of the audit taking place and take steps to project a positive image, such as ensuring staff who may expose poor practice are not on site those days. It has also been reported that clinics will ensure that the most readily accessible paperwork is compliant in the expectation (usually realised) that auditors will not dig deeper. The Review has heard that auditors are not always specialists in the field and may not have the expertise to detect technical or clinical problems.

3.2.1. Driving improved quality, safety and patient experience

The Review does not disagree with those respondents who highlight that Victoria's level of ART regulation is greater than other states and territories. The Review would argue that government should not resile from this. Victoria has long been recognised as leading the way in the regulation of ART to promote quality and safety.

At this point in time VARTA remains the 'best practice' model for an example for other Australian jurisdictions.

Submission – Professors Millbank, Karpin and Stuhmcke – University of Technology Sydney

Nonetheless, much of this Report is dedicated to understanding the impacts of regulatory restrictions on access to particular treatments. Other areas of regulation, unique to Victoria, such as requirements for police and child protection checks, are outside the scope of this Review. In these respects, Professor Millbank and others argue that:

... the Victorian ART legislation is unduly intrusive and still fails to find the right balance between State concern to prevent harmful practices and patient autonomy.

This part of the Report is focused not on these elements of the regulatory framework, but rather on the extent to which the existing co-regulatory regime is delivering effective leadership and oversight of quality and safety. It is noted, as was outlined in the consultation paper, that the introduction of the existing Act saw a removal of some of the oversight and approval powers previously exercised by the Infertility Treatment Authority in favour of the national self-regulating model. It introduced a deemed registration scheme where RTAC accredited clinics are required to be registered by VARTA and the state-based regulator has limited oversight of process and practice. The evidence heard by the Review, and outlined above, indicates that this is an area where improvement and revisiting of the adequacy of the regulatory regime may be warranted.

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.

It has been noted by the Review that, while the RTAC Code of Practice is comprehensive in relation to a number of critical practice issues, other important drivers of quality and safety, including patient-centred care, open disclosure requirements and staff safety and learning culture are not so well addressed.

VARTA has sought to strengthen this focus through inclusion in conditions of registration for all Victorian clinics (under s. 75(1) of the Act) requirements for the provision of information about quality improvement actions identified and implemented in response to serious incidents. The conditions also require that providers should be guided by the Australian Open Disclosure Framework in communicating with patients about any such incident.

While this approach may go some way to promoting a focus on ongoing learning and a culture of continuous improvement, the Review will continue to consider whether these aims could be better achieved through more direct statutory requirements in regard to clinical governance.

Under the Health Services (Health Service Establishment) Regulations 2013, oocyte retrieval must be carried out in a registered health services establishment. This requirement has been criticised by some providers as unnecessarily increasing costs associated with treatment. These people have noted that no such requirements exist in other jurisdictions where egg-retrieval procedures can be undertaken in clinic rooms. The Review notes, however, that consultation was undertaken to update these Regulations in 2017, with a view to removing ART from the list of prescribed services that fell within the Regulations. This consultation identified sufficient clinical safety concerns around the process of oocyte retrieval to warrant the ongoing inclusion of this practice within the scope of regulated services.

The recent changes to the Regulations, introduced in 2018, also included new requirements for quality and safety review data, driven at least in part by the recommendations of *Targeting Zero*. These requirements cover regular quality and safety reviews, collection and reporting of patient experience data and staff safety culture survey data. The Regulations also include stronger requirements about appointments to senior positions. The Review will consider whether the requirements for private hospitals introduced through the Regulations may provide a model for addressing gaps in quality and safety oversight identified in relation to ART services.

3.2.2. Information to monitor and drive improvements in quality and safety

Targeting Zero: the review of hospital safety and quality assurance in Victoria (Duckett et al. 2016) described information as the 'lifeblood' of a continuously improving system. That report found that a failure to collect, make available or use data significantly limits the capacity of a system to identify risk and opportunities for improvement.

The data reporting obligations of ART clinics are significant and have been described as burdensome. Clinics are required to report data to ANZARD, VARTA and RTAC, however, it is not yet clear to the Review that the information collected can provide a complete picture of the quality of practice or that it is being used to optimal advantage to oversee and improve patient safety and experience. The Review undertook targeted consultation with professional groups including the Royal Australian and New Zealand College of Obstetricians and Gynaecologists, Safer Care Victoria, the Australian Medical Association and The Royal Women's Hospital, among others. There was general agreement about the difficulties of reporting complications, sometimes serious, of ART.

Data reporting requirements

The RTAC Code of Practice requires clinics to provide ANZARD with specified data relating to treatments and outcomes. Clinics must also report to RTAC on all serious notifiable adverse events. A serious notifiable adverse event is defined as an abnormal unintended outcome associated with ART operations which:

- might result in the transmission of a communicable disease
- might result in death or a life-threatening, disabling, or incapacitating condition
- arises from a gamete or embryo identification error or mix-up
- might impact safety of people, gametes, embryos, equipment or facilities as a result of a disaster
- might result in a potential or actual breach of legislation.

Incidents reported to RTAC as part of accreditation requirements must also be reported to VARTA, as a condition of registration, as must information about any incident (resulting from actions of the provider or a doctor carrying out treatment procedures on behalf of a provider) that constitutes:

- an actual or potential contravention of the Act or Regulations
- an actual or potential breach of conditions for registration or conditions attached to any approval granted by VARTA
- a contravention of the 'Guiding principles' of the Act.

Under the conditions of registration, providers are also required to provide to VARTA the information that VARTA must report annually to the Minister for Health under s. 114 of the Act. This includes information about treatment programs, participants in treatment procedures conducted, embryos formed, and embryos and gametes stored.

As a relatively recent development, VARTA has also started collecting (as a condition of registration) information about the use of adjuvant therapies currently offered as part of a program of treatment by an ART provider.

The Review is conscious that any additional requirements for data reporting would need to be well justified. It is also clear that there is scope to streamline reporting to ensure that it does not add to the administrative burden on services. In particular, under the VARTA conditions of registration, providers must report required data to VARTA by the end of the third week in August (or such other date as is notified by VARTA). This timeline is to align with VARTA's annual reporting requirements under the Act. There may be value in considering if these reporting obligations could be amended to enable alignment with national reporting requirements. The Review has heard that this would have the additional benefits of allowing for more ready comparison of Victorian and national data regarding activity and outcomes of treatment and allowing for more meaningful analysis of data by VARTA.

If the review results in an ongoing state requirement for reporting, the dataset must align with ANZARD ... double handling of data adds to patient costs.

Submission – Fertility Society of Australia

There may also be scope to ensure that reporting requirements are clearly defined and consistently applied across clinics.

... [S]elf-reporting forms an integral component of the current self-regulatory model, particularly in relation to incidents and adverse events. Primary IVF believes that the decision criteria around what constitutes a reportable event needs [sic] to be better defined.

Submission – Primary IVF

Complaints, feedback and reports by patients or staff

Complaints, patient and staff feedback are powerful sources of information about quality and safety and can be a strong driver of continuous improvement (Duckett et al. 2016).

AHPRA receives notifications regarding registered practitioners working in the industry, and complaints about ART may be made to the Health Complaints Commissioner (HCC).

Unfortunately, advice received by the Review is that the information held by these regulators is recorded in a manner that allows only part of the picture to be understood. AHPRA does not record notifications on the basis of setting. The HCC is able to provide data on the number of complaints made in relation to

registered clinics, but this data may be incomplete as it does not include complaints made about individual practitioners working within clinics.³

Complaints to the Health Complaints Commissioner

A total of 28 complaints regarding assisted reproductive treatment clinics were received by the Health Complaints Commissioner between 1 February 2017 (when the *Health Complaints Act 2016* commenced operation) and 20 July 2018 (just under 18 months).

The complaints received related to 58 separate issues.⁴ Inadequate or misleading information was the single most common issue cited (10 complaints), followed by inappropriate fees or billing (eight complaints) and inadequate or inappropriate treatment (seven complaints).

While the Review has been advised that clinics regularly undertake client surveys, further information is required from clinics to better understand the scope of these and the use to which the resulting data is put.

All services are required to have and promote an avenue for complaints under the RTAC Code of Practice. However, many recipients of treatment have told the Review they either did not know how to complain or provide feedback, or they feared repercussions impacting on their ongoing treatment if they were to complain.

Patients should have a clear ethical review panel they can turn to if they feel something has not been done correctly, professionally or morally. All patients should have to be educated on how to contact this ethical board / contact person etc. by the clinic they are going through for ART – this should be law.

Survey response – recipient of assisted reproductive treatment

Most of the information about suboptimal quality or safety risks reported to the Review has been provided in confidence and it appears that respondents have not reported these issues to RTAC, VARTA or any other regulatory oversight body. A number of those people who told the Review of the adverse experience stated that they were not aware at all of the existence of the HCC or their rights to complain to the Commissioner.

It is not clear to the Review how consistently regular employee climate surveys are undertaken across all clinics. These surveys provide important indicators of a culture of safety and quality improvement in which staff feel confident that they can raise issues. There are signs that some staff in Victorian clinics do not feel confident about raising their concerns. The Review received a significant number of submissions from people working in the field that were provided on condition of anonymity. Published research has highlighted concerns within the industry of commercial practices compromising patient care (Lipworth 2017). One survey response from a professional in the field stated:

³ The Review notes that new data systems planned for the HCC may address some of the issues identified.

⁴ A single complaint may relate to multiple issues.

... neither VARTA nor RTAC offer a complaint pathway for employees of IVF clinics. It is often only employees who are aware of issues at clinics. Without a complaint avenue for employees, there is no way for many issues to come to light. However, given that the clinics are private, any complaint mechanism which is enacted must come with 'whistleblower protection' as employees are bound by confidentiality agreements, and often threatened with disciplinary action for raising complaints.

Survey response – professional in the field

Those requesting that their information be treated in confidence, both patients and staff of clinics, have expressed concern that reporting this information may result in adverse consequences for them personally.

The Review will continue to seek information about how patient feedback, staff climate surveys and complaints data is currently collected and used, with a view to identifying any possible recommendations aimed at enabling a stronger culture of learning and improvement.

At a minimum, the Review will seek to ensure that avenues exist for all staff and patients to provide feedback easily and safely. The Review would hope to find that information about complaints processes (including those available through the HCC) are readily available.

It is clear, however, that opportunities are being missed for more effective oversight of serious incidents and identification of significant risk due to individuals concerns about the repercussions of raising issues. The Review proposes that a legislative amendment to include protections for those who bring serious matters to the attention of the regulator is warranted.

Recommendation 1

It is recommended that the Act be amended to include protections for individuals who report, or intend to report, breaches, or possible breaches, of the Act, or non-compliance with the conditions of registration of a provider, to the relevant regulator. It should be an offence for any person to refuse to employ, or dismiss another person, to refuse to treat another person or to subject another person to any detriment because the other person makes such a report to relevant regulator.

Other data sources

The Review has also been advised of hospital-level data that may contribute to an overall understanding of the safety of ART. For example, The Royal Women's Hospital was able to provide data about the number of emergency department presentations and admissions for ovarian hyperstimulation syndrome (OHSS).

As described below (see boxed section), the hospital-level data on this condition is of interest as it presents a broader view of the rates of OHSS than the data reported through RTAC. While less serious instances of OHSS may not warrant clinical case review in each individual instance, disproportionately high rates arising from treatment by one provider may well indicate a greater risk of more serious, potentially life-threatening cases.

Indeed, concerns were raised in targeted consultations with health professional groups that an unrepresentatively high rate of these presentations were linked to patients of one particular provider. These professionals have indicated that reporting such information to a regulator is not possible without a specific legislative mandate. At least one clinic had indicated they would support a move to mandate reporting of adverse events associated with ART such as OHSS.

Reporting of OHSS

Ovarian hyperstimulation syndrome (OHSS) is a complication of controlled ovarian stimulation where excessive follicles are produced with high levels of oestrogen, progesterone and secretion of proteins that cause leakage of blood vessels. Women may complain of abdominal discomfort and mild swelling, feeling bloated, nausea and weight gain. If left untreated, OHSS may be life-threatening and/or cause serious health implications.

Rates of OHSS requiring hospitalisation are reported to ANZARD by clinics under the RTAC Code of Practice requirements.⁵ The most recent publicly available report of this data states that there were 215 OHSS cases reported in Australia and New Zealand in 2016. The explanatory notes recommend caution when interpreting this data because OHSS is not consistently reported. ANZARD data are not reported by state and Victorian data is not available publicly. While VARTA is now collecting, through the conditions of registration, information about any adverse incidents reported to RTAC, the Review understands that this information is not yet comprehensively reported. Victorian data made available to the Review indicated that clinics had reported approximately 25 incidents in Victoria in the first nine months of this year.

Data provided by the Victorian Royal Women's Hospital for the period 1 July 2017 to 25 September 2019 (almost 14 months) shows just under 70 presentation for patients presenting to the Emergency Department with OHSS and just over 30 OHSS patients admitted as inpatients .

Given that this data is from just one Melbourne based hospital, and it would be assumed that Monash Health and the Mercy Hospital for Women, for example, might also see significant numbers of women with symptoms of OHSS, it would appear that hospitalisation for OHSS is underreported.

Further consideration will be given to how information from services (like The Royal Women's Hospital) might be collected and utilised to contribute to monitoring and oversight of quality and safety concerns. It may be that a clear legislative mandate for the disclosure of relevant information is required, and the Review will consider this in greater detail before making its final report.

In line with its role in supporting the monitoring and improvement of healthcare quality, Safer Care Victoria has expressed a willingness to assist in identifying how the range of information available may be enhanced and better utilised for the purpose of quality and safety oversight, and in particular the identification of practice issues that may require intervention of a greater level of clinical guidance and the enhancement of patient-centred care.

Transparency of information

Transparent outcome reporting is a key component of a learning culture. It is also something that many recipients of treatment would like to see improved.

⁵ A 2014 [RTAC technical bulletin](https://www.fertilitysociety.com.au/wp-content/uploads/20150211-RTAC-Technical-Bulletin-Number-5.pdf) <https://www.fertilitysociety.com.au/wp-content/uploads/20150211-RTAC-Technical-Bulletin-Number-5.pdf> provides suggested reporting management of adverse events. Reporting as a *serious notifiable adverse event* is recommended for 'Hospitalisation for OHSS that included paracentesis or draining of pleural effusions' and 'Hospitalisation for OHSS with permanent disability'. It is **not** recommended for 'Hospitalisation for observation and fluids after symptoms of OHSS'. (OHSS where hospitalisation is not required is not addressed at all.)

I have never been told the first thing about safety and quality procedures with regard to how samples and embryos are handled or stored etc. We all just have to cross our fingers and hope that standards are being maintained, but it is impossible to determine which clinic does this better or worse than others.

Survey response – recipient of assisted reproductive treatment

The Review has heard a wide range of views on public reporting ranging from the perceived risks of 'league tables' to the value of publicly acknowledging variations in practice. It is noted that the Human Fertilisation and Embryology Authority (HFEA) in the United Kingdom has recently introduced publicly accessible information on their website about each registered clinic including information about how patients rate the clinic; how inspectors rate the clinic; pregnancy and birth rates from different fertility treatments, multiple birth rates and waiting times for donated eggs, sperm or embryos.

Further consideration will be given by the Review as to how public reporting of information may be used to inform improved practice. (More information about information available to patients is discussed in Chapter 3.10.)

Removing barriers to the sharing of information for the purposes of quality and safety

In a crowded regulatory environment, as exists in relation to ART (see for example the overview of the regulatory environment included in the consultation paper and summarised in Figure 1), it is critical that the various individuals and bodies with responsibilities in the area are not restrained from sharing information.

An improved flow of information will allow responsible agencies to better identify and respond to risk. Recent legislative models such as the *Health Complaints Act 2016* (Vic), Family Violence legislation and legislative reforms made as a result of recommendations made in the *Targeting Zero* report have all moved to increase information sharing for the purpose of safety and quality.

The Review has heard that current concerns about confidentiality and the legal basis for sharing information have hampered cooperation between regulators. The PRP, RTAC, AHPRA and the HCC have all indicated that they would welcome reforms to clarify and positively support greater information sharing.

The threat of the breach of confidentiality is the major hurdle for effective communication, not an unwillingness to co-operate. Some form of formalisation that information can be shared directly between RTAC and VARTA would be an improvement

Submission – RTAC

We recognise that effective information sharing arrangements are critically important when operating in a complex regulatory environment such as assisted reproductive treatment.

Submission – AHPRA

A clearer capacity for information sharing with the Department of Health and Human Services and Safer Care Victoria would also support those entities in their system leadership and oversight roles and would also facilitate any role Safer Care Victoria might take on in assisting with better identification of clinical support needs.

Recommendation 2

It is recommended that legislation be amended to facilitate the sharing of information between relevant regulators and other bodies for the purpose of identifying and responding to concerns about safety and quality in assisted reproductive treatment. This will include sharing of quality and safety information between VARTA, the Patient Review Panel, AHPRA, the Health Complaints Commissioner, Safer Care Victoria, the Department of Health and Human Services and the Minister for Health.

In particular, the Patient Review Panel should be empowered to report instances of potential breaches of the Act to relevant regulators for investigation.

Related to this, the Review has also heard that information sharing between professionals working in the field is limited due to concerns about commercial advantage. This is seen by some as a more recent development and a disappointing departure from a previously more collegiate approach to learning and sharing advances across the sector.

3.2.3. Responsive regulation and oversight

As noted above, the introduction of the Act resulted in the removal of state-based oversight powers that had been exercised by the Infertility Treatment Authority under the previous legislation. VARTA has taken a comparatively 'light touch' to system oversight, as a result of both legislative mandate since 2008 and a preferred policy approach.

The safety issues identified earlier in this chapter suggest that there is scope for more responsive regulation to monitor, identify and respond to quality and safety risks, and to support and provide incentive for practice improvement.

This view is supported by the feedback received from many stakeholders.

I strongly believe that independent regulatory bodies should play a more active role in setting and auditing standards, and there needs to be an independent complaints review body to assist in identifying any systemic issues.

Survey response – recipient of assisted reproductive treatment

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

To be effective, a regulator needs clear powers to investigate issues that may arise, whether they are reported directly or identified through routine review of data and information relevant to quality and safety.

One goal of the current self-regulatory model is that ART providers themselves evaluate their own design implementation and outcomes of the compliance management systems. ... Generally however; organisations will only be motivated to do so because they know that regulators (and stakeholders) have powerful, sophisticated evaluative capacities to hold them accountable for their attempts at compliance management.

Submission – Primary IVF

Despite the large number of regulators with functions related to ART, the Review has heard that relevant quality and safety issues may not always be prioritised by agencies with wide ranging regulatory responsibilities. For example, the ACCC 2016 investigation of the claims made by ART services about their rates of success was instrumental in bringing about improved practice in reporting success rates. However, the ACCC and Consumer Affairs Victoria (CAV) have indicated to the Reviewer that this matter is unlikely to be the focus of further sustained effort. They state that, if ongoing concerns exist, it would be appropriate to ensure that dedicated ART regulators have appropriate powers and mandate to identify and respond to advertising or reporting practices that are inconsistent with the relevant laws and guidelines.

Similarly, the Review has heard that reports have been made to AHPRA about advertising and the use of testimonials. While AHPRA agrees these matters are within jurisdiction, they are unlikely to be given high priority given other more serious issues to be addressed.

The crucial laboratory work undertaken by IVF clinics is highly specialised and technical, and outside the competence of general regulators such as the ACCC, CAV or AHPRA. The Review heard that this is a gap in current regulation.

There is no real oversight of quality in IVF laboratories. The audits which do take place are cursory and inadequate Quality management in the laboratory I work in is non-existent If the right regulations and bodies were in place this would not be the case.

Survey response – professional in the field

Effective regulatory oversight not only requires a capacity to obtain and understand information about what occurs in services but also to intervene and take action when practice that falls below an acceptable level is identified. One survey respondent, a professional working in the field, stressed the importance of external accountability as well consequences for misconduct, as an incentive for ethical and responsible practice.

While the changes recommended above to allow for greater information sharing between regulators will improve the capacity for identify risks and opportunities for improvement to be identified, the Review has heard that there are provisions in the Act as it stands that may restrict the capacity of the regulator to identify and fully investigate such issues, for example:

- The ‘deemed registration’ function of VARTA, whereby VARTA must register a provider that has achieved RTAC accreditation, means that VARTA has little if any oversight of the processes and systems of an ART provider. VARTA therefore cannot assess the extent to which these are sufficiently robust or whether a provider has in place appropriate preventative measures to minimise the risk of adverse incidents and/or breaches of the legislation.
- The Act confers powers on VARTA members, for the purpose of determining compliance with a registration under this Act, to enter a premise and require the provision of documents or records for inspection. The Review has heard that the narrow terms of this provision can limit the regulators capacity to fully investigate matters that arise. VARTA is unable to exercise powers to compel doctors (who are not employees of clinics) to provide records or to cooperate with investigations.
- The lack of provision to allow for delegation VARTA’s investigative powers means that they may only be exercised when a member of the VARTA Board is present. This can restrict flexibility and responsiveness in response to issues.

The Review will give further consideration in the next phase to what, if any, changes are required to the regulatory powers currently available under the Act.

While the Act does confer some powers on VARTA, the Review has heard that these may not be sufficiently nuanced or graduated to effectively respond to the types of quality and safety issues that may arise.

Under the Act, VARTA may impose conditions on a provider's registration, if it considers that is necessary in the public interest (s. 75(1)). VARTA has imposed general conditions on all registered providers Victoria, and in the last two years has used this power to impose specific conditions on two providers in relation to specific incidents. There is however, no penalty specified in the Act for a breach of conditions. The Act also provides for VARTA to suspend a provider's registration (ss. 76 and 77). This power has not been used to date.

Possible response to strengthen oversight of quality and safety

The next stage of this Review will focus closely on how regulatory oversight of the quality and safety of ART can best be delivered. This will include consideration of the most appropriate regulatory approach and the entities that should deliver it. Accordingly, the Review notes that references to VARTA in this report are to VARTA or any future regulatory body.

One option that has been proposed to strengthen the regulatory oversight of ART in Victoria is the introduction of a regulated code of practice. Such a code could adopt the RTAC Code of Practice (to avoid inconsistent or unnecessarily duplicative regulation of services) and also address a range of identified regulatory gaps, including requirements for clinical governance and patient-centred care. It might also cover other issues identified throughout this Report such as information provision and counselling practice. By elevating the code of practice to a regulated requirement, this approach would ensure it had greater standing than the current voluntary code, and could allow more responsive oversight of critical quality and safety matters by a state-based regulator.

Alternatively, it may be possible to address some of the gaps identified through changes to the RTAC Code of Practice and the procedures in place to audit provider compliance.

The Review will also consider whether there is scope to expand the range of compliance and enforcement tools available to respond to identified quality and safety issues, or breaches of the Act or conditions of registration. Consideration will be given to the appropriate suite of options which may include – civil penalties for breaches of a condition, powers to publicly name providers who repeatedly fail to comply with particular requirements, powers to suspend or withdraw registration (both generally and/or for the provision of specific services). Consideration will also need to be given to the circumstances in which any such tools may be used, be that where there is a significant risk of harm or when it is considered in the public interest, for example.

Transparency and accountability of the regulator

Any move to strengthen regulatory oversight of ART in Victoria should be accompanied by a move towards increased transparency of decision making and accountability.

There have been some questions asked about the extent to which VARTA's service delivery roles (for example public information and donor linkage services) are consistent with regulatory oversight functions. Others have commented positively that these functions are complementary and allow for the organisation to have wide-ranging in-depth knowledge of the sector and the issues arising.

As discussed in later chapters of this Report, the Review has heard of a range of instances where the basis for administrative decisions under the Act is not sufficiently clear. There is also no capacity under the Act for appeal in relation to administrative decisions made by VARTA.

VARTA has on a number of occasions overreached in its interpretation of the legislation. The pathway to contest some of its decisions is deficient with no independent arbiter available other than the courts.

Submission – Fertility Society of Australia

Some stakeholders have also questioned the capacity and capability of VARTA to assess scientific and clinical incidents and have received little feedback on those incidents they report to VARTA. Concerns have also been raised that the VARTA Board is not representative of all interests within ART regulation and does not include sufficient clinical representation. Section 101 of the Act provides that ‘in making nominations for appointments to the Authority, the Minister must have regard to the need for diversity of expertise and experience’. While the Review would not support a strict representative model of governance for the regulator, consideration will be given in the next stage of this review as to whether there is scope for additional guidance with regard to appointments to regulators of ART to ensure a balance of interests, skills and backgrounds.

The Review will consider, alongside any deliberations about how regulatory oversight in Victoria can best be delivered, any requirements for greater accountability or review of the actions of the regulator.

3.3. Affordability of assisted reproductive treatment

Cost was a key concern among those seeking to use services and those who support them. Of the 110 survey responses received from individuals identifying as recipients of treatment, cost was explicitly identified as a significant issue by 97 people (88 per cent). From the feedback received, affordability of treatment appears to both present a significant barrier to access and to drive decision making about treatment use.

3.3.1. The cost of treatment

Obtaining an accurate picture of the true cost of ART can be difficult. It is clear, however, that costs can vary significantly between clinics as can the treatments included within a quoted price. Table 3 below draws on publicly available information from clinic websites to give an overview of the range of costs (where available information about inclusions and exclusions is provided. It is noted, however, that such information was not consistently provided).

Table 3: Cost of initial stimulated cycle of IVF (sourced from Victorian clinic websites) 2018

Melbourne IVF	The Fertility Centre [#]	Monash IVF	Primary IVF	Number 1 Fertility	Genea	Ballarat IVF	City Fertility
\$4,658*	\$1,500*	\$4,787*	\$600–900 [^]	\$3,478*	\$4,574*	\$3,843*	\$3,395*

[#] The Fertility Centre is the low-cost centre run by Virtus Health (which also own Melbourne IVF)

*Out-of-pocket assuming Medicare rebate and private health insurance (fees do not include day hospital procedure fees (bed fees and anaesthetics or extra medications). (It is unclear from the Fertility Centre site if additional charges for day procedure treatment applies.)

[^]Out-of-pocket assumes treatment is Medicare rebatable – Primary IVF site indicates that all Medicare rebatable services are bulkbilled out of pocket expenses are for counselling, police and child protection checks and day surgery expenses. It is not clear if this estimate assumes private health insurance.

These quoted out-of-pocket expenses assume eligibility for Medicare rebates. Medicare will pay approximately \$3,700 for an initial IVF cycle (and up to \$4,250 for all cycles once the Medicare safety net has been reached) (Commonwealth Government 2018). Even with this public financial support, uncovered costs such as day procedure centre fees, quickly add up to tens of thousands of dollars for people undergoing multiple cycles. There may also be additional ongoing expenses associated with the storage of embryos (approximately \$400–\$600 per annum). It has been submitted that the higher regulatory burden in Victoria has increased costs to patients in Victoria compared with other states. On a very simple analysis of published pricing, this is not obvious.

A review of the websites of major providers in other states and territories indicates that costs vary significantly between providers, and some prices in Victoria are higher and some are lower than in other parts of Australia. For example:

- The quoted price for an initial stimulated cycle of IVF through Monash IVF Melbourne (\$4,787) is higher than Monash IVF Sydney (\$3,130) and lower than to Monash IVF Queensland (\$4,932).
- In the case of full-service clinics operated by Virtus Health, the quoted price through Melbourne IVF (\$4,707) is slightly higher than IVF Australia New South Wales (\$4,685) and significantly higher than the Queensland Fertility Centre (\$3,245).

- The Fertility Centre (the low-cost clinics run by Virtus Health) in Melbourne quotes an out-of-pocket cost of \$1,500 for an initial IVF cycle, the two New South Wales options are each higher (\$1,551 in Liverpool and \$2,178 in Wollongong), and the Queensland-based clinic quote a lower cost (\$995).
- The low-cost Primary IVF services in Melbourne, Sydney, Brisbane and Perth all list an estimate of out-of-pocket expenses of \$600–\$900.

There may be a number of reasons for these variations in prices, including different service offerings. These comparative prices provide an approximate guide only. The advice from clinics is that the major national companies standardise prices nationally to some degree, but that there are additional operating costs in Victoria due to regulatory requirements.

Since 2016, two low-cost providers have entered the market. These clinics have provided a significantly less expensive alternative for people requiring ART. However, they do not offer a full range of treatments (for example, donor treatment is not available) and do not treat people with more complex fertility issues (for example there is a maximum age limit for treatment).

While these low-cost providers have increased the options available to those who may not be able to afford treatment otherwise, stakeholders with long-term experience of the system have pointed out that about 25 years ago, prior to much of the move towards a more corporatised service system, the main providers had offered low-cost or public programs for those facing economic hardship, including health care card holders. Furthermore, the introduction of additional players to the market does not appear to have had a competitive impact on the fees charged by established clinics. The Review understands that there has been a steady pattern of price increases for many years.

Although these costs are high, it is important to recognise that access to ART is comparatively affordable when compared internationally, if public subsidies through Medicare are taken into account. A study undertaken in 2006 found that the average cost of ART 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 (Chambers et al. 2009).

However, the Medicare rebate is only available for patients with medical infertility issues, as that is determined by clinical judgement. People who do not have medically diagnosed infertility but who nonetheless require ART to form a family, such as LGBTIQ+ people or single parents by choice, may face significantly higher costs. The same study found that when Medicare rebates were not included the average cost of ART as a percentage of annual disposable income in Australia was closer to 19 per cent (Chambers et al. 2009).

The biggest problem would be money. Homosexual couples get absolutely no money back from the government or private health funds for the process (egg retrieval, freezing embryos, counselling sessions etc.)

Survey response – recipient of assisted reproductive treatment

Given the recent changes to the *Sex Discrimination Act 1984* (Cth) (regarding sexuality, gender identity, intersex status and marital or relationship status), and the *Marriage Act 1961* (Cth) legislating marriage equality, some stakeholders have pointed out that this policy may be seen as discriminatory.

3.3.2. The impact of cost

Affordability has a clear and direct impact on equity of access. There is a significant difference in utilisation of ART between socioeconomic groups. This difference cannot be explained by other factors

such as the tendency for women in higher income brackets to more commonly delay child bearing, and therefore to be at risk of age-related infertility issues (Harris et al. 2016).

The Review has also heard that costs can impact on treatment decisions, for example delaying treatment based on financial considerations or favouring more aggressive treatment in hope of limiting the number of cycles required.

The biggest barrier I find is the cost. I think people stretch out their treatment so that they can save along the way, so the whole IVF process takes longer than expected. This I believe is counterproductive as time is of the essence with fertility.

Survey response – recipient of assisted reproductive treatment

Single women (and presumably same sex couples) are discriminated against because of Medicare rebates not applying and this affects the treatment that is recommended by doctors. For example, as a single woman using donor sperm I was told to do two rounds of IUI first before moving onto IVF.

Survey response – recipient of assisted reproductive treatment

Cost is also a significant factor in discontinuing treatment for many people.

I have had friends who have stopped trying as the cost becomes too great after several unsuccessful attempts.

Survey response – recipient of assisted reproductive treatment

The burden of costs for ART is significant. The Review has heard that accessing finance and/or early release of superannuation is common among those seeking reproductive treatment.

It is outrageously expensive and does not reflect the costs incurred to provide the treatment. The costs are a barrier to treatment and this is evident with brochures at the reception of many clinics advertising options for finance.

Survey response – recipient of assisted reproductive treatment

ART clinics provide information to prospective patients about credit providers and agencies able to assist with accessing superannuation. Reportedly, IVF treatment is the second most common reason (following bariatric surgery) for people to access their superannuation (Griffiths 2018). Clearly this has implications for people's ongoing financial security.

Financial barriers are again, by far, the most difficult thing that I personally had to overcome while accessing treatment. I have spent close to \$30,000, taking into account rebates from Private Health Insurance. I have recently been granted access to withdraw from my Superannuation fund as I had no personal savings left to continue treatment. These kinds of costs, without any guarantee of a successful outcome are very difficult to come to terms with.

Survey response – recipient of assisted reproductive treatment

It is also noted that the Commonwealth Treasury has been undertaking a review into early access to superannuation (Treasury 2018).

3.3.3. Making low-cost services more accessible – restrictions on the practice of artificial insemination

One approach to addressing the issue of affordability, for at least some people who require assistance to form a family, is to ensure that low-cost services are available and accessible where appropriate.

It has been suggested that, in particular lesbian women and single women may be being ‘over treated’ by fertility specialists.

Unlike treatment protocol models in the United States and Canada which favour 6–8 attempts of IUI before considering IVF, Australian women are receiving IVF almost immediately.

Submission – Professor Fiona Kelly – La Trobe University

It has been suggested that in part this may be explained by people who might benefit from simpler procedures, such as IUI, opting to proceed more quickly to more invasive procedures such as IVF where the cost differential is not so great, and they believe they are more likely to conceive quickly using IVF (with possible cost savings over the course of treatment).

Stakeholders including medical practitioners have identified that more restrictive provisions concerning the practice of artificial insemination introduced when the Act came into effect have forced up the price of IUI.

Prior to the ART Act 2008 coming into effect in 2010, intrauterine inseminations at most clinics were performed by our specialist fertility nurses. This enabled the treatments to be provided in an office environment and in a variety of locations, including rural areas where doctors were often not available. With the introduction of the ART Act 2008, doctors were required to perform the insemination Doctors expect to be paid more, unnecessarily medicalizing the treatment and increasing the cost to the patient.

Submission – Dr Gareth Weston – professional in the field

Section 8 of the Act limits the provision of artificial insemination to a person who is ‘a doctor’, thereby restricting access to reproductive services and increasing patient costs.⁶ There is no requirement that the treatment take place on behalf of a registered ART provider. By contrast, under s. 7 of the Act ‘assisted reproductive treatment’ more broadly can be carried out either by a doctor who is carrying out the treatment on behalf of a registered provider, or a person who is carrying out the treatment under the supervision and direction of a doctor. There appears to be little justification for the inconsistency that allows for more complex treatments to be undertaken by a person other than a doctor, while restricting less complex artificial insemination cases to doctors only.

The Review has heard of no medical evidence to support the more restrictive approach to artificial insemination introduced in 2008, and a review of the legislation, transcripts of the Parliamentary debate and supplementary materials does not provide an explanation.

⁶ In contrast to the current Act, the previous legislation, the *Infertility Treatment Act 1995* provided that donor insemination could be performed – if the treatment was carried out at a facility other than a hospital or licensed place, by a doctor only; or if the treatment was carried out in a hospital or licensed place, by a doctor or a person carrying out the procedure under the supervision of a doctor (s. 7). With respect to the provision of ‘fertilisation procedures’ more broadly (defined to include assisted reproductive treatments but not artificial insemination), the *Infertility Treatment Act* set a higher bar for treatment and required that procedures be carried out at a licensed place by approved doctors only (s. 6).

I can think of no discernible medical reason for banning our nurses from performing the inseminations. The Act allows partners, husbands, and even friends to do inseminations in a home environment (calling this 'self-insemination'), demonstrating how simple the procedure is! Many of our nurses have decades of experience in performing the procedures, and could easily start performing them again if the legislation was modified.

Submission – Dr Gareth Weston – professional in the field

It has also been noted that this provision has a disproportionate impact on patients living in rural areas, where access to medical services is generally more limited. Indeed, it is understood that at least one rural-based artificial insemination clinic was forced to close as it became financially unviable to continue as a result of the legislative change.

After the change in legislation, we had to close an intrauterine insemination service in East Gippsland (The Gippsland Assisted Conception Centre) as the nurse there used to perform the inseminations, and the small size of the clinic could not justify a doctor's salary. A nurse under supervision could recommence a service in Central and East Gippsland, which would be a great benefit for my patients who now have to travel up to 4–5 hours each way to have inseminations in Melbourne.

Submission – Dr Gareth Weston – professional in the field

I believe having doctors perform IUI procedures limits the accessibility to offer service rurally. There is [sic] more costs to the person for travelling because they need to go to Melbourne.

Survey response – other interested professional

In addition, the Review also heard from a number of nurses who felt deskilled and devalued by the change introduced by s. 8 of the Act, particularly in contrast to their counterparts in other jurisdictions.

By taking some of the roles from nurses, the job has become 'an office job' and no longer a specialised job where we nurses can progress.

Submission – fertility nurse

During my career up until to Jan 2010, I was taught and able to perform Artificial Insemination and did so thousands of times prior to ... 2008 In all other states of Australia the nurses can do IUI and even embryo transfers. It seems ludicrous that in Victoria we cannot. Particularly trained nurses in a Registered ART provider clinic!

Submission – Susan Chamberlain – fertility nurse

As summarised in Table 4 below, South Australia is the only other state where the practice of artificial insemination is restricted to medical practitioners. Registration requirements under the *Assisted Reproductive Treatment Act 1988* (SA) do not apply in relation to 'assisted insemination' provided by a health professional approved by the Minister for the purposes of the Act (s. 5). In this instance a *health professional* means a medical practitioner or any other person who belongs to a profession declared by the regulations to fall within the ambit of the definition (at this stage, no such declarations have been made). New South Wales and Western Australia allow for these procedures to be carried out by non-medical practitioners under direction or supervision. There is no specific legislation in other states or territories.

Table 4: Who can undertake artificial insemination – Australian jurisdictions

Jurisdiction	Who can undertake artificial insemination
Victoria	A person can carry out the artificial insemination of a woman only if the person is a doctor (ART Act, s. 8).
New South Wales	An ART provider must ensure that any ART services (defined to include artificial insemination) are undertaken by, or under the supervision of, a registered medical practitioner (<i>Assisted Reproductive Technology Act 2007</i> (NSW), s. 6). An ART provider must be registered under the Act (s. 11).
Western Australia	A medical practitioner can provide artificial insemination without a licence provided certain conditions are satisfied. A person other than a medical practitioner can carry out artificial insemination, provided they do so under the direction of a licensee (<i>Human Reproductive Technology Act 1991</i> (WA), s. 28).
South Australia	The registration requirements (for the provision of ART) do not apply for 'assisted insemination' provided by a 'health professional' approved by the Minister. A 'health professional' includes medical practitioners and any other profession declared in the regulations, however, no such declaration has been made (<i>Assisted Reproductive Treatment Act 1988</i> (SA), s. 5).
Other jurisdictions	Not addressed in legislation; NHMRC Ethical Guidelines or RTAC Code of Practice.

The Review considers that for some people, less expensive access to IUI might remove a barrier to treatment. This may particularly benefit single women and LGBTIQ+ people who may not require more invasive treatments in order to conceive. Furthermore, under current Medicare rules people have no access to Medicare rebates unless there is an indicator of 'medical infertility'. It is understood that for some clinics this is established for single women or LGBTIQ+ couples through two failed attempts at IUI.

Recommendation 3 is intended to allow for properly trained health professionals to undertake the simpler procedure of artificial insemination under supervision, as was the case prior to 2008. Consistent with the approach under the Infertility Act, the recommendation is that a person under appropriate supervision be able to carry out IUI procedures. In practice, this would ordinarily mean that the treatment is carried out by an appropriately trained nurse. It is anticipated that this will have an immediate impact on affordability for those who may benefit from these less invasive procedures. This amendment would also improve access to services and potentially allow for the reinstatement of rural services, thereby allowing fairer access and encouraging greater use of lower risk IUI rather than an overreliance on IVF.

By requiring that artificial insemination is carried out under direct or indirect supervision and direction of a doctor, safety will be maintained. Patients will also be afforded greater choice and, importantly for many patients who prefer to have a female practitioner perform this procedure for religious, cultural or other reasons the chance of this will be much greater where nurses, predominantly female, are able to perform these procedures.

In enacting this recommendation, it will be important to ensure that any amendment maintains current requirements for keeping registers in relation to donor treatment provision and reporting specific information to VARTA and procedures carried out and resultant pregnancies and births.

Recommendation 3

It is recommended that s. 8 of the Act be amended such that artificial insemination may be carried out by (i) a doctor; or (ii) by a person acting under the direct or indirect supervision and direction of a doctor who is carrying out artificial insemination on behalf of a registered provider.

3.3.4. Public provision of assisted reproductive treatment

A further approach to improving affordability of services that has received considerable support from stakeholders is increasing public funding for treatment, either through increased Medicare rebates or direct provision by public health services.

Although not a state matter, and therefore outside the scope of the Review, many respondents to the consultation called for increased Medicare rebates and removals of restrictions that mean those without a medical infertility issue cannot receive this public funding. Others noted that only some aspects of ART attract any Medicare rebate at all. For example, the increasingly popular practice of egg freezing is not eligible for rebate. Primary IVF proposed extending Medicare rebates to donor cycles, preimplantation genetic screening and diagnosis, same-sex couples, single women and couples requiring surrogacy. It is noted that a review of the Medicare Benefits Schedule is currently underway, and members of the Review team have been in contact with those responsible for this work. Developments in this review will be monitored and any relevant outcomes, or indications of likely outcomes, will assist in formulating final recommendations of the Review.

The other means of providing public support for treatment is the provision of services within the public health system. Public clinics exist in a range of jurisdictions around the world including Denmark, Spain, Sweden and the United Kingdom. Indeed, Australia is somewhat unusual in its reliance on private providers, funded through uncapped public subsidies (Keane 2017).

Internationally where there is significant public investment in ART, access may be restricted on the basis of a range of factors such as current smoking and/or substance use status as well as age and body mass index (BMI). Some may also take into account capacity to pay, with subsidised services targeted to those in greater need (Keane 2017).

There are some examples of partnership arrangements between private assisted reproductive clinics and public health services in Australia. The Review team has visited Sydney's Royal Prince Alfred (RPA) Hospital where a fertility unit has been established as a collaboration between the public health sector and a private provider to offer more affordable treatment. Out-of-pocket costs at this clinic are comparable to those charged by the low-cost centres in Victoria (\$1,688 for an initial IVF cycle – it appears that this is inclusive of additional fees for medication etc. that are excluded in the prices quoted in Table 3). Like the low-cost centres in Victoria, the RPA clinic places an upper age limit on women accessing treatment. It also does not treat women over a specified BMI.

The Royal Women's Hospital (Victoria) has a similar arrangement with Melbourne IVF that has been in place for 20 years.

In New South Wales, the University of New South Wales and The Royal Hospital for Women are establishing a more integrated public health IVF service that will be operational in early 2019. This service has been established with contributions from philanthropic funds, support from the university and some funding from the New South Wales Government. The service will build on the Fertility and Research Centre, a multidisciplinary centre for research and clinical excellence in reproductive medicine and fertility, based at The Royal Hospital for Women. The service will provide ART and fertility

preservation services for cancer patients, patients with complex genetic conditions, low-income patients and patients who agree to participate in clinical research. The service would integrate public provision, teaching and public research on improved ART.

The Review has held discussions with two institutions that are considering proposals for the establishment of public health ART services. Monash University is developing a proposal to offer low cost public access to IVF in conjunction with Monash Health. This arrangement would not involve Monash IVF, which was sold by Monash University to private operators in 2007.

The Royal Women's Hospital is considering proposals to establish a public ART service independently of its current arrangement with Melbourne IVF. This service would link with the broader range of women's health services offered by The Royal Women's, and similarly aim to improve public access to ART.

The full business case for both services is not yet developed, and so a detailed assessment of the costs and benefits is premature. These services would, however, require some capital and recurrent funding from the state government to be viable. Both the state government and the public health services will need to make their own assessments of the relative priority of such investment.

In general, it is likely that the establishment of such public IVF services would improve access to, and affordability of, services, particularly if targeting those patients who would not be able to afford or access services otherwise. They would likely exert downward pressure on prices, and the services could develop in a way that promotes best-practice models of patient-centred fertility care. They would provide patients with a choice between public and private services, as is available in most other aspects of the Australian health system. The expansion of publicly provided services could also target people who do not currently use ART services, and so expand access to assisted reproduction rather than merely draw patients away from private clinics.

However, the likely impact of such public services on the current private providers will need to be carefully assessed. In addition, if such services were established, appropriate access criteria for treatment would need to be set. Public providers would also need to fulfil the same regulatory requirements as private clinics including accreditation through RTAC.

There was significant support, in targeted consultations and in public submissions to the Review, for the idea of establishing a public IVF service. This support came from service users, leading clinicians and health practitioner organisations.

The State government should lobby for a public IVF system where clear guidelines are set, such as the amount of cycles a couple can have after certain age or more control when allowing patients to have treatment The Women's has the staff, facilities, nurses, embryologists and the doctors. It only needs more support from the local government to become a centre of excellence and provide a much better service to patients if it was independent from Melbourne IVF.

Submission – professional in the field

The current cost of ART treatment is often well outside of the means of people of low socioeconomic status. I would very much support ART services being provided in a public hospital setting.

Submission – professional in the field

Consideration should be given to a state government subsidy (supplementing the Medicare rebate) for all first stimulated IVF cycles in good potential outcome patients (less than 38 years of age, BMI less than 30, non-smoker and non-drinker).

Submission – Raphael Kuhn – professional in the field

Couples of low socioeconomic status are also disadvantaged. The setting up of a purely public hospital based IVF clinic in Victoria will help these couples.

Submission – Fertility Society of Australia

On the other hand, some clinics commented that current arrangements adequately addressed issues of access and affordability, and that the advent of low-cost bulk-billed services had improved access for low income groups (submissions, Melbourne IVF and Primary IVF).

Given the high level of interest in proposals for public IVF services, the Review will continue to consult and obtain information about these proposals and provide further advice in the Review's final report on the likely impact of such proposals on access, equity, affordability, patient-centred care, the evolving market for ART and the regulatory framework.

This advice will be available to help inform any assessment of whether the state government should invest in these services. However, a decision on this issue rests with government, and will depend on a number of considerations independent of this Review.

3.4. Equity of access: removing discriminatory legal barriers

The Review has heard that, in addition to concerns about affordability, there remain significant barriers to equity of access arising from the existing legislation.

The introduction of the Assisted Reproductive Treatment Act in 2008 removed the legal barrier to access on the grounds of relationship status and sexuality. Nonetheless, the Review has heard that various provisions of the Act have been drafted on the basis of now outdated assumptions and, as a result use language and terminology that has the effect of discriminating against particular groups.

Many of the examples of this relate to provisions that may restrict access for LGBTIQ+ individuals; these discussed in detail in Chapter 3.6 of this Report.

3.4.1. Partner consent in the ART Act

Consultation has confirmed the concerns, foreshadowed in the consultation paper, about the use of the word 'partner' within the Act.

Section 3 of the Act defines the term 'partner', in relation to a person, to mean (a) the person's spouse; or (b) a person who lives with the first person as a couple on a genuine domestic basis, irrespective of gender. The definition is relevant because s. 10(1)(a) of the Act states that a woman may undergo a treatment procedure only if the woman and her partner, if any, have consented, in the prescribed form, to the carrying out of a procedure of that kind. More broadly, the general requirements for treatment procedures set out in Division 2 of the Act, including child protection order checks, mandatory counselling and presumption against treatment (ss. 12–14), operate both in respect of the woman seeking treatment and her partner, if any.⁷

The Review heard that conflicting legal opinions about the effect of these provisions, and whether or not a woman who is separated can be treated, has resulted in different practices among clinics. Nonetheless, it is known that married women who are separated but not divorced have been prevented from accessing ART using donor sperm, without the consent of their former partner.

[W]omen have to be divorced before seeking treatment as a single woman with donor gametes, however men only have to be separated but not divorced to have treatment with a subsequent partner. This is discriminatory towards women so we ask that the wording of the legislation around this be changed.

Submission – counsellor

The current wording of these sections results in a discriminatory situation whereby: a woman is prevented from undergoing treatment as a single woman if she is separated from her spouse but not divorced, however, the partner can undergo treatment prior to the divorce if they re-partner.

Submission – Monash IVF

The impact of this is significant as, under the *Family Law Act 1975* (Cth) (Part VI) women who are married need to have lived separately for at least a 12-month period prior to filing for a divorce. By

⁷ This approach is consistent with earlier Victorian legislation, the *Infertility Treatment Act 1995* (s. 8), which similarly required both the woman and her husband to consent to a procedure before treatment could commence.

contrast, no formal process or time limitation attaches to ending a de facto relationship (unless it was registered in a relationships register, in which case the registration can be revoked with 90 days' notice (*Relationships Act 2008* (Vic), s. 15).

Stakeholders expressed particular concern that there may be urgency for women to commence ART as the consequences for delay can be significant as the prospects for successful treatment decrease with age. Concern was also expressed that agreement to consent to treatment, or to withhold that consent, may be used by a former partner to achieve a more favourable separation settlement.

Recent Federal Court decision

During the course of this Review, the Federal Court considered whether the requirement for a married woman to seek the consent of her estranged husband to seek treatment under s. 10(1)(a) of the Act is discriminatory under s. 22 of the *Sex Discrimination Act 1984* (Cth) (*EHT18 v Melbourne IVF 2018 FCA 1421*). The applicant in the case was a married woman in her mid-40s who was separated and living apart from her husband and wished to access ART using donor sperm without first obtaining her husband's consent.

The registered Victorian assisted reproductive clinic she had approached had refused to treat the applicant without her husband's consent, consistent with the legal requirement in s. 10(1)(a) of the Act (but otherwise had no objection to treating the applicant).

In a decision handed down on 21 September 2018, Justice Griffiths found that because, on its proper construction, the Act operates to require the estranged husband's consent for a married woman to undergo treatment, there is discrimination against the applicant based on her marital or relationship status under s. 22 of the Sex Discrimination Act. As a result, the Court declared s. 10(1)(a) of the Act to be invalid and inoperative to the extent that it requires the applicant to obtain her estranged husband's consent to the applicant undergoing a 'treatment procedure' as defined in that Act. The Court further declared that the applicant could undergo a 'treatment procedure' without the consent of her husband. In the course of proceedings, the applicant gave undertakings to the Court that she would not seek to register her estranged husband as the parent of the child or assert that he is the father for any purpose.

The Review notes that the majority of Australian jurisdictions do not specify eligibility criteria for ART, including in relation to consent to undergo such a procedure, relying instead on national guidelines to instruct ART practice. Apart from Victoria, Western Australia is the only jurisdiction with legislation which sets out express consent provisions in relation to ART (the *Human Reproductive Technology Act 1991*, s. 23) however, consent is only required from persons undergoing treatment or seeking to be regarded as partners.

Melbourne IVF indicated in its submission to the Review that, on the basis of the outcome of this matter, the clinic would support a change to the Act that does not require the consent of the patient's partner if they are separated but not divorced and therefore does not discriminate on the basis of a patient's marital status.

In light of the decision of the Federal Court, it is important that the Act be amended to remove discrimination against married women who wish to access ART following separation from their spouse.

Recommendation 4

It is recommended that the Act be amended to remove any discrimination against married women who wish to access assisted reproductive treatment following separation. The Act should ensure that where a married couple have separated, the consent of a person who would otherwise meet the definition of a partner is not required to undertake treatment, provided that their gametes are not used without specific consent.

The government should undertake further consultation on the most appropriate way to implement this objective, and any implications for related legislation.

One approach to implementing this recommendation may be to create a condition that, for the purposes of consenting to a treatment procedure under s. 10(1)(a) of the Act, and Division 2 more generally, a woman's partner is not required to consent to the treatment if the parties have separated and the woman does not intend for that person to have any parental responsibility of the child to be born as a result of that treatment.

Alternatively, s. 10(1)(a) may indicate that a 'former' partner (defined to include separated spouses who are no longer living together on a genuine domestic basis) is not required to give consent. The Review notes that legislation already captures the distinction between 'current' and 'former' partners in s. 29 of the Act, which deals with family limits for donor gametes, however does not clearly articulate what is meant by 'former' in this instance.

Amending the definition of 'partner' in s. 3 is also a possibility. However, given that the term is used in different contexts throughout the Act, a cautious approach is required to avoid unintended consequences flowing from any redrafting of the provision.

Consideration will need to be given to the potential situation where a person seeks to use the gametes of their former spouse (or de facto partner). In such circumstances the consent of that person would need to be obtained and any potential implication for parentage understood. It will also be appropriate for government to consult with key stakeholders on the specific legislative approach.

Other relevant legislation

Whatever approach is taken, consideration will need to be given to the relationship between the Act and other Victorian legislation, such as the Status of Children Act. The scope and operation of the Commonwealth Family Law Act also needs to be considered.

The Status of Children Act sets out presumptions in respect of parentage in a range of relationships. Partner for the purposes of the Status of Children Act means (a) the person's spouse; or (b) a person who lives with the first person as a couple on a genuine domestic basis (s. 2). Relevantly, this Act provides that where a married woman, in accordance with the consent of her husband, has undergone a procedure as a result of which she has become pregnant, the husband shall be presumed, for all purposes, to be the father of any child born as a result of the pregnancy (ss. 10C(2) and 10D(2)). A husband's consent to the carrying out of a procedure in respect of his wife shall be presumed but that presumption is rebuttable (ss. 10C(4) and 10D(4)).

This is not dissimilar to legislation regarding legal parentage in each of the other states and territories, which provide that when a married woman, or a woman in a de facto relationship with a man, becomes pregnant as a result of ART, her partner is presumed to be the father, so long as he consented to the procedure. Again, a husband or de facto partner's consent to the carrying out of a procedure is generally presumed, but that presumption is rebuttable.

Although the Status of Children Act appears clear on its face that any presumption is rebuttable where the husband of a woman receiving treatment has not given consent to the treatment procedure, it may be appropriate to consider a clarifying amendment to put beyond doubt that the presumption as to parentage does not apply in the circumstances envisaged. A further practical option would be to allow the woman seeking treatment to make a declaration in writing confirming separation, which will provide evidence to rebut the presumption of parentage.

It is envisaged that the declaration would acknowledge that no support for a child will be sought from the other partner, and that this be provided to the clinic before treatment.

The Review notes that the Family Law Act also makes provisions that concern parentage presumptions for children born as a result of ART, and moreover has broad powers in proceedings concerning child maintenance orders to ensure that children receive a proper level of financial support from their parents (Part VII). Consistent with the approach in Victoria, s. 60H of the Family Law Act provides that if a child is born to a woman who is married or in a de facto relationship with an 'intended parent' at the time of artificial conception, then that person is the parent of the child born if they consented to the carrying out of the procedure; or are deemed to be a parent under a prescribed state or territory law. The Victorian Status of Children Act is a prescribed law for the purposes of the provision. A person is presumed to have consented to an ART being carried out unless it is proved, on the balance of probabilities, that the person did not consent. While it is unlikely that the former partner of a woman who did not consent to ART would be deemed an 'intended parent' for the purposes of s. 60H, the Review notes that the amendments to the Victorian legislation will nevertheless need to be mindful of the scope and operation of the Family Law Act.

Further consideration as to the definition of partner

Stakeholders have also raised concerns that the definition of 'partner' differs between the Act and the Status of Children Act, and highlighted the need for greater consistency in use and terminology, given the close interaction between these pieces of legislation.

It would appear that the definition of 'partner' in the Act, which recognises a partner to include 'a person who lives with the first person as a couple on a genuine domestic basis, irrespective of gender' appears to be the clearer formulation.

In considering any clarification of the term 'partner', it has also been pointed out that as currently defined the Act fails to recognise the full spectrum of relationships, including relationships where the couple may not live together on a full-time basis.

In the current social context, people may define themselves as in a relationship, may share financial resources etc., but do not live together full time ... some couples still reside in separate residences but spend several nights per week with each other.

Submission – professional in the field

Similarly, VARTA has highlighted the increasing prevalence of co-parenting relationships where two or more individuals who are not partnered but wish to have a child use ART.

Any amendment to the definition of partner would need to consider the broad range of relationships and wider issues of family law.

3.4.2. Clarifying that a partner is not a ‘donor’

The Review has heard that there is a need for greater clarity in the definition of ‘donor’ in the Act in circumstances where a person provides gametes for use by their partner in ART. Stakeholders have advised that the current definition of ‘donor’ is confusing and unclear.

As a matter of practice for heterosexual couples, clinics in Victoria do not appear to interpret the provisions relating to a ‘donor’ to apply to a person who provides gametes for use by their partner. However, the feedback received indicated that clarity on the matter would be useful.

Feedback from stakeholders is that the interpretation of the donor provisions in respect of LGBTIQ+ couples is inconsistent, and that there may be discrimination against LGBTIQ+ people providing gametes for use by their partner. However, clinics have advised the Review that current practice is changing to treat same-sex couples sharing gametes as partners rather than donors, and that they would value clarification in the Act on this matter. This issue is discussed in more detail in Chapter 3.6.2 of this Report.

A ‘donor’ is currently defined to mean a person who has given consent under s. 16 of the Act (s. 3). This provision states that gametes donated by a person may be used in a treatment procedure only if the person who donated the gametes has consented to the use of the gametes in a treatment procedure of that kind (s. 16(1)). Further, an embryo may be used in a treatment procedure only if each of the persons who donated gametes used to create the embryo has consented to the use of the person's gametes for a treatment procedure of that kind (s. 16(2)). On a plain reading, the current drafting does not exclude the provision of gametes by a person for use by their partner in a treatment process from the definition of a ‘donor’ in the Act. Requirements for donors are set out more generally in Division 3 of Part 2 of the Act, and include provisions on consent, counselling and the giving and receiving of relevant information. The Act also defines ‘donor embryo’, ‘donor gametes’, ‘donor oocyte’, ‘donor sperm’ and ‘donor treatment procedure’.

The relevant New South Wales legislation, the *Assisted Reproductive Technology Act 2007* (NSW), defines a ‘donated gamete’ to mean ‘a gamete donated by a gamete provider for use by a person other than the gamete provider or the gamete provider’s spouse’. A ‘donor’ is separately defined to mean ‘the gamete provider from whom a donated gamete has been obtained’. The *Human Reproductive Technology Act 1991* (WA) defines a ‘participant’ in relation to any artificial fertilisation procedure to mean ‘a person who ... is the donor ... of human gametes’.

Notwithstanding that the Review heard that, as a matter of practice, clinics ordinarily consider heterosexual couples to be exempt from the definition of ‘donor’, the Act does appear to be unclear and internally inconsistent in respect to this matter. (Furthermore as outlined in Chapter 3.6.1 interpretation of the Act with respect to LGBTIQ+ couples is less clear.)

Recommendation 5

It is recommended that the definition of ‘donor’ in the Act be amended, as well as other defined terms which include the word ‘donor’, to make it clear that, regardless of gender, sexuality, gender identity or marital or relationship status, where a person provides gametes for use by their partner in a treatment process, that person is not considered a donor for the purposes of the Act.

As a general observation, the Review considers that the meaning of ‘donor’ could be set out more clearly by making it a self-contained definition, similar to the definition used in the New South Wales legislation. This approach was also supported by a number of stakeholders.

... the definition of 'donor' should be more clearly defined. For example, the NSW ART Act 2007 Section 4 uses the following definition – 'donated gamete means a provided for use by a person other than the gamete provider or the gamete provider's spouse'

Submission – Monash IVF

It is noted however, that in adopting a definition similar to that used in New South Wales, consideration should be given to the appropriateness of the word 'spouse' and to any alternative proposal such as 'partner' given the issues discussed in Chapter 3.4.1 above.

The Review also notes that a number of the defined terms which include the word 'donor' may not require their own definition if the meanings of 'donor' and 'donated gametes' were clearly expressed in the Act.

3.4.3. Use of gametes following separation

Related to the matters described above, the status of gametes provided, or embryos created from such gametes, also needs clarification in the event of separation by a couple.

The Act does not appear to provide guidance in circumstances where, for example, a woman and her partner consent to treatment, form an embryo and one withdraws consent.

Submission – Primary IVF

Section 10(1)(a) of the Act requires that a woman and her partner, if any, consent to a treatment procedure, and it is common practice to require couples to consider their wishes in respect to an embryos created should one of them die. In contrast, there is currently no provision in the Act, nor consideration prior to treatment, which addresses the status or use of gametes provided, or embryos created, following the separation of a couple.

It is proposed that a new provision be included in the Act to create a presumption that consent to use gametes provided by a person's partner, or any embryos formed from such gametes, is withdrawn following the separation of the couple. The presumption would be rebuttable if a person consents to the use of their gametes or embryos by their former partner following the separation.

Recommendation 6

It is recommended that a new provision be included in the Act to create a presumption that where a person has provided gametes for use by their partner in a treatment procedure, consent is withdrawn in respect of the use of those gametes, or any embryos formed from such gametes, following the separation of the couple.

It is envisaged that any consent in such situations would take place as if the former partner were a donor, and all the requirements relating to donor consent set out in the Act would need to be satisfied (see Division 3 of Part 2 of the Act). This approach would engage the relevant parentage presumptions in the Status of Children Act with respect to donors (Parts II and III) that is, the person who produced the donated gametes, or any embryos formed from such gametes, would be presumed not to be the parent of any child born as a result of a pregnancy.

This provision is intended to provide clarity for the clinics regarding the status of gametes and embryos in storage once they are made aware of the separation of a couple. It is not intended that the clinic will

need to make enquiries as to the ongoing relationship status of people receiving treatment. The provision will address a gap, where currently the law is silent.

3.4.4. Posthumous use of gametes

Section 46 of the Act sets out the requirements for posthumous use of gametes or an embryo in treatment provided by a registered ART provider. The conditions which must be satisfied are that the deceased has provided written consent and the treatment procedure is carried out:

- on the deceased person's partner, or
- in the case of a deceased woman, by the woman's male partner commissioning a surrogacy arrangement in accordance with the Act.

The posthumous use can only proceed with approval of the PRP and following counselling in respect of prescribed matters.

The Review has identified two areas of concern with the current treatment of the posthumous use of gametes in the Act, namely that:

- s. 46 is discriminatory in respect of authorising a surrogacy arrangement under this provision, and
- the Act does not address the posthumous use of donated gametes.

The Review notes that apart from Victoria, only New South Wales, South Australia and Western Australia expressly address the issue of posthumous use of gametes or embryos created from such gametes. No other jurisdiction explicitly provides for the posthumous use of gametes or embryos in a surrogate.

The New South Wales *Assisted Reproductive Technology Act 2007* (NSW) requires the deceased person to have consented to the use of gametes after their death but does not restrict use to a partner (s. 23). In South Australia, the *Assisted Reproductive Treatment Act 1988* (SA) provides that semen (or an embryo created from a deceased person's semen) may be used posthumously by the deceased person's partner, provided that the donor had given consent before death (s. 9(1)(c)(iv)). Under the *Human Reproductive Technology Act 1991* (WA) Directions a licence holder in Western Australia must not knowingly use or authorise the use of gametes in an artificial fertilisation procedure after the death of the gamete provider (Direction 8.9).

All other jurisdictions rely on the NHMRC *Ethical guidelines on the use of assisted reproductive technology in clinical practice and research* (the Ethical Guidelines) in relation to posthumous use of gametes. The Guidelines focus on the use of gametes by a deceased person's partner and include requirements to, as far as possible, respect the wishes of the person for whom the gametes or embryos were stored. They furthermore require clinics to ensure parties are provided with information to facilitate an understanding of the potential for posthumous use and that consent to store gametes and embryos should include a person's clearly articulated position on their posthumous use.

Turning to the first of the issues identified, the Review heard concerns that s. 46 is discriminatory in authorising surrogacy arrangements because it precludes:

- a man using his deceased male partner's sperm in a surrogacy arrangement
- a woman using her deceased male partner's sperm in a surrogacy arrangement if she is unable to conceive or carry a pregnancy herself, or
- a woman using her deceased female partner's egg in a surrogacy arrangement if she is unable to conceive or carry a pregnancy herself, or in order to maintain the same biological background of her children.

For example, Monash IVF submitted that this wording had given rise to the unintended circumstance whereby a female patient is unable to commission a surrogacy arrangement if her partner dies and she is unable to carry a pregnancy herself.

The Review has heard no rationale for the limitations imposed by s. 46 of the Act that restrict posthumous use of gametes in surrogacy arrangements to a woman's male partner. Accordingly, it is proposed that the provision be amended and simplified to remove these discriminatory elements. Given the recent Federal Court determination regarding s. 10(1) of the Act being inconsistent with the Sex Discrimination Act, there is a risk that further litigation may result in discriminatory areas of the Act being deemed invalid.

The Review furthermore considers that it would be appropriate to reconsider the need for written consent in cases involving the posthumous use of gametes. The Patient Review Panel should be authorised to approve posthumous use of a deceased person's gametes, or embryos created from such gametes, where it is satisfied that the use is not inconsistent with the deceased person's expressed wishes.

Recommendation 7

It is recommended that s. 46 of the Act, which relates to posthumous use of gametes and embryos, be amended to provide that where written consent was provided by the deceased person, and appropriate counselling has been undertaken, the Patient Review Panel may approve the use of the deceased person's gametes, or embryos created from a deceased person's gametes:

- in a treatment procedure carried out on the deceased person's partner, or
- by the deceased person's partner in commissioning a surrogacy arrangement (regardless of the gender of the person or their partner).

Additionally, the requirement for written consent might be reconsidered, and the Patient Review Panel may be permitted to approve posthumous use where it is satisfied that the use is not inconsistent with the deceased person's expressed wishes.

The second concern identified by the Review is that the Act is unclear on the status of donated gametes where the donor dies. As noted above, the legislation in New South Wales provides that the donated gametes of a deceased person may be used in a treatment provided that the gamete provider has consented to the use of the gamete after their death; and the woman receiving treatment has also given consent to the use of the gamete despite the death or suspected death of the gamete provider. The Review notes that the posthumous use of donor gametes may not be in the best interests of donor-conceived people and their right to access information regarding their donor. As such, the Review intends to undertake further consultation to consider whether legislating for the posthumous use of donated gametes along the New South Wales model is desirable.

3.5. Equity and inclusiveness: addressing barriers to access – social, cultural and practice

Even where no regulatory barrier to treatment exists, the Review has heard that a range of social, cultural and practice issues can prevent equitable access to services or mean that services are not experienced as equally inclusive of all groups in the community. Such experiences may impact negatively on the psychological and emotional wellbeing of those seeking treatment or may influence their engagement with services, with potential impact on themselves health and wellbeing and that of any child to be born. Experiences relating specifically to LGBTIQ+ people accessing services are discussed in Chapter 3.6 of this Report.

When combined with intersectional discrimination due to being Aboriginal, multicultural, living with a disability or living in a rural or regional area, some prospective parents make choices that bypass the institutional gatekeepers, choices that could have long term impacts on the rights and best interest of their child, including the right to access their genetic history as well as legal certainty on who a child's parents are.

Submission – Rainbow Families Victoria

3.5.1. Geographic barriers to access

Access to ART for Victorians living in rural and regional areas can be difficult and travel expenses and additional time off work can add to costs.

I had to travel to Melbourne for IVF (I live 4 hours away) and it was a huge cost in addition to my treatment.

Survey response – recipient of assisted reproductive treatment

ART providers are predominantly located in metropolitan Melbourne.

There are providers based in the major regional centres of Geelong and Ballarat and 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. The Review has heard, however, that these clinics may not always offer a full range of services or may be more restrictive in how those services are provided.

I live in a regional area where the scientists only visit ever quarter so cycles had to all coincide with their dates. It is like sheep herding! And not personalised.

Survey response – recipient of assisted reproductive treatment

One respondent talked about the limited access to counselling through satellite clinics, which forced them to seek counselling through local providers not trained or experienced in IVF counselling.

Furthermore, there are still many areas of the state where people live and work a long distance away from treatment providers.

It is hoped that Recommendation 3 will, by reducing the restrictions on who can provide IUI treatment, potentially lead to the reinstatement of rural services that were discontinued following the tighter restrictions introduced by the Act.

Before producing the final report, the Review will consider whether assessment of any options for public provision of ART (as contemplated in Chapter 3.3.4 of this Report) could include requirements or incentives for the provision of rural services, for example through the inclusion of satellite service provision in currently under serviced regional centres.

3.5.2. The experience of single people accessing services

The Review has also heard that, although the changes made with the introduction of the Act in 2008 removed legal barriers to single people accessing treatment, there remain cultural and practice issues that are experienced as exclusionary by this group.

As outlined in Chapter 3.3.1, single people may not be entitled to a Medicare rebate for treatment unless they are medically infertile, so costs can be particularly prohibitive for this group. This is exacerbated by the fact that they will be undertaking treatment on a single income.

Furthermore, although single women are now a significant part of the population of treatment participants, accounting for 52 per cent of those using donor sperm (VARTA 2018), the Review heard that in some processes, service provision may presume that those using services will be part of a couple.

This lack of sensitivity makes them feel like they do not belong in the clinic environment.

Submission – Professor Fiona Kelly – La Trobe University

For example, it was noted that while many clinics have adapted their paperwork to be inclusive for same-sex couples, this paperwork often still assumes that a woman seeking treatment will have a partner.

From intake paperwork, to the mandatory counselling sessions, to presumptions about who would pick them up after an egg retrieval, single women are constantly required to correct, clarify and sometimes challenge the various people they encountered.

Submission – Professor Fiona Kelly – La Trobe University

While most of the feedback the Review received on this issue related to the experiences of single women, feedback from the LBGTIQ community indicates that similar issues are experienced by people regardless of sexuality or gender.

Our community has told us that as single people seeking treatment, regardless of sexuality or gender, they are treated disrespectfully.

Submission – Rainbow Families Victoria

While addressing these issues should primarily be a matter for individual clinics, the Review will continue to consider if there may be a role for VARTA or another agency to support practice improvement. It might also be anticipated that any action taken to improve clinical governance or support more patient-centred practice (see discussion in Chapter 3.2.3 of this Report) would lead to more inclusive practice for all people seeking ART, including single people.

This option single parenthood by choice is a feature of modern life and the frameworks must include this population group.

Submission – professional in the field

3.5.3. Inclusive practice

The Review received little comment on the extent to which services are inclusive of other groups in the community.

Aboriginal and Torres Strait Islander experiences

It is notable that little is known about the experience of Aboriginal and Torres Strait Islander Victorians accessing ART services.

Neither access to treatment, nor the responsiveness of services to this group, were significant themes in discussions held, or submissions received, during the consultation process.

We do know, however, from experience in other parts of the health sector, that Aboriginal and Torres Strait Islander people are likely to experience a range of barriers to service access. This may include a lack of culturally safe and appropriate services, as well as disproportionate impacts of other barriers such as cost and geographic accessibility (Victorian Auditor-General 2014).

The Review will endeavour, through targeted consultation during the next stage of the project, to gain greater insight into these potential issues and better understand patterns of access and barriers to treatment for Aboriginal and Torres Strait Islander Victorians. In undertaking this work, the Review will draw on the framework articulated in *Korin Korin Balit-Djak: Aboriginal health, wellbeing and safety strategic plan 2017–2027*.

Culturally and linguistically diverse experiences

Similarly, there has been very little feedback received on the experience of people from culturally and linguistically diverse backgrounds accessing, or seeking to access, reproductive treatment services. However, a number of clinics have reported that people from CALD backgrounds have great difficulty accessing donated gametes in Victoria. In addition, clinics report that people of different religions and belief systems have strong preferences for how care is delivered.

While the Review has seen some evidence that services have endeavoured to address potential language barriers, it is less clear whether significant cultural barriers exist, or what efforts services are making to overcome these and to be respectful of particular social or cultural preferences. These matters will also be the subject of further investigation in the second stage of the project.

Experiences of people with disability

Although not an issue raised in the consultation paper, a small number of stakeholders have advised that people living with disabilities can face barriers to access and practice that are not appropriate or inclusive.

Our community have told us that if they, their partner or their donor has a disability, they are sometimes treated differently to a point where some people leave to conceive outside the clinic system ... [one respondent to this submission] indicated that once they realised their own self-recruited donor who was deaf would be 'screened out' they undertook self-insemination at home instead.

Submission – Rainbow Families Victoria

The primary issues expressed regarding access to services for people with disability related to testing and screening of prospective parents, donors, surrogates, gametes and embryos for disabilities and variations of sex characteristics, among other things.

- *Disability eugenics, screening out disability. The screening of all donor sperm for genetic disabilities, and not being able to opt out of this process and choose a donor who has not been screened. Embryo screening for disabilities being encouraged by clinics as though this is the only choice or the best choice for people to make. This does not view disability as an aspect of human diversity but something 'wrong' which must be eliminated.*
- *I am also outraged by the pressure they put on you to screen for disabilities and intersex variations. We had to insist multiple times we didn't want the screening. The system is very ableist.*

Survey responses – Rainbow Families Victoria submission

Approaches to ensuring that practice is appropriately inclusive will likely focus on training and the provision of information to services and staff. It may also be appropriate to consider the extent to which these issues could be addressed through an increased focus on patient-centred care, whether this be achieved through inclusion in a code of practice as discussed in Chapter 3.2.3 or through other mechanisms.

3.6. Supporting LGBTIQ+ Victorians

The terms of reference for the Review specifically ask whether the regulatory framework creates or enables unnecessary barriers to access for LGBTIQ+ people. Formal legislative barriers to LGBTIQ+ Victorians accessing ART were removed in 2008, and the Review has 10 years of LGBTIQ+ experience in accessing services to support these recommendations.

The Review has heard that while the primary legislative barriers to access were removed, the culture and practice of the ART industry still creates or enables barriers to access for LGBTIQ+ people.

This chapter outlines the issues that have the most impact on LGBTIQ+ people. Other issues raised within other chapters of this Report (such as cost) will also impact these communities. This is particularly important to note for Chapters 3.7 and 3.8, relating to donors and surrogates, as access to donors and surrogates is particularly important for the LGBTIQ+ community, and some LGBTIQ+ people assist others by being donors and surrogates themselves.

It is also important to note that some of the issues in this chapter will also impact people in the wider Victorian community. People who identify as LGBTIQ+ may also identify as Aboriginal or Torres Strait Islander, speak English as a second language, experience disability, be a single parent, experience economic stress or live in regional or rural Victoria, among other things.

The Victorian Government's *Inclusive language guide* acknowledges that LGBTIQ+ '... communities experience poorer health outcomes and reduced social engagement due to actual or feared prejudice'. It is important that the ART industry demonstrates itself to be appropriate, culturally competent, relevant and safe for LGBTIQ+ people who are accessing or would like to access ART.

3.6.1. Issues considered – addressing legislative barriers

3.6.1.1. Updating the 'Guiding principles'

As highlighted in the consultation paper, the Review has heard that the 'Guiding principles' of the Act contain potentially discriminating language. Relevantly, the 'Guiding principles' provide that persons seeking to undergo treatment procedures must not be discriminated against on the basis of their sexual orientation, marital status, race or religion (s. 5(3)).

In their submission, Rainbow Families Victoria brought attention to the gendered language within s. 5(b)(i) that states 'the reproductive capabilities of men and women', and highlighted 2013 amendments of the *Sex Discrimination Act 1984* (Cth) that expanded protections to people based on their sexual orientation, gender identity and intersex status, as well as the change from 'marital status' to 'marital or relationship status'. Including gender identity, marital or relationship status and intersex people within the Act brings our legislation in line with federal anti-discrimination legislation.

While the broader Australian legislation calls for protection on the basis of 'intersex status', prominent Intersex advocacy groups call for 'effective legislative protection from discrimination and harmful practices on the grounds of sex characteristics', and indicate that inclusive legal terminology is evolving to include sexual orientation, gender identity/expression, and sex characteristics (The Darlington Statement⁸ of Intersex Human Rights Australia).

⁸A joint consensus statement by Australian and Aotearoa/New Zealand intersex organisations and independent advocates, March 2017

As such, the Review recommends amending the Guiding principles of the Act to remove gendered language (such as ‘men’ and ‘women’ in s. 5(b)(i)) and replace such terminology with the word ‘person’. It is furthermore proposed to expand the anti-discrimination provision in s. 5(e) to include people who were not previously captured, in particular, single people, people in de facto relationships, trans and gender diverse people, and people born with intersex variations. One option to achieve this policy objective would be to amend s. 5(e) to require that ‘persons seeking to undergo treatment procedures must not be discriminated against on the basis of their sexual orientation, marital *or relationship* status, *gender identity/expression, sex characteristics*, race or religion’ (s. 5(e)).

Recommendation 8

Consistent with the objectives of the Victorian *Equal Opportunity Act 2010* and similar Commonwealth legislation, and recognising the diversity of our people and relationships, it is recommended that the ‘Guiding principles’ of the Act be amended to use non-discriminatory language, including in relation to gender, where appropriate. It is also recommended that the anti-discrimination principle in s. 5(e) be expanded to recognise people who are currently excluded.

3.6.1.2. Removing discriminatory language from the Act

The Review has heard concerns that language within the Act assumes that everyone using ART is heterosexual, and that these assumptions have created additional and unnecessary barriers to access for LGBTIQ+ people.

For example, there is a requirement in the Act that the PRP may approve a surrogacy arrangement only if ‘a doctor has formed an opinion that ... the commissioning parent is unlikely to become pregnant, be able to carry a pregnancy or give birth’ (s. 40(a)(i)). The Review heard that this requirement has resulted in male same-sex couples having to provide a letter from a doctor stating that they are unable to become pregnant.

The Patient Review Panel asked us to prove why we needed a surrogate and could not carry a baby ourselves. We are a gay male couple, it is obvious. The fact that they demanded ‘evidence’ of our condition was demeaning and offensive.

Survey response – Rainbow Families Victoria submission

Gendered language within the Act is also an issue, particularly for trans and gender diverse people. For example, the use of the term ‘woman’ in s. 10(1) of the Act in respect of the provision of treatment, and other gendered identifiers in other sections of the Act can be problematic where individuals who are trans or gender diverse wish to undergo a treatment procedure.

The treatment of transgender people is even more complex and this will require very careful consideration in the new legislation. This group of very vulnerable people should not have to wait another 10 years for the next review to see the barriers to ART access lowered for them.

Submission – Fertility Society of Australia

Remove all gender specific language from the legislation when referring to people undertaking or involved in ART. For example, the use of the words 'man' or 'woman' when referring to people accessing particular procedures will exclude trans or gender diverse individuals who may have reproductive organs or tissue or gametes usually associated with a particular sex but whom do not identify as, nor have legal identification documents specifying their gender identity as 'man' or 'woman'.

Submission – The Royal Children’s Hospital Gender Service

These examples demonstrate the additional unnecessary barriers faced by LGBTIQ+ people accessing ART because of assumptions of heterosexuality and gender inherent in the Act.

A range of stakeholders raised concerns that the wording is discriminatory towards lesbian women ‘donating’ an egg to their partner because they are treated as a donor rather than the patient’s partner. For example, Monash IVF indicated that changes to the definition were required to ‘reflect the accepted practice for women in same-sex relationship to undertake “egg sharing” rather than being considered a donor to their partner’.

The sharing of eggs between lesbian couples is neither a donor egg situation nor a surrogacy situation, as both women are in a relationship together and intending to have a child together. The legislation should be changed to remove this ambiguity.

Submission – Fertility Society of Australia

The definitions of partner and donor are explored in Chapter 3.4.1 of this Report, and a proposed amendment to the definition of donor to address the issue highlighted is set out in Recommendation 5.

Recommendation 9

It is recommended that the Act be amended to remove any language that is potentially discriminatory against, or not inclusive of, particular individuals or groups on the basis of their sexual orientation, marital or relationship status, gender identity or sex characteristics. This will include (but should not be limited to):

- replacing discriminatory terms and using more inclusive language in the Act.
- amending s. 40(1)(a) of the Act so that the Patient Review Panel may approve a surrogacy arrangement if satisfied that there is a medical or social need for the surrogacy arrangement, to remove the requirement for same-sex couples to demonstrate that they are unlikely to become pregnant.

Gendered language can also be found in other pieces of Victorian and Commonwealth legislation which are relevant to ART.

In particular, the Review notes that the *Prohibition of Human Cloning for Reproduction Act 2002* (Cth) contains a number of provisions that restrict access to ART for trans and gender diverse and people. Most relevantly, s. 12 of the Act makes it an offence to create a human embryo for a purpose other than achieving pregnancy in a woman (s. 12). A ‘woman’ is defined to mean a female human (s. 3)

These provisions are mirrored in state legislation, consistent with the Council of Australian Governments (COAG) agreement of 2002 (and renewed in 2007), that the Commonwealth, states and territories would introduce nationally consistent legislation to ban human cloning and other unacceptable practices, and to

regulate research involving excess ART embryos. In Victoria, the offence is replicated in s. 8 of the *Prohibition of Human Cloning for Reproduction Act 2008* (Vic).

The *Research Involving Human Embryos Act 2002* (Cth) similarly states that a person commits an offence if the person intentionally uses, outside the body of a woman, a human embryo that was created through an ART process (s. 11). The term 'woman' is again defined to mean a female human (s. 7). In Victoria, the offence is replicated in s. 9 of the *Research Involving Human Embryos Act 2008* (Vic).

Victoria should work towards ensuring that gender neutral language is used in all pieces of Victorian legislation that impact on the provision of ART. In doing so, Victorian lawmakers should work with Commonwealth counterparts to encourage similar legislative reform to relevant Commonwealth legislation.

3.6.1.1. The 10-woman limit

Feedback received from a broad range of stakeholders, including clinics, patients and lawyers, highlighted that the wording in s. 29 of the Act has a discriminatory effect on female same-sex couples wishing to form a family using donated sperm. Although the section is headed 'ban on using donated gametes to produce more than 10 families', the section imposes an upper limit of 10 women having children using gametes (or embryos formed from gametes) from the same donor.

In effect, this means that where two women in a relationship each wish to use the same donor to ensure their children are genetically related, they may be unable to do so. A number of stakeholders expressed dismay that this aspect of the law failed to recognise their relationship as family.

This means that if my partner and I each wanted to conceive a child using the same donor, we would be considered separate families. In a context where the availability of donor sperm is limited, this has very real implications for who our donor may be and/or decisions around who will carry subsequent children.

Survey response – recipient of assisted reproductive treatment

The current section of the Act that limits sperm donation to 10 women, ignores the fact that many women wish and choose to have families 'together', and use the same donor ... this reflects the hetero-normative bias of the legislation and its administrators.

Survey response – Rainbow Families Victoria submission

As outlined in Chapter 3.7.2.1 in relation to donor conception, most jurisdictions impose an upper limit on the use of gametes from the same donor. However, the limits imposed relate to the number of families, rather than the number of women who can use the gametes. In Western Australia, the Act specifies that the limit on the use of donations refers to the number of families. In New South Wales, the relevant provision imposes a limit of five women for the use of gametes from the same donor. 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 (s. 27). All other Australian jurisdictions rely on the NHMRC Ethical 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'.

Further consideration is needed to determine the appropriate limit for the use of gametes donated by a single donor. However, the Review has heard that not only does the current wording of s. 29 impact negatively on women in same-sex relationships, but also that restricting the choice of donors may be detrimental to the children born as a result. Although there are not yet any adult donor-conceived

children born to same-sex parents under the Act, donor-conceived people advised the Review of the difficulties they faced when the siblings they had grown up with had different donors. This not only significantly impacted on their feeling of connection but could also be particularly challenging, for example, where one sibling's donor wished to have contact and the other did not.

The limits on the use of gametes from one donor are intended to reduce the possibility of consanguinity between donor-conceived children and also to limit the number of children born as a result of each donor's donation which, as outlined, in Chapter 3.7.2.1 of this Report is important for the emotional wellbeing of donor-conceived individuals. Amending s. 29 to ensure the limit applies to the number of families rather than the number of women will not undermine these aims, but will address the discriminatory effect of the provision and allow for greater genetic connection between donor-conceived children born into and raised in the same family.

Recommendation 10

It is recommended that s. 29 of the Act be amended to ensure that the limit on the use of donated gametes applies to 'families' rather than 'women'.

3.6.1.2. Birth certificates

Throughout consultations, the LGBTIQ+ community raised concerns with the Review about the recognition of diverse family structures in birth certificates.

Rainbow families may include one, two, three, four or more LGBTIQ parents, co-parents or carers who care and nurture the children in their family. Family forms can include, but are not limited to: step parented families, separated families, children who are fostered, in permanent care or adopted, children conceived through assisted reproductive technology, children living across two or more primary homes as part of their parenting arrangement, families with donors and/or surrogates who helped create them, either through altruistic surrogacy in Victoria or through international surrogacy arrangements.

Submission – Rainbow Families Victoria

Birth certificates issued in Victoria currently record parentage as 'mother' and 'father/parent'. A female partner will be listed as a 'parent'. Upon request, the birth certificate can also list 'parent' and 'parent'. Victorian birth certificates also list all 'previous children of the relationship', which combined with the limit of two parents, does not allow for some siblings to be recognised on younger children's birth certificates. The Review also heard that in some cases birth certificates do not present all relevant information for rainbow families, and can cause confusion and dismay on the part of the person born when birth certificates become necessary to prove identity.

- *I have had one obstacle that I didn't foresee that has some significant impact. I embarked as a single lesbian woman to conceive ultimately on IVF. I was in a co-parenting arrangement with the donor ... placed Dad and Mum on birth certificate and had to ultimately remove Dad. We had no idea this would happen. He was donor and dad and we had to get a court order. It was devastating to remove him from the certificate and now she only has me on the certificate. I wish there had been information about this and that we could have some flexibility as we both wanted her father to be on the certificate.*
- *It should be possible to recognise all four parents where the 'donor' and his partner is intended by all involved to be dads involved*
- *Yes – need to allow for 3 or 4 parents on the birth certificate, to allow prospective parents to greater clarity about the role*
- *Can there be 3 names on a birth certificate here?? Donor & intended parents*

Survey response – Rainbow Families Victoria submission

The Review was referred to the model in British Columbia, where children are now able to have three parents listed on their birth certificates, including partners of the birth mother and donors in the definition of potential parents.

Birth certificates are fundamental identity documents that directly impact federal identity documents such as passports and Medicare eligibility. The Review will consult further with Births, Deaths and Marriages Victoria and the LGBTIQ+ community to identify ways to enhance the information presented on birth certificates, to better meet the needs of LGBTIQ+ families.

3.6.2. Issues considered: addressing social, cultural and practice barriers

We also respectfully remind the Review that many people within the LGBTIQ+, gender diverse or non-binary communities are under minority stress where high levels of stress unique to being a member of a stigmatised minority group are present, with interpersonal prejudice and discrimination a key factor. Under some conditions, for example engaging with a medical system or attending counselling to access ART, people's experiences of stress can become heightened, enhancing their hypervigilance. It is under these conditions that some people are accessing ART, regardless of how inclusive the service is attempting to be.

Submission – Rainbow Families Victoria

3.6.2.1. Language in clinic forms and information

The Review has heard that the lack of inclusive language is a considerable concern for the LGBTIQ+ population, as well as for single parents by choice (see Chapter 3.5.2 of this Report). Language on promotional, marketing and clinic material that assumes all patients are partnered, heterosexual or cisgender (identified gender the same as assigned sex at birth) may deter people from using ART services.

The most common issues heard during consultation regarding clinic forms were no options to indicate a person's preferred pronouns (he/she/they), a lack of gender-neutral terminology and titles, and an assumption that people accessing treatment are partnered.

- *I am non binary ... don't think any of the forms gave options around my pronouns or using my Mx title.*
- *The paper work we had to sign used antiquated language around woman and woman's partner (instead of gestational parent or carrier etc).*
- *Absolutely not Trans inclusive. I am non binary but all of the language is regarding women/ female.*
- *There was some discomfort at times in dealing with forms that still had hetero terminology. Some embarrassment for us.*

Survey response – Rainbow Families Victoria submission

The Review also heard during LGBTIQ+ consultations that clinic websites and information often exclude them and do not reflect inclusive practice. Stakeholders advised that even those websites that provide LGBTIQ+ specific information contain discriminatory and/or exclusionary language.

While language on promotional, marketing and clinic material should be a matter for individual clinics to manage, the Review will look into strengthening approaches to quality, safety and patient-centred care, as further outlined in Chapter 3.2. The next recommendation, regarding education of clinics and staff on inclusive practice, will also assist in providing guidance to clinics on inclusive language use in their materials.

3.6.2.2. Staff involved in assisted reproductive treatment

Education of staff involved in all stages of the ART process was a significant issue raised by a variety of stakeholders during the consultation process. In fact, Rainbow Families Victoria indicated in their submission that the most significant, immediate change ART services could make would be education and training of all staff within clinics, and other bodies associated with ART, in LGBTIQ+ inclusive practice.

Ensure adequate education and training within all ART service providers to optimise inclusive practice.

Submission – The Royal Children's Hospital Gender Service

During consultations, the Review heard many examples of inappropriate treatment by staff of LGBTIQ+ people accessing ART. There is a perception that staff lack adequate knowledge of issues facing LGBTIQ+ people accessing ART, and therefore may make inappropriate or harmful assumptions. For example, a patient in a same sex relationship advised the Review that clinic staff referred to her future baby as a 'child of loss' because there was not going to be a male parent.

Another patient reported that across two clinics both doctors and support staff struggled with addressing their non-binary partner, resulting in them being repeatedly misgendered.

- *Heteronormative assumptions about families and the roles people play are made by some clinicians/clinics – this can be distressing and difficult to address when you already feel vulnerable as a client.*
- *Training for every person involved in IVF service provision. Regularly.*
- *More LGBTI+ support training for doctors, nurses, admin staff & especially counsellors.*

Survey responses – Rainbow Families Victoria submission

A survey response received from the female partner of a woman undergoing treatment reported that she was required to get a blood test even though everyone understood that she was to be a non-biological parent. The blood test slip was labelled 'male bloods' and she stated that no explanation was given as to why the test was necessary. She also advised that she never received any results of the test.

It is important to note that these responses do not only refer to medical staff but also relate to reception and administration staff.

GLHV (formerly known as Gay and Lesbian Health Victoria) is an LGBTI health and wellbeing policy and resource unit funding by the Victorian Government. GLHV provides a services accreditation, The Rainbow Tick, which consists of six standards against which services can be formally accredited to demonstrate LGBTIQ+ inclusive practice and service delivery. Stakeholders have suggested that this may be an appropriate way of educating clinic staff. However, others have suggested that this approach does not lead to long-lasting, inclusive practice being embedded in their policies.

It may also be appropriate to consider whether the proposed code of practice (as discussed in Chapter 3.2.3) may be used as a mechanism to ensure that staff receive appropriate training and support in responding the diverse needs of LGBTIQ+ people accessing services.

The Review considers that the concerns raised by LGBTIQ+ community should be addressed through appropriate inclusive practice and cultural competency training for all staff within clinics and other bodies associated with ART. In order to be effective, such training needs to be developed and delivered in consultation with the LGBTI+ community.

Recommendation 11

VARTA and the Patient Review Panel should work together with the LGBTIQ+ community to develop embedded, regular inclusive practice and cultural competency training for ART industry members and staff.

VARTA should amend the conditions of registration to require clinics to ensure that all staff involved in patient contact be required to undertake training in LGBTIQ+ inclusive practice.

3.6.2.3. Counselling

While broader issues with counselling are outlined in Chapter 3.11.2 of this Report, we heard from during LGBTIQ+ consultations that there are a range of counselling issues that specifically impact their communities.

The Review heard that counselling is usually framed as *infertility* counselling. While members of the LGBTIQ+ population may experience infertility, it is not necessarily the primary reason that they need to access ART services.

How does the classic definition of infertility which applies to heterosexual couples being unable to fall pregnant apply to LGBTI people?

Submission – Harrington Family Lawyers

There were a large number of submissions that indicated that LGBTIQ+ people accessing ART services found counsellors in particular to be undereducated in LGBTIQ+ inclusive practice.

- *The counselling at [clinic name withheld] was an absolute joke. The woman we saw was so ignorant to LGBTQ+ knowledge that it was almost laughable. I felt like we were doing her a favour by educating her during or sessions. At our final session I was so upset by the atrocious and inaccurate things she said I could hardly see straight. As a queer person in a queer relationship, I should expect to walk into a counselling service (that is compulsory, mind you) and not have to do LGBTQ+ 101. Such a waste of time and emotional energy. As a person going through IUI/IVF, feeling vulnerable then meeting with incompetent counsellors put me in an incredibly vulnerable position.*
- *Our counsellor was inappropriate in their questioning and commentary regarding same sex couples. A good counsellor would have made the process a useful reflective exercise despite it being mandatory.*
- *Our counselling experience in Victoria was terrible. Very focussed on what we 'lacked' as a same sex couple. What we would do when our relationship failed 'because same sex relationships are not as stable as heterosexual ones' etc etc. It was pretty terrifying as it felt as though this ill-informed individual held the keys to our access to treatment.*

Survey response – Rainbow Families Victoria submission

Additionally, while counsellors are encompassed in the above recommendation regarding training, the Review heard that counsellors should be aware of issues facing the LGBTIQ+ community in addition to inclusive practice.

For example, a prominent LGBTIQ+ educator and advocate advised the Review that people are more likely to be estranged from their parents and families, and that beginning their own families can raise some sensitivities that are not as common in the mainstream population – and that more tailored counselling could assist with.

Due to these issues, LGBTIQ+ stakeholders made suggestions to improve the experience of counselling for their communities.

LGBTIQ people should be able to access counsellors of their choice, from an LGBTIQ service for counselling ... one option may be a phone advice line for advice and support by LGBTIQ culturally inclusive, trained medical staff.

Submission – Rainbow Families Victoria

3.6.2.4. Public information and data

Information and data is discussed in more detail in Chapter 3.10 of this Report; however, these were prominent topics discussed during LGBTIQ+ consultations.

The Review heard that ART data does not adequately reflect the amount of LGBTIQ+ people accessing ART, nor their success rates.

Include client info on gender identity status in data collection to maximise research and development opportunities.

Submission – The Royal Children’s Hospital Gender Service

Additionally, information on fertility preservation for trans, gender diverse and intersex people is confusing and not widely available, in clinics or external sources.

There is limited information regarding Testicular sperm extraction (TESE) as an option for XXY adolescents who want to preserve their reproductive options ahead of testosterone treatment. We also tried to ask about options for my husband to freeze sperm for potential use by our XXY son to use in the future – it was hard to get information about the legalities, costs and process.

Survey response – recipient of assisted reproductive treatment

The Review understands some additional information is being included in revisions to ANZARD, and believes that it is appropriate that further consideration be given to collecting data on LGBTIQ+ issues.

3.6.2.5. Intersex people and assisted reproductive treatment

The Darlington Statement explains that intersex people are born with physical or biological sex characteristics (such as sexual anatomy, reproductive organs, hormonal patterns and/or chromosomal patterns) that are more diverse than stereotypical definitions for male or female bodies. For some people, these traits are apparent prenatally or at birth, while for others they emerge later in life, often at puberty.

The Review has heard that people born with variations of sex characteristics (intersex people) have been overlooked in the healthcare system more generally, as well as within ART.

*We recognise the **trauma and mental health concerns** caused by the unnecessary medicalisation of intersex people, as well as stigmatisation of intersex characteristics that has resulted in a legacy of isolation, secrecy and shame.*

The Darlington Statement

The Review heard of further issues relating to genetic testing, where some intersex variations can be identified early in embryo development, and lead to possible termination on that basis.

We remain concerned about the possible de-selection of fetuses on the basis of intersex status and call on clinics to provide a strong commitment that this does not, nor will continue to, occur. We also call on ART services with the 'Rainbow Tick' to consider their role in supporting infants born with variations of sex characteristics and the support provided to their families.

Submission – Rainbow Families Victoria

The Review considers that amendments to the NHMRC Ethical Guidelines, and removing gender-specific language in the Act, is a first step in addressing some of the ways people with intersex variations have been overlooked. However, the Review acknowledges that significantly more work needs to be done. The Review intends to undertake targeted consultation with the intersex community in the coming months regarding the specific issues they face within the ART industry, and identify ways to meet their needs better.

3.7. Access to donor gametes and embryos and support for all involved in donor conception

Issues related to donor conception were important to a significant number of participants in consultations undertaken to date, with 69 of the 189 survey responses received raising issues related to the use of gametes and/or embryos.

After cost, access to donor gametes and embryos was identified as one of the most significant barriers to treatment. The Review has heard that access to donor gametes and embryos is limited.

Demand for donor sperm has risen significantly since the Act commenced allowing single people and those in same-sex relationships to access treatment. At the same time demand for donor eggs is being driven by a consistently large cohort of older women seeking to undergo treatment⁹ (VARTA 2018).

Table 5: People accessing donor sperm

Demographics	Percentage of donor sperm treatments
Single women	52 per cent
Women in same-sex relationships	33 per cent
Heterosexual women	15 per cent

Source: VARTA 2018

The lack of supply of donor gametes, in particular donor eggs, is leading to an increasing reliance on importation of gametes and to people travelling interstate or overseas to receive treatment.

It has also been suggested that a lack of supply of donor sperm may be one of the drivers for fertility specialists moving more quickly in Australia (compared with other countries) to the use of IVF rather than persisting with IUI, in particular for single women or lesbian women who do not have diagnosed infertility or advanced age that may justify more invasive treatment. Less sperm is required for IVF (and even less for ICSI) when compared with IUI.

Women report being told that IUI 'wastes' sperm and so they should move straight to IVF treatment.

Submission – Professor Fiona Kelly – La Trobe University

There is little data about the numbers of people who travel to other jurisdictions to access treatment or their reasons for doing so.

We felt the small pool of donors and inability to access international donors cemented our decision to access treatment interstate.

Survey response – Rainbow Families Victoria submission

The Review heard that the process for gaining approval for the importation of gametes can be slow and that costs for transportation are prohibitive for many people.

⁹ Approximately 25 per cent of women accessing assisted reproductive treatment are aged over 40 years.

While many stakeholders reported positive experiences of treatment outside Victoria, others highlighted the risks that this could expose people to, particularly when travelling overseas, and the potential impacts on people born of these arrangements.

This means they are likely to be using anonymous donors ... that potentially their child may never know. They may also experience a lower standard of medical care.

Submission – professional in the field

The consequences of these increased barriers are reproductive tourism often to jurisdictions where gamete donation is completely anonymous. It is the view of the FSA that ignoring what happens beyond the Victorian border is both harmful and irresponsible and therefore inconsistent with the ART Act's cardinal guiding principle.

Submission – Fertility Society of Australia

The Review heard from many stakeholders who were keen to see less restrictive regulation regarding access to donors in Victoria and additional effort put into recruitment of donors to ensure that Victoria can become closer to self-sufficiency in the supply of donated gametes. They suggest that this will enable better access to treatment for those who need donor gametes or embryos in order to form a family.

One way to improve the affordability of treatment would be State investment in a service that engages in recruitment, counselling and support of gamete and embryo donors and surrogates. This would reduce the cost of treatment for those utilising gamete donation (including through the increasing use of high cost importation).

Submission – Professors Millbank, Karpin and Stuhmcke – University of Technology Sydney

Within smaller communities such as particular ethnic groups, the size of the pool of donors accessed may be small. This can increase the risk of donor-conceived people inadvertently entering into consanguineous relationships. The Review has also heard that members of the LGBTIQ+ community may frequent particular clinics that are known to be more inclusive in their practice. This has resulted in members of this community also accessing a smaller pool of donors, resulting in instances of donor sibling children attending the same childcare or local school and their genetic relationship being discovered by parents recognising striking physical similarities.

Any change in regulation and policy around donor conception must endeavour to anticipate the impact of all of these societal developments and the diversity of the people involved in donor conception.

3.7.1. Addressing the shortage of local donors in Victoria

As pointed out by a range of stakeholders, improving the supply of donor gametes and embryos sourced in Victoria would have a dramatic impact on accessibility of treatment, alleviate costs associated with the importation of gametes and embryos and would allow more people to receive treatment locally where they could avoid some of the risks identified with travelling overseas for treatment.

In 2017–18, in Victoria there were only 246 egg donors and 424 sperm donors (including donations sourced from overseas egg and sperm banks), a slight decline from the previous year. There were 2,151 recipients treated with donated gametes (VARTA 2018).

Donor-conceived people also favoured the use of local donations over gametes sourced outside the state. They explained the importance of the possibility of connections with donors and donor siblings and the difficulties posed for this if those people live in other countries and may even speak a different language.

3.7.1.1. Restrictions on reimbursement of donors

The restriction on reimbursement payable to donors was cited as one of the key barriers to recruiting more local donors of gametes and embryos.

Under Victorian legislation, donations must be altruistic and not commercial in nature. Sections 38 and 39 of the *Human Tissue Act 1982* provide that it is an offence to sell or buy human tissue including eggs, sperm or embryos. Under s. 17 of the *Prohibition on Human Cloning for Reproduction Act 2008*, 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). No commercial incentive or reward for donation is payable, however, reimbursement of reasonable expenses is allowed.

Reasonable expenses in relation to the supply of a human egg or sperm includes, but is not limited to, expenses relating to the collection, storage or transport of the egg or sperm. The corresponding provision of the *Prohibition of Human Cloning for Reproduction Act 2002* (Cth) also applies (s. 21). The NHMRC Ethical Guidelines provide that gamete donation must be altruistic, and that commercial trading in human gametes or the use of direct or indirect inducements is prohibited by legislation. This position reflects concerns about the potential exploitation of donors (particularly egg donors) and the potential risks to all parties.

While direct or indirect inducements are prohibited, it is reasonable to provide reimbursement of verifiable out-of-pocket expenses directly associated with the donation, including, but not limited to:

- medical and counselling costs, both before and after the donation
- travel and accommodation costs within Australia
- loss of earnings¹⁰
- insurance
- child care costs when needed to allow for the donor's attendance at donation related appointments and procedures
- legal advice.

The Review notes that RTAC also released a *Technical bulletin on donor issues* (the Bulletin) in April 2011 to clarify the meaning of reasonable donor expenses. The Bulletin advised that where state legislation does not apply, 'reasonable expenses' should be based on the principles set out in the *Surrogacy Act 2010* (NSW), which applying to sperm donation would cover:

- reasonable medical, travel or accommodation costs associated with offering to be donor and associated with the donation, and
- receiving any legal advice associated with donation.¹¹

¹⁰ The Guidelines advised that donors who access paid leave during the donation process cannot be reimbursed for loss of earnings. Loss of earnings can be demonstrated by the donor providing payslips verifying that unpaid leave was taken.

¹¹ Adapted from s. 7 of the *Surrogacy Act 2010* (NSW), which sets out a broad range of surrogacy costs which can be recovered by a surrogate in New South Wales.

The Bulletin indicates that a cost is reasonable only if the cost is actually incurred and the amount of the cost can be verified by receipts or other documentation. For the convenience of donors and units, it is suggested that units may decide to waive requiring receipts for individual items below \$50.

Stakeholders expressed concern that the rules around reimbursement and what constitutes reasonable expenses are vague and open to interpretation, and argued that this lack of clarity has resulted in different interpretations and different levels of compensation paid by different clinics within Victoria. It has been suggested this could dissuade those who may otherwise be interested in making altruistic donations. Further, this could result in gaming by clinics to attract donors or in donors 'shopping around to get the best deal'.

Clinics themselves report that they find it difficult to source donor gametes, and identify the lack of appropriate compensation as a barrier to attracting donors. They would like to see more generous reimbursement based on the time, inconvenience, risk and discomfort associated with donation.

We believe that the lack of compensation for surrogates and gamete donors is a barrier for those seeking IVF treatment in Victoria. It results in women and men moving their treatment overseas to fulfil their dream of creating a family. This is expensive for patients and carries risks. We would recommend that further compensation for donors and surrogates be considered, not to commercialise this, but rather to compensate surrogates and gamete donors adequately. Examples of further reimbursement could be remuneration for time or remuneration for gamete storage fees that patients have incurred in keeping their gametes in storage.

Submission – Melbourne IVF

Monash IVF is committed to providing ART to the widest range of Victorians possible. Regulatory restrictions imposed on the import of donated gametes from overseas and extended timelines for advertising approvals (currently >6 weeks) have restricted our ability to resource the donor program with donated gametes. Monash IVF would welcome any move to simplify this process, including ... reimbursement policies to accurately reflect the risk and personal time investment of the donation process.

Submission – Monash IVF

Fertility clinics have difficulties producing enough donors and donor gametes to meet community need. This has been attributed to the removal of donor anonymity and low reimbursement of costs. Irrespective of the narrow flexibility built into the words 'but is not limited to' in the definition of reasonable expenses when considered in the light of the Guidelines, Primary IVF is of the view that:

- 1. Donors should receive financial compensation based on a reasonable assessment of the time, inconvenience, and discomfort;*
- 2. Payments should be fair and not so substantial that they become undue inducements that will lead donors to discount risks.*

However, Primary IVF believes that the following issues should be tabled for consideration:

- 1. Whether compensation incorporating the elements of point 1 above should be distinguished from payment for the oocytes themselves.*
- 2. Whether compensation should be fixed.*

Primary IVF acknowledges that although the States are restricted as a result of section 109 of the Constitution of Australia which provides that the laws of the Commonwealth shall prevail over those of a State it nevertheless believes that the uncertainty around payments must be clarified in Victoria, perhaps in the form of professional standards aligned to the Legislation.

Submission – Primary IVF

ART recipients and professionals have also highlighted difficulties in accessing donor gametes, and have identified lack of appropriate reimbursement as a possible source of the shortage.

There are very few local donors, mainly due to lack of financial reimbursement and the requirement of donor details release, which means that anyone wanting a sperm donor sometimes has to wait months for a suitable donor. Someone undergoing IUI would have to wait even longer.

Survey response – recipient of assisted reproductive treatment

Limited sperm, egg and embryo donors [is a problem] as recruitment is difficult, time intensive and limited reimbursement for time and commitment to the process. This precludes people from engaging in the process and exploring donation as an option.

Survey response – professional in the field

Other stakeholders have argued that the laws around a reasonable expenses model, while designed to protect against exploitation actually result in perverse outcomes and may lead to the exploitation of donors overseas.

We submit that the 'reasonable expenses' model, while attractive in principle, has been implemented in a manner that actually drives CBRC cross boarder reproductive care and gamete importation and is ultimately unworkable and deeply hypocritical. ... Australian women who are unable to self-recruit an egg donor are able to import 6 eggs from the 'World egg bank' at a cost of \$20,000 ... The egg donor or provider is paid \$3,000–\$5000, while profit-making middle people are able to charge storage, administration and transportation expenses of up to \$17,000. This not only makes a mockery of the much vaunted principle of altruism, which is applied only to the one person at risk in the procedure, but makes a trip to Greece or South Africa for the woman seeking treatment look rather more affordable.

Submission – Professors Millbank, Karpin and Stuhmcke – University of Technology Sydney

This issue of compensation for donors was explored by the Australian Human Ethics Committee (AHEC) in developing the updated NMHRC Ethical Guidelines. The AHEC consultations found a range of views within the community. There was concern that compensation, even at a modest level may act as an inducement for some individuals, which may diminish a person's ability to provide valid consent and is inconsistent with altruistic donation. These consultations also heard views that compensation may increase the supply of donors by more readily acknowledging the risk and reproductive efforts of the donor. This could in turn reduce demand for potentially higher risk international donor arrangements. The AHEC recommended further consideration of this issue with a view to identifying a level of compensation that was appropriate to acknowledge risk and effort without acting as an inducement.

Of interest to some stakeholders are moves in other jurisdictions to simplify the approach to compensation of donors. For example, in the United Kingdom, egg donors may receive a fixed rate of compensation. In 2012 this rate was increased from up to £250 (approximately \$435) to up to £750 (approximately \$1,300) per donation 'cycle' to cover their costs. There is the option to claim additional compensation to cover higher costs such as travel, accommodation and child care (HFEA 2018). Preliminary assessment of the impact of the change suggested the increased rate of reimbursement had been immediately followed by an increase in egg donation. While it is unclear the extent to which this resulted from the change or from increased awareness and marketing, services in the United Kingdom have nevertheless seen a significant reduction in waiting time to access donor services and a reduction in the number of people heading overseas for treatment.

A number of stakeholders have argued that an approach similar to that adopted in the UK would assist in attracting more donors and remove the burden on donors of having to produce evidence of expenses incurred. The Review notes that this approach is currently not considered consistent with the relevant legislation and understands that the NHMRC 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).

The Review considers that the law on donor reimbursement, combined with the NHMRC Ethical Guidelines and RTAC Technical Bulletin, provides clear guidance on the range of expenses which are currently eligible for reimbursement. These include reasonable medical, travel, counselling, legal and insurance costs, as well as compensation for loss of income. The key issue identified by submissions to the Review is whether this category should be expanded to recognise the time, inconvenience, risk and discomfort which is associated with donation.

As discussed below, the Review will continue to explore options for enhancing access to donor gametes, including through the removal of advertising restrictions, and establishment of a clearinghouse, as well as an egg bank. At this stage the Review considers that these options are likely to be preferable to expanding the current grounds for donor reimbursement. Consultations will continue in the coming months with relevant stakeholders to explore the issue further.

3.7.1.2. Recruiting donors and connecting them with those who need them

Advertising

Restrictions on the advertising for donations of eggs and embryos were also raised as a significant barrier to access. The lack of available donor eggs and embryos mean that most people do not access these through clinics but rather seek to find their own donor.

Advertising for donation of eggs and embryos is strictly regulated and Ministerial approval is required before a person may advertise for a donor (s. 40 of the *Human Tissue Act 1982* (Vic)). The Minister is able to delegate the power for this approval to VARTA, however, no delegation has yet been made.

The Review has heard that advertising approvals currently take in excess of six weeks to be processed. This is viewed as challenging given that any delays in commencing treatment can reduce the likelihood of a successful outcome, especially for older women who are heavy users of donated eggs.

Others have argued that these requirements are unnecessarily burdensome on those who may be:

battle-weary from long periods of trying to conceive who then move on to donation.

Submission – professional in the field

During consultations with stakeholders concerns were raised regarding the advertising approval process. It is intimidating for people to approach the Minister's Office for approval for such an intimate matter. The process is difficult to navigate and adds to the emotional burden of families seeking treatment.

The requirement for Ministerial approval for advertising does not apply in other states.

The Review will consider whether amendments should be made to remove these advertising restrictions or to give the function directly to VARTA or the Department of Health and Human Services. Any such consideration will take into account the impact of other proposals aimed at facilitating the recruitment of donors and connection of donors with those who need them.

Facilitating connections

For many people who require donor assistance to form a family, the process of reaching out and connecting can be highly challenging:

Many people in this situation needing to find an egg donor feel vulnerable and unprepared to raise this delicate subject with friends or family and find the thought of advertising for a donor repugnant.

Submission – professional in the field

The Review has heard that people commonly reach out to potential donors via online forums. While this may be a quick way of connecting, concerns have been raised that in these unmoderated settings, there is a risk of exploitation of both donors and recipients and that arrangements are being made which may be in breach of the prohibition on payments under the *Human Tissue Act 1982* (Vic), and the *Prohibition of Human Cloning for Reproduction Act 2008* (Vic).

It has been proposed that one means to better facilitate recruitment of donors and to link donors with those needing their assistance to form a family would be through the establishment of a statewide online moderated clearinghouse or linking service. There may be some benefits to publicly facilitated service of this kind. In the second stage of the Review, consideration will be given to how such a model might

provide a regulated, safe place for people to connect while obtaining appropriate advice, information and support.

Egg and sperm banks

A number of other countries, including the United Kingdom and the United States, have well-established donor egg and sperm banks. Such banks may increase supply by having a dedicated focus on recruitment of donors and also allow for more equitable access to donor gametes.

Not surprisingly these agencies have better outcomes in sourcing donors ... as this is their target group.

Submission – professional in the field

While individual clinics or groups of affiliated clinics in Victoria may have donor egg and sperm stores, these supplies fluctuate and are available only to patients using those clinics. There is no established egg bank in Victoria or elsewhere in Australia.

The issues associated with the establishment of an egg bank were also considered briefly by the AHEC during the revision of the NHMRC Ethical Guidelines. Consultations in relation to this issue identified questions as to whether or not it is the role of government to establish or fund a donor egg bank. Nonetheless, there was some suggestion that such a move could increase the supply of donor eggs and thus reduce the incidence of people travelling overseas seeking donor conception support. It was also found that such a model could allow for greater regulation of reimbursement, advertising and compensation with positive benefits in reducing the potential for exploitation.

Concerns were raised as to whether an egg bank under industry control could leave donors and recipients vulnerable to commercial exploitation. In this regard, a publicly run egg bank was considered by some to be preferable.

While further research and targeted consultation is required to better understand the potential for a Victorian based egg and/or sperm bank, the Review has received positive interest from assisted reproductive clinics for the idea. In some cases, clinics have expressed a willingness to contribute financially on a cost recovery basis, but have stressed that this would be contingent on equitable access for all providers.

3.7.1.3. Public education and awareness

A number of stakeholders indicated that greater public awareness and information about donor programs in Victoria may assist in improving access to gametes and embryos.

It has been argued that demystifying donation would be valuable, and it was suggested that there was widespread misinformation and a lack of understanding of the process and legalities involved.

We believe Victorian society could benefit from a continued public communication and education campaign where the public are invited to view the donation of gametes in a similar light to organ donation.

Submission – professionals in the field

One example is the confusion as to whether gay men are allowed to donate sperm. While there is no impediment to them doing so, the Review heard that both potential donors and staff are frequently

unsure. It appears this stems from the eligibility criteria of blood donations in Australia, where donations are deferred if the potential donor is a man who has had sex with men in the last 12 months (Australian Red Cross Blood Service n.d.). The Review was advised that recent campaigns in NSW targeted at recruiting gay men to donate sperm have substantially addressed sperm shortages in that state.

Donor-conceived people have also called for greater public information, including about the experiences of donors, donor-conceived people and recipient parents, to normalise donor conception, reduce fears and misconceptions within the community and to highlight the risks and consequences of overseas anonymous donation.

It's my great wish that we could see ART and specifically donor conception through the eyes of the children who don't have any barriers to love other people, unless we create them.

Submission – donor-conceived person

It has been suggested that VARTA would be well placed to coordinate such a campaign if adequately resourced to do so. If the donor clearinghouse or egg bank proposals described above were found to be viable options, these models might also form the basis for launching a statewide donor recruitment campaign.

3.7.2. Limits on the use of donations

3.7.2.1. Limits on the number of families formed

As discussed in Chapter 3.6.1.1 of this Report, s. 29 of the Act restricts the number of people who may conceive a child using gametes donated by the one person.

The limit imposed by s. 29 is intended to reduce the risk of donor-conceived people unknowingly forming consanguineous relationships. Throughout the consultation, donor-conceived people have also informed the Review of the importance of limiting the number of siblings a person has. They have advised the Review that it can be challenging, indeed traumatising, for a person to discover they have a large number of siblings they do not know, and that this can leave them 'questioning all past relationships that we have ever had' (statement made by donor-conceived woman during consultation meeting).

Others have pointed out that a limit is also important to protect donors who may themselves be overwhelmed by discovering they have a very large number of donor offspring across many families. It is more common today for parents (especially single parents) of donor-conceived children to approach their donors when their children are in their early years, rather than waiting until their child is an adult. Little is yet known about the emotional impact of this early contact.

How do donors and their families manage this? How do they manage a large number of their donor-conceived offspring wanting to know more about them and have direct contact?

Submission – professional in the field

Indeed donor-conceived people, some donors and others have called for a lowering of the limit to five families, which would align with provisions in relevant legislation in New South Wales and Western Australia. Other Australian jurisdictions rely on the NHMRC Ethical Guidelines and the RTAC Code of Practice. The Guidelines state that 'gametes from a single donor must be used to create only a limited number of families' and recommend that, in the absence of specific state regulation, clinicians should

consider a range of factors including – the number of persons already born from the donor’s gametes, the risk of a person born inadvertently having a sexual relationship with a close genetic relative, and whether the donor has already donated gametes at another clinic. There is nothing in the RTAC Code of Practice that sets out family limits. However, the RTAC Technical Bulletin advised that ‘a maximum of 10 donor families per sperm donor’ is acceptable.

Internationally, it is common for limits to be placed on the use of donated gametes, but these limits vary significantly between jurisdictions. Hong Kong imposes a limit of three live-birth events (defined as meaning the event of the birth in Hong Kong of one or more live children from a single pregnancy); while the Netherlands allows for up to 25 children per donor. Sweden sets both a limit of the number of children to be born (10) and the number of families (four). The United Kingdom sets a limit of 10 families worldwide, and in the United States gametes from one donor are used in up to 25 births per population of 850,000 (Allan 2014).

In contrast to the views described above, some stakeholders have advocated strongly against any lowering of the limit, arguing that this would further reduce the availability of local donors, thus increasing the use of donors from outside of Victoria, with all the undesirable consequences outlined above.

The Review also heard that there are conflicting views about whether the limit imposed by s. 29 applies to the use of gametes in Victoria or if it is a worldwide limit. VARTA have interpreted s. 29 as limiting the use of gametes worldwide. A number of respondents to the consultation paper supported this approach, arguing that globalisation has increased the likelihood of people born in different countries coming into contact and, more importantly, that the psychological impact on donor-conceived people knowing they have a large number of genetic half-siblings is not related to where those siblings were born or reside.

In contrast, a number of clinics have expressed the view that the limit should only be interpreted as applying in Victoria and that any alternate interpretation is incorrect and unreasonably restricts access to donor gametes.

Monash IVF obtained legal advice ... in February 2018 which advised that ... ‘the view that the cap might be Australia wide or worldwide is misconceived, without substance and contrary to the clear intention of Parliament’

Submission – Monash IVF

It is noted that the New South Wales legislation is, like the Act, silent on the geographic reach of the limit. In Western Australia, directions have been issued that stipulate that the five-family limit includes families that may be outside Australia.

Clinics have also raised the practical difficulties of complying with the requirements of s. 29, as it relies on potential donors disclosing where they have donated previously. There is no national donor register. Prior to donation potential donors are asked to provide this information and consent for any other clinics to be contacted about previous donations. Clinics have advised the Review that experience shows that not all donors are truthful when it comes to responding to these questions.

One suggested approach is that VARTA manage a potential donor register with capacity to disclose to clinics whether a potential donor has previously donated and confirm the number of families formed using the donated material.

3.7.2.2. Donor control over gametes: consent and withdrawal of consent

Section 20 of the Act provides that a person who gives consent, under s. 16, to the use of donated gametes or embryos may withdraw consent at any time 'before the procedure or action consented to is carried out'. Although providers have reportedly received competing legal opinions on the interpretation of this provision, one interpretation is that a donor of gametes may withdraw consent after an embryo has been created any time up until transfer of the embryo, and providers have reported occasions where this has occurred.

The Review heard that the current legislation should be amended to create greater certainty in respect of the use of embryos created from donor gametes. Monash IVF submitted that s. 20 should be amended to mirror the New South Wales legislation and remove the ability for donors to withdraw consent after an embryo has been formed with their donated gametes. The clinic also observed that whereas both partners in a couple undergoing treatment must consent to treatment, the non-gamete providing partner is not recognised when it comes to the ongoing storage, donation or discard of the embryos created.

Table 6: Donor consent and withdrawal of consent – Australian jurisdictions

Jurisdiction	Consent requirements
Victoria	A person who gives consent, under s. 16, to the use of donated gametes or embryos may withdraw consent at any time 'before the procedure or action consented to is carried out' (ART Act, s. 20).
New South Wales	Consent may be modified or revoked by the donor at any time up until the gamete is placed in the body of a woman or an embryo is created using the gamete (<i>Assisted Reproductive Technology Act 2007</i> (NSW), s. 17).
Western Australia	Prior to the donation of gametes for their use in an ART procedure, consent to the donation and use of gametes must be given by the gamete provider (Direction 3.3 of the <i>Human Reproductive Technology Act 1991</i> Directions). The WA Act provides for the withdrawal or variation of consent unless the gametes have been used (<i>Human Reproductive Technology Act 1991</i> (WA), s. 22).
Other jurisdictions	Not addressed in any specific state-based regulation. Practice is guided by the NHMRC Ethical Guidelines and RTAC Code of Practice (see below).

Most jurisdictions rely on the NHMRC Ethical Guidelines and the RTAC Code of Practice to guide consent requirements for donors. The Ethical Guidelines state that:

*A gamete donor can withdraw or vary consent for donation at any time before the treatment cycle of the recipient commences, or at any time **before the creation of an embryo, whichever is sooner** [emphasis added].*

The RTAC Code of Practice requires consent practices consistent with these guidelines.

As the Victorian consent provisions allow for the withdrawal of a gamete donor's consent after an embryo is created, they are inconsistent with the Ethical Guidelines and the RTAC Code of Practice. It is

proposed that the Act be amended to ensure that a donor cannot modify or withdraw consent following use of the gamete for insemination or creation of an embryo.

Recommendation 12

It is recommended that the Act be amended to allow for gamete donors to modify or revoke consent only up until the time the gamete is used, either for insemination or to create an embryo.

Donor consent for extension of storage or disposal of embryos in storage

Section 33A of the Act requires donor consent for the extension of storage of embryos created using donated gametes. Further, s. 34 of the Act prohibits the removal of embryos from storage without the consent of both of the persons who produced the gametes from which the embryo is formed. This has the effect that recipients of donated gametes subsequently used to create embryos are unable to make independent decisions about the storage or disposal of such embryos. This can be particularly distressing in cases where recipients have used their own gametes along with donated gametes to produce embryos and they are forced to dispose of these embryos if the donor does not consent to an extension of storage.

Again, Victoria is unique in providing donors with ongoing control over gametes and embryos and in requiring their consent in this way. Consistent with the amendment proposed in Recommendation 12, the Act should remove the requirements for a donor to consent to the extension of storage or the disposal of any embryos created from donated gametes. The Review considers that decisions relating to the use, storage or disposal of embryos formed from donated gametes are best made by the recipients of the donation.

Recommendation 13

It is recommended that the Act be amended to remove requirements for donors to consent to the extension of storage or disposal of embryos formed from donated gametes.

Posthumous use of donated gametes

It has been noted in Chapter 3.4.4 that the Act currently does not address the posthumous use of donated gametes. The Review has heard that some donors have expressed a desire to be able to allow recipients to use their donated material in the event of their death (particularly where the same donor has contributed gametes used to create a sibling for a child already born). Some stakeholders have therefore argued that the Act should be amended to allow for donors to consent to the use of their gametes after their death.

The Review will consider this matter further and any likely implications. In particular, there are competing concerns about the impact on any person conceived using gametes donated by a deceased person as this could effectively remove their capacity to find out about their genetic heritage.

Donor partner consent

Some stakeholders provided feedback to the Review about the significant impact of donation on not only the donor but also their partner and family.

Although currently at most Victorian clinics, the partner of a donor will attend counselling and acknowledge their partner's donation, there is no requirement for formal consent to the donation occurring.

It has been proposed that consideration should be given to whether the donor's partner, if any, should also be required to consent to the making of the donation. Further consideration of the potential impacts of such a change will be considered in the second stage of this Review.

3.7.2.3. Other limits on the storage and use of donated gametes

New South Wales legislation (*Assisted Reproductive Technology Act 2007* (NSW), s. 26) specifically provides that an ART provider must not provide treatment using a donated gamete if the gamete was obtained from the donor more than 15 years prior to treatment; or an embryo created from a donated gamete if the embryo was created more than 15 years before the provision of the ART treatment.

This provision is designed to minimise the age gap between a donor and their donor-conceived offspring and thereby minimise the risk of a donor being deceased when their donor-conceived offspring reaches adulthood and may seek to learn about their genetic heritage. There does not appear to be a comparable provision in any other state or territory.

As outlined earlier in the Report, many donor-conceived people have indicated in the course of consultations that they have a strong interest in having an opportunity to meet their donor, and this may be hindered where older gamete stock is used.

As discussed in Chapter 3.12.1, the New South Wales Act also makes different provision for the length of storage of donor gametes and embryos formed from donor gametes when compared with gametes and embryos stored by the provider for their own use.

It appears to the Review that the New South Wales provisions relating to storage and the use of donated gametes, or embryos created from donated gametes, are well-crafted and carefully balance a range of interests. While further consideration will be given to the best way forward, the New South Wales approach may offer a useful model.

3.7.3. Importation of gametes and embryos

The Review heard a range of divergent views on the issue of the importation of gametes and embryos. On the one hand clinics, and some potential recipient parents, called for a loosening of restrictions on the importation of gametes to address issues of supply shortages and thereby improve access to treatment for those who require it, without people needing to travel overseas for treatment.

Some stakeholders made the point that people from non-Caucasian backgrounds find it more difficult to find a suitable gamete donor in Australia, and that restrictions on the import of gametes exacerbates these issues.

On the other hand, some stakeholders expressed concern about the quality of imported materials and the extent to which it is possible to ensure that they meet the requirements for treatment under Victorian legislation.

Section 36 of the Act provides that approval from VARTA is required for the movement of gametes or embryos into or out of Victoria.

Some stakeholders have argued that these requirements restrict the ability of clinics to resource their donor programs with donated gametes and have proposed that this approval should be removed.

Others have supported these requirements as an important adjunct to Victoria's approach to ensuring that donor-conceived people are able to access information about their donor's identity.

Victoria has the most comprehensive donor linking laws in the world which will ensure that all donor offspring have the right to know their donor's identity ... These laws are working extremely well and are recognized internationally as best practice. Importing gametes from jurisdictions with weak or no law (e.g. the United States) will jeopardize the efficacy of our laws and the rights of children conceived.

Submission – Professor Fiona Kelly – La Trobe University

The process for seeking approvals for importation of gametes has also drawn criticism from some stakeholders. It has been stated that the time taken for approvals is unacceptably long and that there is a lack of clarity as to how VARTA makes decisions under s. 36.

Section 36(3) sets out matters to which VARTA must have regard in making decisions about whether to approve gametes or embryos being taken out of Victoria. However, no such provision exists in relation to decisions about importation.

Providers have reported that VARTA is not consistent in the evidence requested to make decisions about whether to allow or disallow gametes being brought into Victoria. This has been of particular concern in relation to applications for import of classes of gametes.

VARTA needs to set clear guidance for overseas gamete donor import approvals ... to streamline the process and make proposals consistent for all ART providers, VARTA should ... set up a checklist for provider proposals.

Submission – professional in the field

It would appear that this may be one area where more transparent and accountable administrative decision-making criteria for VARTA would be appropriate.

This could be achieved through legislative amendment or prescribing relevant matters for consideration in regulations. This may also be a matter about which it would be appropriate to include an appeal mechanism in relation to the administrative decision made.

The Review will consult further and consider how greater clarity might best be achieved and how the various competing interests regarding importation of gametes can be balanced in setting any criteria for decision making.

3.8. Access, protection and support for surrogates and intended parents

Stakeholders indicated that there are a number of areas of the legislation focusing on surrogacy which would benefit from greater clarity and a reconsideration of the most restrictive provisions which hinder access to such arrangements. The Review heard that patients who are contemplating surrogacy have often gone through years of their own treatment and may not have the emotional energy to navigate the complexities of finding and entering into a surrogacy arrangement in Victoria. Feedback indicates that improving the local system will give more opportunities for intended parents to access surrogacy locally rather than travelling interstate or overseas.

The key issues raised by stakeholders were:

- reimbursement of reasonable costs that are incurred by a surrogate
- terminology used in respect of surrogacy arrangements
- advertisements and publications regarding surrogacy arrangements
- counselling for surrogates and intended parents
- traditional surrogacy arrangements
- parenting orders in respect of overseas surrogacy arrangements.

Matters relating to surrogacy arrangements are set out in Part 4 of the Act. Surrogacy arrangements in Victoria require the approval of the PRP and are otherwise tightly regulated. Presumptions concerning the status of a child born as a result of a surrogacy arrangement, and the process for making substitute parentage orders, are set out in Part IV of the Status of Children Act.

Feedback from professional advisers indicated generally that it would be useful to expand the surrogacy section in the Act, or create a separate Surrogacy Act, to provide a greater level of detail and certainty on key surrogacy matters. Stakeholders have advised that a number of the issues discussed in this chapter could usefully be set out in an expanded or dedicated piece of legislation relating to surrogacy issues. The Review heard that inconsistent laws and policies between jurisdictions makes this area difficult to navigate and may result in 'jurisdiction shopping' by intended parents. To the extent possible, reforms to Victorian legislation should be seen as an opportunity to move towards a nationally harmonised approach to surrogacy laws and policies.

Some stakeholders also advised that the requirements for surrogacy arrangements to be approved by the PRP may also deter people from entering into surrogacy arrangements in Victoria. The role of the PRP is outside the scope of this Review. However, the feedback received is reported in Chapter 4.1.2.

3.8.1. Reimbursement of reasonable costs that are incurred by a surrogate

Section 44 of the Act provides that a surrogate mother must not receive any material benefit or advantage as a result of a surrogacy arrangement. However, this prohibition does not prevent payment or reimbursement for the prescribed costs actually incurred by the surrogate as a direct consequence of entering into the surrogacy arrangement. To the extent that a surrogacy arrangement provides for a matter other than the reimbursement of costs actually incurred by the surrogate, the arrangement is void and unenforceable. For the purposes of s. 44, prescribed costs are limited to any reasonable medical expenses associated with the pregnancy or birth that are not recoverable under Medicare, health insurance or another scheme; any legal advice obtained for the purposes obtaining information about the legal consequences of entering into the arrangement; and travel costs related to the pregnancy or birth (ART Regulations, r. 10).

Altruistic surrogacy arrangements are permitted in all jurisdictions, with the reimbursement of reasonable expenses. While Queensland, New South Wales, Western Australia and Tasmania have specific legislation on surrogacy, other jurisdictions manage surrogacy through the making of parenting orders which can specify conditions in respect of surrogacy arrangements.

Surrogacy costs in Queensland, New South Wales, Western Australia and Tasmania include expenses associated with an extensive range of matters, including:

- reasonable medical cost for the birth mother and for a child born as a result of the surrogacy arrangement
- a premium payable for health, disability or life insurance that would not have been obtained by the birth mother if the surrogacy arrangement had not been entered into
- reasonable cost of counselling and legal advice obtained associated with the surrogacy arrangement
- the value of the birth mother's actual lost earnings because of leave taken
 - for a period of not more than two months during which a birth happened or was expected to happen, or
 - for any other period during the pregnancy when the birth mother was unable to work on medical grounds
- other reasonable cost associated with the surrogacy arrangement or the making of the order transferring parentage.¹²

Other jurisdictions rely on the NHMRC Ethical Guidelines, which provide guidance on reimbursement of surrogacy costs, as follows:

Arrangements for any reimbursement of verifiable out-of-pocket expenses should be between the commissioning parent(s) and the surrogate and each party should be encouraged to seek legal advice before reimbursements are given or received to ensure compliance with relevant state or territory legislation.

It is reasonable for the commissioning parent(s) to reimburse a surrogate's verifiable out-of-pocket expenses directly associated with the procedure or pregnancy, which may include:

- *medical and counselling costs, before, during, and after the pregnancy or birth*
- *travel and accommodation costs within Australia*
- *loss of earnings (Surrogates who access paid leave during the pregnancy and birth cannot be reimbursed for loss of earnings. Loss of earnings can be demonstrated by the surrogate providing payslips verifying that unpaid leave was taken.)*
- *insurance*
- *child care costs when needed to allow for attendance at appointments and procedures related to the surrogacy arrangement legal advice.*

The Review heard from a range of stakeholders that Victoria has a very restrictive approach to reimbursement compared with other jurisdictions in Australia, and that this needs to be addressed to ensure a fairer outcome for surrogates and encourage more people to consider becoming surrogates in Victoria.

¹² *Surrogacy Act 2010 (QLD)*, s. 11; *Surrogacy Act 2010 (NSW)*, s. 7; *Surrogacy Act 2008 (WA)*, s. 6; *Surrogacy Act 2010 (Tasmania)*, s. 9

Such reform is necessary to recognise the significant financial risks undertaken by surrogates and their families, and to promote domestic surrogacy as an option to Victorian intended parents and surrogates.

Submission – Surrogacy Australia

I am concerned that the wording in the current Act is too restrictive, potentially leaving donors and surrogates out of pocket. I am sure this was not the intention of the Act. I would like to see greater clarity so that donors and surrogates are fairly compensated for costs incurred. I would not like to see this go beyond compensation as I think it is important for the motivation to remain that they want to assist in the creation of the child and to help people to become a family.

Submission – counsellor

The fact that loss of wages and other expenses are not covered by law for a surrogate, impacts on the number of women who may consider surrogacy in Victoria. During my surrogacy pregnancy, I never faced needing to take a significant amount of time off work, fortunately. Intending parents should be able to guarantee that they will be able to reimburse their surrogate if she needs to go on bed rest, for example, without fear of being prosecuted.

Survey response – surrogate

We are concerned about the lack of post-care support for surrogates and their families and the impact of not being able to pay or remunerate surrogates for their work.

Submission – Rainbow Families Victoria

Medical experts also observed that surrogates go above and beyond to help others, including risking their own life to carry a baby and give birth to a child on behalf of another person or couple, and their efforts should be recognised accordingly. This includes a fair and consistent approach to the reimbursement of costs incurred. VARTA noted in its submission that ‘even where a surrogate is reimbursed for medical, legal and counselling expenses, she suffers a loss of income due to time taken off work for appointments associated with the process’.

It was also noted that the current provisions are unclear and lack sufficient detail on the types of payments that may be made to a surrogate, which can lead to confusion and concern that parties to a surrogacy arrangement may be breaking the law.

Intended parents living in Victoria report feeling anxious about being denied a Parentage Order should they reimburse their surrogate for expenses beyond those allowed within section 10 of the Regulations. Parties engaged in surrogacy within Victoria are left with only two options – that the surrogate and her partner will be significantly out of pocket and will bear the cost of surrogacy upon themselves, or the intended parents will provide reimbursement beyond those allowed within section 10, and risk prosecution and the denial of a Parentage Order.

Submission – Surrogacy Australia

Many hours are spent trying to discern the meaning of 'reasonable expenses'. ... It would be helpful in the Victorian legislation set out with some particularity what is reasonable and gave examples. It would be even more helpful if the regulations set figures as to what is reasonable. These figures should be generous to reflect reality.

Submission – Harrington Family Lawyers

The Review has also heard that the requirement for surrogates to pay expenses up front and be reimbursed by the intended parents is difficult and results in them being out of pocket. Feedback from VARTA highlighted a specific case where intended parents had agreed to reimburse the surrogate mother for medical, legal and counselling costs, but failed to do so following the birth of the child. This example highlights how physically, emotionally and financially vulnerable surrogate mothers may be in the context of a surrogacy arrangement. Unlike some other jurisdictions, including Queensland, New South Wales, Western Australia and Tasmania, an obligation under a surrogacy arrangement to pay or reimburse expenses is currently not enforceable in Victoria.

The surrogate was in difficult financial circumstances and stated that she had agreed to be a surrogate 'out of the goodness of her heart'. She did not expect to be in a worse financial situation following the birth of the child. She described her vulnerability and felt physically and financially exploited [when the intended parents failed to reimburse her expenses]. She felt that Victorian law in relation to surrogacy arrangements protects commissioning parents, but not surrogates.

Submission – VARTA

Further, stakeholders indicated that negotiating payment directly with the intended parents can negatively impact on the relationship as the arrangements may feel like an employer/employee arrangement. Feedback to the Review indicated that it may be preferable for payment to be managed through a third party to bring greater transparency and independent oversight to the process.

The Review considers that the category of surrogacy expenses currently eligible for reimbursement in Victoria is overly restrictive and inconsistent with the NHMRC Ethical Guidelines. It is recommended that Victoria's legislation be brought into line with other jurisdictions, to allow for the payment or reimbursement of reasonable costs that are incurred by a surrogate. It is envisaged that the nature of costs agreed by the parties to a surrogacy arrangement would be disclosed to the PRP as part of the application for approval of the surrogacy arrangement. Costs listed on the application could be amended if gaps were subsequently identified by the parties. The Review will continue to consider issues around the enforceability of surrogacy arrangements to better protect surrogates in respect of costs incurred; and the possible role of a third-party intermediary in processing payments between surrogates and intended parents.

Recommendation 14

It is recommended that the Assisted Reproductive Treatment Regulations be amended to allow for the payment or reimbursement of reasonable costs that are incurred by a surrogate where the costs would not have been incurred but for the surrogacy arrangement. It is intended that this should better reflect the actual costs incurred by surrogates as a result of taking on that role. Costs that may be covered should include, but not be limited to:

- medical costs for the birth mother (including costs incurred prior to conception, during pregnancy and after delivery) or a child born as a result of a surrogacy arrangement where these are not payable by Medicare or private health insurance
- a premium payable for health, disability or life insurance that would not otherwise have been obtained
- counselling expenses
- reasonable legal costs for the birth mother and their partner (if any)
- lost earnings because of leave taken — (i) for a period of not more than two months during which a birth has happened or was expected to happen; or (ii) for any other period during which the surrogate was unable to work on medical grounds as a result of the surrogacy
- other out of pocket expenses including travel, accommodation and childcare.

The nature of costs agreed by the parties to a surrogacy arrangement should be disclosed to the Patient Review Panel as part of the application for approval of the surrogacy arrangement.

The Review heard feedback that while s. 44 of the Act prohibits a surrogate from receiving a material benefit or advantage as a result of a surrogacy arrangement, there is no corresponding offence for intending parents to offer such inducements. To remedy this inconsistency, the Review recommends that s. 44 be amended to make it an offence for intended parents, as well as a surrogate, to enter into, or offer to enter into, a commercial arrangement.

Recommendation 15

It is recommended that s. 44 of the Act be amended to make it an offence for all parties to enter into, or offer to enter into, a commercial surrogacy arrangement. A surrogate must not receive any material benefit or advantage as a result of the surrogacy arrangement and the intending parents must not provide or offer to provide material benefit or advantage in exchange for the surrogacy arrangement.

3.8.2. Terminology used in respect of surrogacy arrangements

Feedback to the Review highlighted that the current reference to 'commissioning parents' may be offensive to people who hope to become parents through surrogacy, and that the term 'intended parents' more accurately reflects these aspirations.

Time and again we have heard from those who want to be parents that the reference to commissioning parents sounds as though they are buying a child, much in the same way that they might be buying a fridge, a car or a house. Many of them find this term offensive. We urge a legislative language change.

Submission – Harrington Family Lawyers

To address this issue, the Review considers that it would be appropriate for references to ‘commissioning parents’ to be replaced with ‘intended parents’ throughout the Act. The proposal aims to use more sensitive language preferred by parties to a surrogacy arrangement and is consistent with terminology used in a number of other Australian jurisdictions (see for example, Queensland, New South Wales and Tasmania surrogacy legislations).

Recommendation 16

It is recommended that references to ‘commissioning parents’ in the Act be replaced with the term ‘intended parents’.

3.8.3. Advertisements and publications regarding surrogacy arrangements

Section 45 makes it an offence for a person to publish a statement, advertisement, notice or document to the effect, among other things, that a person is or may be willing to enter into a surrogacy arrangement; that a person is seeking a surrogate; that a person is willing to act as a surrogate mother; or may be willing to arrange a surrogacy arrangement. For the purposes of the section, ‘publish’ is defined broadly to include publication in any newspaper; by means of television, radio or the Internet; or otherwise disseminate to the public.

Similar to Victoria, a number of other jurisdictions including Queensland, Western Australia and South Australia and Tasmania have a general prohibition on all publications or advertising material which is intended or likely to induce a person to agree to act as a birth mother; states or implies that a person is willing to agree to act as a birth mother; demonstrates a willingness to enter into a surrogacy arrangement. Conversely, while New South Wales prohibits advertising generally, it takes a more nuanced approach by creating an exception where the surrogacy arrangement is not a commercial arrangement and no fee has been paid for the advertisement, statement, notice or other material.

The Review heard from a range of stakeholders who are of the view that the current restriction on publications makes it extremely difficult to source a surrogate in Victoria. Feedback indicates that this often drives intended parents to seek surrogacy arrangements overseas.

The inability to advertise for a surrogate creates a real barrier for couples to source a surrogate and in turn creates a barrier to IVF treatment. We believe we could increase the number of clinic recruited surrogates if we were able to advertise for surrogates, like we do for gamete donors.

Submission – Melbourne IVF

Sourcing a surrogate is extremely difficult and commissioning parents are often seeking surrogacy overseas as they cannot find a surrogate within Australia.

Submission – Monash IVF

Due to the strict prohibitions on advertising for a surrogate, intended parents are often left with no alternative but to pursue surrogacy overseas.

Submission – Surrogacy Australia

Surrogacy laws need to be made more accessible - there is a law against advertising for a surrogate, and this is outdated and inappropriate. I think people are going overseas to access surrogacy because they cannot advertise for a surrogate in Victoria, and this limits their capacity to find someone to carry for them. I also think this results in further stigma of surrogacy – people think it is illegal because it is not normalised.

Survey response – surrogate

Medical experts similarly raised concerns that intended parents are travelling overseas because the process in Victoria is too complex.

We will never begin to hope to meet the ART needs of gay male couples as long as we deny them the right to respectfully and with Ministerial supervision advertise in newspapers / magazines for altruistic surrogates (gestational carriers) to help them. Not allowing them to do this forces many couples to go overseas to expensive units in the USA, or to cheaper commercial surrogacy units in other countries without legislation and where medical care is often sub-standard. It is a terrible shame that we continue to place barriers in the path the treatment access for same sex male couples in Victoria by preventing this supervised advertising. It simply drives it underground to internet forums, and overseas units.

Submission – Dr Gareth Weston – professional in the field

Surrogacy Australia highlighted that it is in the best interests of a child that their donor and surrogate are within Australia, with regulatory frameworks to support the child's access to information about their donor and surrogacy conception, and to ensure the wellbeing of all parties concerned. This is also the preference of many donor-conceived adults. Others observed that intended parents would rather go to their local clinic than undertake surrogacy overseas at a higher price, particularly in light of the minimal regulatory oversight or protection for surrogates and intended parents in some of the developing countries where such arrangements are pursued (Submission – Harrington Family Lawyers).

Feedback indicates that the provision relating to publication is interpreted strictly and poses a real barrier for those seeking to find a surrogate in Victoria. Surrogacy Australia stated in its submission that it is aware of two cases within Victoria, where the parties have faced threatened prosecution for breaching s. 45 of the ART Act for publishing their desire for a surrogate.

Publishing a personal story in an online forum, or on social, print or audio media is a breach of section 45 of the ARTA. Intended parents are unable to share their own stories for threat of prosecution, which means they cannot seek a surrogate within Australia and thus are pursuing surrogacy overseas.

Submission – Surrogacy Australia

The Review also heard that the strict ban on publication in a surrogacy context is inconsistent with the current approach in respect of advertising for donor gametes, which is legal, subject to Ministerial approval. Accordingly, a number of stakeholders observed that it would be useful to align advertising for a surrogate with the current requirements for advertising for an egg or sperm donation. Counsellors in the field further submitted that the current difficulties in finding surrogates could be addressed through a

publicly funded brokerage agency. Feedback from Monash IVF and Melbourne IVF also indicates that it would be useful to amend the legislation to allow clinics to advertise, with approval, for surrogates to register interest in the possibility of becoming a surrogate.

The Review considers that the current prohibition on advertising creates a significant barrier to access for those seeking to have a child through a surrogacy arrangement. Feedback from a range of stakeholders highlights strong support for amending the current provision to allow advertising to occur where it is not for the purpose of a commercial surrogacy arrangement. As noted above, New South Wales has already introduced legislation which achieves this objective. The Review will undertake further consultation to help develop a way forward which will better meet the needs of those who wish to connect with an altruistic surrogate in Victoria within an appropriately regulated advertising environment.

3.8.4. Counselling for surrogates and intended parents

Where a surrogacy arrangement is contemplated, s. 43 of the Act provides that before a surrogacy arrangement is entered into, the relevant parties must obtain counselling in respect of a range of prescribed matters, including:

- the social and psychological implications of entering into the arrangement and the relationship between relevant parties
- the possibility of medical complications for the surrogate mother or the child
- the possibility of any party deciding not to proceed with the surrogacy
- the attitudes of all parties towards the conduct of the pregnancy
- the implications of the relinquishment of the child and the relationship between the surrogate and the child once it is born (ART Regulations, r. 9).

The Review heard that good counselling is essential for optimal outcomes in a surrogacy arrangement, and a number of individuals reported that the counselling they received in respect of their surrogacy journey was positive and helpful.

Once we had expressed interest in surrogacy our experience of counselling and nursing services from MIVF from beginning to end was nothing short of wonderful. We appreciated the process, access, level of expertise and proactive support provided, including support following the birth.

Submission – Deb Martindale – recipient of assisted reproductive treatment

I found the counselling valuable in our surrogacy journey. I really liked that it was all inclusive, so that I could access an extra appointment at any time I felt necessary. I found it helpful that my intended parents had paid upfront for the counselling package and that meant I didn't feel guilty asking for the cost of an extra appointment. I think built in counselling should be widely available.

Survey response – recipient of assisted reproductive treatment

While the counselling offered prior to entering into a surrogacy arrangement is valuable, the Review heard that more comprehensive support is required to meet the needs of surrogates and intended parents throughout the surrogacy process and post-relinquishment.

I feel that further access to unlimited counselling should be provided throughout the pregnancy and post birth as required. The cost of access this privately could be a limiting factor for many couples when they are already dealing with significant costs.

Survey response – recipient of assisted reproductive treatment

We sought external counselling after we left the Clinic, but this was self-motivated and not required. I think ongoing counselling and support services should be provided for all surrogacy matters during the pregnancy and post-birth.

Survey response – recipient of assisted reproductive treatment

I like that it is not mandated in Victoria to have a post birth relinquishment counselling session, but that the option is open if you wish to access one. Some other surrogates however, I have found would like to see it compulsory to have one with all parties post birth.

Survey response – recipient of assisted reproductive treatment

Feedback from counsellors similarly highlighted that offering ongoing counselling for surrogates and intended parents during pregnancy, as well as post-relinquishment, would benefit all concerned.

Providing ongoing counselling for surrogates would be an important addition to legislation, as currently the Act does not cover post-relinquishment counselling (see NSW legislation). Similarly ongoing counselling could be provided to both surrogate and intended parents during any pregnancy.

Submission – counsellors

While Victorian law mandates counselling prior to entering into a surrogacy arrangement, it does not require counselling to occur during pregnancy or at the time of relinquishment. The Review notes that a number of other jurisdictions take a more robust approach to counselling in this area, and require that the parties obtain counselling not only prior to entering into a surrogacy arrangement, but also following the birth of the child, as part of the process for making parenting orders.

For example, the Queensland and New South Wales, surrogacy legislation mandates that a surrogacy guidance report be prepared by an independent and appropriately qualified counsellor in respect of a range of matters, including an assessment of each relevant person's understanding of the social and psychological implications of the making of a parentage order on the child and relevant persons; and whether the making of a parentage order would be for the wellbeing, and in the best interests, of the child. In considering an application for a parentage order, a court in Western Australia or Tasmania must similarly be satisfied that the child's birth parents and the arranged parents have received appropriate counselling about the effect of the proposed order. The NHMRC Ethical Guidelines similarly provide that individuals and couples involved in an altruistic surrogacy arrangement must undergo counselling on a broad range of matters before, during and after ART treatment, because of the complex nature of the issues involved. A number of submissions to the Review favoured the approach taken in other jurisdictions over the current Victorian model.

Surprisingly, there is no requirement in Victoria for there to be a post birth assessment that the proposed arrangement is in the best interest of the child. The assumption is made that because approval has been obtained from the Patient Review Panel, the surrogacy arrangement must be an appropriate one. In our view this is misguided. Having an independent assessment as seen in New South Wales and Queensland is a vital tool in informing the judge that the proposed arrangement is in the best interests of the child.

Submission – Harrington Family Lawyers

Other States, including New South Wales and Queensland, require the parties to engage in relinquishment and post-surrogacy counselling prior to obtaining a Parentage Order. It is in the parties' interest and the interests of any child born through a surrogacy arrangement that the parties engage in post-surrogacy counselling. Feedback from past surrogates and intended parents is that the need for counselling does not end once the parties have gained approval for the arrangement.

Submission – Surrogacy Australia

The Review is persuaded that, consistent with the approach in other jurisdictions and the NHMRC Ethical Guidelines, more counselling support should be provided for intended parents and surrogates during the pregnancy and following the birth of a child. It is envisaged that further consultations in the coming months will explore ways to achieve better outcomes for all participants to a surrogacy arrangement. In addition to offering counselling during the pregnancy on an optional basis, the Review will consider the need for counselling to be undertaken prior to the finalisation of parentage orders in Victoria in a surrogacy context.

The Review also heard concerns in the course of consultations that the current requirements for counselling in the legislation lack flexibility and are not sufficiently tailored to meet the needs of participants. In particular, feedback highlighted that individuals would prefer to choose their own, suitably qualified counsellor, and would like to have options to access counselling services remotely, including through online videoconferencing platforms.

There should be more flexibility with where the surrogacy counselling appointments take place. They should be allowed to be with a qualified counsellor anywhere in Australia, not just from the IVF clinics. ... Other states allow counselling to happen with non-clinic counsellors, in the state of the surrogate, provided it is with a certified counsellor/psychologist.

Survey response – surrogate

Furthermore Victorians should be allowed to access ART counsellors from other states by the use of remote communication services such Skype. This would allow patients to seek services from those who are extremely experienced in the field of ART counselling, including donor and surrogacy counselling. As well provide counselling access to those who reside in regional Victoria and reduce the onerous time and cost involved in traveling to Melbourne for a 45 minute appointment.

Survey response – future recipient of assisted reproductive treatment

A further, related issue raised with the Review, concerned the perception that counsellors in Victoria lacked sufficient independence because they were employed by the clinics.

Under section 43 of the Act, counselling must be done with a counsellor employed through a registered ART provider. This prevents parties from seeking their own counsellor and limits the counselling to that which the ART provider is willing to offer. In the interests of continuity in treatment and the therapeutic relationship, Surrogacy Australia submits that parties should be able to choose their own counsellor if they wish. It is our submission that counsellors engaged in surrogacy counselling should be full members of ANZICA and have requisite experience with surrogacy arrangements.

Submission – Surrogacy Australia

The counselling for the surrogacy process was comprehensive, but I think we were lucky that we had such a good counsellor who was attentive and thorough. However, she had a clear conflict of interest, when her employer (the Clinic) was causing me frustration and distress and I needed to debrief about it. Was she to raise my concerns with the Clinic? How could she be my counsellor while her employer was the cause of my distress?

Survey response – recipient of assisted reproductive treatment

The Review notes that the approach to counselling in respect of surrogacy arrangements in other jurisdictions is much more robust than in Victoria, with a clear focus on the independence and quality of the service provided. The Review heard that stakeholders with expertise in surrogacy matters consider Queensland and New South Wales to offer the best models for surrogacy counselling.

For example, the Queensland legislation requires that counselling be provided to the relevant parties prior to entering into a surrogacy arrangement by an ‘appropriately qualified counsellor’ who is required to prepare a report in respect of the counselling which has taken place (*Surrogacy Act 2010 (QLD)*, s. 31). A person is deemed to be appropriately qualified if they are:

- a member of the Australian and New Zealand Infertility Counsellors Association; a psychiatrist who is a member of the Royal Australian and New Zealand College of Psychiatrists
- a psychologist who is a member of the Australian Psychological Society
- a social worker who is a member of the Australian Association of Social Workers
- and have the relevant experience, skills or knowledge appropriate to prepare the report (s. 19).

There is no requirement that the counsellor be providing services on behalf of an ART clinic.

Following the birth of a child, an application for a parentage order by the intended parents must include a surrogacy guidance report addressing a range of matters, prepared by an ‘independent’ and ‘appropriately qualified counsellor’ (s. 32). The word ‘independent’ is defined to mean that the counsellor did not give counselling about the surrogacy arrangement to the relevant parties; and is not, and has not been, directly connected with a medical practitioner who carried out a procedure that resulted in the birth of the child (s. 19). The legislation indicates that a counsellor is directly connected with a medical practitioner if the counsellor is engaged to give fertility counselling at the fertility clinic where the medical practitioner carried out a procedure that resulted in the birth of the child.

New South Wales takes a similar approach. Each of the affected parties must have received counselling from a qualified counsellor about the surrogacy arrangement and its social and psychological implications before entering into the surrogacy arrangement. The birth mother and the birth mother’s partner (if any) must have received further counselling from a qualified counsellor about the surrogacy arrangement and its social and psychological implications after the birth of the child and before consenting to the parentage order (*Surrogacy Act 2010 (NSW)*, s. 35).

To exercise the functions of a counsellor under the New South Wales Act, a person must:

- hold a qualification conferred by a university (whether within or outside New South Wales) after at least three years full-time study or an equivalent amount of part time study, and
- be a qualified psychologist, qualified psychiatrist or qualified social worker, and
- have specialised knowledge, based on the person's training, study or experience, of the social and psychological implications of relinquishing a child (*Surrogacy Regulation 2016* (NSW), reg. 7(2)).

Further, an application for a parentage order must be supported by a report about the application prepared by an independent counsellor. The report must contain the independent counsellor's opinion as to whether the proposed parentage order is in the best interests of the child and the reasons for that opinion, having regard to a broad range of matters (NSW Surrogacy Act, s.17). For the purposes of this section, an 'independent counsellor' is defined to mean a qualified counsellor who:

- is not the counsellor who counselled the birth mother, the birth mother's partner (if any) or an intended parent about the surrogacy arrangement, to meet a precondition to the making of a parentage order, and
- is not, and is not connected with, a medical practitioner who carried out a procedure that resulted in the conception or birth of the child.

The Review finds the arguments for clarifying the qualifications of those offering surrogacy counselling compelling, and will consult on the most appropriate set of qualifications and skills to incorporate into the Act in the coming months. The Review will also consider whether that there is a need to make independent counselling available to individuals going through a surrogacy process. Further consideration will be given to whether independent counselling should be optional or mandatory. The Review will also reflect on whether different counselling requirements might be appropriate for different stages of counselling in the surrogacy process.

3.8.5. Traditional surrogacy arrangements

Traditional surrogacy arrangements, where a surrogate's egg is used to conceive a child, currently fall outside the scope of the legislation and cannot be facilitated by clinics in Victoria. This is because s. 40 of the Act provides that the PRP may approve a surrogacy arrangement if the Panel is satisfied of a range of matters, including that the surrogate's egg will not be used in the conception of the child. The Review heard that the restriction is unique in Australia and denies access to clinic services which would be beneficial for traditional surrogacy arrangements, including screening, ovulation tracking, and expert assistance with IUI or IVF procedures.

Traditional surrogacy arrangements should be treated in the same way as gestational surrogacy arrangements. This would allow parties to engage with an ART provider should they wish, and apply to the Patient Review Panel for approval. It would provide all parties with protections offered by ART providers, including screening, and an appropriate framework to enter the arrangement.

Submission – Surrogacy Australia

Traditional Surrogacy, which is legal, should be facilitated by the clinics rather than people being forced to do it in their own homes.

Survey response – surrogate

As the clinics refused to assist us, we were forced to organise it ourselves. We had independent counselling and legal advice. We had to trust each other in regards to STD checks and had no access to genetic testing. I had to check my own ovulation using at-home stick tests, then we met at my home or theirs for a number of days for inseminations. If clinics were to support traditional surrogacy, they could carry out all the same testing and counselling that is undertaken as part of egg donation and surrogacy, they could use more accurate ovulation tracking, they could assist with IUI or IVF procedures, and they would be able to charge for it all and make some money from it.

Survey response – surrogate

Concerns were also raised that IVF doctors and counsellors have incorrectly advised patients that traditional surrogacy is illegal in Victoria.

Moving into traditional surrogacy was a big unknown void. We were kind of just following the lead of other couples and groups who had been there before us. Trying to make contact with a counsellor who had any idea about traditional surrogacy was a nightmare and because the clinics would make no money off that scenario and were happy to tell us it was illegal.

Survey response – surrogate

We are very concerned by the low up take of altruistic surrogacy since 2010 and understand that there are some rainbow families engaging in 'traditional surrogacy' to circumvent the Act. Given that Rainbow Families Victoria places children's rights and best interests at the centre of our advocacy, we recommend that the altruistic surrogacy provisions in the Act to be amended to ensure that the practice of traditional surrogacy does not flourish 'under the radar' in any way that continues to negatively impact upon women's health nor the legal certainty for the child about the identity of their parents.

Submission – Rainbow Families Victoria

The Review also heard concerns that parties cannot apply for a substitute parentage order for children conceived through traditional surrogacy arrangements, due to an administrative oversight in s. 23(3) of the Status of Children Act. This provision states that relevant parties to a surrogacy arrangement must receive counselling from a counsellor within the meaning of s. 61(3) of the *ART Act 2008*.

While home insemination for traditional surrogacy is not prohibited by the legislation, there appears to be a perception in some parts of the community that this is in fact the case. The Review considers that it would be appropriate to bring traditional surrogacy within a clear and supportive regulatory framework which would allow individuals to access clinic services, and will give consideration to the appropriate way forward on this issue.

The Review agrees that the cross-reference in the Status of Children Act to s. 61(3) of the *ART Act* requires amendment as the provision has been repealed. It is proposed that s. 23(3) of the Status of Children Act be amended to require that counselling be provided by a counsellor providing services on behalf of a registered ART provider or an independent counsellor who meets specified qualification criteria and has relevant experience and skills in providing such counselling.

Recommendation 17

It is recommended that the Status of Children Act be amended to remove the now redundant reference in s. 23(3). A new provision should allow for parties to a surrogacy arrangement to receive counselling from a counsellor providing services on behalf of a registered ART provider or an independent counsellor who meets specified qualification criteria and has relevant experience and skills.

3.8.6. Parenting orders in respect of overseas surrogacy arrangements

Part IV of the Status of Children Act provides that commissioning parents of a child born under a surrogacy arrangement may apply to the Supreme or County Court for a substitute parentage order if the child was conceived as a result of a procedure carried out in Victoria; and the commissioning parents live in Victoria at the time of making the application (s. 20). The court may make a substitute parentage order in favour of the commissioning parents if it is satisfied, among other things, that the surrogacy arrangement was commissioned with the assistance of a registered ART provider and that the PRP approved the surrogacy arrangement (s. 22). A more comprehensive set of conditions apply to the approval of substitute parentage orders where a surrogacy arrangement was commissioned without the assistance of a registered ART provider and the surrogate mother became pregnant as a result of artificial insemination (s. 23).

While there is nothing in Victorian legislation to prevent individuals or couples from entering into surrogacy arrangements overseas, the effect of the Status of Children Act is that only commissioning parents who have engaged in domestic surrogacy may apply for a substitute parentage order in Victoria. The Full Court of the Family Court confirmed in the case of *Bernieres and Anor and Dhopal and Anor* [2017] FamCA 769 that there was no legal basis for making parentage orders in respect of a child born to a Victorian couple through a surrogacy arrangement in India. This was because the Victorian legislation does not provide for the circumstances of birth in this case. While the case considered the situation of a couple from Victoria, the problem is not unique to Victoria and raises similar problems in other jurisdictions.

Family law experts indicate that the current state of the law in this area represents a fundamental failure to protect children born as a result of overseas surrogacy arrangements, and argued that Victoria should legislate to enable the making of parentage orders under the Status of Children Act when parents have undertaken surrogacy overseas (Submission – Harrington Family Lawyers). These concerns were echoed by other interested stakeholders.

The ability to apply for a Substitute Parentage Order should be extended to intended parents who have engaged in surrogacy outside Australia. Such a reform would prioritise the rights of the child, and provide intended parents with recognition as the child's parents, equal to other parents engaged in domestic surrogacy.

Submission – Surrogacy Australia

Establish a process for conferring legal parentage for children living in Victoria born through international surrogacy, while working to ensure children's best interest are protected under such arrangements.

Submission – Rainbow Families Victoria

The Review will consider how the current gap in the law with respect to available parenting orders in overseas surrogacy arrangements can best be resolved. The Review anticipates that an appropriate solution will need to be pursued at the national level, in consultation with other Australian jurisdictions.

3.9. Fertility management and preservation

Fertility management and preservation emerged as a significant issue for a number of stakeholders.

3.9.1. Fertility education

A number of respondents to the consultation noted that at least part of the demand for ART has been driven by changing social behaviours, including a tendency for people to opt to have children later in life.

Recent research has found 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 number of stakeholders stressed the importance of greater public information and education to ensure people understand how age and other factors affect fertility. This was seen as particularly important for young people making decisions about delaying starting a family.

I believe it is absolutely vital to implement a public media campaign regarding not taking your fertility for granted. I also believe that the public in general needs to be much better educated about fertility issues and just how common it is.

Submission – recipient of assisted reproductive treatment

The Your Fertility program run by VARTA, in conjunction with Andrology Australia, Jean Hailes Research Unit and the Robinson Research Institute received praise from some respondents, while others called for additional investment in this area. The Review considers that VARTA or the Department of Health and Human Services may be well placed to play lead roles in any additional activity in this area.

3.9.2. Fertility preservation

Fertility preservation is the process by which gametes, embryos or ovarian or testicular tissue are collected and frozen for later use – this may be because of concern about impending loss of fertility due to increasing age or treatment for serious illness. A small number of stakeholders raised concerns about the processes available for those who need to undertake fertility preservation before undergoing treatment for cancer in particular.

It was pointed out that any delay in treatment while waiting for fertility preservation may delay the commencement of cancer treatments and can be very distressing for patients.

The Review has heard that there is a lack of clarity about whether or not fertility preservation falls within the definition of a 'treatment procedure' (s. 3 of the Act) for the purposes of the Act. Some stakeholders have suggested it does not meet this definition as it does not, on its own, 'procure or attempt to procure a pregnancy'. However, the Review has heard that this interpretation is not consistently applied across clinics.

If fertility preservation is interpreted as meeting the definition of a treatment procedure then the requirements set out in Part 2 of the Act (which include requirements for pre-treatment counselling and consent – including police and child protection checks) apply. The Review understands that the approach taken is not consistent across clinics and has formed the view that amendments to the Act may be required to ensure clarity.

As noted in Chapter 3.6.2.4, issues, processes and requirements associated with fertility preservation for trans, gender diverse and intersex individuals are also unclear and not widely understood.

Further consideration will be given to the appropriate regulatory requirements. However, it would seem inappropriate that time-consuming processes such as obtaining police and child protection checks should apply in this instance. This was also raised specifically in relation to egg freezing.

Concerns were also raised about the high cost of fertility preservation, which may deter some people from taking this course of action, or may add to stress they are already facing as a result of their diagnosis. Although there may be a small number of related Medicare items, in general, Medicare does not cover fertility preservation, including onco-fertility treatments. A number of submissions to the Review proposed extending Medicare rebates to cover fertility preservation.

The Review notes that the soon to be launched UNSW and Royal Hospital for Women (NSW) public IVF service plans to provide subsidised fertility preservation for cancer patients as a key focus of its work (up to 50 per cent of the patients they expect to treat).

The Review will give further consideration to whether any proposed public provision of ART in Victoria might similarly provide support for those requiring fertility preservation for a range of reasons.

3.9.3. Regulation of egg freezing

Elective egg freezing is increasingly being offered and marketed by ART providers, and there has been a substantial rise uptake of this service by Victorian women. In 2017–18 there were 1,064 egg collection cycles resulting in egg freezing, this was up from 828 in 2016–17 and 665 in 2015–16.

Studies have shown that for most women who elect to freeze their eggs the primary concern is time. Egg freezing is seen as a way of being able to accommodate biological timelines. This is reflected in some advertising by some clinics for egg freezing with prompts such as ‘Busy career? Freeze your eggs’ and ‘Waiting for the one?’ appearing on some websites.

A number of respondents expressed concern about the intensive marketing of egg freezing to women concerned about age-related fertility loss and that the promotion of these services may give women false assurances about their future fertility. Egg freezing is a more recent procedure with a lower success rate than embryo freezing. It must not be forgotten that fertility also relies on male factors and that sperm quality also declines with age, although not as dramatically as in women. In addition, ovarian stimulation for egg collection carries with it risks, such as OHSS, which need to be weighed carefully against uncertain future fertility benefits. There are reports that many women ultimately do not use their frozen eggs for reasons including having achieved conception naturally. There appear to be mixed views among clinicians about the risks and benefits of egg freezing at different ages. Given the high costs of this procedure and the strong social and psychological pressures on women who are making decisions about their fertility, there is a need for the practices of clinics in this area to be guided by a clear ethical framework and evidence-based medicine.

As with other forms of fertility preservation, the Review has heard there is a lack of clarity about whether the requirements of Part 2 of the Act apply in relation to egg freezing and a lack of consistency across clinics in the approach taken. Some practitioners expressed the view that egg freezing was not covered by the Act, since it does not involve a fertilisation procedure. Some stakeholders argued that those considering egg freezing would benefit significantly from counselling and information provision to assist them to understand the limitations of this approach and the consequences of storing their genetic materials for later use.

... an increase in women who are educated that their egg supply is finite and are choosing to freeze their eggs electively and we would like to ensure the legislation covering assisted reproduction has included this population group.

Submission – professionals in the field

As noted above, the Review will give further consideration to which, if any requirements of the Act ought to apply in relation to elective egg freezing and fertility preservation treatments more generally. It will also consider whether any additional guidance should be provided to ART services about fertility preservation practices.

3.10. Information provision

Just over half (50.8 per cent) of the 183 survey respondents who provided an answer to the question 'In your experience have you, or people you know of, received appropriate information to make informed choices about treatment?' responded 'No'.

We didn't know about side effects physically and psychologically.

We didn't understand why one procedure was needed and what the other options are.

We didn't know why our results were the way they were.

We didn't understand the logic behind success rates and conception probabilities.

Survey response – recipient of assisted reproductive treatment

As for any health services, people need comprehensive, accessible and accurate information about treatment options, risks, possible outcomes and costs to enable them to make informed choices. People need to have the right information at the right time, so they can understand options available to them at all points in their engagement with services.

It is critical that people understand the medical, legal, financial, social and emotional consequences of the decisions they make and are able to give fully informed consent – both financial and clinical.

Poor or inadequate information can also significantly impact on their expectations of outcomes and experience of care.

3.10.1. Information about success rates

Information about success rates of clinics in assisting people to form families is important to allow people to make choices about which clinic is right for them and to weigh up the costs, risks and likely outcomes. Accurate information about success rates can also help manage people's expectations. This is critical in the context that up to half of all people who access services may never have a baby.

Information about the likelihood of treatment not succeeding was not addressed well. While treatment providers don't want to put people off by being negative, I had very little comprehension of the toll 'failure' would have on me.

Survey response – recipient of assisted reproductive treatment

3.10.1.1. Compliance with existing regulatory requirements

An ACCC investigation undertaken in 2016 found that some clinics made claims and comparisons about their rates of success without adequate disclosure, or explanation of the data, and that some used technical terms which may be misleading to consumers.

In response to this finding, the revised RTAC Code of Practice, issued in 2017, included greater requirements in relation to public information (item 2.2.2). In particular, the code states that public information about success rates must:

- i. *be divided by age,*
- ii. *specify live birth rates for fresh and frozen embryo transfers separately. Use of clinical pregnancy rates in advertised success rates may be permissible provided that the live birth rates are also available for comparison in the same communication,*
- iii. *be accompanied with the following clarifying information: the time period during which the advertised data was collected and unambiguous details of the population group from which they are derived (e.g. whether they relate to IVF, ICSI, preimplantation genetic testing (PGT)/preimplantation genetic diagnosis (PGD) or FET, and age group),*
- iv. *be accompanied by a qualifying statement of broad factors that affect success rates e.g. age, weight, and cause of infertility, and that individual results will vary with individual circumstances,*
- v. *be accompanied by a statement that not every treatment cycle will result in an egg collection, an embryo transfer or embryo cryopreservation,*
- vi. *be accompanied by a reference and/or hyperlink to the Fertility Society Australia (FSA) statement on “Interpreting Pregnancy Rates: a consumer guide”*
- vii. *ensure that any clarification, qualifying statement or reference be clear and prominent and not hidden in a disclaimer.*

The VARTA conditions of regulation for ART providers also includes a requirement that:

published claims, comparisons and advertising by an ART provider must comply with section 133 the Health Practitioner Regulation National Law (Victoria) Act 2009 and have due regard to the AHPRA Guidelines for Advertising Regulated Health Services.

Section 133 of the National Health Practitioner Regulation Law (National Law) states that:

A person must not advertise a regulated health service, or a business that provides a regulated health service, in a way that – a) is false, misleading or deceptive or is likely to be misleading or deceptive; or b) offers a gift, discount or other inducement to attract a person to use the service or the business, unless the advertisement also states the terms and conditions of the offer; or c) uses testimonials or purported testimonials about the service or business; or d) creates an unreasonable expectation of beneficial treatment; or e) directly or indirectly encourages the indiscriminate or unnecessary use of regulated health services.

A number of clinics have advised the Review that they have invested significant resources and effort into ensuring that their public information about success rate is now compliant with Australian Consumer Law and the RTAC Code of Practice and the National Health Practitioner Regulation Law (National Law).

The Review has found that, despite some continued, isolated instances of clinics and individual fertility specialists publishing information which may mislead, there have certainly been improvements in the accuracy and clarity of the information available as a result of these developments.

Of concern, however, is that the Review has observed the continued consistent use of testimonials by some providers and individual clinicians. This issue has been raised as a concern by a number of stakeholders who have pointed out that this practice is inconsistent, not only with the RTAC Code of Practice ('ART Units must not incorporate patient comments on social media that promote their practice or service') but also s. 133 of the National Law ('a person must not advertise a regulated health service,

or a business that provides a regulated health service, in a way that uses testimonials or purported testimonials about the service or business’).

3.10.1.2. Availability of information to compare providers

The Review has also heard that the current requirements for advising people about success rates may not go far enough. A number of stakeholders called for more information to be made publicly available to enable people to compare treatment outcomes from one provider to another.

It is very difficult to access information on clinics' credentials, quality systems, facilities and success rates. As a result, it is difficult to compare clinics and make an informed decision as a consumer.

Survey response – recipient of assisted reproductive treatment

Some stakeholders cautioned strongly against any move to introduce ‘league tables’ of providers, arguing that these could be misleading and may not take into account a range of factors that can influence the outcomes achieved by an individual clinic.

Having legislation imposed on Victorian clinics to dictate the publication of success rates and not have these same conditions imposed across all states would not benefit Victorian patients, who would likely find the differences even more confusing.

Submission – Monash IVF

The goal to provide easy to compare information on costs and success rates is a difficult undertaking as it will often mean comparing apples and oranges The best advice to specific patient(s) is a detailed discussion with a fertility specialist who will take into account all these factors.

Submission – Fertility Society of Australia

Others, however, advocated for an approach that would allow people to make informed choices between provider options and pointed to information available on the HFEA website. The HFEA make available a range of detailed information about individual clinics on the ‘choose a clinic site’. Information includes inspection ratings, patient ratings, a range of outcome data and activity statistics, details of services offered and waiting times.

I'd like to have a rating system for fertility specialists. One that includes their success rates and also the patients' rating of their specialists on communication, qualifications, and care and support. I believe if we had this rating system, then the patients would be more empowered to make meaningful choices relating to their care.

Survey response – recipient of assisted reproductive treatment

Options for increasing the availability and transparency of clinic specific information will be considered in the next stage of this Review.

3.10.1.3. Towards more personalised information to inform treatment decisions

Stakeholders also highlighted the importance of providing information that reflects the likelihoods of success of a range of treatments for individuals based on their personal circumstances. Such information might take into account factors such as age, health, diagnosed fertility issues, obesity status, lifestyle factors (like smoking) and previous pregnancies.

Others pointed out that combining success rates for the diversity of people accessing treatment for a range of different reasons makes understanding an individual's personal likelihood of success very difficult.

We had trouble accessing information about rates of success for different treatment methods because success rates same-sex couples and heterosexual couples were combined, which skews the data because each cohort is accessing ART for different reasons.

Survey response – recipient of assisted reproductive treatment

Pregnancy prediction models can be useful decision aids for distinguishing couples who are unlikely to achieve pregnancy naturally and probably need fertility treatment from those who can reasonably expect to achieve natural conception and can therefore delay seeking similar treatment (van der Steeg et al. 2007). The Review understands that both VARTA and RTAC have been working to progress development of tools that can more accurately compare outcomes and provide more personalised success rates particular to an individual's circumstances. While it is understood that tools of this type exist in some other countries (for example the United Kingdom), tools constructed using Australian data and taking into account as many relevant variables as possible (especially age) would be welcome. These would be likely to assist those seeking fertility treatment in their decision making.

The Review will continue to monitor this work and consider whether any additional recommendations are required to support the development and provision of more accurate and personalised information.

3.10.2. Information about costs

The Review heard from many recipients of ART that information about costs can be confusing and misleading. Patients reported being surprised by a range of extra costs not disclosed at the outset of the treatment and talked about 'hidden costs' that were not included in the global treatment cycle figures quoted by clinics.

Costs definitely are not clear cut and it always costs a lot more than stated at first.

Survey response – recipient of assisted reproductive treatment

Full cost of services are not clearly communicated and constantly change. E.g. Drugs use to be included in the cycle cost, then they were extra to the cycle, then the first script is at PBS rate, but next script full price. None of that is clearly communicated up front, in fact it feels like the industry is trying to deliberately hide the cost and trick you.

Survey response – recipient of assisted reproductive treatment

The process was always clear, but throughout the process we just kept getting hit with additional surprise costs.

Survey response – recipient of assisted reproductive treatment

Certainly, the Review found that there was little consistency between clinics in how they presented their costs and the items that were included or excluded from these.

Many IVF centres give 'out of pocket' expense quotes based on assumption that you've already hit safety net. Very difficult to compare between providers if you're just starting out.

Survey response – recipient of assisted reproductive treatment

Some patients also found it difficult to obtain from clinics accurate breakdowns of what they had spent over time. This information is vital to people who may be making difficult decisions about whether or not to proceed with further treatment.

Costs were uncoordinated, paper based, via postal mail and difficult to breakdown.

Submission – Deb Martindale – recipient of assisted reproductive treatment

The Review considers that there may be value in additional guidance or requirements for clinics in how they present cost information to patients. A more standardised approach that reflects the full costs and the likely duration of treatment would allow patients to make more informed choices about providers, and to manage their financial commitments when undergoing treatment. Consideration will be given to whether such matters could be addressed through inclusion in any regulated code of practice that may be developed (as proposed in Chapter 3.2.3).

3.10.3. Information about adjuvants

The Review heard that ART providers are increasingly offering adjuvants or 'add-ons' in addition to standard IVF treatments. Medical adjuvants are offered by the treating fertility specialist. They can be distinguished from 'complementary' or 'alternative' therapies (such as acupuncture) that many service users access in a desperate attempt to conceive a child, sometimes without telling their fertility specialist.

Recent research has found a wide array of add on therapies and tests offered on websites of Australian and New Zealand ART providers (Hammarberg et al. 2018). There is widespread concern that these medical adjuvants do not have an adequate evidence base for their use in a non-research setting and that the ethics of offering them to a vulnerable population who are already paying often crippling out-of-pocket costs are questionable.

Recent research has found a wide array of add on therapies and tests offered on websites of Australian and New Zealand ART providers (Hammarberg et al. 2018). The five most commonly offered adjuvants identified were preimplantation genetic screening (PGS), sperm selection, assisted hatching, embryo culture enhancements and time-lapse imaging. The costs associated with treatments varied dramatically. For example, the study found time-lapse imaging was provided at no additional cost at some clinics while one charged up to \$950. A range of different sperm selection methods were offered with costs ranging from \$150 per cycle to nearly \$3,000. The study found that most providers mentioned on their websites the benefits that may arise from each add-on, but very few cited published literature to support these claims. In some cases, the claims were quite misleading. Indeed, the study found that there was

evidence for only one of the five most commonly offered adjuvants having a slight increase in the change of a live birth.

A small number of stakeholders argued that, despite the lack of evidence available as yet, it is important to continue to support specialists undertaking experimental or emerging treatments.

There are specialists out there who have been practicing for many years, using techniques that have not yet been scientifically proven yet they are having great success.

Submission – recipient of assisted reproductive treatment

Many others expressed unease about the widespread advertising of these treatments. They noted that adjuvant treatments can be very costly, and were concerned that people are being misled by the unfounded claims about the benefits of these treatments found on some clinic website.

Some clinicians are advertising and marketing adjuvant medications which are not proven to make any difference to pregnancy rates. This is misleading to patients. This influences patients in their decision to choose a fertility provider, as they may think one provider will provide an advantage or improved success over enough. Providers offering adjuvant medications often charge far more for not only their consultations but profit on the adjuvants/add-ons offered too.

Survey response – professional in the field

Some stakeholders told the Review that the increase in the use of these treatments is being driven by patients who, having heard of the treatments, pressure their specialist to provide them in hope of maximising their chance of having a baby.

Others suggest that, at least in some cases, clinics provide treatments as a matter of course with significant additional costs associated.

The dr chooses what treatment and sometimes will not move from that treatment despite several failed attempts, some do things like scratches and some think it is ineffective, some recommend acupuncture while others claim it does nothing. It is very confusing and difficult to know if you are getting the best service. I think doctors should discuss all these 'add ons' with patients and let them choose if they want these things.

Survey response – recipient of assisted reproductive treatment

Regardless of the drivers for the increased use of adjuvants, accurate information that is clear about what evidence does or does not exist about the efficacy of these treatments is critical. This will enable people to make informed choices about whether they wish to use them and whether they personally consider them worth the additional costs.

Patients should be aware they are paying thousands of dollars to be part of what is really a trial (usually something that is usually free and requires ethics approval).

Survey response – professional in the field

There should be a consent for 'add ons' which clearly states in plain language (in the patients' language) the level of proof for the efficacy of the proposed treatment, the postulated mechanism of action, side effects and cost

Submission – Raphael Kuhn – professional in the field

It would be useful to have more information regarding the statistics relating to add-on treatments such as endometrial scratches etc.

Survey response – recipient of assisted reproductive treatment

With the intention of ensuring that more accurate information is available, VARTA has included within the conditions of registration for providers (item 2.5) that ‘an ART provider must provide its patients and the public with accessible and easily-understood information about the risks and benefits of adjuvant therapies and new treatment procedures that are offered ... including accurate information about the evidence base which demonstrates those risks and benefits’.

VARTA is also moving to produce independent information on adjuvants on its website.

The Review notes the resource available on the HFEA website which presents clear and concise information about the possible benefits or otherwise of commonly used adjuvants.

3.10.4. How information is delivered

While there is widespread support for ensuring that patients have access to clear and accurate information about costs, efficacy of treatments and risks, there were divergent views about how this is best achieved and who should be responsible for delivering the information.

A number of people who have been recipients of ART raised issues with the amount, quality and consistency of information generally, as well as the manner in which it is delivered.

The amount of people I talk to in a month is mind-boggling and I often find out that I was told inconsistent information.

Survey response – recipient of assisted reproductive treatment

I could go on and on about the lack of information and how aggressively and rudely I have been treated when I have tried to stand up for myself and get information.

Survey response – recipient of assisted reproductive treatment

Providers pointed to websites and patient information materials as evidence of the wide-ranging information available to people in a range of formats.

Such materials were commended by some service recipients as being a useful reinforcement of information provided in face-to-face settings.

Face to face initial consultations from specialists, nurses, counsellors and finance are all very useful, however I found them to be extremely overwhelming. Just getting your head around the fact that you require ART can be difficult enough without being lumped with all the information in one go and trying to process it.

Submission – recipient of assisted reproductive treatment

Others, however, stated that they found the materials overwhelming and too general to enable them to understand their own circumstances.

It was clear from feedback received that some of the information available to people is provided by counsellors through the mandatory pre-treatment sessions, some is provided by their treating health

practitioners, and some is sourced by patients through their own research, including from a range of sources on the internet.

AHPRA have pointed out that the National Boards' codes of conduct for registered health practitioners emphasise the importance of informed consent and patients understanding, as fully as possible, the likely risks and outcomes of treatment. The Review has heard concerns that, in some instances, it appears that medical practitioners may have abrogated their professional responsibility for providing patient information on the assumption that counsellors will provide information and obtain necessary consents (Chapter 3.11.2 discusses issues related to counselling in some detail).

The overwhelming message from people with experience of the ART system was that, when it comes to information, 'one size does not fit all'. Information must be provided in a range of ways, and many called for more information up front, so they can better understand the journey they are about to embark on, as well as being repeated throughout treatment.

I realise that it can be overwhelming to bombard patients with too much information at once, but the drip feeding approach means that the patient feels like information is an afterthought or only in response to their questions.

Survey response – recipient of assisted reproductive treatment

The types of fertility treatment and pathways should be explained to you up front rather than learning things month to month.

Survey response – recipient of assisted reproductive treatment

3.10.4.1. Role of VARTA in providing information

A number of stakeholders praised the work of VARTA in providing public information about ART and regulation in Victoria.

There was some support for the availability of an independent organisation and a single 'point of truth' about treatments, adjuvants, success rates, reasonable costs and regulation. The HFEA website was seen as a positive model for achieving this.

The regulator should provide guidance on how to navigate the ART market and what good, professional conduct by ART businesses looks like. It should be simple and user tested by health consumers. A community reference group will give the regulator great advice on how to help consumers make the best choices.

Survey response – recipient of assisted reproductive treatment

Some recipients of treatment, however, felt that the availability of this information should be better publicised, including within clinics.

The clinic never provided any information about independent bodies such as VARTA and access.org.au, which may have provided initial guidance to consumers. I only found out about these organisations many cycles (and too late) into the process through my own research.

Survey response – recipient of assisted reproductive treatment

The Review believes that the public information role of VARTA is critical and should continue to be supported, expanded and promoted.

3.11. Providing patient-centred care and support before, during and after treatment

The need for support was a consistent theme in submissions and survey responses from current and past recipients of ART. Many described experiences of inadequate support.

When asked, 'Do providers do enough to look after people who are participating in assisted reproductive treatment (this might include people who are seeking treatment, donors or surrogates)?', 63 per cent of the 174 people who responded said, 'no' (110 people).

Many of those respondents highlighted how different the experience of ART is to other forms of healthcare. They talked of the huge emotional toll. This derives both from the experience of infertility and the treatment itself.

The psychological and social impact of infertility is complex ... with a large proportion of infertile women experiencing high levels of anxiety, guilt and social isolation.

Submission – Victorian Women Lawyers

While many people recounted positive interactions with staff, others felt that clinics focused on the job of getting them pregnant, discounting the impact on their psychological wellbeing.

There is a lack of focus on the enormity of the impact of a failed cycle on individuals and couples.

Submission – recipient of assisted reproductive treatment

The loss I felt each time I received yet another negative blood test result was profound ... Each time I got the news I became more and more broken, and yet unless I sought assistance myself, nothing was done to help me cope.

Submission – recipient of assisted reproductive treatment

Others talked of the limited availability of support services when they were needed.

3.11.1. Towards supportive patient-centred care

Counselling services were recognised as one of the main sources of support for those going through ART and, as a result, this area of clinic practice received a great deal of comment from stakeholders.

However, the Review was also alerted to the growing body of literature on patient-centred infertility care. This literature stresses that patient support and responsiveness to patient needs cannot be the sole domain of designated counsellors (for example Mourad 2018; Hotler et al. 2014; Dancet et al. 2011). Models based on this research were presented to the annual Fertility Society of Australia conference in September 2018, and broadly welcomed by the range of professions attending the conference. Studies have found that:

although patients valued the presence of psychologists in fertility clinics, they primarily expected emotional support from doctors and nurses.

Dancet et al. 2011

This is the most emotional, personal journey in someone's life – more time should be taken by specialists with their patients I found everything is just so rushed.

Survey response – recipient of assisted reproductive treatment

A range of dimensions of patient-centred infertility care have been identified across both system factors (such as information, competence of clinic and staff, coordination and integration, accessibility, physical comfort) and human factors (attitude and relationship with staff, communication, patient involvement and emotional support). Much of the feedback received from recipients of treatment indicated that the services they received fell well short of their expectations.

I had just been a five-digit patient number (it was literally how I introduced myself when I phoned reception), and the nurses had been a bewildering rotation of people.

Submission – Deb Martindale – recipient of assisted reproductive treatment

The doctors are busy and can provide support to a certain degree but the service itself can be very impersonal for such a personal service.

Survey response – recipient of assisted reproductive treatment

During treatment - if you've been unsuccessful all they want to do is sign you up for another round. Part of that is because they are working on limited timelines for treatment to recommence. But it feels more like a way to override grief and disappointment and not have to acknowledge it.

After treatment – from my personal experience, if you're successful you are just left hanging in the wind and shut out of the high level care and support you have received and have to wait 12–15 weeks to be seen by an obstetrician. You are also given a form that you have to complete and return when your child is born. It feels very impersonal and just administrative.

Survey response – recipient of assisted reproductive treatment

The Review heard from clinicians who spoke about offering patient-centred care and their endeavours to provide effective psychosocial care. However, it was clear from the feedback that this is not a consistent experience across the sector, and that a stronger culture of patient-centred care is required.

The delivery of quality patient-centred care is dependent on a culture that supports this approach. The Review considers that improvements in patient-centred care may best be achieved through the options canvassed in Chapter 3.2 of this Report that aim to support more effective co-regulation and an increased focus on clinical governance. Consideration will also be given in the next stage of the Review to identifying any current regulatory requirements that may hinder the capacity of clinics to provide more holistic support.

It is not possible to mandate compassionate care and professional bodies (the FSA and medical colleges) are committed to undertaking educational and supportive initiatives in this domain of provision of good medical care.

Submission – Fertility Society of Australia

3.11.2. Counselling

The Act contains a number of provisions which set out mandatory counselling requirements for ART procedures, the donation of gametes or embryos, surrogacy arrangements and the posthumous use of gametes or embryos.¹³

Specifically, before a woman consents to undergo a treatment procedure, the woman and her partner, if any, must have received counselling (s. 13). Counselling is similarly required before a person gives consent to become a donor (s. 18). Counselling is also required before a treatment procedure is carried out involving the posthumous use of gametes or an embryo (s. 48).

While the qualification of counsellors is not prescribed, counselling is restricted to a counsellor who provides services on behalf of an ART provider.

Counselling must address the prescribed matters set out in the Assisted Reproductive Treatment Regulations:

- The range of matters prescribed for those contemplating ART includes the options or choices available for treatment; the possible outcomes of treatment procedures; and issues relating to the use of donated gametes or embryos in the treatment procedure (r. 6).
- For donors, counselling must focus on the requirements of the Act in relation to disclosing the identity of the donor to VARTA and to the person born if they seeks that information; the ability of the donor to obtain identifying information about a person born as a result of a donor treatment procedure; and the possible impact of donation on the donor's partner or children (r. 8).
- In cases involving the posthumous use of gametes or an embryo, the matters prescribed relate to the grieving process and the possible impact on the child to be born as a result of the treatment procedure (r. 11).

The *Infertility Treatment Act 1995* (Vic) that preceded the current legislation also included requirements for mandatory counselling. In contrast with the current Act, it also included requirements for approval of counsellors. Under the *Infertility Treatment Act* (ss. 103 and 104), a counsellor could be approved for the purposes of the Act by applying to the Infertility Treatment Authority for approval, and was then able provide counselling for the kinds of treatment procedures, research or other circumstances specified in the approval. There was no requirement that they be attached to an ART practice.

Outside of Victoria, only New South Wales and Western Australia legislation sets out counselling requirements in respect of ARTs. Counselling is not mandatory in these jurisdictions. In New South Wales, a provider must ensure that counselling services are available to any woman who seeks treatment from the provider, any spouse of such a woman and any person proposing to provide a gamete to the ART provider before the treatment is provided (*Assisted Reproductive Technology Act 2017* (NSW), s. 12). Counselling requirements are set out in similar terms in the Western Australia legislation (*Human Reproductive Technology Act 1991* (WA), s. 22(7)). Other jurisdictions are guided by the NHMRC Ethical Guidelines to regulate the provision of ART, including in respect of the counselling that is offered.

¹³ Counselling requirements also attach to the disclosure of information recorded the Central Register under the Act, but fall outside the scope of this Review and are not considered in this Report.

Table 7: Counselling requirements for ART procedures – Australian jurisdictions

Jurisdiction	Counselling requirements
Victoria	Before a woman consents to undergo a treatment procedure, the woman and her partner, if any, must have received counselling (including counselling in relation to the prescribed matters) from a counsellor who provides services on behalf of a registered ART provider (ART Act, s. 13). ¹⁴
New South Wales	An ART provider must ensure that counselling services are available to any woman who seeks ART treatment from the ART provider and any spouse of such a woman. The counselling service must: (a) be available at the place where the ART treatment is provided, (b) be provided by a person with such qualifications as may be prescribed by the regulations, and (c) be offered before the ART treatment is provided or, in the case of a person proposing to provide a gamete, before the gamete is provided. Nothing in this section requires a person to make use of the counselling service (<i>Assisted Reproductive Technology Act 2007</i> (NSW), s. 12).
Western Australia	Before a licensee gives effect to a consent given for the purposes of this Act the licensee shall ensure that each participant has been provided with a suitable opportunity to receive — (a) proper counselling about the implications of the proposed procedures; and (b) such other relevant and suitable information as is proper or as may be specifically required by the Code or Directions (<i>Human Reproductive Technology Act 1991</i> , s. 22(7)).
Other jurisdictions	Not addressed in any specific state-based regulation. Practice is guided by the NHMRC Ethical Guidelines (see below).

Relevantly, the NHMRC Ethical Guidelines state that clinics must provide accessible counselling services from professionals with appropriate training, skills, experience and competency to support individuals and couples in making decisions about their treatment, before, during and after the procedures. Clinics should actively encourage participation and keep a record of participation. Clinics should be satisfied that each individual makes their own independent decision to participate in counselling and that this decision is reached without undue pressure. In some circumstances, however, participation in counselling is mandatory, including for donor conception and surrogacy arrangements.

The RTAC Code of Practice also sets out requirements for counselling, noting in particular that an ART unit must ensure that appropriate counselling is provided in respect of donor and surrogacy arrangements. The Code indicates that counselling is mandatory for all donors, partners, recipients and surrogates and their partners, and for known donation, an additional joint session involving all parties must be undertaken prior to the signing of consents.

¹⁴ ART Regulations, r. 6: 'For the purposes of section 13 of the Act, the following matters are prescribed—
 (a) the options or choices available to the particular woman and her partner, if any;
 (b) the possible outcomes of a treatment procedure;
 (c) any issue or concern raised by the woman or her partner, if any, in relation to the treatment procedure;
 (d) advising children about their donor origins and rights to information;
 (e) the Central Register and the information required to be kept in the Central Register;
 (f) issues relating to the use of donated gametes or embryos in the treatment procedure;
 (g) issues relating to genetic siblings who share a common genetic parent but are raised in different families.'

3.11.2.1. The mandatory nature of counselling

As outlined above, the counselling requirements currently set out in the Act are mandatory in nature. However, a range of industry players indicated that mandatory counselling was unnecessary or undesirable.

Whilst the FSA ... upholds the important role counsellors have in the team which provides ART, consideration should be given to removing the requirement for mandatory counselling for all people accessing ART. This will align with other states in Australia, ensure better utilisation of the vital resource of skilled counsellors and reduce barriers to access to care. Access to counselling should be in accordance with NHMRC guidelines. In addition, there is no evidence that this mandatory counselling for all has produced different outcomes to all other states in Australia where this is not enforced on those seeking fertility treatment.

Submission – Fertility Society of Australia

Consideration should be given to removing the requirement for mandatory counselling for all parties undergoing ART and should be optional for patients undergoing treatment which do not involve a donor component and/or surrogacy arrangement. In no other state is counselling mandated, yet no significant issues arise from those states and we believe that patients who elect to participate in counselling will gain more from the experience than those merely attending because they are obliged to. Monash IVF believe that the optional counselling can be incredibly valuable for certain patients but would prefer to divert resources from mandatory counselling for reluctant participants to providing more accessible support throughout the patient journey, including grief, pregnancy loss and deciding to cease treatment.

Submission – Monash IVF

Pre IVF/UI Mandatory counselling has moved away from its original intent to support people to explore the implications of ART. With an ever growing number of couples and individuals seeking treatment, lengthy waiting times are common, adding further burden and stress to patients wanting to start treatment, and therefore not necessarily in their best interests. Clients are often well informed on many aspects of treatment and view the counselling process as a tick the box exercise. ... Given that other states of Australia do not currently require mandatory counselling prior to commencing ART it is difficult in the current climate to justify why clients only in Victoria require this level of intervention. There is currently no evidence or research into the efficacy of mandatory counselling and as such, it is difficult to justify its ongoing inclusion in the ART Act.

Submission – Primary IVF

Some people observed that while mandatory counselling was valuable, more could be done to ensure that patients transferring between clinics could have recognition for counselling they have already undertaken.

The main criticism from recipients of ART about the mandatory nature of counselling was that it made the experience feel more like a 'tick box' activity than support for effective decision making and psychological wellbeing.

3.11.2.2. Availability and timing of counselling

The Review heard from a range of stakeholders, including counsellors and patients, that counselling should be available and provided before, during and after treatment to better support patients, and should be accessible whenever the patient feels they need it.

In my experience counsellors were overbooked or only available in very limited times.

Survey response – recipient of assisted reproductive treatment

The Review heard that counselling is not always available when people feel they need it most.

Occasional weekend phone counselling should be available. I would often receive pregnancy test results in a Friday afternoon, and then have to spend the weekend trying to cope and process the news before I was able to access some support the following Monday. At one point I was so distraught that I called Lifeline because I didn't know where else to turn on a Saturday.

Submission – recipient of assisted reproductive treatment

The Review has also heard that those seeking to access counselling services in rural Victoria are particularly disadvantaged.

There are so many barriers in accessing counselling appointments for patients living in rural or regional areas. This is particularly hard to juggle with work commitments as well as very limited availability of counsellors travelling from Melbourne to these areas.

Survey response – recipient of assisted reproductive treatment

For many people the fertility journey is one of coming to terms with the fact that they may not have a baby, and while counselling prior to the commencement of treatment is mandated by the Act, there are no similar requirements for counselling to be provided during or following the conclusion of treatment. A range of stakeholders have observed that where treatment has been unsuccessful, individuals are likely to benefit from counselling which focuses on managing grief or discontinuing treatment. Clinics do refer some patients for mental healthcare following treatment and provide peer support groups for patients ending treatment. The feedback from patients is that end of treatment support remains inadequate.

Some stakeholders, however, cautioned against mandating counselling following unsuccessful treatment. For example, the FSA noted that clinics 'are already required to make counselling available for consumers, especially following an unsuccessful treatment cycle'. The submission also noted that it is difficult to assess how well compulsory additional support may be viewed by consumers who exit treatment, given that follow-up surveys suggests that further communication from IVF units is often not welcomed.

3.11.2.3. Format and quality of counselling

Many respondents to the consultation provided very positive feedback about the value and quality of the counselling they had received. However, the Review also heard a range of concerns from patients about the way counselling was delivered and the quality of that experience. It has been observed that the skills and experience of counsellors can vary significantly.

The Review also heard that counsellors are under pressure to meet clinic targets, and this can lead to lower quality service and cutting corners to meet demand.

In many instances, these concerns appear to stem from the approach taken by clinics to comply with mandatory counselling requirements.

There are a range of approaches to ensuring compliance with the current legislative counselling requirements. The Review has heard that some providers are offering group sessions in place of some individual counselling sessions. For example, Monash IVF indicated that 'alternatives to one-on-one counselling are already being used in certain Victorian clinics, which highlights that some people are only attending to meet the legislative requirement'. Melbourne IVF reports that a group model of psycho-education is well-received by patients and is intended to provide more flexible and ongoing support for patients throughout the course of treatment.

While this format may be appropriate for the purposes of providing general information to those considering ART, a number of stakeholders stressed that they are not a substitute for therapeutic counselling sessions. In particular, there are concerns that individual issues, affecting a particular couple, may not be adequately addressed in this group model. A number of counsellors observed that they see the group counselling model as undesirable.

Future consideration by the Review about how counselling and support should best be delivered will give consideration to whether greater clarity is needed as to how any mandatory counselling requirements can be satisfied, as well as any need to improve access to therapeutic counselling more generally.

A number of patients have observed that peer support groups are very valuable and should be more widely available so that people can share their experiences with others.

It should be mandatory for providers to offer/facilitate support groups for patients undergoing IVF treatment. Online forums do exist, but it seems only for some providers. What would be better would be small group forums, either online or in person, led by a nurse and genetic counsellor – so that patients can share their experiences, ask general questions, and receive support when things don't go to plan. Undergoing IVF/ART can be a lonely time and I have seen women in tears in waiting rooms at service providers, their partners sitting next to them entirely at a loss as to how to comfort them. Providers have a responsibility to ensure patients are adequately supported during this incredibly emotional time, and other patients going through IVF/ART, are the best people to do this, because you truly cannot understand what it is like until you go through it.

Survey response – recipient of assisted reproductive treatment

I believe support groups and networks should be promoted and counselling accessible. I don't believe more mandatory sessions are necessary but I think support networks / independent counselling could be promoted so there is support there if needed.

Survey response – recipient of assisted reproductive treatment

3.11.2.4. Role and independence of counsellors

There are concerns that counsellors attached to fertility clinics are not independent and this hinders the counselling process. The Review heard that counsellors can feel an ethical conflict between meeting the needs of the patient and any child to be born, and meeting the needs of the business.

Other patients reported that having clinic-based counselling impacted on the confidentiality of the relationship between the individual and the person providing therapeutic support.

... [T]he information was forwarded to the doctor who then wanted to cease treatment, so I stopped seeking counselling.

Survey response – recipient of assisted reproductive treatment

Some noted that the ‘mandatory’ counselling was really about information sharing or mandatory information giving. This could be provided separately by others, to allow counsellors to focus on the therapeutic aspects of counselling, in a more patient-focused manner.

There is no requirement in any other jurisdiction that a counsellor provide counselling services on behalf of a registered ART provider.

A range of stakeholders also observed that counsellors’ responsibility for police checks can give rise to tension in therapeutic relationships. A number of counsellors noted that the current requirement to review police checks puts them in a very difficult position, as patients may perceive the counselling role as that of gatekeeper rather than support person. This perception adversely impacts on the primary role of counsellors to support patients.

Consideration should be given to removing the requirement from the counsellors, who hold a therapeutic and supportive relationship with the patient and this can be compromised by also being the barrier to treatment. The clinic could instead be compelled to have policies and procedures to nominate the personnel responsible and the process to address any issues raised.

Submission – Monash IVF

If mandatory counselling pre ART is to continue and appropriately balance the interests of all participants, it would be advantageous to consider assessment criteria for treatment as a separate and independent function to counselling. ... It is our view that counsellors cannot continue to be placed in the dual role of providing support and engaging in assessment. If the current system of National Police check and Child Protection Order check continues then the legislation should be amended to enable a designated officer to sight and assess all police checks and child protection checks and to determine whether a presumptions against treatment applies.

Submission – Primary IVF

Regulatory requirements around counselling and the best way to ensure that patients across all clinics receive the support they require will be a key focus of more targeted consultation as the Review progresses. While the requirements for police checks is out of scope for this Review (see Chapter 4 of this Report), there may be scope to revisit the role of the counsellor in this process. Other issues identified may well be addressed through some of the proposals to support more effective co-regulation, such as the possibility of a regulated code of practice, discussed in Chapter 3.2.3 of this Report.

3.12. Storage of gametes and embryos

A range of matters related to the storage of gametes and embryos were raised during consultation. Although not an area about which a significant number of respondents made comments, the issues raised are important and certainly warrant consideration in the context of this Review. These included concerns that the time limits on the storage of gametes and embryos, and the processes for extending storage periods, are unnecessarily restrictive. Stakeholders also raised concerns that current regulation in relation to research involving stored gametes may unreasonably restrict the capacity for important research.

3.12.1. Time limits on the storage of gametes and embryos

Section 31 of the Act limits the storage of gametes to a period of 10 years. However, in circumstances where the gametes have been obtained from a child or adult who is at a reasonable risk of becoming infertile, a limit of 20 years applies.

Section 31A provides that the PRP can approve an extension to these limits, subject to the consent of the person who produced the gametes. If written approval cannot be obtained from the person who produced the gametes, the Panel may approve the longer storage period if it considers there are exceptional circumstances for doing so in the particular case. Approvals for extensions may be subject to conditions. The issues surrounding donor consent for ongoing storage is discussed in Chapter 3.7.2.2.

The criteria for the storage of embryos are set out in similar terms in ss. 33 and 33A of the Act. However, storage periods are limited to five years, unless the persons who produced the gametes from which the embryo has been formed consent to storage for an additional period of not more than five years, or the PRP approves a longer storage period.

The PRP's Guidance (Note No. 3, 'Extension of gamete and embryo storage') indicates that the Panel will usually consider there may be reasonable grounds to grant an extension in the following circumstances:

- where patients who store gametes or embryos are undergoing treatment for a chronic illness which may affect their fertility
- the gamete provider is a donor and the gametes are still required for use by recipient families
- the patients are not ready to use them in their own treatment due to their personal circumstances
- the patients have not completed or are undecided about completing their ART or family
- the patients are considering donation to another or to research.

Upon application to the Panel, extensions for gamete storage are typically provided for a further 10 years. Extensions for embryo storage are usually granted for a period of five years. The Panel's Guidance indicates that there is a preference to grant a shorter period for embryos, in comparison to gametes, to ensure that embryos do not remain in storage without the consent of both the gamete providers, and that decisions about the use and ongoing storage of embryos are regularly reviewed by both persons who are equally responsible for decision making about embryos.

In the course of consultations, this Review heard that the current five-year limit on embryo storage is too short, and should be increased to 10 years, in line with gamete storage periods in the Act.

I find it absolutely appalling that after 5 years I will have to apply to have the storage of our embryos extended. They are the tissue and property of my husband & I, why should a stranger have that power to destroy them? I can understand there needs to be a time limit, maybe 15 or 20 years, but 5 years is incredibly short & arbitrary period for people to start and finish making a family.

Survey response – recipient of assisted reproductive treatment

Further, there was a view that clinics should be able to approve storage extensions where conditions described in the legislation are met, rather than referring these to the PRP, unless a dispute arises between the parties consenting (Submission – Monash IVF).

The storage limits in Victoria are the most conservative in Australia. Storage limits are regulated by specific legislation in two other states. Western Australia takes a similar approach to Victoria in respect of the storage of gametes and embryos and sets a maximum storage period of 15 years for gametes and 10 years for embryos unless the Western Australian Reproductive Technology Council otherwise approves (*Human Reproductive Technology Act 1991 (WA)*, s. 24).

The New South Wales Act authorises significantly longer storage periods and makes a distinction between donated materials and those being stored by the gamete provider for personal use. Donated gametes or embryos created from donated gametes can be stored for a period of 15 years, plus any additional period that may be authorised by the Secretary of the New South Wales Ministry of Health. Otherwise gametes or embryos are stored in accordance with the consent of the gamete provider or the time limit specified by the ART clinic (*Assisted Reproductive Technology Act 2007 (NSW)*, s. 25).

Other jurisdictions rely on the NHMRC Ethical Guidelines to regulate the provision of ART, which does not specify a time limit for the storage of gametes and embryos.

Table 8: Gamete and embryo storage – Australian jurisdictions

Jurisdiction	Gamete and embryo storage requirements
Victoria	Limits the storage of gametes to a period of 10 years. In circumstances where the gametes have been obtained from a child or adult who is at a reasonable risk of becoming infertile, a limit of 20 years applies. PRP approval needed for extension (ART Act, s. 31). Limits the storage of embryos to a period of five years. PRP approval is needed for extension (s.33).
New South Wales	An ART provider must not store a gamete or an embryo except with the consent of the gamete provider and in a manner that is consistent with the gamete provider’s consent. Storage of donated gametes and embryos is limited to 15 years (<i>Assisted Reproductive Technology Act 2007 (NSW)</i> , s. 25).
Western Australia	Gametes are not to be stored without the approval of the Council for longer than 15 years (Direction 6.8 of the <i>Human Reproductive Technology Act 1991 Directions</i>). No human egg undergoing fertilisation or human embryo shall be stored for a period in excess of 10 years except with the approval of the Council (<i>Human Reproductive Technology Act 1991 (WA)</i> , s. 24).
Other jurisdictions	Not addressed in any specific state-based regulation. Practice is guided by the NHMRC Ethical Guidelines (see below).

The NHMRC Ethical Guidelines provide that clinics must obtain specific consent from each relevant party before gametes or embryos are stored. Consent must include consideration of the duration of storage; and the use, storage or discarding of gametes or embryos.

The RTAC Code of Practice does not specify conditions around the storage of gametes.

The Review notes that in revising the NHMRC Ethical Guidelines, consultation undertaken by the NMHRC found that the limits in the 2007 Guidelines (10 years for embryos) were arbitrary and not evidence based (NHMRC 2017). As a result, the current NHMRC Ethical Guidelines do not include a maximum time period for the continued storage of gametes and embryos, but rather indicate that the suitability of continued storage depends on both personal and clinical considerations.

The Review notes that the current legislation is complex and potentially confusing, with storage limits ranging from five to 20 years or longer, subject to extensions available upon application to the PRP. While it is not desirable to leave gametes or embryos in storage indefinitely, a more flexible approach to the storage periods for gametes and embryos which could be tailored to individual circumstances of the affected parties may be more appropriate. At the same time, the Review recognises concerns around potential cross-generational use of donor gametes, and so will give careful consideration to a model such as that in place in NSW which differentiates donor materials from other stored gametes and embryos.

3.12.2. Counselling to support decision making on storage issues

For many people, making decisions about the fate of stored gametes and embryos can be particularly confronting.

I wanted to take all my embryos home with me somehow – even the ones that were not used. This was not an option – there were three options and none of them were right for me. I had planned to plant my unused embryos [in a] lovely pot with a beautiful rosebush, so their matter tiny as it maybe, could become life. This needs to be a choice for some couples – destroyed, research or donation as the only options are not the right ones for some people.

Survey response – recipient of assisted reproductive treatment

As discussed in more detail in Chapter 3.11.2, there is a need for individuals to be offered counselling at the conclusion of treatment. The Review heard that such counselling should also include information and support for decisions with respect to the fate of additional embryos or gametes in storage.

The Review will continue to consider how appropriate support can be provided to those facing such decisions.

3.12.3. Prohibition on undertaking research on stored gametes

A further issue raised with the Review concerns the operation of s. 26(3)(b) of the Act, which provides that a person must not use stored gametes for research purposes when they are obtained from a child who is at risk of becoming infertile.

The Review heard that the provision excludes all research on such gametes, including procedures which may be carried out for the benefit of the individual whose tissue is involved, or for others in comparable situations.

For example, it may seem rational to view the assessment of tissue under a microscope using an antibody (immunohistochemistry) as part of routine diagnostic practice and, therefore not a research activity whereas grafting of the tissue into a mouse (xenografting) would be more likely to be immediately classified as research. However, it is clear that the intent of both procedures is to determine the suitability of the tissues being assessed for potential clinical use i.e. for the future benefit of the child. The rapid adoption of research-based methodology into clinical practice, when seen as beneficial, makes delineation almost impossible in some circumstances.

Submission – Dr Debra Gook – professional in the field

The Review heard that, in effect, the law prohibiting research on this tissue means these patients will have no information on the potential of this tissue for future fertility or the possible malignant contamination in the tissue. The restrictions will also exclude the possibility that the application of any future developments may benefit these children.

While this issue will require further consideration, the Review considers it is likely to be appropriate to exempt research undertaken for the benefit of the child concerned from the broader prohibition.

Further, feedback from the NHMRC indicates that the Act lacks clarity on whether embryos that are excess to the reproductive needs of the people for whom the embryos were created and that have been donated for the purposes of research cease to fall within the remit of the Act.

The NHMRC expressed concern that if embryos continue to be regulated by the Act even though they have been declared excess, this may result in inadvertent legislative breaches by those licensed to undertake research or training activities using excess embryos. The Review will reflect on the issues identified and consider whether legislative amendment is required to clarify the treatment of embryos donated for research and training purposes.

4. Reflections on matters beyond the scope of this review

4.1. Overview

The terms of reference for this review, while broad, specifically exclude some matters from consideration. These matters are:

- *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.*

Although the consultation paper and other communications with stakeholders made it clear that the Review was not addressing these matters, there was considerable feedback received in relation to a number of key areas.

Given the weight of the feedback received, this chapter provides an overview of the key concerns raised and proposals presented.

4.1.1. Requirements for police and child protection checks

The requirement for people seeking ART to obtain police and child protection checks received more comment than almost any issue besides cost.

Many stakeholders supported the removal of police check requirements.

The requirement to conduct a police check before being able to undertake IVF in Victoria is an humiliating experience. It is as if our right to parent is being judged on the result of this check. What a joke. No other individuals or couples are required to submit themselves to this prior to conceiving a child.

Submission – recipient of assisted reproductive treatment

It is a requirement that discriminates; fertile members of the public against whom similar convictions are recorded are not required to have these checks before starting a family. ... Safeguards exist to protect children at risk whether they are born following a natural conception or an ART conception.

Submission – Fertility Society of Australia

The criminal check takes approximately 5 weeks to receive Child Protection Order Check (CPOC) takes approximately 2 weeks to receive. Both are a barrier to immediate treatment. Often patients cannot enter into treatment when they desire to do so due to the time taken to receive their criminal check and CPOC by the clinic. We estimate that those patients that have a presumption against treatment driven from the outcome of their criminal check or CPOC would be less than 1 % of our total patient population.

Submission – Melbourne IVF

Stakeholders commented that Victoria was the only jurisdiction in the world to have such checks. Clinics commented that the administrative process related to the checks adds to the costs for patients.

Counsellors commented that their role in reviewing the police checks is an impediment to providing a supportive therapeutic relationship to patients. A wide range of service users complained of the indignity and inconvenience of submitting a police check while undertaking an emotionally burdensome process such as ART. Legal groups and clinics questioned the effectiveness of this screening device in preventing child abuse.

For the patients with a presumption against treatment who have then been referred to the patient review panel (the 'PRP'), to our knowledge we have not had the PRP decline the patient undergoing treatment in the last 5 years.

Submission – Melbourne IVF

Submissions also acknowledged that within the current legislative framework, there may be options to make the police check more effective and less burdensome to patients. Stakeholders have questioned the need for clinics to receive information about all offences on a person's Police Check rather than being limited to those that give rise to the presumption against treatment. Others have suggested ways in which the process could be streamlined or improved, for example:

- clarifying the type of Police Check required for non-Victorian residents
- allowing for a Working with Children check to be considered in place of a police check
- considering whether the scope of the offences that gives rise to the presumption against treatment is appropriately targeted at risk
- clarifying the approach that should be taken where a prospective parent has been charged but not yet convicted of a serious offence.

Some stakeholders also support better targeting of the assessment of presumption against treatment to those crimes or behaviours that pose a serious and high risk to the child to be born.

We would recommend having more relevant crimes as presumptions such as breaching of intervention orders, family violence etc. We would also suggest making the process quicker/easier for those whose presumptions are not recent.

Submission – counsellors

The Review is persuaded that the assessments should consider breaches of family violence intervention orders, and pay less attention to less relevant crimes.

While these issues are outside the scope of the Review, the Review does note that the current procedures for assessing the presumption against treatment may need to be reviewed to ensure the system is appropriately focused on the most serious risks to the unborn child, and so that the system causes less frustration, cost and delay for patients.

4.1.2. The role and operations of the Patient Review Panel

Related to the issues raised above, the operation of the Patient Review Panel received significant feedback.

The Patient Review Panel is established under s. 82 of the Act and is independent of the Department of Health and Human Services and providers. The Panel makes determinations on whether patients for whom a presumption against treatment applies can proceed to treatment as well as a number of other matters such as applications for storage extension, surrogacy arrangements, posthumous use of gametes and the use of preimplantation genetic diagnosis for the purpose of sex selection.

In making its determinations, the Act requires the Panel give effect to the 'Guiding principles' (s. 5), including that 'the welfare and interests of persons born or to be born as a result of treatment procedures are paramount'.

In a 2018 decision, the Victorian Civil and Administrative Tribunal (*OMU & RGJ v Patient Review Panel and the Secretary to the Department of Health and Human Services*) stated that this guiding principle means that:

no matter how much a person wants to have a child or how much of a positive difference it would make to their lives, we must put the welfare and interests of the potential child to be born first.

To that end, the Act requires each division of the Panel hearing an application to include a child protection expert.

In addition to the widespread concerns about the requirements for police and child protection checks under the Act (as discussed above), some stakeholders also argued that the Act should be amended to remove requirements for the Panel to be involved in approving other applications such as for preimplantation genetic diagnosis for sex selection, storage extension or posthumous use of gametes.

Surrogacy Australia submitted that the requirement to have surrogacy arrangements approved by the Panel is deterring people from pursuing surrogacy in Victoria.

A number of stakeholders, however, provided feedback suggesting that while the Panel's function under the Act remain, there could be improvements to the processes of the Panel and the experience of Panel hearings.

There is a perception among some respondents to the consultation, including both those who have had matters determined by the Panel and providers, that Panel processes are slow. This can be frustrating and distressing for people.

The panel put us off the first time as they wanted to find out more information about my prognosis ... this felt totally out of line. Our fertility specialist, lawyer and oncologist professionally expressed why this wasn't ok. This put our progress back over a month.

Survey response – recipient of assisted reproductive treatment

The panel is busy, and has huge delays. I am turning 40 next month. My chances are getting lower every day as I age.

Survey response – recipient of assisted reproductive treatment

Some stakeholders suggested that delays may result from difficulties experienced by the Panel in accessing information it requires to make determinations, while others acknowledge the increasing workload of the Panel.

The Review understands that matters determined by the Panel are increasingly complex. The Review notes that while the number of applications fluctuate year by year, the Panel workload in the last year for which information is publicly available was significantly higher than five years earlier (175 applications were received in 2012 compared with 349 in 2016), and there has been a large increase in some of the more complex types of application such as surrogacy applications and those related to the use of preimplantation testing for sex selection.

In this context, it was suggested by one clinic that the requirement for the Panel to approve all extension of storage applications could be removed and clinics granted power to approve applications where the conditions described in the Act are clearly met. The clinic proposed that Patient Review Panel could be responsible for hearing only more complex storage applications where a dispute arises.

Other amendments to address workload issues for the Panel, and therefore delays in hearing times, proposed during the course of the consultation, included that the Act:

- provide a clear statutory capacity for the Panel to consider matters on the papers rather than through formal hearings
- provide that the Panel need only give written reasons for decisions if:
 - an application is not approved, or
 - the applicant requests written reasons, or
 - the Panel considers it appropriate in the circumstances that written reasons be prepared
- clarify the power of the Patient Review Panel to obtain information necessary for its decision-making role (for example access to child protection information, court reports or police records).

Some stakeholders have reported that needing to attend the Patient Review Panel can be stressful for people, even if the experience of the hearing turns out to be fine. They argued that more user-friendly information about what to expect would be valuable.

Our PRP hearing was not horrible at all and the questions and comments were quite fair. But the anxiety we all faced especially my intended parents was agonising. No one really knew what was going to happen and collecting so much paper work and answers was a nightmare. The lead up to PRP hearing in Victoria is the worst time recorded for a lot of couples and I find lots of surrogates are avoiding choosing Victorian intended parents for that reason.

Survey response – surrogate

[There should be] more information about what to expect from the PRP process in Surrogacy. I didn't mind the PRP experience but the anxiety of not knowing what exactly we were walking into and how much pressure was put on was hard to cope with.

Survey response – surrogate

Others, including individuals who have had matters heard by the Panel, report that the experience itself can be confronting and difficult. One clinic relayed feedback from patients that 'the meetings are intimidating, daunting, unpredictable and that they feel the system is punitive'.

A number of individuals told the Review they found the conduct of Panel hearings to be overly formal and legalistic. Some said they were asked questions they found intrusive, insensitive or rude. This was particularly the perception of some from the LGBTQI+ community.

Surrogacy Australia states that it has received feedback that people feel judged by the Panel on their ability to parent, and that the process is 'demoralising and dehumanising'. Donors and surrogates report feeling that their altruism and motivations are questioned by the Panel member. Others felt they were asked questions that were sexist or homophobic.

They do nothing to assist or inform patients. Many members of the panel are rude and judgemental, particularly in regards to LGBTI families.

Survey response – surrogate

Some stakeholders, including clinics, recipients of treatment and their representatives, have made claims that the Patient Review Panel is not consistent in the information it seeks from clinics or from parties to surrogacy arrangements.

They change the 'rules' for different people, allowing some flexibility while being difficult and unyielding with others about the same issues.

Survey response – recipient of assisted reproductive treatment

Others stated that there is a lack of transparency surrounding Panel processes and decision making, or that the Panel may seek information or set requirements that go beyond what is required to make determinations under the Act. For example:

- A number of clinic representatives commented there is a lack of clarity as to what constitutes acceptable evidence to demonstrate a deceased partner's consent for the posthumous use of gametes. One clinic proposed that the *Patient review guidance note* on this matter requires review.
- People involved in surrogacy arrangements stated that the guidance note regarding the approval of surrogacy arrangements required review to accurately reflect the role of the Panel in these cases.
- A clinic reported that, in relation to surrogacy matters, the Panel is 'requesting multiple legal opinions and comparing the contents, rather than ensuring the patient has sought legal advice and understands the advice provided'.
- A surrogate understood that the PRP requires all parties, including donors, to attend hearings in person, even where parties reside interstate and travel has significant impact on health, employment and child care.

I think the Patient Review Panel should be more transparent, approachable, and less dogmatic in its approach and processes.

Survey response – surrogate

The Review is reporting these matters, given the high level of interest among those consulted, but has not investigated the claims made by stakeholders, nor do we know the context or facts associated with them. The Review also notes that this information has been collected in a way that means it is unlikely to be representative of the views of all people who have had experience with the Panel.

Nonetheless, the perceptions described are common among stakeholders who provided feedback to the Review. The Review observes that there may be scope for some amendments to address workload issues for the Panel, and some scope to consider how the processes of the Panel might be made more transparent and responsive for participants in those processes. However, as these matters are outside the scope of its terms of reference the Review makes no specific findings or recommendations in relation to the operation of the Patient Review Panel.

4.1.3. Implementation of the *Assisted Reproductive Treatment Amendment Act 2016*

Some stakeholders raised concerns about the implementation of the *Assisted Reproductive Treatment Amendment Act 2016*. These concerns were broadly related to:

- extending rights of donor-conceived people to contact their donor siblings
- the process by which donors applications for identifying information about their donor-conceived offspring are actioned.

A number of donor-conceived people have advocated for rights to access information about their donor siblings. Currently they are entitled to access identifying information about their donor, but not any genetically related half-siblings also born as a result of donation by the same person.

Donors are able to apply for identifying information about their donor-conceived offspring and to receive that information with that person's consent.

Donor-conceived people have, therefore, pointed out that to find out about their donor-conceived offspring they must do so through their donor. This means that if the donor passes away, or does not wish to contact offspring, donor-conceived people will not get the chance to find out about their genetic half-siblings.

I often dream of meeting the rest of my family, but know this dream may never be a reality. This has devastated me in many ways and has continued to impact my mental health greatly.

Submission – Chloe Allworthy – donor-conceived person

It has been suggested that many donor-conceived people are more interested in outreach to siblings than their donor. Some wish to make contact, others just wish to know who their siblings are so they can avoid inadvertently entering into a relationship with a genetic relative.

Siblings have a deep shared experience.

Submission – donor-conceived person

I worry that we will only stop and consider the implications of unknown, secret siblings when a case of incest becomes public knowledge by which point the damage and trauma to those involved could be devastating.

Submission – donor-conceived person

Without this capacity, many people are connecting with donor siblings via DNA testing and sites such as ancestry.com and 23andme.com. This has resulted in people discovering siblings online. Where that sibling is unaware that they are donor-conceived, it is up to their sibling to break the news.

It is argued that if the Act were amended to allow for donor-conceived people to access information about their donor siblings, these connections could be made through VARTA where counselling and support could be available to all parties.

During the course of the Review, there were a number of media reports about VARTA initiating contact with donor-conceived adults to inform them of their birth origins as a result of a request for outreach from their donors. In some cases, these adults had not been informed by their parents that they were donor-conceived. There have been reports that this contact caused considerable distress to some families as a result of the unexpected disclosure of the person's birth origins.

The Review has not examined this issue since it is outside its terms of reference. However, the Review's consultations more broadly did highlight the need to monitor and undertake research on the emerging family and social relationships that are developing in response to ART and its regulation, especially the changes over recent years to the regime for accessing information on birth origins.

4.1.4. Prohibition on sex selection

A small number of stakeholders urged the Review to consider the removal of the prohibition on sex selection in light of recent evidence that people are travelling overseas for treatment for sex selection, or terminating pregnancies on discovery that the fetus is of a non-preferred gender, either for purposes of family balancing or cultural reasons. Again, this matter is outside the scope of the terms of reference, so no recommendation is made.

5. Next stage of the Review

As noted throughout this Interim Report, many of the matters raised with the Review require additional information or further consideration before a policy response can be proposed. The Report considers a range of potential directions that have not yet been fully investigated or canvassed with key stakeholders to enable refinement of proposals, confirmation of likely impact and assurance that no undesirable outcomes will result. Some of the major proposals to be examined in more depth in the coming months through the second stage of the Review are set out below.

Working towards a more transparent oversight of quality and safety in ART

The Review has heard that there is scope to strengthen the oversight of quality and safety of ART services and improve clinical governance. Further to the preliminary observations set out in Chapter 3.2 of the Report on patient safety and effective regulation, the Review will investigate ways to ensure adequate monitoring of services without unnecessarily increasing regulatory burden. To this end, the Review will consider reforms introduced following the *Targeting Zero* review of hospital quality and safety oversight in Victoria, which included expanded and better aligned reporting and clinical governance requirements for public and private health services. The Review will also consider what, if any, role Safer Care Victoria, the state's healthcare quality and safety improvement agency, might play in supporting any proposed changes.

The need for more effective co-regulatory arrangements

ART in Victoria is, and will remain, subject to a co-regulatory regime. The Review will continue to consider the most appropriate regulatory model to support this, taking account of both specific ART regulation and broader health service regulation. This will include consideration of the most appropriate regulatory approach and the entities that should deliver it.

In addition, the idea of a regulated code of practice was also considered in Chapter 3.2 of the Report, with a view to strengthen the regulatory oversight of quality and safety of ART in Victoria. One option would be to adopt the RTAC Code of Practice, and potentially also address a range of regulatory gaps and issues identified including information provision, counselling, requirements for clinical governance, patient-centred care and inclusive practice. The Review observed that elevating the code of practice to a regulated requirement would ensure it had greater standing than the current voluntary code, and could allow more responsive oversight of critical quality and safety matters by a state-based regulator. Alternatively, the Review observes that an alternative approach might be for RTAC to initiate changes to its Code of Practice and procedures, to address the concerns raised in this Report.

Exploring opportunities for the public provision of ART services

Chapter 3.3 of the Report considered the affordability of ART and highlighted that the cost of treatment is currently a significant barrier to access in Victoria. Improving access to ART through direct provision by public health services received considerable support from stakeholders in the course of consultations. The Review understands that two Victorian institutions are considering proposals for the establishment of public health ART services, particularly targeting patients who may not be able to afford private health services. In general, it is likely that the establishment of such public ART services would improve access and affordability of in vitro fertilisation (IVF) services, and offer a model of high-quality care that integrates teaching and research that is common across the health system. The Review will continue to consult and obtain information about these proposals and provide further advice in the Review's final report on the likely impact of such proposals on access, equity, affordability, patient-centred care, the evolving market for ART and the regulatory framework for ART.

Establishing a Victorian sperm and egg bank

After cost, access to donor gametes and embryos was identified as one of the most significant barriers to treatment. Chapter 3.7 of the Report explored opportunities to improve access to donor gametes and embryos in Victoria. One of the proposals which will require further research and targeted consideration is the establishment of a public sperm and egg bank service that would recruit gamete donors, store gametes, and make them available fairly to all ART providers. It is envisaged that this approach would help reduce pressures on Victorians to travel overseas to source donor gametes, provide a supportive framework for altruistic donations, and support the Victorian regulatory framework that provides donor-conceived people a right to know their genetic heritage. The Review has received positive interest from assisted reproductive clinics for the idea, which may be supported financially on a cost-recovery basis. Establishment of such a bank raises a number of complex ethical, regulatory and business issues, and the Review will test proposals further with stakeholders.

Providing better support services to connect patients, donors and surrogates

A key issue highlighted in both Chapters 3.7 and 3.8 of the Report was that the current restrictions on the advertising for donations of eggs and embryos, as well as finding a surrogate, are a significant barrier to access. This often drives intended parents to seek donated gametes or surrogacy arrangements overseas, which may not be in the best interests of the parties involved or the child to be born. The Review will undertake further consultation to help develop a way forward that will better meet the needs of those who wish to connect with donors or altruistic surrogates in Victoria, within an appropriately regulated advertising environment. One option that will be explored further is the establishment of a statewide service to facilitate connections between donors, surrogates and recipients to assist in increasing supply of, and improving equity of access to, donated gametes and altruistic surrogacy. The Review considers that such a service might also provide a safer option for connection, and better information and education, and thereby reduce the risks of exploitation and misinformation associated with some of the unmoderated online forums currently being used.

Improving information available to people seeking treatments

Chapter 3.10 of the Report highlighted that clear and timely information about success rates of clinics in assisting people to form families is important to allow people to make choices about which clinic is right for them and to weigh up the costs, risks and likely outcomes. Stakeholders also highlighted the importance of providing information that reflects the likelihoods of success of a range of treatments for individuals based on their personal circumstances. Accurate information about success rates can also help manage people's expectations. The Review has heard of a number of initiatives that would improve the information available to patients on their individual prospects of having a child through ART. Feedback has also been received about the need to improve information about costs and the efficacy of treatments. Options for increasing the availability and transparency of clinic specific information will be considered further. The Review will further examine the best means that this information could be provided to patients within an overall model of patient-centred care.

Enhancing patient-centred care and counselling

As outlined in Chapter 3.11, stakeholders have raised concerns in respect of a range of issues concerning counselling. For example, the Review heard that recipients of ART often feel that the mandatory nature of counselling makes the experience feel more like a 'tick box' activity than support for effective decision making and psychological wellbeing. Further, there was a widely held view that counselling should be available and provided before, during and after treatment to better support patients, and should be accessible whenever patients need it. The Review also heard concerns about the way counselling was delivered to patients and the quality of that experience. It has been observed that the skills and experience of counsellors can vary significantly. In order to address these issues, the regulatory requirements around counselling and the best way to ensure that patients across all clinics

receive the support they require will be a key focus of more targeted consultation in the next stage of the Review. Consideration will also be given to identifying any current regulatory requirements that may hinder the capacity of clinics to provide more holistic, patient-centred support

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 ART.

ART

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

Assisted hatching

A laboratory technique where the outer layer of an early embryo is thinned or perforated to assist with 'hatching' and hopefully implantation in the uterus.

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).

Blastocyst

An embryo that is about five to six days old and comprises about 100 cells.

BMI

Body mass index – BMI is a formula that uses weight and height to determine whether an adult is within a healthy weight range, underweight, overweight or obese.

CAV

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

Cisgender

A person whose gender identity matches their assigned sex, as opposed to transgender, a person whose gender identity does not match their assigned sex.

Cleavage-stage embryo

A two- to three-day old embryo that has developed about eight cells.

Donor conception

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

Egg

A reproductive cell containing the female contribution of genetic material. Usually only one egg is released per monthly cycle.

Egg or oocyte pick-up

The process by which eggs (oocytes) are collected from the ovaries usually via a needle through the vagina, guided by ultrasound.

Embryo

A fertilised egg that has divided at least once and is up to eight weeks old or 10 weeks gestation.

Embryo transfer

The process during which one or more fresh or frozen embryos are transferred to the uterus or fallopian tube. Embryos may be at the cleavage stage or slightly later blastocysts.

Endometrial scratching

Sometimes known as endometrial injury, this procedure intentionally disrupts the lining of the uterus (endometrium) in the hope that this will assist the embryo to implant into the uterus. It is simple and low cost and can be done on an outpatient basis, but risks infection or uterine perforation, although rare.

Fertility preservation

The process by which gametes, embryos or ovarian or testicular tissue are collected and frozen for later use – this may be because of concern about impending loss of fertility due to increasing age or treatment for serious illness, especially cancer.

Fetus

The stage in prenatal development from nine weeks after fertilisation (11 weeks gestation) and continuing to birth and in which all the major bodily organs are already present.

Fresh cycle

An ART that uses, or intends to use, one or more embryos that have not been frozen.

FSA

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

Gamete

An egg (oocyte) 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 ART 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.

LGBTIQ+

Lesbian, gay, bisexual, trans and gender diverse, intersex, and queer. This acronym describes the lesbian, gay, bisexual, trans and gender diverse, intersex and queer communities, and is also sometimes written as GLBTI or LGBTIQA (including asexual) among other variations. The Review has chosen to include the + symbol at the end to represent any and all additional identities that may fall under this banner but are not captured by the acronym itself.

Live births

A birth event in which a live born baby is delivered. A twin or triplet live birth is counted as one birth event.

Liveborn babies

A fetus delivered with signs of life beyond 20 completed weeks of gestation after complete expulsion or extraction from its mother. Twins are counted as two liveborn babies from one live birth.

Medical infertility

Infertility due to reasons other than gender orientation; there may be one or more or no physical causes for infertility able to be medically diagnosed in a couple who have failed to conceive naturally or in a woman who has not conceived by IUI.

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 Council – 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 ART at a national level.

Oocyte

A reproductive cell containing the female contribution of genetic material. Usually only one egg is released per monthly cycle.

OHSS

Ovarian hyperstimulation syndrome, a complication of ovarian stimulation for ART. Often it is mild, but it can be serious and rarely fatal. Symptoms include abdominal pain, nausea, fluid retention including in the abdominal cavity, progressing to reduced urine production by the kidneys and fluid accumulation in the lungs with difficulty breathing.

Ovulation

The release of eggs from the ovaries.

Ovulation induction

The process of stimulating ovaries to produce eggs in larger numbers than usual as part of ART.

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.

PGS

Preimplantation genetic screening – PGS is where preimplantation genetic testing (PGT) is used in couples who do not have a specific genetic abnormality. It tests whether the embryo has a normal number of chromosomes.

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 ART through an audited Code of Practice and grants licences to practice ART within Australia.

Safer Care Victoria

Victoria's healthcare quality and safety improvement agency.

Sperm

A reproductive cell containing the male contribution of genetic material. Each sperm sample normally contains large numbers of sperm.

Sperm selection

Range of emerging techniques that aim to select the best sperm for use particularly in ICSI.

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.

Thaw cycle

An ART where one or more frozen embryos are thawed with the intention of embryo transfer.

Time-lapse imaging of embryos

An emerging non-invasive technique to assess embryo quality; thousands of photographs are taken of developing embryos to study their appearance and movement during development in the laboratory before selecting embryos for use.

VARTA

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

- registration of ART 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 donor conception 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 ART 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 for the Review

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.

The terms of reference are published on the Department of Health and Human Services website. <https://www2.health.vic.gov.au/hospitals-and-health-services/patient-care/perinatal-reproductive/assisted-reproduction/regulatory-review>.

Appendix 2 – Consultation meetings

Date	Consultation
Tuesday, 31 July 2018	Regulators (10 attendees)
Tuesday, 31 July 2018	Euan Wallace, Safer Care Victoria
Wednesday, 1 August 2018	ART Clinics (1 of 2) (10 participants)
Monday, 6 August 2018	Academics (teleconference – two participants)
Monday, 6 August 2018	Stephen Page, Harrington Family Lawyers
Tuesday, 7 August 2018	Patient Review Panel
Thursday, 9 August 2018	LGBTIQ+ advocacy (12 participants)
Friday, 10 August 2018	David Bevan, Safer Care Victoria
Monday, 13 August 2018	ART Clinics (2 of 2) (10 participants)
Wednesday, 15 August 2018	Victorian Infertility Counsellors (attendance at regular meeting)
Thursday, 16 August 2018	Births, Deaths and Marriages (two participants)
Friday, 17 August 2018	Mark Bowman, Royal Prince Alfred Hospital Fertility Unit and Genea (NSW)
Friday, 17 August 2018	Georgina Chambers, National Perinatal Epidemiology and Statistics Unit (NSW)
Friday, 17 August 2018	Department of Health and Human Services LGBTI Working Group (attendance at regular meeting)
Thursday, 23 August 2018	Peter Temple-Smith, Monash University
Friday, 24 August 2018	Monash IVF (five participants)
Friday, 24 August 2018	Inter-Clinic Meeting of Operational Staff (attendance at regular meeting)
Tuesday, 28 August 2018	Sarah Jefford, Surrogacy Australia
Tuesday, 28 August 2018	Beverly Vollenhoven, Monash IVF
Wednesday, 29 August 2018	Royal Women's Hospital Victoria (five participants)
Tuesday, 4 September 2018	Kate Bourne, VARTA
Wednesday, 5 September 2018	Donor-conceived (two participants)
Friday, 7 September 2018	Patient Review Panel
Tuesday, 11 September 2018	Fertility Society of Australia (two participants)
Wednesday, 12 September 2018	Industry professional
Friday, 14 September 2018	Professional Groups (including RANZCOG and AMA) (13 participants)
Friday, 17 August 2018	Phil Matson, Chair of RTAC
Monday, 17 September 2018	Department of Justice and Regulation LGBTI Working Group (attendance at regular meeting)

Wednesday, 19 September 2018	VARTA (5 participants)
Wednesday, 19 September 2018	Bridget Dwyer, previous PRP member
Wednesday, 19 September 2018	Melbourne IVF (two participants)
Thursday, 20 September 2018	Service users – donors, parents, donor-conceived people etc. (seven participants)
Thursday, 20 September 2018	David Bevan, Safer Care Victoria
Thursday, 20 September 2018	ART current patient
Friday, 21 September 2018	Legal issues and human rights group (nine participants)
Friday, 21 September 2018	Prof William Ledger, University of New South Wales
Tuesday, 25 September 2018	Medicare Benefit Scheme Review, Department of Health
Thursday, 4 October 2018	Sandra Dill, Access Australia

Appendix 3 – Survey responses

A total of 191 responses to the Engage Victoria survey were received.

Characteristics of survey respondents

Table A: Gender of survey respondents

Gender	No. of respondents	Percent
Female	153	80.1%
Male	27	14.1%
Other identity	3	1.6%
No response	8	4.2%

Table B: Age of survey respondents

Age range	No. of respondents	% of respondents
Under 25	0	0%
25-29	26	13.6%
30-34	38	19.9%
35-39	48	25.1%
40-44	33	17.3%
45-49	11	5.8%
50-54	10	5.2%
Over 55	16	8.4%
No response	9	4.7%

Table C: Aboriginal or Torres Strait Islander identity

Do you identify as Aboriginal or Torres Strait Islander?	No. of respondents	Percent
Yes	1	0.5%
No	178	93.2%
No response	12	6.3%

Table D: Languages other than English

Do you speak a language other than English at home?	No. of respondents	Percent
Yes	19	10.0%
No	157	82.2%
No response	15	7.8%

Table E: Place of residence

Do you live in:	No. of respondents	Percent
Metropolitan Melbourne	147	77.0%
Rural / Regional Victoria	31	16.2%
Other	10	5.2%
No response	3	1.6%

Table F: Categories of respondent

Would you describe yourself as:	No. of respondents	Percent
Recipient of ART treatment	110	57.6%
Professional working in the field	21	11.0%
Other professional with interest in the area	10	5.2%
Donor	5	2.6%
Surrogate	6	3.1%
Person born as a result of treatment	9	4.7%
Interested member of the public	7	3.7%
Other	21	11.0%
No response	2	1.1%

Survey questions and responses

Table G: Survey questions, rates of responses and responses to fixed response items

Survey question	Response
1. Reflecting on your own experience, what are the key issues relating to assisted reproductive treatment in Victoria?	180 open-ended responses received. 11 respondents did not answer this item.
2. What would you like to see addressed or changed about how assisted reproductive treatment is delivered in Victoria?	174 open-ended responses received. 17 respondents did not answer this item.
3. What works well about how assisted reproductive treatment in Victoria is delivered?	157 open-ended responses received. 34 respondents did not answer this item.
4. Do you believe access to assisted reproductive treatment is a problem in Victoria?	Yes: 147 (77.0%) No: 36 (18.8%) No response: 8 (4.2%)
5. If yes, in what way is access a problem?	151 open-ended responses received. 40 respondents did not answer this item.
6. Have you, or do you know of someone who has, faced barriers accessing assisted reproductive treatment?	Yes: 137 (71.7%) No: 46 (24.1%) No response: 8 (4.2%)
7. If yes, what were these barriers?	137 open-ended responses received. 54 respondents did not answer this item.
8. What do you believe could be done to overcome these barriers?	142 open-ended responses received. 49 respondents did not answer this item.
9. In your experience have you, or people you know of, received appropriate information to make informed choices about treatment?	Yes: 90 (47.1%) No: 93 (48.7%) No response: 8 (4.2%)
10. If no, what was lacking in the information received?	100 open-ended responses received. 91 respondents did not answer this item.
11. What additional information, if any, should be available?	97 open ended responses received. 94 respondents did not answer this item.
12. Do providers do enough to look after people who are participating in assisted reproductive treatment (this might include people who are seeking treatment, donors or surrogates)?	Yes: 64 (33.5%) No: 110 (57.6%) No response: 17 (8.9%)
13. How should people participating in assisted reproductive treatment be supported before, during and after?	153 open-ended responses received. 38 respondents did not answer this item.
14. What can be done to improve the oversight of safety and quality?	109 open-ended responses received. 82 respondents did not answer this item.

114 respondents also took the opportunity to share their personal stories of their experience of assisted reproductive treatment with the Review.

Appendix 4 – Submissions received

Identified submissions received:

AHPRA	Chloe Allworthy – donor-conceived person
Harrington Family Lawyers	Dr Fiona Kelly – La Trobe University
Dr Gareth Weston – professional in the field	Dr Michelle Taylor-Sands – University of Melbourne
Dr Debra Gook – professional in the field	Deb Martindale – recipient of assisted reproductive treatment
Monash IVF	NHMRC
Primary IVF	Surrogacy Australia
Rainbow Families Victoria	Melbourne IVF Counselling department
Melbourne IVF	Victorian Infertility Counsellor’s Group
VANISH	VARTA
Professors Millbank, Karpin and Stuhmcke – University of Technology Sydney	Dr Raphael Kuhn – professional in the field
RTAC	Feminist International Network of Resistance to Reproductive and Genetic Engineering (FINRRAGE)
Victorian Women Lawyers	Dr Nadine Richings – professional in the field
Susan Chamberlain – infertility nurse	

De-identified or anonymous submissions received:

Recipients of assisted reproductive treatment	8 submissions
Professionals in the field	3 submissions
Donor-conceived people	3 submissions
Other stakeholders	1 submission