Helping Victorians create families with assisted reproductive treatment


May 2019

Mr Michael Gorton AM
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Foreword


This review began in 2018 – 10 years after the passage of the Assisted Reproductive Treatment Act 2008. This legislation gave legal access to treatments in Victoria to single women and same-sex couples, and enabled altruistic surrogacy. The legacy of these law reforms is clear – thousands of Victorians have since been helped to create a family.

The Act also changed the role of the Victorian regulator, reducing its regulatory functions and powers, and relying more on the national industry self-regulatory body. This weakening of the Victorian regulatory framework for assisted reproductive treatment (ART) occurred just before major changes in commercial and clinical practices in the industry. In the 10 years since, a growing chorus of patient concerns with ART or in vitro fertilisation (IVF) and its regulation has developed: high costs, unclear success rates, misleading information, limited psychosocial support for patients, intrusive legal requirements on patients, and unproven treatments. As my Interim Report stated in October 2018, the verdict of the users of ART on the 2008 regulatory framework is clear: it does not meet the standards of today.

The 2008 Act itself had a long, difficult birth story. It began in 2000 when leading fertility specialist from Melbourne IVF, Prof. John McBain, challenged the restrictions of Victorian legislation that limited IVF to married women (McBain vs State of Victoria). Ultimately in 2002, the High Court agreed the Act was discriminatory. In response, the Victorian Government asked the Victorian Law Reform Commission to review these laws. This review, which ran from 2004 to 2007, provided the foundations for the Bill, presented to the Victorian Parliament in mid-2008 by the then Attorney General, Rob Hulls. On 4 December 2008 the Bill was passed by the Upper House by a single vote.

Ten years on, and much has changed in social attitudes, reproductive medicine, health regulation and the ART industry itself. Those changes have exposed flaws in the design of the 2008 Act, and led to many frustrations – for patients, surrogates, donors, donor-conceived people, clinics, doctors, counsellors and regulators – with the compromise reached in December 2008. My Interim Report reported the voices of frustration I heard during public consultations in 2018. Together, those voices demanded a renovation of both the regulatory framework for ART and how we deliver fertility services in Victoria.

While acknowledging the many clinicians, nurses, counsellors and others providing excellent care for their patients, the Final Report recognises the need for improvement and evidence of harms across the ART sector generally. It sets out a renovation plan, and outlines the harms related to ART that matter most to Victorians today. It recommends reforms to laws, regulations, services and policies that will ensure fertility services better meet the needs of the tens of thousands of Victorians who rely on them.

The Interim Report set out recommendations to ensure the Act is not discriminatory and to effect other immediate improvements. These recommendations complement the broader system reforms set out in this Final Report, and they may be considered as a single package of reforms that may be implemented progressively over several years.

These reforms aim to:

- improve the quality, safety and experience of ART
- provide clear information and supportive counselling to people involved in ART
• promote inclusive practice responsive to the diversity of people who use ART
• improve access, affordability and equity through the provision of public fertility services that offer a model of excellence in quality, evidence-based fertility care
• establish a public sperm and egg bank
• remove legislative and regulatory barriers to accessing donated gametes
• provide a more supportive, comprehensive legal framework for all forms of altruistic surrogacy
• support national efforts to review or harmonise related laws, especially those affected by recent scientific developments in gene editing and reproductive medicine
• design a state regulator of ART with the right tools that can manage the contemporary risks and harms of ART.

This package of reforms responds to the many community concerns expressed during our public consultations about the quality, affordability and accessibility of ART services. My Interim Report exposed some serious shortcomings. Victorians expect better of this industry, which has such a proud record of delivering world-class fertility care to so many. I am pleased to report that, notwithstanding those critical reports on industry practices, the response to this review from the Victorian ART industry has been constructive, engaged and focused on improving patient care.

This Report has been a team effort. The Review team energetically and enthusiastically ensured that all voices were heard and that this report responded accordingly. I thank them for their contribution.

I thank the many clinicians, counsellors, scientists, researchers, legal experts and leaders in this field who are passionate about improving patient experience and who contributed to this review. I also thank the board and staff of the Victorian Assisted Reproductive Treatment Authority who shared their expertise generously. Most of all, I thank the many Victorian patients, donors, surrogates, families and donor-conceived people who shared their insights with the Review.

All welcomed this opportunity to redesign Victoria’s framework for ART so that it better serves the needs of everyone involved. All are willing to work with the government to ensure the fertility care delivered to Victorians meets the high standards that our diverse community today expects.

Michael Gorton AM
The Reviewer

The Review was 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, the Australasian College for Emergency Medicine and Holmesglen Institute.

The Review team

The Review was supported by staff from the Department of Health and Human Services. The members of the Review team were:

- Dr Jeff Rich, Assistant Director
- Dr Genevieve Cowie, Principal Clinical Policy Officer
- Rebekah McDonald, Policy/Project Officer and Consultation Manager
- Alison Morris, Principal Policy Officer
- Sophie Vasenszky, Principal Legal Policy Officer.

The team and Michael were assisted by Emma Turner, Principal at Russell Kennedy, Lawyers, Deloitte Access Economics, and Simon Corden, an independent regulatory policy specialist.
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Executive summary

Victoria’s regulatory framework for assisted reproductive treatment (ART) is no longer fit for purpose, and the system for delivering ART does not adequately put people at the centre of fertility care, nor provide the access, affordability and quality of care and support that Victorians expect.

This conclusion does not imply that all is wrong with Victoria’s ART industry or its regulatory institutions – the Victorian Assisted Reproductive Treatment Authority (VARTA), the Department of Health and Human Services (the department), and the national industry regulator, the Reproductive Technology Accreditation Committee (RTAC). The industry and its regulators have much to be proud of. The industry has supported tens of thousands of Victorians to create families. It has led the country on many technical and clinical improvements to fertility care, and supported world-leading research on in vitro fertilisation (IVF) practices and health outcomes for persons born as a result of ART. On its own initiative, it has taken many measures to improve patient care and to protect safety, and is a world leader on the key measures of safety. The state regulator is respected nationally for its contribution to public education on fertility issues and its protection of the interests of donor-conceived people. It has acted effectively in response to concerns with practices in the industry, and, in recent years, has led the introduction of major reforms that support connections between donor-conceived people and donors.

But the verdict of the users of ART and many ART practitioners, as reported in the wide-ranging consultations of this Review, is clear – the 2008 framework no longer meets the standards of today. As documented in both the Interim Report and this Final Report, there have been growing patient concerns with ART and its regulation over the last 10 years: high costs, unclear success rates, misleading information, limited psychosocial support for patients, intrusive legal requirements on patients, unproven treatments, and a small number of cases of unethical practices.

In addition, since 2008, much has changed in social attitudes, reproductive medicine, health regulation and the ART industry itself, exposing flaws in the design of the 2008 Act and causing frustration with the limitations of the regulatory framework across the board – for patients, intended parents, surrogates, donors, donor-conceived people, clinics, doctors, counsellors and regulators. New risks and harms have arisen, and this Review sets out an understanding of those risks. Changes in society, healthcare and the market have also led to new and higher aspirations for quality of care from patients, clinicians and governments. Together, these frustrations and aspirations demand a renovation of both the regulatory framework for ART and how fertility services are delivered in Victoria.

This Final Report sets out a renovation plan. Starting from a fresh assessment of the risks and harms of ART and public expectations for fertility care, the plan sets out:

- the components of the regulatory framework for ART
- system changes in the delivery of fertility services
- the design of the state institutions responsible for co-regulation of these services.

Together with the recommendations of the Interim Report, this Final Report provides a comprehensive set of recommendations for the Victorian Government to redesign the regulatory framework in this state, improve access to quality fertility care, and to raise the standards for this industry.

The Review believes, however, that some issues addressed in this report could be tackled well at a national level. While this may be difficult in the short to medium term, it is heartening that the issues raised through the course of this review have led to some commitments by the FSA and RTAC to
review some of the process and requirements of the national self-regulatory system. In this way, Victoria is seen by many in the sector as setting a benchmark for improved ART provision and regulation across the nation.

**Interim Report recommendations**

The recommendations of the Interim Report (restated here for completeness) related especially to the Review’s 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. These recommendations would remove discriminatory or outdated provisions from the Act. They are expected to have an impact on strengthening capacity for the timely identification of potential quality and safety risks by facilitating whistle-blower reports and information sharing between regulators. They will improve access to low cost services through allowing fertility nurses to perform artificial insemination procedures again. They will reduce unintended discrimination resulting in barriers to access for some women and members of the LGBTIQ+ community, and they will improve access to donors and surrogates for those who need them.

**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.

**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.

**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.

**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

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Note – recommendations in the Interim report made reference to VARTA as the Regulator for ART in Victoria. As outlined in Chapter 11 of this report, the Review is proposing that the government give consideration to which entity or entities should be responsible for regulatory functions under the Act. This may be a refocussed VARTA or a different entity. Therefore, references to VARTA should be read as references to the Regulator.
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.

**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.

**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.

**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.

**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.

**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.
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’.

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.

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.

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.

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 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.

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.
Recommendation 16

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

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.
Findings and recommendations of the Final Report

Experience, quality and safety

The Review’s terms of reference required it to consider if the regulatory framework for ART protects consumers and remains appropriate given the changing nature of the market. The Review found that, although ART in Victoria is generally considered safe and effective in comparison with other parts of the world, there remains significant scope for improvements in quality, safety and the experience of those using services.

The recommendations in relation to improving experience, quality and safety (Chapter 3) are intended to refocus the regulatory framework and the ART industry on the highest standards of person-centred care. They aim to reframe Victorian ART legislation to reflect contemporary approaches to managing quality and safety in healthcare, and establish systems for the measurement and continuous improvement of quality, safety and patient experience.

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<th>Recommendation</th>
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<tr>
<td><strong>Recommendation 18</strong> Guiding principles of quality, safety and person-centred care</td>
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<td>It is recommended that the Act be amended to include:</td>
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<td>• a new Guiding principle stating that ‘registered ART providers must provide safe, person-centred services and foster continuous improvement in the safety and quality of the treatment procedures they provide’, and</td>
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<td>• an amendment of Guiding principle 5(d) to require that ‘the health and wellbeing, including emotional and mental health, of persons undergoing treatment, donors and surrogates must be protected’.</td>
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<td>The guiding principles of the Act provide a powerful statement of Parliament’s intent, priorities and expectations and are critical in guiding the actions of providers and regulators carrying out activities and functions under the Act. The recommended changes to the guiding principles will signal the importance of a focus on quality, safety and patient centred care and that the health and wellbeing of all participants in ART are protected.</td>
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<td><strong>Recommendation 19</strong> Clinical governance requirements for ART providers</td>
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<td>It is recommended that the Regulator develop clinical governance compliance standards for ART providers. These compliance standards should form part of the conditions of registration. It is recommended that clinical governance compliance standards should, to the extent possible, align with requirements contained in the Health Services (Health Service Establishments) Regulations 2013 and the National Safety and Quality Health Service Standards. The Review considers that the development of these standards should be undertaken in collaboration with appropriate</td>
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<td>While many ART services have in place robust clinical governance processes, they are not consistent across the industry, not equivalent to recent standards set in the wider Victorian health system, and not sufficient to promote ongoing improvements in safety and quality. The Review received many submissions on shortcomings of clinics in addressing these issues.</td>
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<td>Recommendation 20 Guidelines for person-centred care</td>
<td>The Review has heard numerous reports from people who have used ART services that their experience has not reflected a strong focus on person-centred care. This recommendation is intended to drive practice improvements with a view to lifting standards of person-centred care across the ART industry.</td>
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<td>Recommendation 21 Measures of patient experience</td>
<td>Measures of patient experience are key indicators of quality and can drive improvements. While there is significant data collected in relation to ART outcomes, there is no routine collection of consistent measure of patient experience or the perceptions of patients on what matters in their experience. A consistent approach to measuring patient experiences across the industry will drive improved standards.</td>
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<td>Recommendation 22 Complaint handling</td>
<td>Complaints can be a powerful driver of quality and safety improvements in health services. Although there are some existing regulatory requirements in relation to complaint handling, the Review has consistently heard that patients of ART services are frequently unaware of how to make a complaint or unwilling to complain for fear of repercussions. The proposed compliance standard would ensure that patients are made aware of the avenues available to them and the legal protections that exist.</td>
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<td>Recommendation 23 Inclusion of fertility preservation in the Act</td>
<td>The Review has noted the significant increase in uptake of elective egg freezing services offered by ART providers. The recommendation aims to address the current lack of clarity about the extent to which the Act applies to this practice and to ensure that an appropriate regulatory framework is in place for these services.</td>
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| • provision of appropriate information about procedures, risks and costs  
  • any relevant counselling standards  
  • the need for valid informed consent. | |
| **Recommendation 24** National assessment of evidence-based treatments | ART is characterised by extensive use of unproven, innovative tests and treatments. Independent guidance would assist patients, clinicians and researchers to better understand the treatments they participate in, the evidence base for treatments, and the circumstances in which treatments should be adopted into routine practice. A national approach to this issue is desirable. |

It is recommended that the Victorian Government consult with the NHMRC and relevant professional organisations on the establishment of national independent advice and clinical guidelines on evidence-based treatments for infertility and ART procedures that can inform practitioners, researchers and patients.
Information and support

The Review was asked to determine if consumers have access to adequate information to facilitate informed choices. The Review has found that, although improvements have been made over recent years, many people considering, or receiving, ART still do not believe they have been given sufficient, appropriate information to make fully informed decisions about their treatment. The Review has also heard concerns about a lack of ongoing emotional and psychosocial support for people undergoing treatment.

The Review’s recommendations on providing clear information and supportive counselling (Chapter 4) will establish a new approach in Victoria to ensuring all users of ART provide informed consent and receive the supportive counselling they require. Victoria’s distinctive approach to mandatory counselling has brought many benefits to patients over the years, but has become too prescriptive and inflexible. The Review’s reforms will clarify the responsibility of the treating doctor for ensuring the patient’s informed consent to the treatment plan, and its risks, benefits and costs. They will ensure patients are better informed about fertility issues and the likely outcomes of treatment for them as individuals. They will ensure more patients receive the support they need – before, during and after treatment – and in a way that is tailored to their individual needs, not dictated by government regulations.

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| **Recommendation 25** Prevention through fertility education  
The Review supports the priority given to public fertility education in the Women’s sexual and reproductive health: Key priorities 2017–2020, and recommends that government build on these priorities through appropriate resourcing of preventative activities, public education and information about male infertility, and public education on treatments for infertility including donor and surrogacy treatments. | The Review has heard evidence that the level of knowledge within the community about fertility, infertility and the steps that can be taken to improve the chance of conception is not high. There is also a lack of community understanding about ART, in particular those that involve donors or surrogates, and some specific issues of male infertility. |
| **Recommendation 26** Compliance standards for reporting of success rates and costs  
It is recommended that the Regulator work with the ART sector and patient representatives on compliance standards for public information published by ART providers on success rates and costs. These compliance standards should form part of the conditions of registration and should include a consistent format for the public reporting of costs and success rates. | The Review heard from many stakeholders who were concerned about the way in which ART services are advertised and promoted in the community.  
Since the 2016, Australian Competition and Consumer Commission (ACCC) investigation of claims made by ART clinics about their rates of success, considerable work has been undertaken by regulators and within the industry to improve these practices. However, those using ART services still report significant confusion when trying to interpret likely success rates, and difficulty in making decisions about costly treatments when faced with complex, overwhelming, information on treatment options and unclear cost breakdowns. |
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<td><strong>Recommendation 27</strong> Compliance standards on advertising, testimonials and social media</td>
<td>ART providers are subject to a range of regulatory requirements in relation to the advertising of services. This includes requirements under consumer law and National Health Practitioner Registration legislation. Nonetheless, the establishment of clear guidelines in relation to advertising, in particular social media and testimonials, would ensure all ART providers comply with these standards appropriately given the specific risks and emotional sensitivities of fertility.</td>
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<td><strong>Recommendation 28</strong> Obligations on treating doctor to support informed consent</td>
<td>The Act currently requires counsellors to provide information on a range of prescribed matters, which including the options and choices available to the patient, as well as possible outcomes of a treatment procedure. The Review considers that this has led to the undesirable situation of counsellors being expected to provide advice and information about matters that may more appropriately fall within the treating doctor’s clinical responsibilities. This recommendation aims to clarify that responsibility for discussing these matters, which are critical to the capacity of a person to give fully informed consent, falls to the treating doctor.</td>
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<td><strong>Recommendation 29</strong> Information on modifiable lifestyle factors affecting fertility</td>
<td>The Review considers that people may benefit from greater information about the ways in which the outcomes of ART are influenced by a number of modifiable lifestyle factors. While this is a requirement of the RTAC Code of Practice, the Review understands that compliance with this requirement could be improved across all services.</td>
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<td><strong>Recommendation 30</strong> Information on adjuvant and complementary health treatments</td>
<td>There is widespread and increasing use of adjuvant (‘add on’) services, such as assisted hatching, time-lapse imaging and endometrial scratching. The costs of these treatments vary significantly but can be very high, and many of them lack an adequate evidence base to justify use in a clinical setting. Fertility specialists and other health practitioners are also concerned about the common use by many patients of a range of complementary health practices (such as acupuncture,</td>
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<td>offered to support fertility. It is recommended that the Regulator develop compliance standards for the provision of information in relation to adjuvant treatments, which includes a requirement to advise patients how to access the resources developed by the regulators. These compliance standards should form part of the conditions of registration.</td>
<td>homeopathy or herbal medicines) that may not benefit patients. This recommendation aims to improve access to quality information about the evidence for adjuvant and complementary treatments to assist patients in making informed decisions.</td>
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<td><strong>Recommendation 31</strong> Information on social, emotional aspects of infertility and ART</td>
<td>The social and emotional impact of infertility and ART can be significant. The Review considers that patients should be aware of these impacts in order to make informed choices about their treatment. This includes information about the social and emotional impacts on patients as well as potential impacts for donor-conceived children.</td>
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<td>It is recommended that providers be required to provide verbal and written information to patients about the range of social and emotional impacts of infertility and ART, the specific issues for donor-conceived people and their parents, and the value of supportive counselling in assisting them to manage these issues. Providers, regulators and relevant professional organisations should contribute to the ongoing development of these materials.</td>
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<td><strong>Recommendation 32</strong> Ensuring all patients receive an individual plan of support</td>
<td>Section 13 of the Act provides that, 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 a set of prescribed matters) from a counsellor who provides services on behalf of a registered ART provider. Victoria is the only state in Australia to mandate counselling for all ART procedures in this way. The Review considers that counsellors have a valuable role to play in helping patients navigate their ART but that the current format of counselling and mandated requirements is not sufficiently tailored to meet the needs of individual patients. This recommendation is intended to ensure that support is focused on the personal needs of each patient.</td>
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<td>It is recommended that the Act be amended to remove the mandatory counselling requirement and all prescribed matters for discussion between the counsellor and patient, unless the treatment involves donor or surrogacy arrangements, or the posthumous use of gametes or an embryo. In place of this requirement, the Act should require that, before treatment commences, each patient has an individual plan of support, developed by the patient and an appropriately qualified counsellor. This plan of support will include, where appropriate, counselling as required under the Act that meets the relevant compliance standard to be developed by the Regulator. A compliance standard on counselling may include requirements for particular matters to be addressed in counselling before treatment commences.</td>
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Recommendation 33 Compliance standards for counselling

It is recommended that the Regulator develop compliance standards for the provision of counselling. These compliance standards should be developed through appropriate evidence reviews and stakeholder consultation, and reviewed on a regular basis to ensure that they continue to meet patient needs. It is intended that the compliance standards form part of the conditions of registration.

The requirements set out in the compliance standards will be in addition to matters prescribed in regulations which will include the matters to be covered in counselling related to donor or surrogacy arrangements or the posthumous use of gametes or embryos.

Recommendation 34 Duty to offer counselling during and after treatment

It is recommended that the Act be amended to make clear that ART providers have a duty to offer patients counselling during and following the conclusion of their treatment. Such counselling should be offered on an optional basis. The legislation or regulations should oblige ART providers to offer reasonable access to timely and responsive counselling to help patients and intended parents who may experience distress following an unsuccessful treatment cycle or for any other appropriate reason, and to arrange appropriate referral pathways for any person with ongoing grief, mental health or counselling needs.

The establishment of clear standards in relation to the provision of timely and accessible supportive counselling is intended to ensure that all patients have access to high-quality support and a failure to meet these standards being a basis for regulatory action.

Consistent with other jurisdictions, the NHMRC Ethical Guidelines and the RTAC Code of Practice counselling on prescribed matters will continue to be required in relation to surrogacy arrangements, donor treatments and the posthumous use of gametes.

The establishment of a clear duty on providers to offer patients counselling during and following the conclusion of treatment will address a key concern of patients and other service users that ART providers do not offer sufficient supportive counselling before, during and after treatment, especially in the large proportion of cases where treatment is unsuccessful.
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<td><strong>Recommendation 35 Qualifications and eligibility to provide counselling</strong>&lt;br&gt;It is recommended to remove the requirement in the Act that a counsellor must be providing services on behalf of an ART provider, so that patients may choose to seek counselling outside a clinic setting from a person who meets the definition of ‘appropriately qualified counsellor’. It is recommended that the Act be amended to state that counselling in respect of ART must be provided by an ‘appropriately qualified counsellor’. The term ‘appropriately qualified counsellor’ should be defined in regulation or compliance standards as a person who is eligible for membership of ANZICA and has the relevant experience, skills and knowledge, including in respect of key legislative requirements, appropriate to the counselling undertaken.</td>
<td>The Act currently requires that counselling be undertaken by a counsellor who provides services on behalf of a registered ART providers. Service users have said that in some circumstances they would prefer to be supported by a counsellor of their choice. This flexibility and patient choice will enable people to receive support from a suitably qualified person with whom they already have a therapeutic relationship, or who is known to specialise in a field important to them (for example, LGBTQI+ family issues). There should remain, however, a clear standard for the appropriate qualifications of fertility counsellors, and this standard should be set in regulation or compliance standards, not in legislation.</td>
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<td><strong>Recommendation 36 Assigning responsibility for screening to the ART provider</strong>&lt;br&gt;It is recommended that the Act be amended to make it clear that the completion of mandated police and child protection checks is the responsibility of the ART provider, rather than a counsellor.</td>
<td>Under s. 11 of the Act, counsellors are responsible for sighting criminal record checks as part of the process of obtaining consent for treatment. The Review considers that placing the onus for these checks on the counsellor adversely affects the therapeutic relationship, and may create difficulties for the clinical governance and management of ART providers.</td>
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Inclusive practice

The terms of reference for the Review required consideration of whether the regulatory framework for ART creates or enables unnecessary barriers to access. The terms of reference specifically to access for LGBTIQ+ people, and a number of the recommendations of the Interim Report sought to address regulatory barriers identified for people from this community.

Throughout the course of consultations, the Review has also heard that there are other social or cultural groups of people who face barriers to access in ART, or who have reported concerns to the Review about how well ART providers respond to their needs.

The Review makes a number of recommendations on delivering inclusive practice for LGBTQI+ people and other groups with specific needs (chapter 5). These recommendations apply the general principles of person-centred care, informed consent and supportive counselling to the specific needs of these groups.

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<td><strong>Recommendation 37</strong> Research on diverse service user needs and experiences</td>
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<td>It is recommended that the Regulator facilitate research into the diverse experiences of people affected by ART in collaboration with research institutions, ART providers, community organisations, and service users. This research should include, but not be limited to:</td>
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<td>• the diverse family forms of people accessing treatment,</td>
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<td>• the different needs of people accessing treatment, including people with intersex variations, people from culturally and linguistically diverse communities, Aboriginal people and people with disability</td>
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<td>• the range of experiences of donor-conceived people and their families.</td>
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<td>The Review identified a lack of information about the diverse experiences of people making use of ART services. The proposed research would offer an opportunity to identify opportunities for improvements in clinical practice, the provision of support and communication with service users.</td>
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<td><strong>Recommendation 38</strong> Access to translated information resources on ART and fertility</td>
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<td>It is recommended that the Regulator work with ART providers and community organisations to expand the range of translated materials available to ART service users.</td>
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<td>Consultation with community organisations has revealed that a lack of information about ART in community languages remains a significant barrier to people from culturally and linguistically diverse backgrounds accessing services.</td>
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| **Recommendation 39** Inclusive practice in ART  
It is recommended that the proposed compliance standards on clinical governance (Recommendation 19) include a requirement for ART providers to develop inclusive practice policies. It is further recommended that the Regulator develop guidelines on inclusive practice with the active involvement of service users, community representatives, parents and intended parents, their families, surrogates, donors and donor-conceived people. | Inclusive practice is a critical component of person-centred care. Ensuring that the ART industry is responsive to the needs of all people accessing the services, and that their diversity is acknowledged and respected, is fundamental to equitable access to ART. Inclusive practice policies are best developed locally to address the needs of the particular client group rather than detailed in a mandatory compliance standard. |
| **Recommendation 40** Improving ART data collection on diverse user groups  
It is recommended that the Department of Health and Human Services work with the Regulator, RTAC, ART providers and the data custodians of the Australian and New Zealand Assisted Reproduction Database to improve the collection of ART data related to sexuality, relationship status, cultural background, languages spoken, and variations in sex or gender. Appropriate voluntary consent requirements and protections of privacy should be ensured as part of any data collection. | Data reported and publicly available about the use and outcomes of ART does not currently include sufficient information about matters such as sexuality, relationship status, cultural background, languages spoken, or diversity of some aspects of sex or gender. Such information would assist people seeking treatment to better understand their own likely outcomes as well as assisting the sector to better respond to the needs of the diverse range of people who access ART. This data collection is voluntary, and encouraged, and should be done a way that ensures privacy. |
**Access and affordability**

The Review was asked to consider whether the evolving market and regulatory framework has implications for access and affordability of ART services. The Review found that the high cost of services was a significant barrier to access, and that while the recent emergence of low-cost private providers has improved affordability for some patients, these services are narrowly focused and not available to all who needed them.

Since the release of the Interim Report, the government has committed $32 million to establish public IVF services, and to undertake a full business case assessment of the model. The recommendations outlined in Chapter 6 therefore relate to the public provision of ART services and provide guidance on how these services may be established. The establishment of public fertility services will be among the most significant outcomes of this Review, and is strongly supported by the Review and many stakeholders. The design and development of these services has the potential to change fundamentally the system for delivery of fertility care through a model of excellence in public health services that is primarily designed around the needs of users.

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<td><strong>Recommendation 41</strong> Scope of public fertility services</td>
<td>It is recommended that, in addition to IVF, public fertility services should provide general fertility advice and support and assisted reproductive treatments more broadly – this includes intra-uterine insemination and other donor services as well as offering preimplantation genetic diagnosis for those at higher risk.</td>
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<td><strong>Recommendation 42</strong> Policy and service design framework for public fertility services</td>
<td>Although the government’s commitment is to establish public IVF services, any public provision of IVF should progressively incorporate a broader range of fertility services, including other assisted reproductive treatments, such as IUI. Some of these services are cheaper and less medically complex than IVF. This will ensure the most cost-effective and clinically appropriate treatments are used in public health services.</td>
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<td>Any public fertility services should be developed within a clear policy and service design framework, as with other public health services. Existing government strategies on sexual and reproductive health will assist in ensuring a comprehensive and coordinated approach to fertility treatment. However, the existing strategy does need to be reviewed to incorporate recent government priorities and the findings of this Review.</td>
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<td><strong>Recommendation 43</strong> Model for delivery of public fertility services</td>
<td>The establishment of public fertility services offers an opportunity to provide an exemplar in evidence-based practice, including person-centred care, research and training, and to better place this within governmental reproductive health strategies.</td>
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<td>It is recommended that public fertility services should be progressively developed over time to be a high-quality system to ensure better health outcomes for a broad range of service users and families, not just low-income earners. This should be achieved through provision of a comprehensive range of person-centred, evidence-based services, including care for people with complex medical needs and a specific focus on the needs of LGBTIQ+ people, culturally and linguistically diverse people, Aboriginal people, people with disability, single women, rural and regional Victorians, and other relevant groups who have difficulty accessing ART.</td>
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<td><strong>Recommendation 44</strong> Issues to assess in the business case for public fertility services</td>
<td>To ensure that the government’s commitment results in the best outcome for people who may rely on public provision to access fertility treatment, it is critical that the business case consider a broad range of critical design features as identified by the Review.</td>
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| It is recommended that the business case for public fertility services should consider the following key design features:  
  • elements of co-design with consumers and practitioners with a view to improving person-centred care  
  • improving access for underserved groups  
  • model of care, including mix of public and/or public-private service provision  
  • consideration of any links with the proposed sperm and egg bank  
  • mix of capital and recurrent funding  
  • patient fees  
  • workforce recruitment, retention and continuing professional development  
  • management of laboratories and scientific practice  
  • research capability and funding  
  • opportunities for partnerships with universities and private sector firms  
  • the pace and scale of implementation, including the phasing of service development subject to both resources and demand. | |
Establishing a public sperm and egg bank

Stakeholders identified a serious shortage of donated gametes as a key barrier to access to ART services for many people. This shortage can result in delays in treatment and constraints in the treatment options available. In Chapter 7, the Review proposes the establishment of a public sperm and egg bank to assist in addressing this shortage and enabling equitable access to donated gametes.

The Review has conducted a preliminary feasibility assessment of the sperm and egg bank and proposes the government undertake a comprehensive assessment of the bank as part of the business case for public IVF services. There are a number of complex business issues to resolve before committing to a specific model for the delivery of the bank. Nonetheless, the Review considers this proposal is the most effective way to deal with the shortage of donated gametes in Victoria that is adding to costs, delays and access difficulties for many Victorians.

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<td><strong>Recommendation 45</strong> Establishment of a public sperm and egg bank</td>
<td>The Review considers that the establishment of a public sperm and egg bank would be an effective means of increasing access to donor gametes and would offer the opportunity to provide a range of services that would be of benefit of the Victorian community. A feasibility assessment of the public sperm and egg bank, undertaken by Deloitte Access Economics, demonstrated a strong case for public investment in a sperm and egg bank, and identified a number of viable models for such a bank.</td>
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- sourcing and storage of donated gametes and embryos through the development and delivery of suitable education and awareness programs in the community about the need for donations
- proactive recruitment of local donors
- importation of gametes into Victoria to address any local shortfall in supply
- storage of gametes and embryos for personal use by individuals seeking treatment through public fertility services
- provision of storage options for elective fertility preservation, in collaboration with public fertility services
- testing of donated gametes where the donor and recipient know each other but wish to undertake screening of the gametes through the bank
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<td>• some fee for service components where appropriate (for example, access to donated gametes by ART providers).</td>
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<td><strong>Recommendation 46</strong> Legislative and regulatory requirements for sperm and egg bank</td>
<td>If the sperm and egg bank is established, it will need an appropriate legal and regulatory framework, depending on its range of services, and may need to comply with standards set by both RTAC and any Victorian regulator.</td>
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<td>It is recommended that the Act be amended to include provisions for the storage of gametes and embryos which may occur independently of the provision of ART, and clearly articulate that regulatory obligations will apply to the sperm and egg bank or any other private storage facility. These obligations include matters such as donor consent, relevant counselling, information provision, prohibition on commercial incentive or reward for donation, record keeping, reporting requirements, and the storage and use of gametes.</td>
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<td><strong>Recommendation 47</strong> Resourcing the sperm and egg bank</td>
<td>The establishment of a public sperm and egg bank may require both capital and ongoing funding and may be phased over time. It may be appropriate to undertake a business case assessment alongside the planned business case for the establishment of public fertility services.</td>
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<td>It is recommended that consideration be given to appropriate funding to establish a sperm and egg bank. Funding requirements and appropriate phasing of these services should be assessed through a comprehensive business case assessment. The ongoing cost of the sperm and egg bank could be, in full or in part, funded directly by fees for both ART providers and individuals accessing the bank.</td>
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<td><strong>Recommendation 48</strong> Education and donor recruitment functions of the bank</td>
<td>Limited and fragmented marketing by private providers and a general lack of public awareness of gamete donation issues contribute to the current local donor shortage. Coordinated public health marketing by either the Victorian Government or the sperm and egg bank would increase the local donor pool.</td>
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<td>It is recommended that the Victorian Government and, if established, the sperm and egg bank develop and deliver education and awareness programs in the community about the need for donations, and undertake proactive recruitment of donors to increase the local supply of gametes in Victoria.</td>
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<td><strong>Recommendation 49</strong> Promoting the wellbeing of donors and donor-conceived people</td>
<td>A sperm and egg bank would need to operate as an exemplar of good practice and to ensure support for the wellbeing of participants as well as providing fair access for those requiring donated gametes in order to conceive a child. Given the sensitivity of some issues in selecting donors, appropriate guidelines should be developed to prevent discrimination and promote wellbeing.</td>
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<td>It is recommended that the sperm and egg bank develop appropriate donor support policies, guidelines and information packs to ensure that it operates on a best practice model that prioritises the wellbeing of donors and donor-conceived people in Victoria.</td>
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<td>Recommendation 50 Access to gametes and embryos supplied by the bank</td>
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<td>It is recommended that the sperm and egg bank develop appropriate guidance and policies to ensure fair access to gametes and embryos by potential recipients. Recipients should be eligible to access gametes through the sperm and egg bank irrespective of whether they wish to do so via public fertility services, an ART provider or general practitioner.</td>
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<td>A key business issue for the bank will be determining access or allocation rules for donated gametes. These rules will need to allocate scarce resources efficiently and fairly, and treat all ART providers or individual clients fairly and reasonably. These rules are best developed by the bank if established.</td>
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<th>Recommendation 51 Regulation of known donor screening by the bank</th>
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<td>It is recommended that the sperm and egg bank provide a service for known donor screening and the government establish appropriate legislative or regulatory requirements for known donor gamete screening by the bank, including:</td>
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- provision of appropriate information to the donor and recipient seeking to screen known donor gametes, including the existence and function of the Central and Voluntary Registers
- supportive counselling required for donors and recipients of donated gametes
- acknowledgement by the donor and recipient that they have been provided with the relevant information and counselling to make an informed decision about using known donor gametes. |
| It is envisaged that the bank could offer a screening service for gametes where the donor and recipient know each other but wish to undertake proper medical checks before attempting conception through home insemination. The availability of this service is likely to improve access and affordability for single women and LBGTIQ+ people who access ART. The Act currently excludes self-insemination from the definition of ‘treatment procedure’, therefore the Review considers that it would be appropriate to amend the legislation to specifically cater for this scenario to ensure appropriate support and protections are in place. |
Removing regulatory barriers to access to donated gametes and embryos

The Interim Report identified a range of proposals to address regulatory restrictions that contribute to the shortage of donated gametes and embryos. Chapter 8 sets out further recommendations to remove statutory barriers to the donation of gametes.

The Review proposes to reduce regulatory burden on both clinics and individuals in relation to the donation of gametes, and other changes to improve the processes related to donation for donors, patients and donor-conceived individuals. Together with the establishment of the sperm and egg bank, these recommendations to improve reimbursement for donors, simplify storage and importation of gametes, and improve processes of donation, aim to promote a stronger culture of local donation of sperm and eggs in Victoria. They will simplify the process of donation, improve access, and preserve Victoria’s model of ethical, altruistic donation that prioritises the interests of donor-conceived people.

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<td><strong>Recommendation 52</strong> Regulatory guidance on donor reimbursement</td>
<td>State and Commonwealth laws ban selling or buying human tissue including eggs, sperm or embryos, and giving or receiving valuable consideration to another person for the supply of a human egg, human sperm or human embryo. Reimbursement of reasonable expenses is allowed. However, there is no clear guidance on what is fair, non-commercial reimbursement. This leads to access difficulties and inconsistent levels of compensation paid by ART providers or individuals. Using the successful UK model of defining a recommended amount of reimbursement (with different rates for sperm and egg donation) would improve this situation.</td>
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<td>It is recommended that Victorian legislation authorise the Regulator to publish guidance on acceptable reimbursement amounts for costs incurred by donors, and storage and other costs incurred after a decision has been made by people to donate gametes and embryos that become surplus to their personal needs.</td>
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<td><strong>Recommendation 53</strong> Regulatory guidance on donor screening</td>
<td>Stakeholders have told the Review that it would be useful for the Regulator to develop guidelines, in collaboration with ART providers and industry experts, on matters relating to donor eligibility, including in respect of medical history or known conditions. The Review considers it appropriate that where a medical condition is identified, the people concerned should be supported to access appropriate treatment or support. Guidelines would prevent unfair or discriminatory practices that occur in some other countries (for example, screening on the basis of intelligence, education, levels, or mental illness).</td>
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<td>It is recommended that the Regulator develop appropriate guidelines for donor eligibility in Victoria in consultation with relevant stakeholders, to ensure a consistent and streamlined approach to the recruitment and screening of donors. The Regulator should also develop guidelines for the handling of disqualifying medical conditions when they are identified, to ensure the timely referral of the individual concerned for treatment of infectious diseases, or genetic or other counselling. Where a donor’s medical condition becomes known after the birth of donor-conceived offspring, the individual(s) concerned should be notified through appropriate reporting to the Regulator, and proactively provided with information and options for managing the condition. Guidelines developed by the Regulator should apply to ART providers and to any sperm and egg bank that is established.</td>
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| **Recommendation 54 Advertising for donated gametes**
It is recommended that the existing advertising restrictions and requirement for Ministerial approval be removed from s. 40 of the *Human Tissue Act 1982*. In place of these restrictions, the Regulator should be given powers to:
- develop and publish guidelines on advertising
- monitor advertising for donated gametes in Victoria and require the removal or amendment of material which is inconsistent with the guidelines. | Currently, advertising for donation of gametes and embryos in Victoria is strictly regulated under s. 40 of the *Human Tissue Act 1982*. Ministerial approval is required before a person may advertise for a donor, and may not be delegated to an administrative decision maker. The Review heard that a requirement for Ministerial decision making on such a personal matter can be intimidating and time-consuming for patients, and cause delays and other difficulties in accessing treatment. |
| **Recommendation 55 Supporting safe communication between donors and intended parents**
It is recommended that the Victorian Government consider facilitating the operation of a community-led moderated online forum in Victoria, to allow safe channels of communication between potential donors and recipients of donated gametes or embryos, and people who are contemplating entering into a surrogacy arrangement as a surrogate or as intended parents. | Restrictions on advertising for donations of eggs and embryos represents a significant barrier to access and makes it difficult for ART providers or individuals to connect with potential donors.
The Review heard that unmoderated online forums connecting donors and recipients have become common, and that there is a potential for bullying or other undesirable conduct to occur. A moderated forum may allow people to connect in a safe and supported way. |
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<td><strong>Recommendation 56</strong> Simpler process to approve the importing of gametes</td>
<td>Section 36 of the Act requires written approval from VARTA for the importation of gametes into Victoria. The Act does not offer guidance on the matters to which VARTA must have regard in making decisions about whether to approve gametes or embryos being imported into Victoria. Some stakeholders reported that approvals take too long and that there is a lack of clarity as to how VARTA makes decisions under the Act. It has also been suggested that patients can and do access treatment outside Victoria if they are unable to source gametes locally. The Review considers it preferable to specify in legislation or the regulations the criteria that need to be satisfied in order to import gametes into Victoria. These requirements should be clear, comprehensive and consistent with the principles of the Act, and facilitate reasonable access to overseas gametes. This would enable a more streamlined approach where people seeking to import gametes are able to certify that conditions are met. It would be an offence to make a false attestation or to import without having first provided certification to the Regulator that the specified conditions are met.</td>
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<td>It is recommended that the current legislative and regulatory guidelines on importation arrangements for donated gametes be amended to ensure they are not a barrier to access for those Victorians who seek to use imported gametes or embryos as part of their treatment. Accordingly, the Act should be amended to set out the criteria that need to be satisfied in order to import gametes and embryos into Victoria, through a certification process that attests, to the Regulator, that the following matters have been satisfied:</td>
<td>Part 3, Division 2 of the Act sets out provisions for the storage of gametes and embryos. Storage limits in Victoria are set at 10 years for gametes and five years for embryos, subject to extensions that may be available upon application to the PRP. These limits are the most conservative in Australia, and do not reflect current scientific knowledge on the storage of gametes and embryos or the period of time that an individual may realistically want to store their gametes for future use. While the Review does not consider it necessary to apply a statutory storage limit to gametes or embryos stored for personal use, it is considered appropriate to set some</td>
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<td>• the donation is altruistic, and any payments made to the donor are consistent with the Victorian approach to reimbursement</td>
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<td>donor. The Patient Review Panel should have the power to authorise storage and use beyond this limit, if it is considered appropriate to do so in the circumstances. The Act should state that a donor may only consent to a storage period of up to 10 years, and should be prompted to renew their consent at reasonable time intervals of at least every 10 years.</td>
<td>limits on the storage and use of donated gametes. This is intended to ensure that there is a realistic prospect for a donor-conceived person to connect with their donor. The Review also considers that the donor should be prompted to renew their consent to the use of their gametes at least every 10 years, to ensure that they remain comfortable with this decision over time as their circumstances change.</td>
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**Recommendation 58** Posthumous use of gametes or embryos

Further to Recommendation 7 of the Interim Report, it is recommended that s. 46(b) of the Act be amended to remove the requirement that the deceased person must have provided ‘written consent’ for the posthumous use of their gametes in a treatment procedure by their partner. The Patient Review Panel should determine each application by reference to all available information about whether the deceased person had provided consent to support the posthumous use of their gametes.

The Act should furthermore be amended to state that the posthumous use of donated gametes, or any embryos created from such gametes, is prohibited except if the Patient Review Panel approves such cases where:

- there is evidence that the donor has consented to such use, and
- the gametes will be used to complete a family with biologically related siblings where at least one child has already been born using the donated gametes, or
- other exceptional circumstances apply.

The Act should make it clear that the posthumous use of gametes for research purposes is permitted, provided this is consistent with the wishes of the donor or person storing the gametes for personal use, as recorded in their consent form.

The Act currently prohibits the posthumous use of gametes unless they are to be used by the deceased person’s partner and provided certain conditions have been satisfied, including that the deceased person has provided written consent for the posthumous use of their gametes or embryos in an ART procedure. The Review considers this to be a high threshold to satisfy.

There is no scope under the Act for the use of donated gametes, or embryos created from such gametes, after the death of a donor. The Review considers that as a general rule the posthumous use of donated materials is not desirable, however, it would be appropriate that the PRP be empowered to approve their use where the gametes are to be used to complete a family with biologically related siblings, or other exceptional circumstances exist.

**Recommendation 59** Review of 10 family limit after addressing gametes shortage

Further to Recommendation 10 of the Interim Report, which proposed the amendment Section 29 of the Act restricts the number of people who may conceive a child using gametes donated by the one person to 10 women. The Review recommended in its Interim Report that the limit should be applied to families, rather than women, to avoid
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<td>of s. 29 of the Act to ensure that the limit on the use of donated gametes applies to ‘families’ rather than ‘women’, it is recommended that the proposed 10 family limit be reviewed after five years with a view to reducing the limit to five families if increased donor supply becomes available. The review will need to consider harmonising arrangements with other jurisdictions, ensuring that any changes are prospective only, and that appropriate transitional arrangements for the use of existing donor gametes and embryos are in place.</td>
<td>discrimination against same-sex couples where both partners may wish to have children using gametes from the same donor. The limit on the use of donation is intended to reduce the risk of donor-conceived people unknowingly forming consanguineous relationships and ensuring that donors do not have very large numbers of donor conceived offspring. To meet this aim, the Review considers that it may be appropriate over time to reduce the limit from 10 to five families. However, this is not considered realistic at this time given the current shortage of donor gametes.</td>
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<td><strong>Recommendation 60</strong> Mandatory and contemporaneous reporting of all donations</td>
<td>Recommendations 60, 61 and 62 aim to respond to the circumstances that have occurred where a donor may have concealed information about previous donations or where records have not facilitated identification that a donor has donated at multiple clinics, resulting in recipients being unable to use donated gametes or embryos created from such. Recommendation 60 would allow more effective monitoring of numbers of donation by changing the time at which donations are reporting to the regulator to the time of donation, rather than the birth of the child. It would also authorise selected information sharing between the Regulator and providers on donation numbers.</td>
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<td>It is recommended that the Act be amended to require the mandatory and contemporaneous reporting of all donations to the Regulator by ART providers and any sperm and egg bank. The Act should authorise the sharing of relevant donor information by the Regulator with providers for the purpose of determining if donation limits have been reached.</td>
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<td><strong>Recommendation 61</strong> Offence for knowingly donating in excess of the family limit</td>
<td>Recommendation 61 aims to communicate a clear standard and responsibility to donors to comply with statutory family limits. This is intended to promote positive compliance by donors – not only clinics – with existing laws.</td>
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<td>It is recommended that the Act create an offence for a person to knowingly conceal or fail to disclose previous donations to an ART provider or any sperm and egg bank, where they wish to register as a donor.</td>
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<td><strong>Recommendation 62</strong> Authorising use of donated gametes in exceptional circumstances</td>
<td>There has been a recent case where it was discovered that the statutory 10 family limit was exceeded through the actions of a donor, and this led to a couple being barred from proceeding with planned treatment. This has caused significant distress to those affected. This recommendation provides decision makers some flexibility in applying the statutory limits proportionate to the risk where compelling exceptional circumstances exist.</td>
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<td>It is recommended that the Patient Review Panel be given residual powers under the Act to determine an application to authorise use of donated gametes above the statutory limit set out in s. 29, where exceptional circumstances apply, and it is considered appropriate to do so.</td>
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Supporting altruistic surrogacy arrangements

Just as a shortage of donated gametes and embryos limits access to ART services, so too does a shortage of people willing to act as altruistic surrogates for people who require a surrogate to fulfil their desire to form a family. The Review found that current surrogacy laws in Victoria are dated, and do not offer a sufficiently robust or detailed framework for those who wish to enter into a surrogacy arrangement.

Victoria’s regulatory framework for surrogacy needs to be more comprehensive and truly supportive of altruistic surrogacy. The recommendations outlined in Chapter 9 in no way support commercial surrogacy. They are intended to build on the Interim Report’s recommendations to improve reimbursement for surrogacy, and reorient the legal and support processes to be supportive of both surrogates and intended parents. Importantly, by including traditional surrogacy within the regulatory framework, it will ensure all altruistic surrogates receive the support and access to treatments they need. These changes will also support the gradual harmonisation of Australian surrogacy laws over time.

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<td><strong>Recommendation 63 Legislative guiding principles tailored to surrogacy</strong></td>
<td>The Guiding principles set out in s. 5 of the Act create a useful framework for the provision of treatment procedures, however, they are not sufficiently tailored to assist with the interpretation of the law relating to surrogacy arrangements. The inclusion of more comprehensive Guiding principles in relation to surrogacy is consistent with the recommendations of a 2016 Commonwealth parliamentary committee report – Surrogacy matters – and the approach in place, or being considered, in a number of other Australian jurisdictions. In addition to the safeguards that currently exist and will remain, these amendments will strengthen support and protections for the surrogate and provide greater clarity for others involved.</td>
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<td>It is recommended that Guiding principles specifically tailored to articulating the policy objectives of surrogacy legislation be developed. At a minimum, the Guiding principles should articulate the following key ideas:</td>
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<td>• The welfare and best interests of the child to be born as a result of a surrogacy arrangement, both through childhood and for the rest of life, are paramount.</td>
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<td>• Commercial surrogacy is prohibited in Victoria.</td>
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<td>• The regulation of surrogacy should promote positive relationships of trust between the parties to a surrogacy arrangement.</td>
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<td>• The parties to a surrogacy arrangement should have certainty and clarity about their rights and obligations.</td>
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<td>• The surrogate should be able to make a free and informed decision about becoming a surrogate and be protected from exploitation.</td>
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<td>• The bodily autonomy of the surrogate should be protected throughout the surrogacy process.</td>
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<td>• The autonomy of consenting adults in their private lives should be respected.</td>
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<td>• A surrogate should not be financially disadvantaged as a result of acting as a</td>
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<td>surrogate and should be able to recover any costs incurred as a result of the pregnancy and birth, including in respect of any unforeseen medical complications and income foregone.</td>
<td>Arrangements where the surrogate’s own egg is used are referred to as traditional (as opposed to gestational) surrogacy. The Act does not prohibit traditional surrogacy arrangements, however a registered ART provider may carry out a treatment procedure on a woman under a surrogacy arrangement only if the surrogacy arrangement has been approved by the PRP, and the PRP may approve a surrogacy arrangement only if satisfied of a range of matters, including that the surrogate’s egg will not be used in the conception of the child (s. 40(1)(ab)). Often traditional surrogacy involves other family members. Current legal arrangements aim to minimise legal requirements for traditional surrogates. However, they also exclude traditional surrogates from treatment by ART providers, such as screening, ovulation tracking, and expert assistance with IUI or IVF procedures. This restriction is unique in Australia. Given the complexity, medical risks and sensitivities involved in any surrogacy, legislation should ensure that all surrogacy arrangements are appropriately oversighted by the PRP approval process, and, most importantly, all surrogates receive access to quality health care.</td>
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<td><strong>Recommendation 64</strong> Ensuring access to ART services for traditional surrogates</td>
<td>It is recommended that treatment by an ART provider is available to the parties of all surrogacy arrangements, including where the surrogate’s own egg is used. The Act should be amended to require all surrogacy arrangements (including these ‘traditional’ surrogacy arrangements) to be the subject of appropriate oversight through mandatory Patient Review Panel approval. Treatment by an ART provider would be available to support all surrogacy arrangements which have received Patient Review Panel approval. Part IV of the Status of Children Act 1974 may need to be revised to ensure a consistent and streamlined approach in the consideration of parentage orders arising from all surrogacy arrangements. There should be a residual discretion for the court to grant a parentage order if exceptional circumstances apply and the making of the order would serve the best interests of the child.</td>
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<td><strong>Recommendation 65</strong> Supportive counselling for surrogacy</td>
<td>Section. 43 of the Act requires that before a surrogacy arrangement is entered into, the relevant parties must obtain counselling in respect of a range of prescribed matters, as set out in the ART Regulations (r. 9). Unlike a number of other jurisdictions, however, there is no requirement for additional counselling to take place following the birth of the child and prior to the making of any parentage orders in favour of the intended parents. The Review has also heard that the current requirements for reporting to the PRP on counselling in relation to surrogacy matters are unnecessarily onerous and investigative in nature. These changes simplify these processes, while protecting the legal interests of all parties.</td>
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<td>It is recommended that the Act be amended to expand the current counselling requirements relating to surrogacy. Specifically, the legislation should mandate appropriate counselling for parties to a surrogacy arrangement at two distinct points during the surrogacy process, namely: • before the parties enter into a surrogacy arrangement and seek Patient Review Panel approval • following the birth of the child and prior to the making of any parentage orders. Reporting to the Patient Review Panel on these counselling requirements should be less detailed than current arrangements. Following counselling after the birth of the child, the relevant counsellor should certify that appropriate counselling has been</td>
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<td>provided to the parties. Both the Patient Review Panel and the court should be given express powers to seek a more detailed report from a counsellor, or any other relevant expert, if this is considered necessary and appropriate in the circumstances to help aid the decision-making process.</td>
<td>Consistent with Recommendation 35, the Review considers that the current requirement that counselling under the Act be undertaken by a counsellor who provides services on behalf of a registered ART provider should be removed, and in its place, a clear standard be set for who can deliver counselling services associated with ART (including surrogacy arrangements). It is expected that counselling will still be provided by ART clinics. The intent of this recommendation is to allow flexibility and patient choice. This will enable people to receive support from a suitably qualified person with whom they already have a therapeutic relationship, or who is known to specialise in a field important to them (e.g. LGBTIQ+ family issues or surrogacy).</td>
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<td>Recommendation 66 Qualifications and eligibility to provide surrogacy counselling</td>
<td>Consistent with Recommendation 35, the Review considers that the current requirement that counselling under the Act be undertaken by a counsellor who provides services on behalf of a registered ART provider should be removed, and in its place, a clear standard be set for who can deliver counselling services associated with ART (including surrogacy arrangements). It is expected that counselling will still be provided by ART clinics. The intent of this recommendation is to allow flexibility and patient choice. This will enable people to receive support from a suitably qualified person with whom they already have a therapeutic relationship, or who is known to specialise in a field important to them (e.g. LGBTIQ+ family issues or surrogacy).</td>
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<td>It is recommended that the Act be amended to state that counselling in respect of surrogacy arrangements must be provided by an ‘appropriately qualified counsellor’. Consistent with Recommendation 35, the term ‘appropriately qualified counsellor’ should be defined in regulation or compliance standards as a person who is eligible for membership of ANZICA and has the relevant experience, skills and knowledge, including in respect of key legislative requirements, appropriate to the counselling undertaken. The Act should be amended to allow for the counselling required before parties enter into a surrogacy arrangement, and seek Patient Review Panel approval, to be provided either by a counsellor providing services on behalf of an ART provider or by an independent counsellor who meets the definition of ‘appropriately qualified counsellor’. In order to preserve impartiality and objectivity, the Act should state that counselling provided following the birth of a child and prior to the making of a parentage order must be undertaken by a person who meets the definition of an ‘appropriately qualified counsellor’ and who is independent of any ART provider or medical professional involved in the conception of the child born.</td>
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<td>Recommendation 67 Matters to be discussed in surrogacy counselling</td>
<td>Current legislative requirements mandate that the surrogate (and their partner, if any) and the intended parents receive counselling on matters prescribed in the Regulations (r. 9). Consideration of the matters for discussion in surrogacy counselling outlined in the NHMRC Ethical Guidelines and those required in other jurisdictions has led to identification of a number of additional matters that should be addressed.</td>
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<td>It is recommended that the regulations be amended such that, prior to parties entering into a surrogacy arrangement, counselling must be given in relation to all the matters currently prescribed under the Act, and: • the social and psychological implications of the surrogacy arrangement on the child and relevant persons</td>
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<td>• the surrogate’s motivation for entering into an arrangement with the intended parents</td>
<td>It is also considered appropriate to prescribe matters to be discussed in counselling following the birth of the child and prior to the making of any parentage orders (as proposed be mandated in Recommendation 65)</td>
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<td>• an assessment of the parties’ mental and physical health in the context of ability to cope with the stress of treatment, pregnancy and parenting</td>
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<td>• the need for the surrogate and their partner, if any, to provide free and informed consent to enter such an arrangement</td>
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<td>• the surrogate’s right to bodily autonomy and to make informed decisions about their medical treatment in respect of the pregnancy and birth</td>
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<td>• the potential significance of the gestational connection, the right of the child born to know the details of their birth and background, and the benefits of early disclosure</td>
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<td>• any implications where it is proposed that the surrogate will provide their own ovum for use within a surrogacy arrangement.</td>
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It is recommended that the required counselling following the birth of the child under a surrogacy arrangement and prior to the making of any parentage order should, at a minimum include discussion of each relevant person’s understanding of:

<p>| • the social and psychological implications of the making of a parentage order on the child and relevant persons |                                                                                         |
| • openness and honesty about the child’s birth parentage being for the wellbeing, and in the best interests, of the child |                                                                                         |
| • the care arrangements that the intended parent(s) have proposed for the child |                                                                                         |
| • expectations in respect of any future contact arrangements between the child and the surrogate |                                                                                         |
| • whether any consent to the parentage order is informed consent, freely and voluntarily given |                                                                                         |
| • whether the making of a parentage order would be for the wellbeing, and in the best interests, of the child. |                                                                                         |</p>
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| **Recommendation 68 Requirements for surrogacy arrangements**<br>It is recommended that the Act be amended to include requirements in respect of a surrogacy arrangement, namely that the arrangement:  
- is evidenced in writing and signed by the surrogate, and their partner, if any, and the intended parents  
- is entered into by the parties after they have obtained independent legal advice about the effect and implications of the arrangement  
- sets out the reimbursement of the surrogate’s costs associated with the pregnancy, subject to any subsequent revisions which may become necessary if costs change  
- protects the surrogate’s right to bodily autonomy in managing their pregnancy and the birth of the child  
- is clear about the parties’ expectations in respect of applying for a substitute parentage order  
- makes arrangements in the event that there is a medical emergency for the child prior to the making of a parentage order  
- includes provisions for dispute resolution  
- has been seen by the Patient Review Panel as part of the surrogacy application process.  |
| Unlike a number of other jurisdictions in Australia, there is currently no requirement in Victoria for a surrogacy arrangement to be set out in the form of a written document signed by all of the relevant parties. While the legislation interstate makes it clear that written surrogacy arrangements are not legally enforceable, except insofar as they relate to the reimbursement of the surrogate, they nevertheless offer a clear and detailed record of the parties’ expectations and intentions. |
| **Recommendation 69 Legal advice on surrogacy arrangements**<br>It is recommended that the content of legal advice provided to the parties to a surrogacy arrangement under the Act focus, at a minimum, on the:  
- legal effect of the proposed surrogacy arrangement  
- categories of costs recoverable by the surrogate under the arrangement  
- legal status of the child when born.  |
| Section 43 of the Act provides that before a surrogacy arrangement is entered into, the relevant parties must obtain information about the legal consequences of the arrangement. The PRP’s guidance note no. 1, *Approval of surrogacy arrangements in Victoria*, sets out matters that should be addressed in the legal advice.  
The Review considers there is value in these requirements being formalised in regulations and that the legislation clarify what is required for the PRP to be satisfied that appropriate legal advice has been received. |
### Recommendation

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<td><strong>Recommendation 70</strong> Regulatory guidance on altruistic surrogacy reimbursement&lt;br&gt;Further to Recommendation 14 of the Interim Report that proposed expanding the range of costs for which surrogates can be reimbursed, it is recommended that the Regulator publish guidance on reasonable surrogacy cost categories and amounts, to help surrogates and intended parents negotiate an appropriate basis for the reimbursement of costs. To the extent possible, it would be appropriate to harmonise these arrangements with similar provisions in Australian jurisdictions. The Regulator should publish guidance on the reasonable range of costs for the counselling and legal advice services which need to be satisfied by parties who enter into a surrogacy arrangement in Victoria.</td>
<td>Recommendation 14 of the Interim Report recommended that the 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. This was intended to better reflect the actual costs incurred by surrogates as a result of taking on that role.&lt;br&gt;Consistent with Recommendation 52, it is further proposed that the Regulator publish guidance on reasonable reimbursement categories and amounts for surrogates. This guidance will achieve similar goals to the guidance on donor reimbursement.</td>
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## Recommendation 71 Enforceability of surrogacy reimbursement

It is recommended that a provision be included in the Act to clarify that:

- a surrogacy arrangement is not enforceable
- an obligation under a surrogacy arrangement to pay or reimburse costs incurred by a surrogate is enforceable
- costs incurred should be paid or reimbursed where a surrogate has tried to become pregnant, irrespective of whether a child is ultimately born as a result of the surrogacy arrangement, and
- the surrogacy agreement may include an exception to the enforcement of costs, where the surrogate, without reasonable grounds, fails to relinquish the child to the intended parent(s) or fails to consent to the making of a parentage order in relation to the child.

Unlike a number of other jurisdictions, an obligation under a surrogacy arrangement to pay or reimburse expenses is currently not enforceable in Victoria, and the Review has heard examples where the intended parents have refused to pay for some or all of the agreed expenses incurred by a surrogate. This recommendation will better protect surrogates, without changing the fundamental legal status of surrogacy agreements.

## Recommendation 72 Right of surrogate to manage pregnancy

It is recommended that a provision be included in the Act to make it clear that a surrogate has the same rights to manage their pregnancy and the birth of the child as any other pregnant person. This principle prevails over anything that the parties to the surrogacy arrangement may have agreed, whether or not in writing.

In some circumstances, surrogates may feel pressured to undergo certain medical treatments or screening procedures requested by intended parents who may have strong views or preferences in respect of specific aspects of the pregnancy or birth. The proposed approach is consistent with law in Queensland and Tasmania and the approach proposed in a recent South Australian Law Reform Institute Review into surrogacy (2018).
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<td><strong>Recommendation 73</strong> Permitting advertising of altruistic surrogacy arrangements</td>
<td>Section 45 of the Act provides that it is 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. The provision relating to publication is interpreted strictly and poses a real barrier for those seeking to find a surrogate in Victoria.</td>
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- it is an offence for a person to enter into, or offer to enter into, a commercial surrogacy arrangement
- it is an offence for a person to induce, or seek to induce, another person to enter into a commercial surrogacy arrangement
- commercial brokerage of any surrogacy arrangement, whether commercial or altruistic, is prohibited
- advertising relating to a commercial surrogacy arrangement is prohibited
- advertising relating to an altruistic surrogacy arrangement is permitted, provided that it is consistent with guidelines developed and published by the Regulator
- the Regulator has the power to oversee advertising activity in Victoria relating to altruistic surrogacy arrangements, and to require the removal or amendment of material which is inconsistent with the advertising guidelines
- any decision by the Regulator in respect of a breach of these guidelines is reviewable.
Preparing for emerging issues in ART

ART is a rapidly changing field with some novel therapies that challenge social norms and have other ethical implications.

In considering, as required by the terms of reference, if Victoria’s regulatory framework for ART remains appropriate, the Review has identified a need to ensure that any proposed changes will be future-proofed, given the major, ethically challenging scientific developments that are likely to occur over the next 10 years.

The announcement of the world’s first gene-edited baby in late 2018 shocked the world. It has stimulated a global effort to establish global standards for the governance and oversight of human genome editing. Victoria is well positioned with its strengths in national medical and health research and the regulation of ART to play a leading role in the community debate on how to respond to these emerging challenges of reproductive medicine. Chapter 10 highlights some of the challenges that will emerge over the coming years and recommends progressing a national approach to responding to these challenges.

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<td><strong>Recommendation 74</strong> Review of laws on human embryo research and gene editing</td>
<td>The response to the emerging issue of human embryo research (and in particular germline gene editing) requires a nationally harmonised approach that takes into account community concerns and international developments, such as the recommendations of the World Health Organization Advisory Committee.</td>
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It is recommended that the Victorian Government propose to COAG Health Council a joint Commonwealth–state review of national laws related to human embryo research and human somatic and germline gene editing. This is particularly important for the *Prohibition of Human Cloning for Reproduction Act 2002* (Cth), given current developments in heritable gene editing. The review should establish an appropriate framework for the control of these technologies and related research that is consistent with community standards. The review should include consideration of the work of the World Health Organization Advisory Committee on Human Genome Editing over the next 18 months, and consider a governance framework for this field of scientific research and its application to clinical trials.
Ensuring the regulatory framework is appropriate and relevant to the current state of ART provision in Victoria

The final set of recommendations of this Review concern the design of the regulatory institutions for ART (Chapter 11). The aim of these recommendations is to design a more effective co-regulatory system in which the industry self-regulatory bodies, primarily the Fertility Society of Australia and the Reproductive Technology Accreditation Committee, can work in effective partnership with the state regulator to raise standards in this industry and improve the experience for patients, donors, surrogates, donor-conceived people and the families they all belong to.

The proposed approach recognises the role of RTAC in setting standards and accreditation requirements at the national level. It is intended that the Victorian regulator will adopt the RTAC Code of Practice as a compliance standard included as a condition of registration in Victoria, where necessary this will be supplemented by additional compliance standards to address identified areas of concern. The Victorian Regulator will not actively audit compliance with the compliance standards, and will accept RTAC accreditation and provider self-assessment of compliance with additional standards. The Victorian Regulator will have access to a graduated set of compliance and enforcement tools to be used as a last resort in response to ongoing areas of risk or non-compliance that are not adequately dealt with through the self-regulatory system.

The Review commissioned Deloitte Access Economics to undertake a preliminary impact assessment of the regulatory changes proposed in this report. This assessment found that the proposed changes appear well-targeted and are likely to drive a net positive impact. The assessment considered the impact of the proposed regulatory changes from a range of stakeholder perspectives including: ART users, donor conceived people, donors, ART providers and the Regulator.

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<td><strong>Recommendation 75 Compliance standards</strong></td>
<td>The Review has identified a need for strengthened requirements, greater clarity of standards or improved oversight in relation to a number of matters. Many of these areas are already subject to existing requirements (including under the National self-regulatory scheme and general health and non-health regulation). However, these requirements may not be sufficiently robust, of sufficient scope or subject to sufficient oversight and enforcement. The Review does not consider it desirable to add an additional layer of regulation that is inconsistent with existing requirements or unable to be changed to reflect changes made by other regulators. It is intended that proposed compliance standards be reviewed, revised or revoked over time if the risk they are designed to mitigate diminishes, or in response to changes in the broader regulatory environment (for example, if future revisions of the RTAC Code of Practice address some matters in a more comprehensive manner that removes the need for a specific additional requirements).</td>
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<td>It is recommended that provision be made for the Regulator to make compliance standards that articulate specific measures of compliance, in respect to a range of matters, which may include, but not be limited to:</td>
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<td>• clinical governance</td>
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<td>• complaint handling</td>
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<td>• public information and advertising – including public reporting of success rates and costs</td>
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<td>• patient information</td>
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<td>• counselling</td>
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<td>• reporting requirements.</td>
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<td>The Regulator should be required to keep compliance standards under review and</td>
<td>Inclusion of compliance standards within conditions of registration will provide a mechanism for the Regulator to oversee compliance with the standards, investigate potential failures to comply and to impose a range of regulatory responses (see Recommendation 78) depending on the nature and extent of the issue identified.</td>
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<td>consult with relevant stakeholders (including patients, the ART industry, professional organisations, RTAC and, where appropriate, certifying bodies under the RTAC scheme) in the making and review of the standards. It is recommended that compliance standards form part of the conditions of registration, with failure to comply grounds for a range of regulatory responses.</td>
<td>Where existing regulatory requirements exist the Regulator may adopt, with or without modification, these existing requirements within the compliance standards. This will ensure that ART providers are not subject to duplicative or inconsistent regulatory requirements. In these circumstances, the value of the compliance standard will be in clarifying the obligations of ART providers and allowing for effective oversight and, where necessary, enforcement activities.</td>
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<td>Recommendation 76 Conditions of registration</td>
<td>It is recommended that providers be subject to routine audit of compliance with the compliance standards. Providers will be required to declare that they comply prior to receiving registration in Victoria. Additional monitoring and audits may be imposed where the Regulator identifies potential failures of comply or concerns about practice.</td>
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<td>All conditions of registration of each ART provider, including all compliance standards, should be published on the Regulator’s website and the Regulator should report on the making and review of compliance standards to the Secretary of the Department of Health and Human Services. It is recommended that the RTAC Code of Practice, as modified by the Regulator, form part of the conditions of registration.</td>
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<td>It is recommended that the Regulator retain the power to impose conditions on registration in addition to those contained in compliance standards where necessary, in the public interest, to respond to specific risk relevant to an individual ART provider (or providers) or immediate or imminent risk relevant to all registered ART providers.</td>
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<td>It is recommended that, prior to registration in Victoria, an ART provider be required to:</td>
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<td>• achieve RTAC accreditation</td>
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<td>• undertake a self-assessment in order to make a declaration that the ART provider complies with all conditions of registration, including any relevant compliance standards made by the Regulator.</td>
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### Recommendation 77 Reporting to the Regulator of adverse events, treatment and outcome data

It is recommended that the Regulator develop compliance standards in relation to reporting requirements, including requirements for the reporting of adverse events, and the use of adjuvant therapies. The adverse events reported should include, but not be limited to, the reporting, by ART providers, of all diagnosed cases of OHSS (whether mild, moderate or severe) to the Regulator. The compliance standards should, as far as possible, align the timing and format for reporting to the Regulator with existing requirements for reporting to ANZARD, and form part of the conditions of registration.

To facilitate this, it is recommended that the requirement (s. 114 of the Act) for the Regulator to report to the Minister on the activities of the ART sector in Victoria be amended to allow for the report to be made by the end of the calendar year.

### Background / rationale

The Review has heard concerns about the extent to which data that is collected and reported is routinely used to identify service level risks and opportunities for improvement. There is also a duplicated system of data collection and reporting that adds to regulatory burden without improving public understanding of treatment outcomes. This recommendation aims to ensure that reporting requirements allow for appropriate information to be available to inform the Regulator while minimising duplication and burden for services. Amendments to the requirements for the regulator to report to the Minister will assist in aligning data reporting requirements with requirements to report to the national data collection held by ANZARD.
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| **Recommendation 78** Comprehensive, graduated compliance and enforcement powers  
It is recommended that provision be made for a more extensive and graduated set of compliance and enforcement powers to be available to the Regulator to respond to significant issues of non-compliance or where lower level compliance activities have been unsuccessful. This should include:  
• strengthened inspection and investigation powers  
• a power to impose periodic audits on ART providers to ensure compliance issues are remedied  
• powers to require undertakings or issue compliance notices  
• powers to impose monetary penalties and to suspend or withdraw registration both generally and/or for the provision of specific service types  
It is recommended that the Regulator be required to notify RTAC and the Secretary of the Department of Health and Human Services in relation to the use of these more significant powers and any serious breaches or instances of non-compliance. There should be a clear process for the initiation of prosecution under the Act. | The Act provides the Regulator with only very blunt instruments to respond to more significant instances of non-compliance of ART providers in Victoria. This recommendation aims to ensure the Regulator has access to a more adequate suite of graduated compliance tools to support improvement and proportionately respond to risk.  
It is expected that use of the more significant powers would be limited to circumstances in which the Regulator is satisfied there is a significant risk to the health and safety of an individual or individuals, or where there is evidence of a significant breach of the Act or registration conditions, or where lower level compliance activities have failed to remedy identified issues.  
The use of any of these powers should be subject to appropriate procedural fairness requirements and review. |
| **Recommendation 79** Accountability and administrative review of the Regulator  
It is recommended that specific provision be made for review of the administrative decisions of the Regulator.  
It is recommended that the Regulator be required to provide an annual report to the Minister by 30 September each year on the performance of the Regulator’s statutory functions, including the use of significant enforcement or compliance powers. | The Review has heard concerns that the basis for administrative decisions under the Act are not always clear and that there is no capacity for appeal in relation to a number of administrative decisions made by VARTA.  
Under s. 114 of the Act, VARTA is required to report annually to the Minister on the activities of the sector. VARTA currently fulfils this obligation within an annual report that also provides an overview of the organisation’s activities and finances. The Act currently contains no specific requirements for reporting on the exercises of VARTA’s statutory functions. |
| **Recommendation 80** Institutional design of the state Regulator  
It is recommended that the Victorian Government identifies and resources a Regulator that: | The Review has not formed a view, and is not making any recommendations, as to which entity or entities should take on the regulatory functions in relation to ART in Victoria. The Review has, however, identified a number of desirable features of the |
<table>
<thead>
<tr>
<th>Recommendation</th>
<th>Background / rationale</th>
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<tbody>
<tr>
<td>• has clarity of role and purpose and a complementary balance of functions</td>
<td>Regulator which may inform government’s decision making on this issue.</td>
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<tr>
<td>• is knowledgeable about practices relevant to the provision of ART and related science</td>
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<td>• is capable of engaging the community in dialogue on ethical, social, medical and scientific issues</td>
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<td>• has strong regulatory capacity</td>
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<td>• is able to command the confidence of the sector and the public.</td>
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Implementation

In total, the Review has proposed 80 recommendations in its Interim and Final Report. The Review considers that this set of reforms may be best implemented over a number of years. They will require an overhaul of Victoria's ART legislation, and for the government to consider the best approach to that legislative change. They will also involve complex change and communication processes for the industry, the public and for regulators. They will require additional public spending on the high priority initiatives – public fertility services and the public sperm and egg bank – that will have the most direct impact on improving access and affordability for patients. They will also involve a significant reprioritisation of resources and changes in approach across Victorian Government regulators of ART. The focus of this reprioritisation should be reducing red tape in areas of ineffective regulation in order to free up resources for a collaborative effort with other health and industry regulators to set higher standards of person-centred care in ART.

While some of the functions and activities proposed for the regulator of ART will need to be actioned in the short to medium term, others may be progressed as part of a program of work over a number of years. Government should work with the Regulator to determine this work program to ensure that prioritisation meets government’s expectations.
1. Changing standards for assisted reproductive treatment

The year 2018 marked the 40th anniversary of the world’s first in vitro fertilisation (IVF) baby – Louise Brown in the UK – and the 38th anniversary of Australia’s first IVF child – Candice Reed, born in Victoria. Over that time, assisted reproductive treatment (ART) has become an essential medical service for many Victorians forming a family. One in 20 Victorian children is born through some form of ART. One in 12 children born to mothers aged over 35 is conceived through IVF or similar procedures. In the last year, approximately 13,000 people used Victorian ART services. Over 2,150 used donation services, and more than 4,450 clinical pregnancies were achieved. In 2016–17 (the year for which the most recent live birth data is available) 3,725 babies were born with the support of Victoria’s fertility clinics. Sadly, also over decades, many tens of thousands of patients have not been successful in their attempts to have a child, despite the best efforts of the intended parents, and the donors, surrogates, clinicians and scientists who supported them.

2018 also marked the 10th anniversary of Victoria’s ART legislation, the Assisted Reproductive Treatment Act 2008. This Act is the most recent in Victoria’s long-standing record of regulating ART. Victoria was among the early jurisdictions around the world to adopt state regulation of ART. On advice from Professor Louis Waller and other distinguished local experts, Victoria framed legislation in the mid-1980s to govern the distinct clinical, scientific, legal and ethical challenges of ART. Many of the fundamental principles of this framework have endured, such as the prevention of commercial exploitation of human reproductive capacities, and the protection of the interests of the child to be born. Other aspects of this regulatory framework have changed over time in response to the evolution of ART services and social attitudes towards these treatments.

Over the last 10 years, three major changes have occurred in Victoria’s regulatory framework for ART. First, legal access to diverse families was granted through the removal of discriminatory provisions of the Act that restricted access to IVF to married women, and through the introduction of legal arrangements for altruistic surrogacy. As a result of these changes, and the recent introduction of marriage equality, many thousands of single women and LGBTIQ+ people have had their families affirmed and supported. Second, Victoria significantly reduced the role and powers of the state regulator, and established a deemed registration scheme that effectively adopted the national self-regulatory code of practice for ART without question or change. Third, Victoria has progressively extended right-to-know legislation to donor-conceived individuals and donors, and has arguably gone further than any other jurisdiction in the world to promote access to information and connections between donor-conceived people and their biological donors.

Despite these changes, one key characteristic of ART services has remained the same in Victoria and indeed in Australia: ART is delivered almost exclusively by private health services. While there are public subsidies provided through Medicare, public health services play little to no role in the provision of ART. The state government plays a minor role in public education on fertility issues, despite extensive involvement in other aspects of reproductive health. Even in the area of regulation, the government plays a restricted role. The state regulator’s monitoring of the quality and safety of ART services is constrained by the model of regulated self-regulation that applies in this field. This makes ART unusual in the health industry. Despite relating to such a sensitive aspect of human experience (the conception of children and the grief of infertility), care in this field is predominantly provided by self-regulated commercial operators. The commercial character of these firms has intensified over the last 10 years, with firms being listed on the stock market, some firms being purchased by major overseas venture capital consortia, and new firms entering the market and promoting their new services intensively. While many aspects of these commercial operations support the delivery of high-
quality care, many in the industry have raised concerns about whether this system is the best approach to patient care.

Indeed, many families undergoing treatment have begun to question whether these commercial arrangements really put people at the centre of fertility care. The last 10 years have seen more and more patients express concerns with the costs, disappointments and emotional ordeals of IVF treatment. Out-of-pocket costs for IVF treatment are high, and compounded by multiple cycles of treatment and additional supplementary services, both in ART clinics (such as genetic screening) and in complementary services (such as acupuncture), which sometimes lack clear evidence of effectiveness. Success rates are hard to calculate, and many people proceed with treatment despite a very low statistical likelihood of having a baby. In 2016, an Australian Competition and Consumer Commission (ACCC) investigation into how the ART industry reported and advertised success rates has led to some improvements. Nonetheless, many patients are unsure about their real prospects of having a child after treatment. All ART patients need to wrestle with the ups and downs of the treatment journey, and the possible frustration or failure of what some see as a fundamental life purpose – forming a family. Many experience grief after repeated failures, miscarriages and delays. All patients want better support for their physical, emotional and mental health needs, and people born through ART procedures, especially donor-conceived individuals, also want long-term support for the challenges they encounter in coming to terms with their family history.

These concerns of patients have been voiced increasingly over time, and been amplified by more public figures, such as journalist Virginia Trioli or former netball champion Liz Ellis, sharing their experiences of ART. Within the media and the public conversation on health issues, the ART industry has not responded as well as it could to these concerns. Despite its proud world-leading record of physical safety in IVF treatment and innovation in science and clinical methods, patients and individuals born through ART procedures are calling on the industry to raise its standards. These concerns are at the heart of this Review.

1.1. The approach of this Review

The Victorian Government established the Review in April 2018. The detailed terms of reference for the Review are included in Appendix 1. Broadly, the Review was tasked to assess whether:

- the regulatory framework for ART creates or enables unnecessary barriers to access – with a focus on affordability and on issues for LGBTIQ+ people
- consumers have access to adequate information to facilitate informed choices
- the regulatory framework remains appropriate given the changing nature of ART services.

The Review has interpreted this brief broadly. It has not adopted a narrow interpretation of the regulatory framework, but rather has looked at how regulation should contribute to a broader system for the delivery of ART services. The Review has made proposals for reframing Victorian legislation, regulation, public health services and community education relevant to ART. To respond well to the broad challenge of putting people at the centre of fertility care requires both more responsive regulation and better services designed around the diverse needs of all people who use ART to create a family.

Still, a number of sensitive issues were excluded from the terms of reference of the Review – notably recent legislative changes to provide donor-conceived Victorians access to available identifying information about their donors, and requirements for people undergoing treatment to first be screened through police and child protection checks. Nonetheless, many members of the community raised these specific issues during the review’s public consultations. While the Review has not made recommendations on these issues, it has reported back on community concerns.
1.2. Interim Report

As requested in its terms of reference, the Review completed an Interim Report in October 2018. This Interim Report was based on extensive public consultation including with clinics, practitioners, lawyers, regulators, parents and intended parents, donors, surrogates, and donor-conceived people. The recommendations of the Interim Report are included in the summary of recommendations in this Final Report so that all the recommendations of the Review can be considered as a package.

The recommendations of the Interim Report related especially to the Review’s 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. These recommendations would remove discriminatory or outdated provisions from the Act. They would enable reporting of concerns within the industry and information sharing between regulators. They proposed removing the current legislative restriction that prevents fertility nurses from performing artificial insemination procedures, as they do in other states and did in Victoria before the 2008 Act. Recommendations were also made to make the language of the Act gender neutral, to remove unintended discrimination resulting in barriers to access for some married women and members of the LGBTIQ+ community, and to improve reimbursement for surrogates.

The government indicated it will respond to the recommendations of the Interim Report after receiving the Final Report, and has also made some policy announcements in response to the Review. These include:

- an election commitment of $32 million to establish public IVF services, including conducting a full business case for the model for these services
- the establishment of a Health Complaints Commissioner inquiry into unsafe and unethical practices by IVF and ART providers.

The Interim Report also flagged the key proposals to be considered in the Final Report. These proposals were:

- working towards a more transparent oversight of quality and safety in ART
- the need for more effective co-regulatory arrangements
- exploring opportunities for the public provision of ART services
- establishing a Victorian sperm and egg bank
- providing better support services to connect patients, donors and surrogates
- improving information available to people seeking treatments
- enhancing patient-centred care and counselling.

Following the re-election of the Victorian Government, the Department of Health and Human Services was tasked with undertaking a detailed business case for the public provision of ART, in response to the government’s election commitment to establish public IVF services. The Review has consulted with the department on how the Review can best fulfil its terms of reference – specifically concerning access, affordability and the changing nature of the ART market – given this commitment to the establishment of public IVF services.

The Review determined it would provide advice to the Government on key policy and service design issues to consider in relation to establishing public IVF services and developing a longer-term framework for the design of public fertility services.
**A note on language**

In its Reports, the Review has used gender-neutral language, and specific terms respectful of the diversity of the community. When not referencing or quoting legislation, regulation or research, the Review has adopted the following approach to key terms:

**LGBTIQ+, LGBTQ+:** 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. The Review has chosen to include the Q+ symbol at the end of the acronym to represent any additional identities that may fall under this banner. Additionally, where appropriate, the Review has removed the I from the acronym, to capture barriers that face the broader LGBTQ+ population, but may not be relevant to some people with intersex variations (Jones 2016).

**People with intersex variations:** The Review uses the term ‘people with intersex variations’, which is understood to be non-stigmatising, person-first and consistent with the language many people use to describe themselves (Department of Health and Human Services 2018b).

**Trans and gender diverse:** This Report uses ‘trans and gender diverse’ as an umbrella term to refer to those people whose gender identity is not typically associated with the administrative sex category they were assigned at birth (Department of Health 2014).

**Aboriginal:** 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.

**Person-centred care:** While the terms patient-centred and person-centred are used interchangeably, the Review has adopted the term “person-centred care” to include the full range of people involved in ART, including intended parents, donors, surrogates, and persons born as a result of ART.

**Intended parents:** The Review uses ‘intended parents’, particularly in relation to surrogacy, to avoid any inadvertent association with a commercial transaction.

**Surrogate:** The Review uses the term surrogate, rather than surrogate mother or birth mother, to acknowledge that some surrogates do not identify as a mother, or a woman.

### 1.3. Additional consultation

Following the release of the Interim Report, the Review undertook targeted consultation with ART providers, clinicians, counsellors, experts, parents and intended parents, donors, surrogates, donor-conceived people and concerned community groups. These consultations focused on the key proposals outlined at the end of the Interim Report.

The Review held four stakeholder workshops with a mix of stakeholders, including service users, ART providers, professional groups, regulators and donor-conceived people. These workshops were informed by issues papers that included draft recommendations. Participants at the roundtables were invited to comment on the draft recommendations set out in these issues papers. The topics of the issues papers and stakeholder workshops were:

- ‘Access to gametes’ (roundtable, 5 February 2019)
- ‘Public provision of ART services’ (roundtable, 12 February 2019)
- ‘Person-centred care, information and support’ (roundtable, 26 February 2019)
- ‘The regulatory framework for ART’ (roundtable, 19 March 2019)
The Review commissioned Deloitte Access Economics to make a preliminary assessment of the impact of proposed changes to regulation considered by the Review, and to undertake a feasibility assessment of the proposal to establish a sperm and egg bank. Deloitte Access Economics consulted with Victorian clinics and the Victorian Assisted Reproductive Treatment Authority (VARTA) in preparing these assessments. The summary findings of these assessments are included in this Final Report, and the detailed assessments have been provided to the Department of Health and Human Services.

The Review also held a public forum for service users of ART, including current and past patients, donors, surrogates and donor-conceived individuals. Representatives of clinics, regulators or health practitioner organisations did not attend this forum. This forum was held on Saturday 30 March at the Hawthorn Arts Centre and childcare was provided to support participation from parents. This forum commented on an outline of major proposals set out in the issues papers, as well as responses to the Interim Report. In addition to this specific forum, the Review consulted with the national consumer advocacy organisations, Access Australia and Surrogacy Australia, and several smaller organisations representing key consumer groups, including LGBTIQ+, culturally and linguistically diverse, Aboriginal and disability groups.

The Review has also consulted with the leading national representatives of the fertility industry and national self-regulatory bodies. The Review would like to thank the Fertility Society of Australia and the Reproductive Technology Accreditation Committee for their contribution to this Victorian review. The Review has also received advice from the Australian and New Zealand Infertility Counsellors Association and the Royal Australian and New Zealand College of Obstetricians and Gynaecologists.

In addition, the Review consulted with a number of individual clinics, public health services, leading researchers, clinicians, service users, community groups and government agencies. In particular, the Review would like to thank Rainbow Families for their important contributions to the Review. The Review also consulted with Professor Sonia Allen, who completed her report on the Western Australian legislative and regulatory framework for ART in January 2019, and who also completed a review of the South Australian Assisted Reproductive Treatment Act in 2017.

The Review received extensive advice from the Department of Health and Human Services, and from VARTA, who have provided advice on the many complex issues in this field and assisted the Review in arranging public consultations with donors, patients and donor-conceived people.

Finally, the Review is incredibly grateful to the many parents, intended parents, donors, surrogates and donor-conceived people who took the time and energy to share their often highly personal experiences and their views.

Overall, extensive consultation underpins this Review, and supports the conclusions of both the Interim Report and the Final Report. These consultations suggest there is much support among patients, service users, clinicians, the industry and regulators for more person-centred fertility services, and for regulation that is more responsive to the contemporary social and medical context for ART.

1.4. Current regulation of ART

The current ART regulatory framework in Victoria is co-regulatory. The *Assisted Reproductive Treatments Act 2008* (the Act) and the *Assisted Reproductive Treatment Regulations 2009* (the Regulations) provide for the registration of ART providers in this state, and oversight by VARTA. This is combined with a national self-regulatory accreditation model established by the Fertility Society of
Australia (FSA), and implemented through its Reproductive Technology Accreditation Committee subcommittee (RTAC).

### 1.4.1. VARTA

Registration of ART providers in Victoria is through a ‘deemed registration’ scheme. Section 74 of the Act provides that if VARTA receives an application from a person who holds RTAC accreditation (see below), the Authority must grant the person’s application. 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 in Victoria, and has used this power to impose additional conditions on two providers in relation to specific incidents.

In addition to registration, VARTA’s functions, set out in s. 100 of the Act, include:

- 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
- public education about treatment procedures and the best interests of children born as a result of treatment
- management of the donor conception registers, and the provision of counselling support and advice to people applying for access to information held by 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
- any other functions conferred on it by or under the Act or any other Act.

As noted in the Interim Report, the introduction of the Act and replacement of the then regulator – the Infertility Treatment Authority (the ITA) – with VARTA in 2010, significantly changed the focus of regulation and the role of the regulator.

Some regulatory oversight functions and powers that had been exercised by the ITA under the previous ART legislation were removed. This included a shift away from the initial assessment of application for licences by clinics and from approving practitioners working in those clinics. The intent of the changes was to reduce the regulatory burden on ART providers, with VARTA to ‘take on a more focused role that expands its responsibility for community consultation and community education on matters relevant to assisted reproductive treatments’ (Second Reading Speech as recorded in Hansard, 10 October 2008). The role of VARTA was envisaged to shift focus to the development of resources to ‘support parents who have children born through the use of donated gametes to tell their children of their genetic origin’ and resources for people who use self-insemination to conceive. VARTA was also to have an expanded role in promoting research into the causes and prevention of infertility.

These changes took effect at the same time as significant changes were occurring in the ART industry. Whereas clinics were once majority clinician owned and run, the last decade has seen non-clinician investors taking controlling shares of IVF clinics. Over this time, a number of companies providing ART services have also listed on the Australian Stock Exchange. These developments have
seen an increasingly corporate and competitive approach to service provision and in recent years new entrants to the market in Victoria have increased competition at both the low-cost and premium ends of the market. Unlike most other fields of healthcare provision, there is little competition with these private providers from public health services.

1.4.2. The national self-regulation scheme

Consideration of the Victorian regulatory framework for ART must recognise Commonwealth funding arrangements require all ART services to be subject to the national self-regulatory accreditation model established by the FSA, which is the peak industry body representing scientists, doctors, researchers, nurses, and counsellors in reproductive medicine in Australia and New Zealand. Under s. 11 of the *Research Involving Human Embryos Act 2002* (Cth), accreditation of ART clinics by RTAC (a subcommittee of the FSA) is required for ART clinical practice nationally, and is a prerequisite for receiving Medicare rebates. Membership of RTAC comprises:

- Chairperson (appointed by FSA board)
- Deputy Chairperson (appointed by FSA board)
- Nominee of the Medical Directors Subcommittee of the FSA
- Nominee of the Australian and New Zealand Infertility Counsellors Association (ANZICA)
- Nominee of Fertility Nurses of Australasia (FNA)
- Nominee of Scientists in Reproductive Technology (SIRT)
- Nominee of Access Australia or Fertility NZ (fertility consumer organisations).

Accreditation by RTAC requires ART clinics to comply with:

- the *Ethical guidelines on the use of assisted reproductive technology in clinical practice and research* (the Ethical Guidelines) developed by the National Health and Medical Research Council (NHMRC)
- the RTAC Code of Practice.

As noted above, under s. 74 of the Victorian Act, VARTA must, on application, grant registration in Victoria to a person who holds RTAC accreditation.

The NHMRC, through the work of its principal committee, the Australian Health Ethics Committee (AHEC) has developed and periodically reviews the Ethical Guidelines. These guidelines provide an overarching framework for the conduct of ART in both clinical practice and research and are intended to be read in conjunction with relevant federal and state legislation. They are intended to be primarily for the use of primarily for ART clinicians, clinic nurses, embryologists, counsellors and administrators and researchers.

Review of the guidelines involves a publicly advertised consultation process. Approval of amendments is granted by the Australian Health Ethics Committee. The guidelines were revised in 2017.

RTAC is responsible for setting standards through the Code of Practice. The stated aims of the Code of Practice are to:

- promote continuous improvement in the quality of care offered to people accessing fertility treatment
- provide a framework and set criteria for the auditing process that leads to accreditation of organisations that deliver fertility services
- ensure the auditing process is carried out in an independent, non-adversarial and constructive manner.
The Code of Practice covers requirements for establishing, renaming or closing an ART unit, and defines two sets of criteria (a) critical criteria and (b) good practice criteria (as shown in the table below) against which compliance is reviewed.

**Table 1: RTAC Code of Practice – critical and good practice criteria**

<table>
<thead>
<tr>
<th>Critical criteria</th>
<th>Good practice criteria</th>
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<tr>
<td>Compliance with statutory and regulatory requirements</td>
<td>Quality management system</td>
</tr>
<tr>
<td>Personnel – access to key competent staff (medical, scientific, nursing, and counselling)</td>
<td>Stakeholder feedback (including complaints management)</td>
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<tr>
<td>Disaster management</td>
<td>Medical management (meeting reproductive health needs)</td>
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<tr>
<td>Valid consent</td>
<td>Information (patient and public information)</td>
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<tr>
<td>Management of infection risk</td>
<td>Medication management</td>
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<tr>
<td>Identification and traceability (of gametes, embryos and patients)</td>
<td>Emergency care</td>
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<tr>
<td>Donor and surrogacy requirements</td>
<td>Ovarian hyperstimulation syndrome</td>
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<td>Cryo storage of gametes and embryos</td>
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<tr>
<td>Adverse events</td>
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<td>Multiple pregnancy</td>
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<td>Data monitoring</td>
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<td>Data reporting</td>
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Under the RTAC terms of reference, there is a requirement to review the Code of Practice every three years. The process involves targeted stakeholder consultations. Revisions are approved by the FSA board. The FSA board comprises representatives of the clinics, professions, consumer groups and specific interest groups of the FSA – the Scientist in Reproductive Technology, the Fertility Nurses of Australasia, the Australian and New Zealand Infertility Counsellors Association, and the IVF Directors Group.

An ART Unit’s compliance with the RTAC Code of Practice is assessed via an audit undertaken by an independent certification body that is approved by the Joint Accreditation System of Australia and New Zealand (JAS-ANZ).

Audits, which include site visits to all units, are conducted annually with each audit covering all of the critical criteria and one-third of the good practice criteria set out in the RTAC Code of Practice.

### 1.4.3. State and Commonwealth agency regulation relevant to ART

As outlined in the Interim Report and illustrated in the diagram in Appendix 2, a number of state and commonwealth regulatory agencies (or agencies with quasi regulatory roles) have functions relevant to the provision of ART in Victoria. These include:

- the PRP – responsible under the Act for considering applications by people who wish to access ART where the Act requires they have permission to do so
• the Department of Health and Human Services – regulation of private health services under the Health Services Act 1988.² Under the Health Services Act 1988 and associated Regulations, oocyte collection may only occur within a registered private health service establishment (day procedure centre). While ART providers will access day procedure centres for these procedures, only two providers currently operate their own day-procedure centres to which these regulations would apply
• Australian Health Practitioner Regulation Agency and the National boards – the regulation of health professionals under the National Registration and Accreditation Scheme.³ AHPRA standards and oversight will apply to medical practitioners, nurses or psychologists who may be involved in ART service provision. However, they do not apply to other professionals (for example social workers or embryologists) working in clinics nor to the provider organisation as a whole
• Health Complaints Commissioner – administration of the Victorian health complaints scheme.⁴ The Health Complaints Commissioner may receive complaints and undertake investigations into a wide range of health service providers, including providers of ART, individual health service providers within clinics, and unregistered health practitioners
• Australian Competition and Consumer Commission (ACCC) and Consumer Affairs Victoria – the regulation of businesses, service providers and advertisers.⁵ This includes providers of ART
• National Health and Medical Research Council – administration of legislation related to the use of human tissue, research involving human embryos and prohibition of human cloning for reproduction.⁶
• National Association Testing Authorities (NATA), Australia – standards and compliance in relation to laboratory services
• Therapeutic Goods Administration – regulation of drugs and other therapeutic goods.⁷

Appendix 3 contains more detail on the function and coverage of these agencies in respect of ART services.

1.5. Government commitment to public IVF services

Also of relevance to the consideration of ART regulation in Victoria is the commitment made by the Victorian Government, in the lead up to the November 2018 state election, to establish public fertility services to commence in 2021. Any changes to the regulatory model will need to ensure there is a consistent framework applied to both public and private entities, and that the Regulator’s decision-

² Under the Health Services (Health Service Establishment) Regulations 2013, oocyte retrieval must be carried out in a registered health services establishment
³ Health Practitioner Regulation National Law (Victoria) 2009
⁴ Health Complaints Act 2016
⁵ Under the Competition and Consumer Act 2010 (Cth), in particular, the Australian Consumer Law.
⁶ The Human Tissue Act 1982 prohibits unauthorised buying or selling of human tissue, this includes eggs, sperm and embryos. The Research Involving Human Embryos Act 2008 regulates the use of embryos for research purposes and licensing of embryo research. The Prohibition of Human Cloning for Reproduction Act 2008, outlines practices that are completely prohibited in Victoria (such as commercial trading in human eggs, human sperm or human embryos); and that are prohibited unless authorised by a licence. The two Victorian Acts that regulate assisted reproductive treatment research mirror Commonwealth Acts of the same name. These mirror acts were introduced at the same time as the revised Assisted Reproductive Treatment 2008 Act, and reflected differences in roles between the Infertility Treatment Authority and VARTA.
⁷ Therapeutic Goods Act 1989 (Cth)
making is sector neutral, independent and accountable. This is to ensure there is a level playing field between public and private providers of ART services.

1.6. Strengthened focus on health regulation in Victoria

In recent years, there have been broader changes to the regulation of health and human services in Victoria, with a renewed focus on improving quality and safety across all fields of health in both the public and private sectors.

There has been an increased focus on regulatory practice and an understanding of the importance of effective regulation. Most notably, Targeting zero: supporting the Victorian hospital system to eliminate avoidable harm and strengthen quality of care, the report of the review of hospital safety and quality assurance in Victoria, highlighted the significant risks of inadequate oversight of safety and quality in health services. It has led to significant change across the Victorian health system, including amendments to key health services legislation to:

- place safety and quality improvement at the core of priorities for health services across the public and private sector
- improve service governance
- make better use of information and data
- strengthen the focus on patient’s experience of care and to increase the effectiveness of service oversight.

The government has also established Safer Care Victoria (SCV), the state’s healthcare quality and safety improvement agency and the Victorian Agency for Health Information (VAHI), with responsibility for monitoring and reporting on public and private hospitals and health services.

1.7. Changes to the social and medical context for ART

From its inception in the 1980s, regulation of ART has been shaped around how the community responds to the risks and challenges posed by the specific medical and social context of ART. Uniquely among health services, this form of treatment leads to the creation of human lives, and a host of ethical, social, familial, scientific, medical and legal issues related to that singular characteristic.

The original committee that examined the introduction of IVF in Victoria was established in 1982 and chaired by Professor Louis Waller. It was asked:

To consider whether the process of in vitro fertilization (IVF) should be conducted in Victoria and, if so, the procedures and guidelines that should be implemented in respect of such processes in legislative form or otherwise. In relation to this issue, particular consideration should be given to: whether the process and practice of IVF (whereby conception occurs outside normal physiological, emotional and social conditions and relationships) give rise to undesirable social and moral practices.

Since the 1980s, IVF and ART has grown to become an essential health service for thousands of Victorians, and acceptance of these technologies is widespread. There remains only very limited religious opposition to ART procedures, and there is widespread social acceptance of the many paths people can take to form families that suit their unique social and medical circumstances. Over the last
10 years in particular, three broad changes have reshaped the context for the regulatory framework for ART in Victoria:

- social changes affecting demand for ART services and the expectations of families
- scientific and medical changes that are reshaping ART practices and technologies
- market changes affecting the supply of ART services and the incentives of practitioners.

Aspects of these changes were discussed in some detail in the Interim Report and public consultation paper, and will be discussed further in later chapters of this Final Report. However, it is important to emphasise the big picture of how these changes in society, science and technology, and the market have created pressures on the current regulatory system. These pressures have created new challenges for regulators, providers, patients and governments, and the regulatory system has not responded effectively to these challenges.

### 1.7.1. Social changes

Social changes over the last 10 years have increased demand for ART, increased acceptance within the community of these forms of treatment, and led to increasingly diverse patterns of creating families. There has been a gradual increase in the average maternal age at birth, and significant pressure, especially for working women, to balance career and children, which contributes to demand for ART services. This included new services such as elective egg freezing, which was considered experimental at the time of the 2008 Act. Similarly, the removal of discriminatory provisions and growing acceptance of both same-sex couples and single parents by choice has led to growth in demand for ART services, especially for donor treatments, and diversity of the patients presenting to clinics.

Unlike 2008, there is little if any organised opposition to the use of IVF treatments as such, nor to the use of these treatments by single women and same-sex couples. This acceptance is reflected in more acceptance of surrogacy and more states legalising altruistic surrogacy.

There is also generally greater openness in community discussions of fertility issues, with extensive online support groups and much discussion of IVF and other treatments in the media. These discussions are informed by generally higher expectations from patients and families concerning the quality of healthcare and support, including both physical and mental health. Over the last 10 years, the experiences of adult donor-conceived people have been increasingly included in the discourse, stimulated by the growing access to one’s genetic information, whether obtained through medical testing or DNA tests offered through genealogy services, such as ancestry.com.

In summary, there is no longer a major moral debate about the permissibility of IVF in the Victorian community, and this debate has been replaced by a broader conversation about the quality of the experience for all involved – patients, intended parents, donors, surrogates, families, and donor-conceived people.

### 1.7.2. Scientific, medical and technological changes

Notwithstanding these changes in community attitudes to ART, there are still significant ethical issues concerning scientific and medical advances in the industry. ART is a field of rapid developments, and increasingly needs to be considered within a broader context of technological and practice change in healthcare. Reframing Victoria's regulatory framework will need to consider these major changes in scientific, technological and medical practice.
Over the last 10 years, there have been major technical advances, the emergence of potentially transformative technologies on the horizon, and the consolidation of new approaches to evidence-based care in both ART and general healthcare. Technologies that have become mainstream practice since the last Act include egg freezing, greater successful use of single embryo transfer, widespread genetic testing, and the use of artificial intelligence in embryo selection. The evidence base for treatments has significantly expanded, and in 2017 the NHMRC published the first revision of its Ethical Guidelines for ART since 2000. In 2008, the technique of CRISPR-Cas9 for gene editing had not even been invented, and in 2018 the world’s first gene-edited baby was born through the use of this technique in conjunction with ART. The challenges and opportunities created by these new technologies and methods affect all areas of healthcare, not only ART.

More broadly, there is a growing attention to quality, safety and patient experience in healthcare. There is greater scrutiny of over-treatment or inappropriate treatments, including through the systematic reviews undertaken by the Commonwealth Government’s Taskforce on the Medicare Benefits Scheme. There is more attention to the provision of person-centred care, to managing variation in care, and to reducing avoidable harm. There is also continuing growth in the awareness of mental health for all patients, and the need to integrate physical and mental healthcare.

In some respects, the regulatory framework established in 2008 sought to regulate ART just like any other medical treatment. The last 10 years have highlighted ongoing technical advances that point to unique risks and special characteristics of reproductive medicine. But they have also led to a major change in how both the community and professional groups expect medical treatment to be overseen and regulated. It is no longer adequate to expect the public simply to trust doctors alone to regulate themselves and the quality of care. Both public and government expectations are now higher. What is assumed now about how any medical treatment is regulated is different to the assumptions of 2008. It is essential that both Victoria’s regulatory framework for ART and the national self-regulatory bodies adapt to these new expectations.

1.7.3. Market changes

The terms of reference for the Review drew attention to the evolution of the market for ART in Victoria. There have been significant market developments in the last 10 years that require adjustments to the regulatory framework.

The industry has grown and now generates revenues of approximately $550 million a year in Australia, which is predicted to rise to $630 million by 2022. Around 30 per cent of treatment cycles in Australia take place in Victoria. The rates of treatment in Victoria are higher than other states, and it is in some respects a more mature and established market. The range of services offered by the industry has expanded with increases in the use of intracytoplasmic sperm injection (ICSI), genetic testing and elective egg freezing over the last 10 years.

However, as noted in the Interim Report, global figures on Australian revenue growth for this industry need to be compared to the data published by Medicare on the population rate of services in Victoria. MBS data for Victoria shows that the sector grew considerably from the 1990s to 2010. However, since 2010 there has been little change in the per capita rate of MBS-rebateable ART services in Victoria. The revenue growth that has occurred is largely related to population growth and out-of-pocket payments.

The financial growth has all occurred in the private sector, during a time when there have been major changes in the oversight and management of quality in public health services. Unlike other parts of the health system there is not a significant role for public health services in the provision of fertility services, although this is common in many other jurisdictions. It is reliant, however, on uncapped
public subsidies through Medicare and significant out-of-pocket payments by patients. The last major change to the regime of public subsidies occurred in 2010 with changes to the rules for the Medicare Safety Net. There are, however, proposals being considered by the MBS Taskforce that may introduce some caps on rebates, and influence the future market. As noted in the Interim Report, the ART industry in Victoria appears to have plateaued in expanding access to infertility treatments. Significant increases in demand are unlikely to occur without substantial changes in technology or the price of services or other initiatives, such as public health services, that would facilitate access to patients who cannot afford the high cost of IVF.

The character of the companies providing ART has changed with increased commercialisation, corporatisation and competition in this sector. Both Melbourne IVF and Monash IVF have become publicly listed companies, and now have both national and some international operations. There has been significant venture capital investment in the industry, with Genea and City Fertility recently being purchased by international consortia. Connections with innovative biotechnology firms have developed, significantly in the application of artificial intelligence to embryo selection. At the same time, smaller firms with distinctly different offerings have entered the market, with Primary IVF and Number One Fertility taking a significant share of the market in a few years. The large firms have diversified their offerings, with a number of low-cost services being delivered. These changes have brought benefits and risks to patients, changes in the culture of the sector, and some challenges in reordering the relationships between companies, clinicians, scientists and consumers. Fundamentally however, compared with 2008, Victoria today has a more complex, diverse ART industry, and the regulatory framework needs to adapt to these changes.

Finally, the market has also become more involved with overseas suppliers of ART services and gametes. As noted above, several firms are owned by major international consortia, and some major firms have operations overseas. International franchises have announced plans to establish elective egg freezing services in Victoria. A small number of Victorians travel overseas for surrogacy, and a large, but unquantified, number travel overseas for ART. A key driver of this use of overseas services is the shortage of donated sperm and eggs in Victoria. Victorian ART providers have also become more reliant on overseas commercial suppliers of gametes, such as The World Egg Bank, which operate in quite different regulatory regimes. The current regulatory framework is not coping well with the shortage of donated gametes and increased exposure to overseas suppliers of ART services and gametes. Significant changes are required to respond more effectively to these problems.

Overall these changes in society, in medical practice and in the market have led to a new set of risks, harms and community concerns with ART. Neither the regulatory framework nor the broader system of treatment has responded effectively. There need to be changes in both the regulatory framework, and in the provision of public fertility services. The Victorian Government is ideally positioned to play a leadership role in bringing about these changes that together will substantially raise the bar for this important industry and deliver better outcomes for patients and for Victorian families.

These changes highlight gaps in the policy, legislation and regulation – and a need to review the core objectives pursued. They also highlight areas where the current approach is not adequately delivering the outcomes government, community or industry want. The regulatory framework is fragmented and constrained in its ability to respond to the broad changes affecting ART.
2. Key risks in ART

ART is now a well-established clinical treatment, with nearly five per cent of births in Victoria each year resulting from ART. The question arises as to whether or not ongoing specialist regulation is necessary or justifiable. Similar discussions are occurring internationally in other regulated jurisdictions as treatments such as IVF move from novel, ground-breaking science to common accepted practice (Hendriks et al. 2018; Murdoch 2017; Rutherford 2017).  

Good regulatory practice dictates that the purpose of any regulation and the harms it is seeking to address must be clearly understood and articulated. Therefore, as a starting point in attempting to address these questions and assess the broader regulatory framework for ART, the Review has taken into consideration the critical risks that regulation of ART is seeking to minimise.

2.1. Overview of risks in ART

Consultation undertaken in the first phase of this Review has been valuable in identifying the potential harms associated with ART, the consequences of those harms and the most effective approaches to mitigating these. In identifying and trying to understand the likelihood and impacts of various potential risks associated with ART, the Review has come up against an absence of quantitative data in relation to some key risks. This has somewhat limited the capacity for the Review to calculate the extent of some risks and harms. It has therefore been necessary to draw heavily on the stories and experiences of those using ART and those working in the sector, which have been so generously shared with the Review.

2.1.1. Risk to the health and wellbeing of people to be born

The Act clearly articulates that the welfare and interests of persons born or to be born as a result of treatment procedures are paramount. The primary aim of all people involved in ART should be the birth of healthy children who develop into healthy adults whose unique identity is respected and whose wellbeing is supported.

In this context, it is important to note that ART does pose small health risks to children born as a result of procedures, albeit of low probability. These include:

- risk of birth defects – there is a low risk of birth defects and long-term health consequences for children conceived through ART. Infants conceived following IVF and ICSI have a slightly higher rate of birth defects than naturally conceived children
- risk of health impacts in children born as a result of ART – research is ongoing to better understand the impact of the range of existing and emerging reproductive treatments on the longer-term health of those born as a result of those treatments. Some research has suggested, for example, that children born as a result of ART are more likely to have

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8 Also, for example, see various papers presented at the recent Progress Educational Trust annual conference 2018 ‘Make Do or amend: should we update UK fertility and embryo law?’ <https://www.progress.org.uk/conference2018>
respiratory issues such as asthma (Carson et al. 2013; VARTA 2016) than naturally conceived children.

However, towards the end of this Review, Australian researchers, led by Professor Jane Halliday of the Murdoch Children’s Research Institute, published perhaps the most comprehensive follow-up study of the health status of adults conceived through IVF. It compared a complete set of health outcomes, quality of life measures and health service usage in a group of IVF children now aged in their 20s and 30s with a control group not born through IVF. This study found no significant differences in adulthood in health outcomes, quality of life or health service use (Halliday et al. 2019). Differences in rates of asthma and respiratory problems in adolescence did not persist into adulthood.

As outlined in detail in the Interim Report, the Review has heard compelling stories from those born of ART services. In particular, the Review heard concerns from people who had been conceived through donor treatment procedures about the emotional impact of not knowing their genetic heritage or finding out that they have a very large number of genetically related half-siblings.

…I think about [my unknown donor siblings] every single day. It never leaves my mind and I am constantly analysing people in the street comparing features to my own. … I often dream of meeting the rest of my family, but know that this dream may never be a reality. This has devastated me in many ways and has continued to impact my mental health greatly.

Submission – donor-conceived person – donor has 4 children and 11 donor offspring

While some donor-conceived people have been able to meet and form positive relationships with their donors and/or donor-siblings, others have been unable to make such connections and live with the knowledge that they may have genetic relatives they might never know. Regardless of their personal experience, donor-conceived people who responded to the consultation for this Review talked of the importance of knowing where they come from and the significant impact that their donor-conceived status has had on their emotional health and wellbeing.

Donor and surrogacy treatment also brings with it a risk of uncertainty in relation to legal parentage, with impacts on the wellbeing of the child. While this is a complex area intersecting with family law, legal and regulatory frameworks need to provide clear frameworks to manage these risks.

2.1.2. Risk of adverse health outcomes for people undergoing treatment

Like any medical procedure, ART involves inherent risks to the individual undergoing treatment. While many of these risks, such as those associated with surgical complications or the risk of infection, are common across many areas of medicine, some, such as ovarian hyperstimulation syndrome (OHSS), are almost uniquely associated with ART procedures such as IVF and ICSI.

While elimination of all treatment risks is not achievable, the Review has heard that there are significant variations in clinical practice and outcomes between clinics. The Review has also heard that the increased corporatisation of the sector may be contributing to a reluctance to report or disclose adverse outcomes or support a culture of learning and improvement. A number of events highlighting these risks are cited in the Interim Report.

Unlike other areas of medical specialty, ART uniquely involves the fertilisation of human eggs and support of early pregnancy. This brings with it specific risks that require mitigation through robust processes to ensure the right gametes are fertilised at the right time, that the correct embryos are transferred to the correctly identified patient, and that high-quality early pregnancy support and care is available.
2.1.3. Risk to the emotional health and wellbeing of people using ART services

The experience of ART is a highly emotional one for all concerned – treatments can be physically and emotionally difficult, and the impact of failed cycles on people desperate for a family cannot be overestimated.

It has been put to the Review that, given that a large proportion of people who commence ART will not give birth to a child, services must, at a minimum, be provided in a way that ensures people are no worse off when they end treatment than when they commence it. Nonetheless, ART is known to take a significant toll on the emotional and mental health of many people, which can have repercussions for other aspects of their lives and place a burden on the broader health system. Adequate social and emotional support is the key way in which the risk of emotional and mental health impacts can be mitigated. Yet the Review has heard that many participants do not feel that their support needs are met. These issues are discussed further in the Interim Report and Chapters 4 and 5 of this report.

2.1.4. Risk of misleading information

The Review has found that there is a significant risk that people seeking treatment to form a family may be misled by providers who charge considerable sums for ART services and may not adequately communicate to patients the efficacy of treatment and the likelihood of successful treatment.

Many people seeking ART services have already experienced distress arising from infertility and almost all prospective parents come with a high emotional (as well as financial) investment in the treatment. This can leave people vulnerable to pressure to commence or continue with treatments that may have very limited prospect of success. It can also lead patients themselves to push for additional services and treatments, even where there is little evidence of their efficacy and/or safety, and may in fact be harmful.

The arrival of new providers in the market and the increasing corporatisation and competition has also seen a significant increase in marketing and advertising of services. Providers make use of a range of advertising approaches (including testimonials in some instances) and are increasingly using targeted online strategies and social media to promote services. Often this marketing is highly emotive and can be misleading. This can lead to unrealistic expectations or to people making potentially damaging decisions about their reproductive health which may result in emotional, physical or financial harm to the individual.

The Review has identified that information deficiency is a key contributor to the risk of people being taken advantage of or making decisions that may be contrary to their best interests. Like many areas of specialist service provision, there is a clear information asymmetry in ART, with patients reliant on clinics to provide adequate information for them to make informed choices. As outlined in the Interim Report and in Chapter 4, the Review has heard that the information, provided to individual patients and generally accessible by people in relation to ART, is insufficient and of inconsistent quality. This includes advertising materials and information provided directly to patients on success rates, costs, and the evidence in relation to adjuvant treatments. People making decisions about expensive and invasive treatments are often faced with complex information on treatment outcomes and the variety of treatments available.

The Review has been informed by patients of instances where quoted costs for cycles and treatments were substantially exceeded in final invoices, without explanation. In some of these cases, patients were asked to make immediate payment or else treatment would not continue. Inaccurate or misleading information can result in significant harm to individuals who may make detrimental
treatment decisions or suffer negative impacts on their emotional health when their expectations are not met.

Patient experience

Mia recently commenced IVF treatment. She was advised in her initial consultation that the cost to her would be approximately $5,000. She later received an invoice for $8,500. When she queried this with the clinic, she was advised that the initial quote was an estimate and did not take into account the full range of treatments recommended by her doctor.

2.1.5. Risk to donors, surrogates and intended parents

The Review has found there is a significant risk that donors, surrogates and people who require donated gametes or embryos, or the help of a surrogate, to form a family may be subject to exploitation or detrimental effects on their emotional or mental health.

The recently screened 60 Minutes segment ‘Babies at first sight’ highlighted the risks that some people are willing to take to form a family. The report followed ‘Joe Donor’, the American sperm donor who claims to have fathered more than 100 children in the US and was in Australia offering donations to women seeking to conceive a child. The program interviewed a number of women who valued either the anonymity he offered or the ability to access sperm without going through clinic procedures, having a waiting period or paying high costs to access gametes.

Donation, in particular egg donation, involves a commitment of time, inconvenience, risk and discomfort. The Review also notes the significant emotional toll that donors may face as a result of their decision to help another person. Surrogacy involves an even more significant sacrifice. The Review has found that current regulatory provisions are not clear and do not always support adequate recognition of the role played by altruistic donors and surrogates.

As discussed in Chapter 7, the Review has identified the emergence of unregulated, online forums for sourcing donations and surrogacy services. The hidden nature of these activities is such that it is not possible to quantify the extent of this issue. Intended parents, donors and surrogates using such forums are open to exploitation. For example, the Review is aware of at least one recent case in Victoria where a person who had agreed to act as a donor contacted the prospective parents demanding a large sum of money just before the donation was to be made. The Review has also heard of a surrogate not being reimbursed for expenses that had been agreed with the intended parents under the surrogacy arrangement, with current regulation offering no course of redress for the surrogate.

The risk of exploitation can be even greater where people elect to travel overseas to seek treatment that might be prohibitively expensive or, for good reason, not available in Victoria. Donor conception and surrogacy services in many countries remain largely unregulated and, while many stakeholders have reported positive experiences of treatment in other jurisdictions, there remain significant risks for those seeking treatment and those acting as donors or surrogates. A number of countries that were popular destinations (including India and Thailand) have recently banned overseas surrogacy due to concerns about the exploitation of financially vulnerable women. Legislative changes have happened at short notice, leaving the fate of children to be born to intended parents who reside outside these countries in limbo, with those individuals personally devastated that their hopes of becoming parents.

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9 Aired 17 February 2019.
have not been realised, and out of pocket. Data on the numbers of people travelling overseas for donor or surrogacy cases is not available. However, the Department of Immigration and Border Protection estimates that it deals with approximately 250 offshore surrogacy cases (nationally) each year (House of Representatives Standing Committee on Social Policy and Legal Affairs 2016).

2.1.6. Risk of inequitable access to services

Although the Review was unable to quantify the levels of unmet demand for ART services in Victoria, it is clear that access to services is not equitable and that a number of barriers exist for many members of the community.

Cost is a significant barrier, with ART being unaffordable for many Victorians. As detailed in the Interim Report and in Chapter 6, consumers pay high and often escalating out-of-pocket expenses for treatment. The Review heard that some individuals take out personal loans or access their superannuation early in order to meet these costs, putting themselves at significant financial risk.

As outlined in Chapter 5, the Review has also heard that barriers to access exist for people residing in rural and regional Victoria and for people from diverse communities including Aboriginal people, people living with physical or intellectual disability, people from culturally diverse backgrounds and some members of the LGBTIQ+ community.

2.1.7. Risk of scientific practices outside social and ethical norms

The rapidly evolving nature of ART, and the fact that it deals with fundamental issues of human reproduction and identity, mean that ART will continue to raise complex ethical issues and bring with it significant social consequences that must be addressed.

There are a small number of cases overseas of gross violations, such as implanting a human embryo in an animal uterus. While these risks are very low and such extreme practices are unheard of in Australia, there is zero tolerance for these risks.

Other practices that challenge ethical boundaries but may offer some benefits, such as the capacity for genome editing in human reproduction, are rapidly evolving. The possibility of editing embryos to remove harmful mutations and genetic diseases or creating gametes in vitro from cell lines that have undergone genome editing is now real (Nuffield Council on Bioethics 2018). The risk in this field is heightened by the relative simplicity of emerging gene editing technologies. Many scientists working with fertility clinics have the technical means available to make changes to the heritable characteristics of the human genome, and this creates a major risk of events that potentially breach community standards and threaten community trust in science and medicine.

Concerns about these advances have been brought to the fore with the recent announcement by Dr He, an Associate Professor from Southern University of Science and Technology (China), that he had successfully edited the genome of twin girls when they were still embryos with the intention of giving them resistance to HIV. While the claims of Dr He are as yet unproven, the announcement has been met with widespread condemnation.

The actions taken by Dr He would be banned under Australian law, and may indeed be banned under Chinese law. Nevertheless, the case highlights the importance of a social consensus on the use of these technologies. As a society, there is no definitive set of moral values and rules in relation to many of the novel possibilities that arise from the rapid developments in this field of science. This carries the risk that the practices that emerge will fall well outside community expectations. On the
other hand, there is also a risk that genuinely beneficial therapeutic interventions could be held back by a community backlash against the irresponsible actions of a few scientists and/or clinicians.

### 2.1.8. Risk associated with the use of genetic material

ART relies heavily on the skills and expertise of people working within clinic laboratories. There are extensive risks associated with the collection, storage and use of genetic materials.

There is a low but serious risk that genetic material collected may be inaccurately identified, for example, if the identity of a donor is not accurately recorded. There is a risk that material may be lost if storage infrastructure fails or correct procedures are not followed. There is also a small risk that genetic material may be misused, for example, if sperm from two different men is used during an ART procedure.

Although information from VARTA in relation to identified breaches suggests such cases are very rare, the impact is potentially significant. Inaccurately identified materials may lead to inaccurate information about a person’s donor being recorded on the Central Register. This false information could later be released to the donor-conceived person, who may then rely on inaccurate information about their genetic medical background, or form a relationship with someone who later turns out not to be their donor.

The loss of genetic material through storage failures could be catastrophic for people who have gametes or embryos in storage, particularly if those gametes or embryos represent their last chance to form a family. These risks need to be managed through risk management systems in laboratories and clinics, such as continuous power supply, the maintenance of frozen material, and the prevention of physical damage to storage facilities.

### Some of the Risks: a patient's experience

Throughout consultation, the Review heard from several people whose experiences informed the Review’s understanding of the risks associated with ART. Below is the experience recounted by one patient, which touches on almost all of the risks identified in this chapter.
Patient experience - risks of ART

Angela and her husband, Eric, had been trying to have a baby for six months and were referred to a fertility clinic due to her previously diagnosed polycystic ovary syndrome. After she and her partner were tested, her doctor left Angela a voicemail saying Angela’s husband had male factor infertility, and they would never be able to conceive naturally. The doctor recommended ICSI. In the same voicemail, they advised they were going on leave, and that Angela should call the clinic to make an appointment.

At their appointment, Angela and Eric were given information on the cost of the treatments by their clinician, who highlighted a total cost of $5,332 on the form. Afterwards, the administrative staff discussed the costs further with Angela and Eric, without providing any extra clarity. When Angela and Eric were asked to pay for their treatment, they were charged $11,000, as opposed to the $5,332 their clinician had advised them, with no explanation.

Angela and Eric did not feel adequately supported by their counsellor. They felt as though the counsellor had a ‘tick box approach’ to their treatment, and that they were not appropriately listened to.

Angela was advised by her doctor that her first round of treatment was cancelled, due to insufficient egg production. The doctor said that because the round was cancelled at their instruction, there would be no cancellation fee. However, when Angela and Eric arrived for their next appointment, the clinic advised that they owed another $500 in cancellation fees, which they had to pay before treatment could resume.

Angela went through a second round of treatment, using higher doses of medication. Egg collection resulted in only three viable eggs, which was very upsetting to Angela and Eric, who believed they received inadequate support from the clinician and received confusing communications from the clinic about the identity of the sperm used in fertilisation. All three eggs were successfully fertilised, and they received confirmation that Eric’s sperm was used in the creation of their embryos.

Another doctor performed implantation, as the recommended day three was a Sunday. Angela and Eric were taken into a room to discuss the procedure. Angela felt dismissed by the doctor, and that the procedure was not fully explained to her. She was surprised by the number of people involved in the procedure, and felt intimidated. Angela felt unable to question or revoke consent once she felt uncomfortable, because she thought, ‘This is what you need to go through to have a baby’.

Angela was told to call the clinic if she started to bleed. Two weeks after the implantation, it became clear that the procedure had not been successful. When she called the clinic, she was not offered emotional support, and she was told to make an appointment with her clinician.

At the appointment, the clinician advised Angela and Eric to make a decision about their remaining embryos, stating that they could implant both remaining embryos on the next cycle if they chose. Angela was still very upset, and felt pressured to make a decision quickly. She told the clinician that she did not feel truly cared for, and that she felt like she was just money to the clinic.

In response, the clinician started yelling at Angela and Eric, and took them out into the main reception area, where other patients were waiting. The clinician continued to yell at Angela and Eric in front of the other patients and staff.

Following this incident, Angela was contacted by a customer service representative from the clinic, who apologised for the clinician’s behaviour and arranged for a transfer of their remaining embryos to another affiliated clinic.
2.2. Response of self-regulation to these risks

Some ART industry representatives argue that the existence of the self-regulatory scheme at the national level negates the need for specific state-based regulation of ART. It has also been pointed out that Victorian legislation in relation to ART is more prescriptive than any other state or territory, and that some Australian jurisdictions – including Queensland and Tasmania – do not have specific ART legislation (although these states do have Acts covering surrogacy).

As outlined below, however, the Review identified some features of the national self-regulatory scheme that bring into question the extent to which it can be solely relied on to ensure service standards and quality or to address risks that may be associated with ART.

2.2.1. Scope of the RTAC Code of Practice and the NHMRC Ethical Guidelines

The Review considers that the scope of issues addressed by the RTAC Code of Practice is not sufficiently broad to ensure high-quality, safe service provision.

In particular, as outlined in the Interim Report, and discussed in more detail in Chapters 3 and 5, the Review is concerned that the requirements in relation to person-centred and inclusive care, complaints handling, open disclosure practices, patient experience, staff culture and commitment to ongoing continuous improvement in safety and quality are either not present or are not sufficiently robust.

Other reviews into the regulation of ART have similarly found that a reliance on the Code of Practice and the NHMRC Ethical Guidelines may not provide sufficient clarity or interpretation to support uniform practice across clinics (Allan 2017).

The Review also notes that the scope of matters covered by the NHMRC Ethical Guidelines or RTAC Code of Practice does not encompass a number of matters currently subject to regulation under the Victorian Act. These include a number of regulatory requirements that are outside the scope of this Review (such as consent and safety screening requirements, the role of the PRP and the disclosure of information regarding donor treatment procedures), as well as other matters (such as requirements for counselling and the control of the import and export of gametes) that are under consideration by the Review.

2.2.2. Limitations of accreditation audit processes

The Review has heard contested views about the audits undertaken by certification bodies on behalf of RTAC. Although some stakeholders reported a lack of rigour or concerns that auditors lack specialist knowledge, others described comprehensive, professional and detailed review processes that are taken seriously by clinics, and which can and do identify deficits in policies and procedures.

Indeed, the Review had the opportunity to observe one audit process at an interstate clinic. This audit was professionally and rigorously conducted by auditors with specialised knowledge, and demonstrated how the RTAC audit process could contribute to continuous improvement within an ART clinic. This observation was consistent with feedback from FSA, RTAC and some clinics on the rigour of the RTAC process, and its contribution to improving standards.

Notwithstanding the professionalism of the auditors and RTAC, there are some concerns with the system of accreditation audit processes. Concerns have also been expressed about the process by which the certified body undertaking the accreditation audit is selected and paid for by the agency.
being audited. It has been suggested that such processes can result in a conflict of interest where the auditor may try to minimise disruption and unfavourable reports. The Review notes, however, that a number of ART provider representatives have disputed this view and provided examples where auditors have not hesitated in providing frank and open feedback.

Nonetheless, the Review notes that the incidents of suboptimal care, practice inconsistent with the RTAC Code and breaches of the Act, which were identified by the Review and described in the Interim Report, all occurred at clinics that had current, ongoing accreditation. This is not surprising. Accreditation, no matter how well managed, will only ever be a point-in-time assessment.

The concerns raised with the Review in relation to the RTAC accreditation process mirror the issues raised in the Targeting zero: the review of hospital safety and quality assurance in Victoria (Duckett et al. 2016). Targeting zero called out an overreliance on accreditation as a means of assessing quality and safety risk and cited mixed evidence as to the benefits and effectiveness of accreditation. The report noted that accreditation assesses documentation of processes and functions, rather than quality and effectiveness. Further, it is often experienced as an ‘event’ for which the agency prepares rather than a driver of ongoing continuous self-assessment and improvement.

On the other hand, a balance needs to be struck between more rigorous accreditation and auditing, and promoting a culture of continuous improvement and open disclosure in clinics. The Chair of RTAC advised the Review that the approach taken by RTAC promotes continuous improvement for all, and not shaming of individual clinics. This approach is important and essential for long-term improvement in the quality of care and the culture of the industry. Nevertheless, RTAC intends to make a number of changes, subject to approval by its governing bodies, to get this balance right. These improvements include greater public reporting and transparency of RTAC processes, the use of two-person audit teams in all cases, and changes in auditing teams every three years. The Executive of the FSA have indicated they are supportive of such proposals and the Review considers that these changes are positive developments that would strengthen RTAC’s work.

### 2.2.3. Public confidence, transparency and accountability in self-regulatory approach

The Review has identified a widespread perception that there is an inherent conflict of interest in the self-regulatory approach and that the consequences of this conflict may only increase as the industry becomes more subject to commercial and competitive pressures.

It was noted by a number of stakeholders that RTAC, as the setter of the standards in the Code of Practice, reports directly to the board of the FSA which comprises predominantly industry representatives. The Review also heard that the IVF Directors Group (a subcommittee of the FSA established to assist Directors of IVF units to ensure sustainable provision of ART in Australia and New Zealand) has significant influence over this board.

A lack of transparency or external accountability in the setting of standards can contribute to a loss of public confidence in a system of regulation. Unlike many other regulatory codes, the RTAC Code of Practice is not assessed by an independent authority through open and accountable processes. This gives rise to a perceived conflict of interest, with the industry both setting the standards by which it will be judged, and making determinations on whether it meets those standards.

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10 These concerns are similar to those raised regarding building surveyors engaged by developers who have not adequately overseen compliance in that sector.
The Review heard from some stakeholders that positive improvements have been made as a result of stakeholder input into the Code of Practice review process. For example, the inclusion of more rigorous requirements around public information were included in the most recent review of the Code, in response to concerns that information presented by clinics was misleading. However, the Review also notes that a number of significant changes were made in the most recent version of the Code of Practice without any information being made available publicly as to the rationale for these changes. For example, a number of matters listed in the 2015 Code of Practice as ‘critical criteria’ (and therefore subject to annual audit) were made ‘good practice criteria’ in the Code of Practice released in October 2017 (and therefore are now subject only to triennial audit). This includes topics that have been the subject of concerns raised with the Review, such as the management of ovarian hyperstimulation syndrome and emergency care. Requirements for complaints management were also moved from ‘critical criteria’ into the ‘good practice criteria’ which covers more general stakeholder feedback.

Concerns about the transparency of the process for revising the RTAC standards and the extent to which the current process holds clinics to minimum quality standards were also raised in the recent report of the Gynaecology Clinical Committee of the Medicare Benefits Schedule Review Taskforce (2018).

Finally, the Review considered the features of the RTAC Code of Practice against guidelines for developing effective voluntary industry codes of conduct issued by the ACCC. Although compliance with the RTAC Code of Practice is required under s. 11 of the Research Involving Human Embryos Act 2002 (Cth), and is therefore not a voluntary code, the features of an effective code described in this document remain relevant. The RTAC Code of Practice aligns, or partially aligns, with a number of the features identified in the ACCC guidelines. However, there are some notable gaps. In particular, the RTAC Code of Practice does not include clear provisions for complaints handling, and does not include processes for the escalation of complaints that are not resolved at the local level or an independent review mechanism for when a complainant is not satisfied with an outcome. The Code does not contain any specific and graduated consequences when non-compliance is identified. The Code of Practice also fails to include mechanisms to promote community awareness about the Code and to incorporate performance measures to allow for transparent assessment of the code’s effectiveness.

The Review invited the Chair of RTAC and the President of the Fertility Society of Australia to comment on any planned improvements to public reporting and transparency. The RTAC Chair advised that he planned to recommend, subject to the approval of his governing body, a number of significant improvements to the public reporting and transparency of the RTAC scheme. These improvements include the annual publication of an RTAC report on the FSA website, and the inclusion of more information in these annual reports on audit processes, licensing outcomes, non-compliance findings, complaints and adverse events. It has also been acknowledged that there may be scope to strengthen the protocols for the review of key documents (for example, processes may be developed to support the formal inclusion of patient groups in reviews of the Code of Practice and scheme rules). Again, the FSA executive have indicated that they are supportive of these proposals which will be considered by the FSA board in the coming months. These recommendations would strengthen the RTAC scheme and are welcomed and supported by the Review.

2.2.4. Ongoing state-based regulation is required

The Review notes the value of pursuing a consistent national approach to the regulation of ART and acknowledges the work of the FSA and RTAC in promoting this. Nonetheless, the limitations of the self-regulatory scheme identified above, as well as the need to ensure ongoing regulation of matters
(such as consent and safety-screening requirements, the role of the PRP and the disclosure of information regarding donor treatment procedures) that are outside the scope of the RTAC Code of Practice, necessitates the ongoing regulation of ART in Victoria.

Within the context of an increased recognition of the importance of effective regulatory oversight, following Targeting zero, the Review considers that a strong regulatory framework overseen by a competent and empowered Regulator should remain to enhance public confidence and to provide assurance for government and the public about the quality and safety of the ART sector in Victoria.

2.3. Improving regulation of the risks of ART

It has been noted throughout this Review that while the aim of ART services is to help people to form families, many who seek treatment will not achieve this desired outcome. For this reason, the Review considers that it is critical that ART services are provided in a manner that minimises risks to all involved.

It has also been noted that this core feature of ART – that the aim is to create new life – differentiates ART from all other forms of medical treatment. This is borne out in the risks identified above and the complex legal, ethical and social questions that continue to arise in relation to ART.

The vast majority of people working in the ART field recognise these issues and operate in a manner that is ethical and responsible with the best interests of patients at the centre of what they do. Nonetheless, there have been a number of examples over recent years of practices of concern that have received some media attention, and the Review itself has uncovered isolated examples of dangerous and unethical practice. Such incidents have the potential to damage the reputation of the industry as a whole and to weaken public confidence in these health services. The Review believes that effective regulation will support and protect the sector and be of benefit to all providers who are operating in an ethical and responsible manner.

It is within this context that the recommendations contained in the Interim Report and this report are made. Collectively, these recommendations seek to address the factors that contribute to the risks identified above by, for example, addressing information deficiencies, ensuring those participating in ART have access to sufficient emotional support, increasing the supply of locally sourced gametes, clarifying regulatory requirements in relation to surrogacy, supporting more affordable and accessible services and ensuring effective oversight of quality and safety.

To this end, regulatory changes are proposed to:

- ensure the regulatory system provides a proportionate and focused response to the critical risks and harms associated with ART, but does not unreasonably stifle innovation or restrict access
- provide a framework to support improved quality, safety, experience and outcomes for individuals
- avoid unnecessary duplication of regulation where risks are already adequately regulated through existing co-regulatory or related regulatory schemes
- allow sufficient flexibility in regulatory requirements to accommodate changes in technology, markets, risks and community views
- provide clarity and certainty for providers, users and the community about their rights and obligations and the role of relevant regulators in ensuring these are met
- establish a basis for risk-based, proportionate, outcomes-focused and transparent regulation by a regulator or regulators with an appropriate range of tools to monitor, promote and enforce compliance as required.
The Review does, however, note that the key risks and harms associated with ART cannot be solved by regulation alone. Other public action is required to address deficits in the current system. It is these issues that will be addressed by developments such as the establishment of public fertility services, and recommendations for a public sperm and egg bank and a greater focus on fertility in public health policies and programs.
3. Improving quality, safety and experience in ART

Key points

- ART in Victoria is safe and effective in comparison with other parts of the world. However, there is scope to improve its quality and safety, and the experience of people using these services.
- Guiding principles set out the intent of the Act and expectations in relation to services governed by the Act. Changes should be made to the Guiding principles to prioritise quality, safety and patient experience.
- Clinical governance requirements and expectations of person-centred care should be strengthened.
- Patient feedback and complaints are powerful drivers of quality improvement. Systems for routine collection of patient feedback and the handling of complaints should be improved.
- There is a lack of clarity, leading to variations in practice, as to how the requirements of the Act apply to increasingly popular elective egg freezing procedures. There should be specific regulatory requirements in relation to these activities, without imposing undue burden upon patients.
- ART often includes the use of unproven, innovative tests and treatments and a growing array of high-cost ‘premium’ offerings, medical adjuvants and complementary health treatments from outside the ART sector. National independent expert advice should state which procedures can be considered routine, well-evidenced procedures, and which treatments patients should be more cautious consenting to.

All Victorians have the right to expect and receive consistently safe and high-quality healthcare, regardless of why they are accessing that care or who is providing it.

As noted in Chapter 2, there are a number of health and safety risks associated with ART. While all medical treatment carries with it some risk, and the elimination of this risk may not be achievable, health service providers must ensure that, wherever possible, adverse outcomes for patients are avoided and that services, and the system as a whole, strive for continuous improvement in the quality of care and the experience of those receiving it.

ART in Victoria (and Australia more broadly) is generally considered safe and effective. Two of the key indicators of safety in ART practice are the rate of single embryo transfers, and the resulting low rate of multiple births. Victoria, like Australia generally, compares favourably with other parts of the world on these indicators. In 2017–18, 88.6 per cent of embryo transfer cycles in Victoria were single embryo transfers (VARTA 2018) which continues an upward trend seen over the decade. This practice is reflected in a low multiple-birth rate resulting from embryo transfers. In Victoria in 2016–17, 4.2 per cent of all births arising from ART were multiple deliveries. This compares with approximately 11 per cent in the United Kingdom in 2016 (HFEA 2017) and approximately 19 per cent in the United States in the same year (Centres for Disease Control and Prevention, American Society for Reproductive Medicine, Society for Assisted Reproductive Technology 2018). These measures justify the Fertility Society of Australia’s regular claim that Australia is the safest place in the world to do IVF. However, the performance of ART providers on other important dimensions of quality and safety is less clear, and there is limited data available. The Review found that performance across clinics can be highly varied.

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11 The most recent published national data (from the National Perinatal Epidemiology and Statistics Unit Assisted reproductive technology in Australia and New Zealand 2016) showed 87.7 per cent of embryo transfer cycles being single embryo transfers.
and that adverse events, in particular ovarian hyperstimulation syndrome, are underreported, which means there may be risks to patient safety that are not being unaddressed.

Information about other aspects of the quality of services, including the patient experience of ART, is not collected in a consistent manner across services. The Review has seen and heard examples of good practice in a number of clinics and has heard from many stakeholders who have had positive experiences and feel grateful for the opportunity to access treatment. However, patients, as well as donors and surrogates, also widely report that the experience of ART is very difficult and that they feel their needs are not always at the centre of the care they receive.

The Review has concluded that there remains significant scope for improvements in quality, safety and, importantly, the experience of those using ART services.

3.1 Prioritising quality, safety, experience and improvement

The guiding principles set out in s. 5 of the Act provide a powerful statement about Parliament’s intent, priorities and expectations in relation to services governed by the Act. They are also critical in guiding the activities of providers and regulators carrying out activities or functions under the Act.

This Review has provided an opportunity to revisit the guiding principles and consider if they remain relevant and focused on each of the most critical areas of potential risk in ART.

Stakeholders have generally been supportive of the guiding principles, however, changes in the nature and market for ART and emerging quality and safety issues have highlighted some issues that were perhaps not envisaged when the legislation was drafted. The Interim Report has already made a recommendation to address one such issue, namely that the ‘Guiding principles of the Act be amended to use non-discriminatory language, including in relation to gender, where appropriate, and that the antidiscrimination principle in s. 5(e) be expanded to recognise people who are currently excluded (Recommendation 8).

During the second stage of the Review, additional changes to the Guiding principles have been identified that will support an increased focus on quality, safety and experience.

In 2016, in response to the recommendations of the Targeting zero report, the Victorian Health Services Act 1988 and Ambulance Service Act 1986 were amended to emphasise quality, safety, patient-centred care and continuous improvement in the Acts’ objectives and other key provisions. This signalled the need for a greater focus on quality and safety and provided the basis for regulatory action to ensure that services responded to this need. The Review considers there would be value in mirroring this approach in the legislation covering ART by including an additional guiding principle to highlight the importance of safety, quality, person-centred care and continuous improvement.

The guiding principle in s. 5(d) of the Act requires that ‘the health and wellbeing of persons undergoing treatment procedures must be protected at all time’. The Review notes that this may not be sufficient to ensure the interests of donors and surrogates are protected. The Review therefore considers that this guiding principle should be amended to protect all participants in ART, and to overtly recognise the significant emotional and mental health risks associated with ART.
Recommendation 18 Guiding principles of quality, safety and person-centred care

It is recommended that the Act be amended to include:

- a new Guiding principle stating that ‘registered ART providers must provide safe, person-centred services and foster continuous improvement in the safety and quality of the treatment procedures they provide’, and

- an amendment of Guiding principle 5(d) to require that ‘the health and wellbeing, including emotional and mental health, of persons undergoing treatment, donors and surrogates must be protected’.

3.2 Strengthening clinical governance

Targeting zero has emphasised the importance of effective clinical governance and leadership in providing safe, high-quality healthcare.

The Review believes that this is particularly critical in ART, where treatment occurs over extended periods and involves a truly multidisciplinary treatment team. Unlike many other areas of medicine, ART relies heavily on laboratory specialists (who undertake the procedures to fertilise eggs and develop blastocysts to the point of transfer to the uterus) working alongside fertility specialists, counsellors and specialist nurses. This feature of ART means that risks arising from systemic issues may be more difficult for any one individual to identify and resolve. The Review also notes that a strong culture of transparent clinical governance is important given the significant public funding of ART services through Medicare rebates.

While the RTAC Code of Practice includes a quality management systems criterion (Good Practice Criterion 1), the Review is not persuaded that the requirements set out in this Code are sufficient, or comprehensive enough, to promote ongoing improvements in safety and quality. While a number of clinics demonstrated they have systems that exceed the requirements of the Code, this is not consistent across all clinics. The Review believes there is a need for a more rigorous minimum standard of clinical governance. This minimum standard would support safe, high quality service provision, and clearly spans the whole multi-disciplinary treatment team. For the majority of clinics that already have strong clinical governance systems, the Review considers that meeting the proposed minimum standards should not be burdensome.

The Review notes the changes that were made to the regulatory requirements in Victoria for private hospitals and day procedure centres in 2018 in response to the findings of Targeting zero. These changes sought to strengthen the minimum requirements for the quality and safety of care provided by those services. The Health Services (Health Service Establishments) Regulations 2013 (the Health Services Regulations) require services to ensure they have processes in place to continually assess the capacity of the service to provide safe, patient-centred and appropriate services and to ensure that arrangements are in place to monitor and improve quality and safety. Part 15 of the Health Services Regulations contains a range of specific requirements relating to the regular review of quality and safety of the services provided, the routine collection of staff safety culture survey data among other things. Where an ART provider operates its own day procedure centre for the purpose of oocyte collection (which must occur within a registered private health service establishment) the provider must comply with the Health Services Regulations. However, only two providers are currently in this position (although it is understood that this may increase over the coming year). The Review considers that the scope of the
quality and safety requirements contained in the Health Services Regulations (as amended in 2018) might provide useful direction as to requirements that might be relevant to all ART providers.

The National Safety and Quality Health Service (NSQHS) Standards, developed by the Australian Commission on Safety and Quality in Healthcare, provide another framework for promoting stronger clinical governance requirements. Victorian providers that also operate clinics in NSW, for example, are required to comply with these standards where they have onsite oocyte collection services. It is understood that the Regulations are closely aligned to the NSQHS Standards, and the Review considers that any additional requirements on clinics should wherever possible be consistent with these frameworks.

Safer Care Victoria, the state’s healthcare quality and safety improvement agency, has recently developed a new framework for clinical governance: *Delivering high-quality healthcare* (Safer Care Victoria 2017). This framework identifies five interrelated domains of clinical governance:

- leadership and culture – this includes the need for a clear shared vision for quality improvement, clear accountability for planning, monitoring and improving quality and established governance structures to support this
- consumer partnerships – this includes seeking patient feedback and responding to complaints (see below) but also includes a clear consumer advisor governance framework and meaningful representation on quality and other committees
- workforce – including the provision of a safe and fair workplace which encourages a learning culture and supports staff to speak up about concerns
- risk management – including ongoing identification of risk and investigation of clinical incidents to identify underlying systems issues, open disclosure to patients and ongoing evaluation of systems and datasets to ensure they remain effective in supporting safe, high-quality care
- clinical practice – including ensuring that clinical staff have the skills and expertise required, that evidence-based care protocols are clearly articulated and adhered to and that clinicians are supported to participate in the design and review of systems and processes.

This framework may provide useful guidance for clinics in implementing procedures to meet enhanced requirements for clinical governance.
**Recommendation 19 Clinical governance requirements for ART providers**

It is recommended that the Regulator develop clinical governance compliance standards for ART providers. These compliance standards should form part of the conditions of registration.

It is recommended that clinical governance compliance standards should, to the extent possible, align with requirements contained in the *Health Services (Health Service Establishments) Regulations 2013* and the *National Safety and Quality Health Service Standards*.

The Review considers that the development of these standards should be undertaken in collaboration with appropriate experts, and in consultation with RTAC, the ART industry in Victoria, professional groups and patient representatives.

### 3.3 Focusing on person-centred care

Person- (or patient-) centred care is a well-established priority in healthcare and is now considered a core dimension of quality service provision, with a substantial and growing body of literature about the value of the approach and how it can be achieved.

While the terms patient-centred and person-centred are used interchangeably, the Review has adopted the nomenclature of person-centred care as the more inclusive term encompassing the range of people involved in ART.

*Patient-centred care is health care that is respectful of, and responsive to, the preferences, needs and values of patients and consumers. The widely accepted dimensions of patient-centred care are respect, emotional support, physical comfort, information and communication, continuity and transition, care coordination, involvement of family and carers, and access to care.*

*Australian Commission on Safety and Quality in Health Care 2011, p. 1.*

In the course of consultations, the Review has also heard of the growing body of literature on person-centred fertility care. This literature emphasises that delivering person-centred care requires a systems approach across clinics and cannot only be the responsibility of nurses or counsellors. It also highlights the need to address systems issues (such as information, competence of clinicians and other staff, coordination and integration, accessibility, physical comfort) and human factors (attitude and relationship with staff, communication, patient involvement and emotional support).

A person-centred care approach would ensure that patients are able to access information, help and support whenever they may need it.

*No help is available after hours – all injections for egg harvesting/ triggers etc occur outside of 8-5. Clinics say to go to hospital if any problems. There should be a helpline. I had problems and called the Government’s Nurse-on-Call but they didn’t know anything about fertility treatment so weren’t helpful.*

Submission – recipient of assisted reproductive treatment
The Review has heard numerous reports from people who have used ART services that their experience has not reflected a strong focus on person-centred care. They have described ‘feeling like a number’ and being required to fit in with a standard treatment approach rather than having services tailored to their needs. The Review has also heard that approaches to supporting patients narrowly focus on the role of counsellors rather than being viewed as the shared responsibility of all members of the treating team.

The clinic had their own processes we had to fit in with. If we needed anything different, it was up to us to ‘project manage’ the whole experience.

Participant in ART experience from public consultation session

The Review notes there was extensive discussion of the importance of person-centred care at the September 2018 conference of the Fertility Society. The European Society for Human Reproduction and Embryology, the American Society for Reproductive Medicine and the UK Royal College of Obstetricians and Gynaecology have all published a range of guidance documents relevant to adopting person-centred care models in fertility treatment. They have also provided guidance in a range of tools for identifying patient needs and measuring person-centred care.

The Review believes that Fertility Society of Australia, as the national industry body, is ideally placed to promote an improved approach to person-centred care and encourages further consideration of how this can be pursued at a national level. The Review also consulted the Chair of RTAC on whether additional standards for person-centred care would be appropriate and auditable. The Chair supported the establishment of such standards, since they would improve the coverage of the current code of practice, and similar standards are effectively audited in other health and human services standards.

The Review also considers that Victoria may be ideally placed to lead this work and therefore proposes that the Regulator commence a process to develop guidelines for person-centred care in ART that builds on work already undertaken internationally. Any such process should include formal involvement of the NHMRC, the Fertility Society of Australia and other professional organisations such as the Royal Australian and New Zealand College of Obstetrics and Gynaecology, Royal Australian College of General Practice, Australian Nursing and Midwifery Federation and Australian Psychology Society. The guidelines should also be developed with the active involvement of patients, their families, surrogates, donors and donor-conceived people.

**Recommendation 20 Guidelines for person-centred care**

It is recommended that guidelines for person-centred care in ART should be developed by the Regulator in collaboration with relevant national and state organisations and with the active involvement of patients, their families, surrogates, donors and donor-conceived people.

3.4 Patient experience and complaints as drivers of service quality improvements

Targeting zero highlighted the importance of patient experience as a key indicator of quality and a powerful driver of service improvement.

There is a large amount of data reported on ART, both in reports of the Australian and New Zealand Assisted Reproductive Database and the annual reports of VARTA. However, this data reports little or no
measures of patient experience or the perceptions of patients on what matters most to the quality of their experience.

The Review understands that most, if not all, clinics routinely undertake their own surveys of patient satisfaction or experience, and that many clinics respond to this feedback through changes to policies and procedures. However, the Review remains concerned that this practice is not consistent across clinics and that information is not always collected using a clear, generally accepted methodology. The Review also notes that survey instruments employed by some providers are designed to elicit responses that can be used to promote a service rather than to identify core areas for improvement.

Ideally all organisations in the industry should be implementing a common approach to measurement of the dimensions of care and outcomes from treatment that are of most importance to patients. Establishing validated testing across Victoria (and ideally, Australia) would enable comparisons over time within and between clinics, and so would contribute to improved quality, safety and patient experience.

The health sector over the last 10 years has discussed developing patient-reported outcome measures (PROMs) and patient-reported experience measures (PREMs) in many fields of medicine. The Australian Institute of Health and Welfare’s *Australia’s health 2018* reports on a number of both measures.

PROMs are used to obtain information from patients on their health status, usually using standardised and validated questionnaires. When used before and after a healthcare intervention (or at points throughout a longer-term therapeutic intervention), information on the self-reported changes in health status associated with these interventions are considered to be measures of health outcomes. Outcome measures report which results of treatment matter to patients, and can identify outcomes that may not otherwise be prioritised by clinicians. For example, AIHW reports PROMs in palliative care related to the reduction of pain, fatigue and breathlessness. Some evidence from European patient-centred fertility care studies, for example, suggests some ART patients value a clinical pregnancy, even if it does not result in a live birth, as an outcome of treatment since it is a tangible result of their efforts to conceive.

Patient-reported experience measures (PREMs) are used to obtain patients’ views and observations on aspects of healthcare services they have received. This includes their views on the accessibility and physical environment of services (for example, waiting times and the cleanliness of consultation rooms and waiting spaces) and aspects of the patient–clinician interaction (such as whether the clinician explained procedures clearly or responded to questions in a way that they could understand). For example, the AIHW reports measures of whether health professionals listened attentively, showed respect or spent enough time with patients. Public feedback to the review showed that many patients had concerns with how ART providers performed on each of these dimensions of patient experience.

The Review also heard of a number of recent initiatives to improve measurement of patient experience relevant to the ART industry in Victoria. The Department of Health and Human Services has recently introduced a mandatory survey on patient experience for all registered private hospitals. This survey uses a random sampling methodology. As noted by the Chair of RTAC, a standardised patient-centred care infertility questionnaire (PCQ Infertility) has already been developed in New Zealand, a jurisdiction also covered by the collection of ANZARD data (Mourad et al, 2018). The UK Human Fertilisation and Embryology Authority (HFEA) has developed a simpler survey tool that is more suitable for clinical practice. It may be that these approaches could be adapted to the needs of the Victorian ART sector.

Developing suitable surveys of patient experience and valid patient-reported outcome measures (PROMs) and patient-reported experience measures (PREMs) is a complex and technical task. While the Review considers that measures of patient outcomes and experience in ART would ideally be undertaken at a national level, there is an opportunity for Victoria to take a leading role in developing and implementing such measures, drawing on the expertise of Safer Care Victoria, and a range of professional organisations as well as the knowledge and insights of patients and others who have participated in ART.
The Review emphasises that the measurement of patient experience ought to contribute to a culture of continuous improvement and increased engagement with patients. The definition of patients in relation to ART should include the broad range of people that are involved in any treatment process – patients, partners, donors and surrogates. Public reporting of these measures ought not to lead to the creation of league tables. There is considerable expertise and experiences across the Australian health system with reporting such measures in this way, and the Victorian regulator and the ART sector more broadly can draw on this expertise to develop an effective system of measuring, reporting an improving patient experience.

**Recommendation 21 Measures of patient experience**

It is recommended that measures of patient-reported outcomes and patient experience be adopted systematically across the Victorian ART industry and reported by the Regulator. Appropriate person-centred care measures should be developed by the Regulator in collaboration with relevant organisations and participants in ART.

Complaints can be another powerful driver of quality and safety improvements in health services. The RTAC Code of Practice ‘stakeholder feedback’ criterion (Good Practice Criterion 2) requires ART units to acknowledge and investigate complaints, and provide evidence of implementation and review of policies and procedures that include: information on how patients make a complaint and how they receive feedback, acknowledgement and investigation of complaints; and systematic recording, review and corrective action of complaints.

Under the Health Complaints Act 2016, all health service providers in Victoria (which includes ART providers) must meet minimum standards for complaint handling, with failure to meet these standards being grounds for complaint to the Health Complaints Commissioner. In summary health services must:

- promptly acknowledge complaints and make appropriate attempts to resolve them
- provide information on how to make a complaint to health service consumers in an accessible and understandable form
- inform those who have made a complaint of the complaint's progress and its outcome
- keep personal information collected in the course of a complaint in a confidential manner
- keep a record of all complaints, including any action taken in managing them.

Despite these requirements, the Review has heard repeatedly from recipients of ART that they feel unable to make complaints and/or are unaware of how to raise concerns about services or how to escalate these concerns if they do not feel the response has been adequate. It has also been suggested that people may feel uncomfortable escalating their complaints, particularly if services are ongoing and patients fear that complaints may adversely affect their care and treatment, especially where they store gametes or embryos with the clinic.

Others have suggested that some people may be reluctant to discuss sensitive issues associated with infertility and ART with a generic complaints body.

The Review notes that the regulatory requirements on private hospitals and day procedure centres, which were updated in 2018 in response to the findings of Targeting zero, include more rigorous requirements in relation to complaint handling. The Health Services Regulations (as amended in 2018) include requirements similar to those under the Health Complaints Act and also require the nomination of a dedicated person within services to deal with complaints. The regulations also include a requirement that the person making a complaint (and the patient if the complaint was made on their behalf) must not be adversely affected because the complaint has been made. A penalty attaches to failure to comply with the complaint handling requirements under the regulations.
The Review considers that all ART providers should be required to comply with complaint handling standards equivalent to those set out in regulations for private health service establishments and that a failure to comply with these requirements should be grounds for action by the Regulator.

The Review is also concerned by feedback that recipients of ART are unlikely to escalate concerns to the Health Complaints Commissioner. It has been suggested that this stems from a lack of knowledge about the role of the Health Complaints Commissioner and a perception that the Commissioner’s jurisdiction may not include ART services.

The Review proposes that all clinics should be required to inform patients about the role of the Health Complaints Commissioner and the complaints handling services available through the Commissioner in relation to complaints that cannot be directly resolved with the service.

While it has been suggested that these issues might be resolved by giving the Regulator of ART a function to receive complaints about ART, the Review considers that the specialist complaints resolution and investigation processes of the Health Complaints Commissioner are better suited to this task. The Commissioner also has a range of processes and powers to support system improvements arising from complaints. Therefore, the Review believes that efforts should be made to address any concerns among recipients of ART about using these processes, in particular people using ART services should be reassured that it is an offence (s. 80 of the Health Complaints Act) for a person to subject another person to any detriment as a result of a complaint to the Commissioner.

The Review notes that the current inquiry into ART and IVF practices being undertaken by the Commissioner, on referral from the Minister for Health, should raise ART service recipients’ awareness that ART services fall within the jurisdiction of the Commissioner. Nonetheless, the Commissioner may also consider some additional communications to reassure recipients of ART that this is a valid avenue to seek to have their complaints resolved and that their issues will be dealt with sensitively and appropriately.

**Recommendation 22 Complaint handling**

It is recommended that the Regulator develop complaint handling compliance standards for ART providers. These compliance standards should:

- form part of the conditions of registration
- be as equivalent as possible to requirements set out in regulations for private health service establishments as a condition of registration
- require providers to inform patients about the role, complaints handling services and available legal protections of the Health Complaints Commissioner.

### 3.5 Ensuring that quality and safety oversight applies to the range of ART

The Review has identified a need to clarify how the regulatory regime for ART relates to the now common practice of egg freezing. As outlined in the Interim Report, there has been a substantial rise in the uptake of elective egg freezing over recent years.

The Review heard there is a lack of clarity about whether the requirements of Part 2 of the Act apply in relation to egg freezing and, as a result, a lack of consistency across clinics in the approach taken. To
remedy this, the Review considers that specific provision should be made within legislation regarding the collection and storage of oocytes for the purpose of fertility preservation.

The Review does not consider that all of the requirements set out under Part 2 of the Act should be replicated in relation to egg freezing. For example, the provisions set out in s. 10 that relate to persons who may undergo treatment should not apply in this instance, as the purpose is fertility preservation rather than treatment to achieve a pregnancy. The Review also does not consider that a requirement for child protection checks or a presumption against treatment should apply in respect of a person seeking to freeze eggs for fertility preservation. The process of egg freezing alone will not result in the birth of a child and in most cases the stored gametes will be used many years later, if at all. As the legislation currently stands, the person seeking treatment would be subject to these requirements if, and when, they elect to use the stored eggs to form an embryo for transfer.

Nonetheless, the Review notes that the intensive marketing of these services, the high out-of-pocket costs and the health risks of these procedures (which are similar to those of other ART procedures) warrant a clear regulatory framework to support the provision of safe, person-centred care. Therefore, the Review considers that requirements as to who may perform the procedure, the provision of appropriate information and counselling, and the need for valid consent should apply in relation to egg freezing.

**Recommendation 23 Inclusion of fertility preservation in the Act**

It is recommended that new provisions be included in the Act setting out the minimum requirements in relation to the collection and storage of gametes for the purpose of fertility preservation. These requirements should include:

- restrictions on who may perform the procedure, consistent with the requirements of s. 7 which relates to the carrying out of ART
- provision of appropriate information about procedures, risks and costs
- any relevant counselling standards
- the need for valid informed consent.

### 3.6 Ensuring that treatments offered are safe and effective

Of concern to many stakeholders who have responded to this Review is the extensive use of unproven innovative tests and treatments by ART clinics and the growing array of high-cost ‘premium service’ offerings. The Review has observed that the rapid evolution of science in ART, along with an increasingly corporate and competitive approach to service provision, has seen new techniques adopted into practice ahead of conclusive evidence from clinical trials being available. The Review has also heard of the ongoing use and promotion of adjuvant treatments that research has found to be ineffective, and the widespread use by patients of complementary health treatments that lack any supporting evidence.

The emergence of new evidence, new medical techniques and innovations is not unique to ART. Indeed, many areas of medical practice need to negotiate the issue of when a technique is no longer considered experimental and has a sufficient evidence base to move into usual clinical practice.

This is generally managed through adherence to ethical obligations and strict protocols. Medical practitioners have an obligation to ensure that they only provide treatments that are appropriate,
effective, and where the benefits outweigh any risks. Additionally, research protocols for experimental
techniques come with various protections for participants. These include institutional ethics committee
approvals and oversight, a clear and consistent process for informed consent, participant information
statements, safety protocols and appropriately rigorous study design to ensure that study results are
scientifically meaningful and therefore worth exposing participants to a degree of risk. Such requirements
are outlined in the NHMRC research guidelines that cover all medical research in Australia.

The Review has observed that it has become accepted in ART for the line between research and clinical
practice to be more blurred than in other medical specialties. This is despite some specific guidance in
the NHMRC Ethical Guidelines. The Guidelines include an expectation that ‘in routine clinical practice,
clinics utilise interventions supported by evidence of successful clinical outcomes’ and that the
introduction of innovative practices should only be done after an evaluation of ‘safety and efficacy and
consideration of legal and ethical issues’. The Guidelines further state that ‘advice should be sought from
an independent body before the introduction of an innovative practice, or a proposed change to routine
clinical practice, as this may constitute research, even where only one individual or couple is involved’
(NHMRC, 2017).

The Review has been told that interpretation of these requirements varies significantly, and that
experimental techniques continue to enter clinical practice without a sufficiently robust evidence base,
exposing would-be parents to experimental techniques without the protections of a research framework.
Such techniques may be ineffective, and may have unwarranted safety risks to patients, their gametes
and embryos. They also add to already high out-of-pocket financial costs for intended parents. There is
no national or state organisation currently operating as an ‘independent body’ for the purpose of advising
on the introduction of innovative practice as envisaged by the NHMRC Ethical Guidelines. Services (or in
some cases individual practitioners) make their own decisions about when it is appropriate to use new
techniques. On occasion, these decisions may be made within a culture that encourages pushing
boundaries to ‘help’ emotionally vulnerable people who are willing to try anything despite slim chances of
improving their chances of success.

Let’s ensure the revamped regulatory framework allows for innovation in IVF. There are more
experimental/ cutting edge treatments available overseas. Let’s ensure Victoria can be a leader in
IVF innovation & not stifled by regulation.

I would like to be able to access IVM (in vitro maturation) but this is not regularly practised in
Victoria. I am considering overseas options as my medical situation would make this a viable option
for me.

Submission – recipient of assisted reproductive treatment

Increased obligations for information provision by treating clinicians, about the risks and evidence base
for treatments offered, will go some way to addressing these concerns. The Review notes the
responsibility of ART providers for the services provided by clinicians, acting as either their employees or
agents, and therefore expects providers will have in place appropriate systems to ensure that these
responsibilities, and ethical obligations for the provision of evidence-based treatment, are met.

The Review also notes and is supportive of VARTA’s recent move to include reporting on the use of
adjuvants in the conditions of registration for ART providers. Continuation of this requirement will ensure
that providers are aware of practices taking place in their clinics, and assist the Regulator to better
understand the extent to which adjuvants are used in Victoria. Additionally, the Review has been advised
that the FSA intends to provide further guidance on adjuvants through a technical bulletin later this year.

However, the Review considers that there would be value in establishing a process to provide greater
clarity to medical practitioners, clinics and patients about which treatments are sufficiently well
established to warrant their use in routine practice, and which treatments have not yet reached this threshold of evidence. The same process could be used to reassess established treatments that have become part of routine clinical practice, but for which clear evidence has emerged of ineffectiveness, such as endometrial scratching. This will be critical in ensuring that patients are fully informed and are not exposed to undue safety risks or additional expenses for treatments that may not improve the chance of a positive outcome.

The Review has noted approaches adopted in other jurisdictions internationally:

- The New Zealand *Human Assisted Reproductive Technology (HART) Act 2004* (NZ) provides for ‘established procedures’ which may be carried out without further ethics approval. Procedures that are not ‘established procedures’ must be approved by the Ethics Committee on Assisted Reproductive Technology (ECART) (established under s. 27). The ECART may consider and approve applications for procedures about which a guideline has been issues by the Advisory Committee on Assisted Reproductive Technology (ACART) (established under s. 32). Where no guideline exists the ECART must refer the matter to ACART for consideration. The ACART is also responsible for providing advice to the Minister for Health as to which new procedures should be made ‘established procedures’.

- The UK regulator of ART, the Human Fertilisation and Embryology Authority (HFEA) maintains a list of authorised processes that are permitted against each of the licensable activities under the *Human Fertilisation and Embryology Act 1990*. For example, if a centre is licensed for the ‘use of gametes’, then the processes of intrauterine insemination (IUI), gamete intrafallopian transfer (GIFT), IVF and ICSI are all permitted. If a centre wishes to offer a process that does not appear on this list, it must apply to the HFEA to do so. The decision to authorise these ‘novel processes’ is delegated to a Statutory Approvals Committee, which also issues ‘special directions’ that are rules for centres to govern how they use a new fertility treatment or technique.

The Review considers that each of these approaches would best operate on a national level, rather than on a state-by-state basis, to avoid the risk of people travelling interstate to access treatments that are restricted in one particular jurisdiction. The Review suggests that if there were to be a national approach for determining which treatments may or may not proceed (with, or without case-by-case consideration) the NHMRC would be ideally placed to undertake this role. The NHMRC has an established role in developing clinical guidelines as a good practice standard for the use of novel and accepted procedures, and revising these guidelines as changes to the evidence base emerge. The NHMRC also already publishes Ethical Guidelines for ART, but no clinical guidelines.

At the very least, patients should be fully informed when a procedure is innovative, or lacking a fulsome evidence-base, at the time the treatment is offered. Patients should also be fully apprised of any known risks associated with such treatment. Experimental techniques should only be used in the context of a properly constituted research study.

In the absence of a national approach, the government could consider whether there would be value in the Victorian Regulator of ART having a formal role in determining which procedures should be

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12 ‘Established procedures’ include, for example, artificial insemination, IVF, ICSI and the freezing of gametes, embryos and ovarian tissues.

13 Guidelines have been issued, for example, in relation to embryo donation and posthumous use of gametes.

14 For example, advice was provided in 2017 that the use of cryopreserved ovarian tissue become an ‘established procedure’.

15 The Statutory Approvals Committee also decides what conditions can be tested for using PGD and considers applications for mitochondrial donation treatment and human leucocyte antigen tissue typing. The Statutory Approvals Committee is advised by the Scientific and Clinical Advances Advisory Committee, which is itself informed by the Horizon Scanning Panel (a panel of international experts who meet once a year to identify discuss emerging developments which may be several years down the track, in order to prepare the HFEA for future decisions about licensing and guidance required by the sector).
considered routine, well-evidenced procedures and which should be considered novel procedures and therefore should be used with caution and only where the intended patient has been fully informed about the innovative nature of the treatment, the risks and the available evidence. If so, an appropriate expert panel would need to advise the Regulator and include experts outside Victoria.

However, on balance, the Review considers that this function is best performed at a national level through an established, capable organisation. It proposes that the Victorian Government consult further with the NHMRC on addressing this current gap in the regulatory system for ART.

Recommendation 24 National assessment of evidence-based treatments

It is recommended that the Victorian Government consult with the NHMRC and relevant professional organisations on the establishment of national, independent advice and clinical guidelines on evidence-based treatments for infertility and ART procedures that can inform practitioners, researchers and patients.
4. Providing clear information and supportive counselling

Key points

- Information is critical to supporting people to make the right choices, and to give valid consent to procedures.
- Despite some improvements over recent years, many people considering, or receiving, ART still do not believe they have been given sufficient and appropriate information to make fully informed decisions about their treatment.
- There is a need for improved information regarding infertility, treatment options, success rates and costs.
- Although many recipients of ART report positive relationships with their clinicians, nursing staff and counsellors, others raised significant concerns about a lack of ongoing support within clinics.
- Many people perceive that the current approach to mandated counselling has resulted in a ‘tick box’ compliance exercise focused on screening and assessment, rather than providing a therapeutic support.
- Counselling and support requirements should be refocused to ensure patients receive the individualised support they need before, during and after treatment.

The Interim Report highlighted a need to improve the information available to people involved in ART, so that truly informed decisions can be made regarding treatment. The Review has also heard that people participating in ART require support at every stage in the process. Those affected can include intended parents, donors and surrogates (those directly involved in treatment), as well as people born via treatment, particularly those who are donor-conceived. Currently, Victorian law and regulation aims to ensure patients receive the support they need to make informed decisions through prescriptive rules on counselling. The Review’s consultations with stakeholders and service users suggest this framework is ineffective.

Feedback to the Review indicated that many recipients of ART report positive relationships with their clinicians, nursing staff and counsellors, and express gratitude for the opportunity to try and have children. However, the Review also heard significant concerns about a lack of ongoing support within clinics. Many people reported that support drops off during treatment and is poor towards the end, regardless of the reason for ending 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 focused on screening and assessment. This perception is in part driven by the regulatory framework, rather than the professional practices of counsellors and other clinicians. This perceived tendency towards a compliance exercise has been exacerbated by the mandatory nature of counselling and the legislated role of counsellors to assess patients’ appropriateness for treatment with police checks and child protection orders.

The Review heard that some aspects of the information available to people in relation to ART is insufficient, of inconsistent quality or poorly communicated. Particular concerns were: confusion about interpreting likely success rates, and the difficulty of making decisions on costly treatments when faced with complex, even overwhelming, information on treatment options. In addition, consultations revealed that, in practice, people received most of their support and information from fertility counsellors and nurses, and that people received less information and support than they wanted from their doctors and the clinic as a whole.
Many stakeholders were keen to improve the information and support services available to all people involved in ART, so that they can be appropriately supported and make better informed decisions. To meet this need, the Interim Report indicated that the Review would explore opportunities to:

- enhance counselling, including whether there can be improvements to counselling and other activities of clinics that support people in effective decision making and in promoting their psychological wellbeing, or whether any current regulatory requirements hinder holistic person-centred care
- improve information available to people seeking treatments, including clear, timely information on success rates, clear communication about individual prospects of having a child through ART, and the availability and transparency of information on costs, efficacy of treatments, risks of treatment, and performance of clinics.

Building on the findings and recommendations set out in the Interim Report, this chapter identifies ways to improve the support people receive both in making decisions and managing the psychosocial challenges of fertility treatment, including by examining ways to improve person-centred care and the measurement of the patient experience, the provision of information, as well as emotional and psychosocial support.

4.1. Clear information and communication

Information is critical to supporting people to make the right choices for themselves and their families and to give valid consent to procedures. The Review has heard that many people considering, or receiving, ART do not believe they have been given sufficient, appropriate information to make fully informed decisions about their treatment. The information for service users is complex. Patient understanding and informed consent needs to be supported by good communication between service users, their treating clinician and the broader care team.

4.1.1. Community education about fertility, infertility and treatment

The Review heard evidence that the level of knowledge within the community about fertility and, in particular, the age at which fertility begins to decline, is not strong (Prior et al. 2018). It is also apparent that many people are unaware of the factors that may increase the risks of infertility or the steps that can be taken to improve the chance of conception.

Some stakeholders also highlighted a need to improve education about fertility to counter a growing perception that ART is a reliable ‘safety net’ for women who may seek to become pregnant in their late 30s or early 40s. This perception may be encouraged by media stories of successful treatment of celebrities. It has been suggested that this perception may be heightened by ART clinics promoting successful treatments and the increasingly popular egg freezing services that are advertised with tag lines such as ‘Not ready to commit?’ or ‘Busy career? Freeze your eggs’.16

The Your Fertility program run by the Fertility Coalition (VARTA, Andrology Australia, the Jean Hailes Research Unit and the Robinson Research Institute) undertakes a range of public education activities aimed at improving awareness of fertility issues. Activities include the maintenance of a comprehensive website, annual Fertility Week education campaigns, work with a range of professionals including GPs

and health educators to improve targeted fertility education, and distribution of a monthly subscriber-based newsletter. Evaluation of the program has found that it fills a need for greater public awareness and has achieved a broad reach (Hammarberg 2017). It is funded by the Commonwealth Government.

The Review also notes that ‘knowledge and awareness of factors that affect the ability to conceive a child’ has been identified, in the Victorian Government’s *Women’s sexual and reproductive health: key priorities 2017–2020*, as one of four priority areas for both the government and non-government sectors. An identified aim of government is to ‘improve community understanding of the causes of infertility’ with a range of actions planned, including:

- enhanced fertility education programs aimed at women, men and couples to learn about factors that affect the ability to conceive a child
- work with key partners (including the Royal Women’s Hospital, VARTA and women’s health services) to improve women’s knowledge of the factors impacting on fertility
- delivery of age-appropriate contemporary information on all aspects of fertility management in a range of community settings.

The Review supports this focus and suggests there would be value on building on the work of the Your Fertility program to achieve these aims. The Review also suggests that this work should include a focus on educating young people with information to counter the misleading messages they may be receiving through media reports about celebrity ART successes or the advertising of egg freezing services.

A number of stakeholders noted that where public information about fertility and infertility does exist, it is generally focused on women’s fertility. There is significantly less information available about factors that affect male fertility and approaches to treating infertility in men.

A number of individuals have also called for greater public information and education about infertility treatments, particularly those involving donors or surrogates, in order to reduce stigma and improve understanding and acceptance of the variety of ways in which families can be formed. It has been suggested that better information about the processes, impacts, costs and relevant laws might help demystify donation and encourage more people to donate. It has also been suggested that increased public dialogue about donor conception would be of benefit to donor-conceived people and might assist parents to talk openly with their children about their genetic heritage. The Review notes that VARTA is already initiating some of this work and has been active in utilising media interest in some aspects of ART to promote a greater understanding of these issues. Nonetheless, the Review considers that there would be value in a more comprehensive approach to the delivery of this public information and education, and that this should be supported by government through its sexual and reproductive health program.

**Recommendation 25 Prevention through fertility education**

The Review supports the priority given to public fertility education in the *Women’s sexual and reproductive health: key priorities 2017–2020*, and recommends that government build on these priorities through appropriate resourcing of preventive activities, public education and information about male infertility, and public education on treatments for infertility including donor and surrogacy treatments.
4.2. Advertising and promotion of ART services

4.2.1. Advertising of success rates

As noted in the Interim Report, the Review heard from many stakeholders who were concerned about the way in which ART services are advertised and promoted in the community. Following the 2016 Australian Competition and Consumer Commission (ACCC) investigation of claims made by ART clinics about their rates of success, considerable work has been undertaken by regulators and within the industry to improve advertising practices. The ACCC investigation found that some clinics made claims and comparisons about their rates of success without adequate disclosure or explanation of data, and some used technical language that may be misleading. For example, the ACCC criticised the use of clinical pregnancy rates rather than live birth rates to report successful outcomes and concluded that accompanying this data with photographs of newborn babies was likely to mislead consumers.

The revised RTAC Code of Practice, issued in 2017, sought to address these concerns through additional requirements in relation to public information (item 2.2.2). The Code requires that information presented in the public domain be in language that is understandable by the lay public and not be in any way misleading. The Code specifies, among other things, that success rates must be divided by age and present live birth rates for fresh and frozen transfers separately. It also requires an accompanying statement of the factors that affect success rates and that individual results may vary and that a link to the FSA statement *Interpreting pregnancy rates: a consumer guide* accompanies any such public information. Clinics are also required to have appropriate governance in place to ensure information meets relevant regulatory requirements and to only release information that is verified and approved by the Medical Director.

The VARTA Conditions of Registration were also updated to require that ‘public claims, comparisons and advertising by an ART provider must comply with section 133 of the Health Practitioner Regulation National Law (Victoria) Act 2009 and have due regard to the AHPRA Guidelines for Advertising Regulated Health Services’. The relevant section of the National Law relates to the advertising of regulated health services and prohibits false, misleading and deceptive advertising.

The Review heard from stakeholders that, on the whole, there has been a significant improvement in the way clinics report their success rates, and in the way clinicians communicate with their patients about the relevance of these statistics to their individual circumstances. The Review also acknowledges the difficulty in reporting these complex statistics to the general public. Nonetheless, patients and those considering using ART services continue to find the available information confusing and report difficulties in using the available data to help make the decision about where to seek treatment.

It is noteworthy that in April 2019 the Chair of the UK regulator, HFEA, expressed concerns that IVF clinics were using selective success rates to target older women, and that women were not being told their realistic chance of success in having a baby when being sold treatment. These concerns related especially to treatments offered to women in their 40s. While these comments relate to practices in the United Kingdom, it is noteworthy that many in the ART industry continue to oppose the initial proposal of the MBS Review Taskforce to place an age limit on accessing Medicare rebates for ART, even at ages where the average success rate is less than 1 in 20.

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Although conscious of the risks associated with ‘league tables’ of success rates, and the need to ensure that success rate information considers differences in the patient population, the Review is of the opinion that more could be done to ensure that information is presented in a way that is understandable and of value to potential consumers. It is therefore recommended that the Regulator work with the industry to develop a standard proforma for the reporting of clinic success rates and age-based live birth-rates. This proforma would include sufficient explanatory information to ensure patients properly understand variations in success and can make meaningful comparisons.

4.2.2. Advertising of costs

The Review has heard that people considering ART find it difficult to understand and compare the costs quoted by clinics. They report that cost information is presented in different ways by different clinics with global figures from some clinics inclusive of a range of services that are additional expenses at others. Some clinics present out-of-pocket expenses based on an assumption that the individual will be eligible for Medicare rebates or that they will have qualified for the Medicare Safety Net. Others quote total expenses before any rebates. Patients also told the Review of hidden costs that are only disclosed once they have consented to treatment and so are committed to a particular clinic. This can put significant financial stress on people and leave them with unexpected debts.

The Review considers there would be value in a more standardised approach to presenting cost information for prospective patients. Such an approach would reflect the full costs of treatment and what is offered by a particular clinic. This would enable people to make more informed choices about providers and to manage their personal financial commitments.

The Review notes that in 2018 the Cancer Council, Breast Cancer Network Australia, CanTeen and Prostate Cancer Foundation of Australia developed a draft Standard for Informed Financial Consent. This standard aims to guide doctors and health service providers to deliver quality care by providing information about all treatment options and their financial implications, both direct and indirect, and ensuring that service charges are understood by the patient prior to undergoing treatment. It sets out elements required for informed financial consent. Its potential benefit for patients is in avoiding the burden of hidden expenses and avoiding high costs for some procedures. It also aims to reduce variation in the out-of-pocket expenditure of this group of patients. Given the significance of out-of-pocket expenses for ART, this initiative may provide a model for the ART sector.

To address these concerns, the Review recommends that the Regulator work with the industry and patient groups to develop a consistent format for the presentation of costs. This consistent format would include sufficient explanatory information to ensure patients properly understand inclusions and exclusions, as well as any variations in costs, so they can make meaningful comparisons.

**Recommendation 26 Compliance standards for reporting of success rates and costs**

It is recommended that the Regulator work with the ART sector and patient representatives on compliance standards for public information published by ART providers on success rates and costs. These compliance standards should form part of the conditions of registration and should include a consistent format for the public reporting of costs and success rates.
4.2.3. Testimonials and online promotion

Another area of concern in relation to public information promulgated by clinics is the continued inclusion of testimonials and client comments in some advertising materials, websites and/or social media accounts. Section 133 of the 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 … uses testimonials or purported testimonials about the service or business.

Testimonial is not defined in the National Law, so the Medical Board of Australia advises that the word has its ordinary meaning of ‘a positive statement about a person or thing’. The National Law ban on using testimonials means it is not acceptable to use testimonials in your own advertising, such as on your Facebook page, in a print, radio or television advertisement, or on your website.

The Medical Board’s Guidelines for advertising regulated health services advises that this means that “you cannot use or quote testimonials on a site or in social media that is advertising a regulated health service, including patients posting comments about a practitioner” and that “Health practitioners should therefore not encourage patients to leave testimonials on websites health practitioners control that advertise their own regulated health services, and should remove any testimonials that are posted there.”

The guidelines note that ‘testimonials used in advertising a regulated health service through social media may contravene the National Law’. The RTAC Code of Practice states that ‘ART Units must not incorporate patient comments on social media that promote their practice or service.

However, it was not difficult for the Review to find examples of social media accounts controlled by clinics or clinicians which include comments that amount to testimonials. For example, the following comments were found on the social media accounts (Facebook or Instagram) of three different clinics:

Thanks XXX and all of your team XXX, your processes, empathy, communication and attention to detail were flawless every step of the way! What an amazing gift xxx 😊

Just wanted to say thank you! I had an appointment at the XXXX clinic yesterday and your staff are amazing! I felt so down and hopeless about our situation- but on leaving felt sooo positive!!! Thank you, thank you, thank you!!!!

I am 22 weeks pregnant with my baby thanks to the amazing XXXX! She is amazing not just because she got me pregnant but because of the lovely care she gave my husband and i [sic] on our journey!

The Review has heard from stakeholders working in the industry who are greatly concerned that while most clinics comply with the regulatory requirements around advertising and testimonials, there are no consequences for the small number who do not. The RTAC Code of Practice requires that a clinic advises RTAC of any notification from the ACCC or a Department of Fair Trading of a complaint in relation to advertising by the clinic or one of its practitioners. This is intended to enable RTAC to monitor complaints. It is unclear, however, that consumers would be aware that advertising was not compliant with requirements or that concerned stakeholders would be aware of these avenues for complaint.

It is also noted that practices such as the use of testimonials are not necessarily prohibited by consumer law, unless they are fake, false or misleading. Although the use of testimonials is prohibited under s. 133 of the National Health Practitioner Regulation Law, this only applies to the actions of registered practitioners and the Review has been told that AHPRA has expressed reluctance to follow up on such
breaches if public protection is not compromised. This suggests that there is no proactive monitoring of advertising practices or any clear avenues for reporting of potential issues. Therefore, these practices continue. Some stakeholders have argued this gives the non-compliant clinics an unfair competitive advantage as well as being contrary to good professional practice.

The Review has formed the opinion that the Regulator may need to undertake action in relation to advertising and promotional materials that do not comply with relevant standards. It is proposed that the Regulator work with AHPRA and the Health Complaints Commissioner on appropriate action, and that clear guidelines in relation to social media presence and testimonials (based on the AHPRA guidelines) be established. This would have the benefit of ensuring that the requirements are clearly understood by all providers and it is intended that failure to comply with those requirements could be a basis for regulatory action.

**Recommendation 27 Compliance standards on advertising, testimonials and social media**

It is recommended that the Regulator work with the ART sector and patient representatives to develop clear compliance standards in relation to advertising, including the use of social media and testimonials. These compliance standards should form part of the conditions of registration.

### 4.3. Information for intended parents, donors and surrogates

Access to accurate, high-quality information is important in guiding people’s expectations of the impacts and possible outcomes of treatment. This can have a significant effect on an individual’s experience of care. Reflecting the importance of information, both state and national requirements mandate the provision by clinics of specified information to their patients.

The NHMRC Ethical Guidelines require (4.1.1) that clinics provide and discuss information in a way that is appropriate to, and sufficient for, informed decision making. This information is to be provided verbally and supported by written information in plain language. It is to be sensitive to beliefs, diversity and personal circumstances and delivered in a way that is accessible to those with low literacy or disability or those for whom English is not their first language.

The Guidelines set out a minimum set of information that must be discussed including:

- options for the use or discarding of gametes or embryos
- whether the proposed treatment is accepted practice or an innovative practice, acknowledging areas of uncertainty
- the experience of the clinic and the clinician with the procedure, any clinically relevant outcomes and success rates and, where applicable, an explanation that certain procedures may be undertaken by persons other than the individual’s or couple’s treating clinician
- whether any training activities are intended to be conducted in the course of the treatment
- any interests of the clinician, including any commercial, financial or personal interests, relating to services provided by the clinic or any treatment or procedure recommended by the clinician, which may reasonably be perceived as a conflict of interest
- an explanation of all costs involved for relevant parties
- the clinic’s privacy and record keeping policies, including an explanation of any mandatory uses or reporting of data
- any planned or possible clinical follow-up
• options for participation in a current research study or any possibility of future requests for participation in research studies.

The Guidelines also set out information that should be provided in particular circumstances – for example for individuals or couples undergoing ART, those seeking to store gametes and embryos or those seeking or considering overseas treatment.

The RTAC Code of Conduct (Good Practice Criterion 4) also specifies information that clinics must provide patients. This information must be accurate, timely and in formats and languages appropriate to the patient and consistent with NHMRC Ethical Guidelines. The Code of Conduct requires that written and verbal information be provided about:

a) processes, costs, risks and outcomes
b) drugs and side effects
c) availability of individual counselling and support groups
d) patient rights and responsibilities
e) availability of translation and interpreter services
f) preconception advice including the consequences of abnormal weight, smoking, adverse environmental exposure and other relevant factors
g) a statement that donor and surrogacy arrangements are likely to require multiple counselling sessions.

The Act also mandates the provision of certain information. For example, ss. 13 and 18 of the Act require providers to ensure people are fully informed on matters relevant to their treatment. Under s. 25 of the Act, ART providers must, before a person undergoes a donor treatment, provide written advice about the legislated rights to information of donor-conceived people, donors, and other persons, and about Victoria’s donor registers. Section 43 states that persons entering into a surrogacy arrangement must obtain information about the legal consequences of the arrangement, as well as receiving counselling on a range of matters.

Despite all these requirements, feedback received by the Review indicates that many people report that the information they receive before and throughout their treatment can be inadequate, misleading or misunderstood, with a detrimental effect on their experience and wellbeing.

Additionally, donor-conceived people told the Review that the information provided to donors, surrogates and intended parents regarding the whole span of their lives may not be adequate. The Review heard that there is a tendency to focus on donor-conceived people as babies and small children, and not consider the diverse range of responses of adult donor-conceived people to their genetic origins and upbringing. There is a need for more research on the experience of donor-conceived people that can inform evidence-based advice to donors, surrogates and intended parents.

Stakeholders have raised concerns about information provision in relation to fertility generally and to the medical, financial and social or emotional consequences of ART. The Review has given consideration to how the quality, accuracy and accessibility of each of these different types of information may be improved. It is proposed that some changes to the means of ensuring information is provided may be appropriate.

### 4.3.1. Information about treatment options

The Act currently requires that before treatment, people receive counselling on a range of prescribed matters, which include the options and choices available to the patient, as well as possible outcomes of a treatment procedure. The Review recognises that it is valuable for a patient to be able to seek
information and advice from a range of sources before, during and after their treatment, and considers it appropriate that counsellors assist patients to work through their options after they have met with their treating doctor. However, feedback to the Review has highlighted that the current legislative provisions relating to counselling have led to the undesirable situation where counsellors are expected to provide advice and information about matters that may more appropriately fall within the treating doctor’s clinical responsibilities. The existing arrangement has also resulted in counselling being perceived by some as a ‘hurdle’ that must be overcome in order to commence treatment, rather than a beneficial support tailored to individual therapeutic needs.

To address these concerns, the Review recommends that the Act be amended to specify the matters that must be discussed between the treating doctor and patient, prior to informed consent to ART or fertility preservation procedure being sought. These should include, at a minimum:

- the treatment options or choices available to the patient
- the possible outcomes of treatment procedures
- the likely prospects of success, having reference to the specific circumstances of the patient
- any risks associated with the proposed treatment procedures
- any issue or concern raised by the patient in relation to the treatment procedure.

At the same time as the obligation to provide treatment-specific information is strengthened for doctors, the Review considers it appropriate that the requirement for counsellors to discuss prescribed matters be removed, to free up this time to focus on the provision of therapeutic psychosocial care to patients. Proposed changes to how counselling services are provided are discussed later in this chapter.

While some ART providers were concerned that this change may create an unreasonable burden on doctors who already have busy workloads, the more widely held view among stakeholders during consultations was that the proposed amendment reflects general professional obligations of law and is considered to be best practice. It was appropriate for the legislation to make clear that doctors are responsible for discussing medical options, risks and success rates with their patients. Feedback to the Review highlighted that in addition to the matters noted above, patients also feel that doctors should be prepared to discuss the options which may be available if the treatment agreed on is not successful, and that at the very least a follow-up appointment should be scheduled as a matter of course where a pregnancy has not been achieved to plan next steps. The Review agrees that treating doctors and ART providers should work together to ensure that there is appropriate support for patients to ensure they do not feel abandoned when treatment is unsuccessful, and are assisted by a doctor to decide the best course of action going forward.

The Review notes that the proposed approach would simply reinforce the objectives of the NHMRC Ethical Guidelines, which provide that individuals contemplating ART have the right to decide for themselves whether or not to take part in the proposed activities. To assist decision-making, the Guidelines require that individuals and couples seeking ART are provided detailed, accurate, contemporary and relevant information about proposed procedures or treatment and access to counselling about the potential consequences or risks, by a professional with the appropriate training, skills, experience and competency to counsel in reproduction. Valid consent must be obtained from all relevant parties for each specific procedure or treatment.

In addition to the information provided in the course of consultation between the treating doctor and patient, the Review considers it appropriate that supplementary material be made available to patients in a timely and appropriate form, and they are provided with the opportunity to consider the information discussed, seek further advice and if desired, discuss the implications with a counsellor, prior to giving consent. There would be no legislative requirement for the treating doctor to reflect matters discussed with a patient in written form, although they may certainly do so as a valuable reminder the patient can take away and consider further before making a decision about their treatment.
Failure to comply with the conditions relating to the provision of information by a doctor would give rise to a breach of registration conditions by the ART provider. It is furthermore envisaged that the Regulator would have powers to address any concerns about a breach directly with the doctor and/or refer non-compliance for action by AHPRA as appropriate.

**Recommendation 28 Obligations on treating doctor to support informed consent**

It is recommended that the Act be amended to prescribe the matters that must be discussed between the treating doctor and patient prior to the provision of any ART or fertility preservation procedure. At a minimum, these matters should include:

- the treatment options or choices available to the patient
- the possible outcomes of treatment procedures
- the likely prospects of success, having reference to the specific circumstances of the patient
- any risks associated with the proposed treatment procedures
- any issue or concern raised by the patient in relation to the treatment procedure.

4.3.2. Information about the likelihood of success of proposed treatment

In addition to calls for more transparent information about the success rates achieved by clinics as a whole, stakeholders have stressed the need for patients to be provided with more accurate, personalised information about their own likelihood of success. This would take into account a range of personal circumstances and characteristics such as age, health, any diagnosed fertility issues, obesity status and previous pregnancies.

The Review notes that the Gynaecology Clinical Committee of the MBS Review Taskforce, in its 2018 report, also identified a need for tools to allow patients to obtain estimates of their personalised likelihood of success. The Taskforce proposed that this work could be undertaken by the Commonwealth Department of Health if access to appropriate data was facilitated. They envisage for example a web-based application to allow patients to input their personal characteristics and obtain an estimated live delivery rate per complete cycle, and the inclusion in standardised consent forms of an estimate, based on personalised success rates, for a patient’s entire ART process, not just a single cycle. Currently the detailed data captured by providers and given to ANZARD that could support the development of these tools cannot be shared with the MBS or the department under the agreement between providers and ANZARD.

The Review also understands that both VARTA and RTAC have been working to progress tools that can provide more personalised success rates particular to an individual’s circumstances. Models already exist overseas and are in use. For example, researchers in the United Kingdom have established an online calculator that is based on data from more than 100,000 women over 10 years. The data was recorded by HFEA. The Review is strongly supportive of efforts to develop a validated Australian model for predicting personal ART outcomes and would encourage any approach that would expedite the development of these tools. Making them widely available in clinical practice would help to ensure that patients are fully informed about the likely outcomes, duration and total costs of proposed treatment. In this way, they could weigh up the risks and anticipated results to form a realistic view about whether or
not to proceed. The Review proposes that once an appropriate and accepted predictive tool is available, consideration be given to requiring that providers use the tool to give patients information about their personal likelihood of success.

Patients would also benefit from greater information about the ways outcomes of ART are influenced by a number of modifiable lifestyle factors. The Review has heard that many people undergoing ART may underestimate the benefits of the actions within their control that may improve their chances of conceiving. The RTAC Code of Practice includes a requirement that clinics provide patients with ‘preconception advice including the consequences of abnormal weight, smoking, adverse environmental exposure and other relevant factors’ (RTAC Code of Practice Good Practice Criterion 2.2.1).

The Review is concerned that the extent to which clinics comply with this requirement and the quality and extent of the information and advice provided varies significantly across clinics. Accordingly, it is recommended the Regulator give consideration to the need for additional requirements to ensure clinics provide pre-treatment information and education about the modifiable factors (such as diet, smoking, alcohol and exercise) that may impact on treatment outcomes, and the supports available (both within the clinic and outside) to assist people to make appropriate lifestyle changes. It is envisaged that the requirements for this information might be included in a compliance standard.

Recommendation 29 Information on modifiable lifestyle factors affecting fertility

It is recommended that, in developing a compliance standard for public information on success rates and costs (see Recommendation 26), the Regulator consider if any specific requirements should be included for informing people about the impact of modifiable lifestyle factors on treatment outcomes.

4.3.3. Information about adjuvant and complementary health treatments

The Review remains concerned about the information available to patients regarding adjuvant treatments. It is understood there is widespread and increasing use of these ‘add on’ services, such as assisted hatching, time-lapse imaging and endometrial scratching. The costs of these treatments vary significantly but can be very high, and many of them lack an adequate evidence base to justify use in a clinical setting (Hammarberg et al. 2018). There are also concerns about excessive use of ICSI and pre-implantation genetic screening.

In addition, there is a wide range of complementary health practices used by many patients in conjunction with their ART. This may include meditation, acupuncture, herbal medications or homeopathic treatments. In one case, the Review heard of a patient consulting a clairvoyant to identify the best time for embryo transfer. While some of these treatments may be beneficial in reducing stress associated with ART, for many there is no evidence to suggest that they improve the chance of conception, and some may be harmful or interfere with fertility treatments. Experienced fertility clinicians have concerns about the range of treatments, misrepresentations of their effects, and potential side-effects.

There are several ways to encourage the practice of evidence-based medicine by both Victorian ART services and other practitioners who advise people experiencing infertility. One approach is additional regulation to restrict the use of adjuvants or other practices being used without an appropriate evidence base. Another approach is to lead by example through the provision of such care at public clinics. Both state and industry regulators could also promote more active scrutiny of current practice against published evidence and any appropriate clinical guidelines.
However, clearly one important vehicle is to improve communication between patients and clinicians. The Review notes the recent research pointing to significant issues regarding the information available to patients about adjuvant treatments. This research shows that information made available by clinics frequently presents claims as to the benefits of these treatments, but rarely cites published literature to support the claims or discuss possible risks (Hammarberg et al. 2018). This is potentially misleading and certainly does not support people to make informed choices about the cost and benefits of these treatments and whether they wish to use them. Available information of the evidence for complementary health treatments is even worse, and many clinicians have expressed concerns that patients may be reluctant to discuss some of these treatments fully with their treating doctor.

In the UK, the HFEA has developed detailed resources, available on the regulator’s website, that provide clear, concise information about 11 commonly used adjuvants, their possible benefits, risks and the strength of evidence available. It is understood that VARTA is now also producing independent information on adjuvants for inclusion on its website. The Review is supportive of the Regulator working with relevant professional organisations, researchers and patient groups to develop clear information in relation to adjuvants, their risks, costs, possible benefits and the associated evidence for their effectiveness. The Review considers there would also be value in a national approach to the development of such information, with state and industry regulators facilitating the availability of independent advice on adjuvant treatments and similar materials in relation to complementary treatments that may be promoted to people facing fertility issues or accessing ART. It is proposed that when such materials are available, clinics should be required to advise patients of the existence of this resource and provide a web link for them to access it.

The Review believes that there should be an obligation on clinics to provide accurate information to patients in relation to any ‘add on’ treatments proposed. 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’. Nonetheless, the Review heard that clinics continue to promote the potential or possible benefits of these treatments and do not always adequately explain the research findings behind them. The Review is concerned with some cases where reporting of the evidence on endometrial scratching may be considered misleading or dismissive of the evidence available or contribute to poor decisions about treatments. In contrast, other clinics were found to have included information about the recent studies on their website and advised patients to discuss the issue with their treating doctor.

There is inadequate information about the optional ‘add-ons’ which are ineffective at best and harmful at worst. 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

While the Review considers that many clinics have improved the information available to patients regarding adjuvants and do provide balanced accurate information to clinics, this is not universally the case. It is therefore recommended that the existing obligation on clinics to provide patients and the public with information about adjuvant treatments be strengthened through a compliance standard, and the Regulator be empowered to investigate potential failures to comply and take appropriate action, where necessary, to ensure compliance.

The Review notes that the FSA has recently undertaken to consider inclusion of requirements for informed clinical consent for adjuvant therapies and procedures through the RTAC accreditation process.
When this welcome development eventuates, it may obviate the need for a specific Victorian compliance standard.

**Recommendation 30 Information on adjuvant and complementary health treatments**

It is recommended that the Victorian Government consider a national approach for the state and industry regulators to facilitate the development of quality, accessible resources advising patients and clinicians on the evidence base, risks and benefits of adjuvant treatments offered in relation to ART and complementary health treatments offered to support fertility.

It is recommended that the Regulator develop compliance standards for the provision of information in relation to adjuvant treatments, which includes a requirement to advise patients how to access the resources developed by the regulators. These compliance standards should form part of the conditions of registration.

4.3.4. Information about the social and emotional impacts of infertility and ART

As detailed in the Interim Report, the social and emotional impacts of infertility and ART can be significant. The Review considers that patients need to understand these impacts if they are to make fully informed choices and decisions about their treatment.

Currently the Act provides for this by mandating counselling prior to treatment. However, as discussed later in this chapter, the mandatory nature of this counselling can limit its therapeutic benefit. The Review is of the opinion that the therapeutic aims of personal counselling to allow people to come to terms with any infertility issues and to work through issues associated with treatment will be better achieved if people opt to enter counselling voluntarily because they believe it will be of value to them. To this end, the Review proposes that providers be required to provide verbal and written information to patients about the range of social and emotional impacts of infertility and ART and the value of supportive counselling in assisting them to manage these.

The Review has also heard that, while attitudes about donor conception and telling donor-conceived children about their genetic heritage have changed dramatically over recent years, there is still scope to better educate and inform donor recipients about the importance of these conversations with their children and how this can be approached. The Act requires (s. 25) the provision of information about the donor conception registers and the legal aspects of access to information from the Registers, however the Review believes information about the emotional impact on donor-conceived people and ways in which they can best be supported should also be required. VARTA has developed significant expertise in this area and has available a range of resources that can assist parents.

The Review recommends that the ongoing development of materials and advice to assist parents of donor-conceived people be supported. Providers should be required to discuss issues that may arise for donor-conceived people with intended parents and advise them how to access the materials and support available. This advice should be based on quality research that would enable evidence-based advice to intended parents, ART providers and support services. There is a need to encourage more research in this area so that the diversity of experiences and relationships of donor-conceived individuals and people who use ART can be fully understood.
**Recommendation 31 Information on social, emotional aspects of infertility and ART**

It is recommended that providers be required to provide verbal and written information to patients about the range of social and emotional impacts of infertility and ART, the specific issues for donor-conceived people and their parents, and the value of supportive counselling in assisting them to manage these issues. Providers, regulators and relevant professional organisations should contribute to the ongoing development of these materials.

### 4.4. Supportive counselling

The Review considers that responsibility for the emotional and psychosocial support of patients is the responsibility of all the professions and staff involved in the clinic, and is not the sole responsibility of counsellors. The Review has noted that in 2015 the European Society of Human Reproduction and Embryology published *Guidelines on routine psychosocial care in infertility and medically assisted reproduction: a guide for fertility staff*. Those guidelines state that:

> By providing routine psychosocial care, clinics can address the common needs that most patients have. However, to be effective and impactful, this has to be provided in combination with medical care during routine practice in a way that makes it easily accessible for all patients. This implies that routine psychosocial care should be the responsibility of all staff members that have contact with patients (depending on how clinics organize their services, these may or may not include mental health professionals).

There is much that Australian providers of ART could emulate from these guidelines, and they may provide a model that could be adopted here. However, in the Victorian context, discussion of emotional and psychosocial support for patients has primarily focused on the role of counselling.

The Interim Report noted that counselling services are recognised as one of the main sources of support for people going through ART and, as a result, this area of clinic practice received a great deal of comment from stakeholders. Relevantly, the Act contains a number of provisions that set out mandatory counselling requirements before:

- a woman (and her partner, if any) consents to undergo a treatment procedure (s. 13)
- a person gives consent to become a donor (s. 18)
- a surrogacy arrangement is entered into by the commissioning parents and the surrogate mother (and her partner, if any) (s. 43)
- a treatment procedure is carried out involving the posthumous use of gametes or an embryo (s. 48).

Feedback to the Review highlighted that the psychological and social impact of infertility and treatment is complex, with many patients experiencing high levels of anxiety, vulnerability and social isolation. The Review heard that counselling requirements relating to ART, donations and surrogacy arrangements set out in the Act are not sufficiently robust to meet the support needs of patients, donors, surrogates and intended parents. Stakeholders have raised specific issues in respect of the following matters:

- the mandatory nature and scope of counselling
- timing and accessibility of counselling

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18 Counselling requirements also attach to the disclosure of information recorded the Central Register under the Act, but fall outside the scope of this Review. As such, no change is proposed to the requirements relating to counselling in Part 7 of the Act.
the independence, qualifications and role of counsellors.

The Review considers that these matters need to be clarified within legislation and/or developed through appropriate compliance standards, and some options for their resolution are outlined below.

4.4.1. The provision of counselling in respect of ART

Section 13 of the Act provides that 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. The range of matters prescribed in the Regulations for counselling prior to a treatment procedure are:

- 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, and
- g) issues relating to genetic siblings who share a common genetic parent but are raised in different families.

Victoria is the only state in Australia to mandate counselling for all ART procedures. Other jurisdictions in Australia are guided by the NHMRC Ethical Guidelines, which 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. The RTAC Code of Practice similarly provides that an ART provider must make counselling available to individuals undergoing treatment. Both the NHMRC Ethical Guidelines and RTAC Code of Practice mandate counselling for donor and surrogacy arrangements, as well as treatment involving the posthumous use of gametes or an embryo. Surrogacy matters are addressed in separate legislation in a number of jurisdictions and there is an expectation for counselling to occur at key stages of the surrogacy process.

In the course of consultations, the Review received a high volume of feedback on the mandatory aspect of the current counselling requirements in Victoria, with a range of views expressed as to the value of mandatory counselling. The importance of supportive counselling was widely recognised, and a number of patients reported that the counselling process they had undergone was valuable. Others agreed that support should be available to those who need it, but expressed a preference for counselling to be optional rather than mandatory. Those patients who had strong views against mandatory counselling often reported that the counselling did not meet their expectations, felt like a ‘tick box’ assessment activity, and was not targeted to their needs. There was also a view that counselling was not sufficiently flexible or tailored to individuals, and did not address issues of particular relevance to patient groups such as single women and members of the LGBTIQ+ community.

As noted in the Interim Report, there are mixed opinions within the ART industry about the need for mandatory counselling. A number of ART providers felt that the requirement for mandatory counselling should be removed from legislation because it unnecessarily delays patients accessing treatment or requires a uniform model of support that is not tailored to the varied individual support needs of patients. Other stakeholders, including counsellors, highlighted that mandatory counselling prior to all ART is useful in ensuring that patients are appropriately informed about treatment options and benefit from the advocacy, preparation, support, assessment and management that this service provides. It was noted
that mandatory counselling may be the first opportunity that patients have to spend one hour with a clinic representative to ask questions and reflect on the physical and emotional implications that treatment may have. The Review also heard that counsellors bring a specialised skill set that allows them to relate the implications of treatment to the personal concerns of intended parents, and to support them to manage existing mental health or other risk factors. Feedback to the Review claimed that the quality of support available to intended parents in Victoria was higher than in other states where counselling was only optional. There is, however, no independent evidence with which to assess this claim.

Having reflected on the issues raised by a broad range of stakeholders, the Review has formed the view that counsellors have a valuable role to play in helping patients navigate their ART or fertility preservation journey and should continue to support all people contemplating treatment in a targeted way. However, the Review considers that the current model and format of counselling is not sufficiently tailored to meet people’s needs and requires amendment. The Review is concerned that in some cases counsellors provide information and advice about matters that may more appropriately fall within the treating doctor’s clinical responsibilities. To address this, the Review has recommended an obligation on the treating doctor to discuss matters relating to treatment options, risks and prospects of success. In order to ensure that counselling can best meet the individual therapeutic needs of patients, there should be no prescribed matters for discussion between the counsellor and patient, unless the treatment involves donor or surrogacy arrangements, or the posthumous use of gametes or an embryo.

It is recommended that the current counselling requirement in the Act be amended to require that before treatment commences each patient has an individual plan of support. This should be developed with input from clinicians, the counsellor and patient by reference to the patient’s specific circumstances and support needs. The duration, scope and approach of the initial counselling and any follow-up sessions should be developed collaboratively between the counsellor and patient, by reference to the patient’s specific circumstances and support needs.

…pre-treatment counselling serves to provide patients with an opportunity to process the information provided to them by their specialist and to establish reasonable expectations regarding potential emotional reactions during a cycle, the management of possible marital tensions, and the assessment and management of mental health factors.

Submission – Victorian Group of Infertility Counsellors

**Recommendation 32 Ensuring all patients receive an individual plan of support**

It is recommended that the Act be amended to remove the mandatory counselling requirement and all prescribed matters for discussion between the counsellor and patient, unless the treatment involves donor or surrogacy arrangements, or the posthumous use of gametes or an embryo.

In place of this requirement, the Act should require that, before treatment commences, each patient has an individual plan of support, developed by the patient and an appropriately qualified counsellor. This plan of support will include, where appropriate, counselling as required under the Act that meets the relevant compliance standard to be developed by the Regulator. A compliance standard on counselling may include requirements for particular matters to be addressed in counselling before treatment commences.
4.4.2. **Scope of counselling for treatment involving donor or surrogacy arrangements, or the posthumous use of gametes or an embryo**

Consistent with the approach set out in the NHMRC Ethical Guidelines and RTAC Code of Practice, the Review considers that tailored counselling should continue to be provided in Victoria for treatment involving donor or surrogacy arrangements, or the posthumous use of gametes or an embryo.

Where donor gametes are to be used in the course of treatment, it is proposed that the Act require that intended parents receive appropriate information prior to the commencement of treatment to help them make fully informed decisions about treatment. Donor-conceived people highlighted that more emphasis on the need to discuss potential impacts on children conceived through donation in the course of counselling prospective parents is necessary. The Review heard that fertility specialists and other clinic staff need to be more informed about the psychosocial and health risks of donor conception for donor-conceived people. Feedback indicated that open conversations will not only assist donor-conceived people, but also donors and non-biological parents in their management of conception and parenting choices. There is a strong view that more counselling with regards to donor conception and its impact on children needs to occur. In light of this feedback, the Review considers that at a minimum, the issues which would need to be addressed in counselling concerning the use of donated gametes include:

- the psychosocial impacts of being donor-conceived
- the importance of advising children about their donor origins and rights to information
- the Central Register and the information required to be kept in the Central Register
- the right of donors to seek information about a person born as a result of a treatment procedure carried out using the donor’s gametes
- issues relating to the use of donated gametes or embryos in the treatment procedure
- issues relating to genetic siblings who share a common genetic parent but are raised in different families.

Where the treatment involves a surrogacy arrangement, it is proposed that the Act require that the surrogate and their partner (if any), and the intended parents, explore a broad range of issues prior to the commencement of any treatment with the support of an appropriately qualified counsellor. The matters that should be discussed in surrogacy counselling are set out in Chapter 9. Further, in line with the preliminary views expressed in the Interim Report, and consistent with the approach in other jurisdictions and the NHMRC Ethical Guidelines, the Review considers that counselling should be mandatory not only before the parties enter into a surrogacy arrangement but also following the birth of a child, during the pregnancy and prior to the finalisation of parentage orders resulting from a surrogacy arrangement. Such additional counselling will help ensure that a parentage order is underpinned by informed consent by the surrogate. Moreover, it will be a valuable opportunity to provide emotional and psychological support to the surrogate prior to the relinquishment of the child. It is envisaged that counselling at the second stage of the surrogacy process, following the birth of the child, would focus on the social and psychological implications of the making of a parentage order.

The matters that are currently prescribed for counselling in relation to the posthumous use of gametes or an embryo concern the grieving process and the possible impact on the child to be born as a result of the treatment procedure. The Review considers that it is appropriate to require an individual contemplating the posthumous use of gametes or an embryo to participate in counselling to ensure that grief and related emotions do not interfere with their decision making, and they are provided with sufficient information to facilitate an accurate understanding of the potential social, psychological and health implications of the proposed activity for the person who may be born. Further review and consultation by the Regulator may be useful in identifying whether any further topics should be explored through this counselling process.
The Review envisages that matters relating to mandatory counselling for treatment involving donor or surrogacy arrangements, or the posthumous use of gametes or an embryo, as discussed above, should continue to be prescribed in regulations.

Finally, the Review takes the view that appropriate consideration of biological connections and social relationships, as well as the operation of registers in Victoria, is important for prospective gamete donors. As such, the Review proposes that counselling should continue to be provided on mandatory basis to donors under s. 18 of the Act. However, consistent with the approach described below in respect of the qualifications and independence of counsellors, it is envisaged that the counselling services be provided by an ‘appropriately qualified counsellor’, to be defined in the Act, who may, but need not be, providing services on behalf of an ART provider.

4.4.3. Counselling standards

The Review considers that counsellors should have flexibility in how they engage with patients but that all patients should be assured access to high-quality accessible support. To achieve this in a more flexible way, it is proposed that the Regulator develop compliance standards to set out minimum standards for the provision of counselling by ART providers. These compliance standards would be included within the conditions of registration.

It would be useful for ANZICA’s Guidelines for professional standards of practice for infertility counselling to be referenced within a future compliance standard on counselling. However, these standards would also need to be developed in a way that clearly articulates what patients may expect of counselling. It may also be appropriate to develop these guidelines further along the lines of the European Society of Human Reproduction and Embryology’s Guidelines on routine psychosocial care in infertility and medically assisted reproduction: a guide for fertility staff.

The Review is aware that some ART providers offer group rather than individual counselling sessions, and there are a range of competing views about this approach. Some counsellors observed, for example, that they see reliance on the group session model as undesirable because they do not provide a private and confidential space for all people to consider and discuss the implications of treatment in their specific circumstances. Conversely, several people observed to the Review that support groups are very valuable and should be more widely available. There was a strong sense that people undergoing treatment would like more opportunities to access information and share their experiences with others going through a similar experience. The Review sees great value in peer support or education groups delivered in a group format, and in ART providers continuing to develop and offer innovative models of support. However, this should not be seen as a replacement for one-on-one therapeutic counselling when that is required. The removal of prescriptive rules about counselling and a focus on developing individually tailored support for patients should promote innovation in the delivery of counselling models.
Recommendation 33 Compliance standards for counselling

It is recommended that the Regulator develop compliance standards for the provision of counselling. These compliance standards should be developed through appropriate evidence reviews and stakeholder consultation, and reviewed on a regular basis to ensure that they continue to meet patient needs. It is intended that the compliance standards form part of the conditions of registration.

The requirements set out in the compliance standards will be in addition to matters prescribed in regulations, which will include the matters to be covered in counselling related to donor or surrogacy arrangements or the posthumous use of gametes or embryos.

4.4.4. Timing and accessibility of counselling

Feedback from a range of stakeholders, including counsellors, patients, legal groups and academics, highlighted a widely held view that counselling should be available before, during and after treatment. Patients also observed the importance of making sure that counselling is accessible at a range of times and in convenient locations to minimise the burden associated with individuals taking time off work to attend appointments necessary for their treatment.

While clinics provide counselling prior to treatment, there are no legislative requirements in Victoria for counselling to be made available during or following the conclusion of treatment. The Act is furthermore ambiguous as to whether counselling is required while treatment is ongoing, for example before commencing a new treatment cycle, and clinic practice also appears to be inconsistent. The Review is aware that some ART providers in Victoria currently offer a broad counselling service, which has a positive effect on patient experience:

In our current practice model of mandatory counselling, the counsellor has a significant number of clients that continue with additional counselling over a period of time throughout their ART service. Clients have expressed that they have a preference to see a suitably qualified and trained counsellor, and in most cases continue on with the counsellor who provided the initial mandated counselling session that can provide an understanding of the issues concerning fertility / infertility.

Submission – Victorian ART clinic

In addition to pre-treatment counselling, the Review considers it appropriate to amend the Act to make clear that providers have a duty to offer patients counselling during and following the conclusion of their treatment, as developed in their individual plan of support. Provision of ongoing support to patients should form part of the basic obligations of an ART provider and be made available at no additional cost to the intended parents as part of their individual support plan.

Patients also indicated that ongoing counselling should be easily accessible, noting that a lack of responsiveness by clinics in offering support could be very distressing. In particular, there was a view that it should be a basic requirement for a counsellor to contact patients following a failed cycle, to provide proper care and support. One major provider has indicated to the Review that it is introducing this offer as a standard practice in its clinics. While this presents some service design challenges, especially in rural areas, the Review considers that it is reasonable for patients to expect this level of service from clinics.
**Personal experience**

Jayne experienced a number of unsuccessful embryo transfers over the course of her treatment. Each time she was contacted by a clinic nurse, who advised her of blood test results and who immediately made arrangements for her next appointment with the treating clinician. Jayne felt the nurses were very kind and sympathetic, but despite her crying over the phone and sounding recognisably distressed, she was not offered referral to counselling or additional support. Jayne’s perception was that the focus was too much on the next cycle, and not appropriately considerate of Jayne’s emotional experience and mental health needs.

In light of the feedback received, the Review considers it appropriate to amend the Act to clearly articulate an obligation for ART providers to offer reasonable access to timely and responsive counselling to help patients and intended parents who may experience distress following an unsuccessful treatment cycle or for any other reason. Such assistance could be offered in person or by phone or Skype, by appropriately trained counsellor, to assist patients and intended parents in a practical and timely manner. ART providers should also have appropriate referral pathways for patients with ongoing grief or counselling needs.

**Recommendation 34 Duty to offer counselling during and after treatment**

It is recommended that the Act be amended to make clear that ART providers have a duty to offer patients counselling during and following the conclusion of their treatment. Such counselling should be offered on an optional basis. The legislation or regulations should oblige ART providers to offer reasonable access to timely and responsive counselling to help patients and intended parents who may experience distress following an unsuccessful treatment cycle or for any other appropriate reason, and to arrange appropriate referral pathways for any person with ongoing grief, mental health or counselling needs.

**4.4.5. Role and qualifications of counsellors**

As noted above, the Act requires that counselling be undertaken by a counsellor who provides services on behalf of a registered ART provider. This requirement restricts people’s choice of practitioner and may affect the quality of their engagement with their counsellor.

A small number of patient representatives expressed concerns that counsellors had divided loyalties between their client and the clinic, and that these concerns affected their counselling experience. The Review heard that counsellors themselves, on occasion, may be aware of conflicts between meeting the needs of the patient and those of their employer. However, counsellors emphasised that respect for confidentiality, building trust with patients and focusing on the needs of patients were central to their professional obligations as psychologists and counsellors.

Other stakeholders, including ART providers, felt that it would be undesirable to allow counselling services to be offered by an independent counsellor outside the quality framework provided by the clinic. In particular, there was a concern that such a change may affect the quality of service that people would receive by creating poorly coordinated care. It was also observed that counsellors play an important role not only in supporting patients and intended parents but also as integral members of the broader care team within a clinic.
While the Review expects that counsellors providing services on behalf of an ART provider would ordinarily be involved in developing an individual plan of support for the person contemplating treatment, there should be some flexibility in the legislation to allow an individual to seek counselling outside a clinic setting if this better aligns with their support needs. It is envisaged that opening up the provision of counselling to professionals who are not aligned with an ART provider will, for example, allow a person to obtain counselling from a suitably qualified person with whom they already have a relationship, or who is known to specialise in an area of practice that is particularly relevant to the circumstances of the individual concerned. Whereas the cost of attending a counselling session through an ART provider should be free of charge, the costs associated with seeking counselling from an independent counsellor would need to be covered separately by the patient. The Review notes stakeholder views that external counsellor expertise could be built up to enhance choice, with a requirement for counsellors to be linked to ANZICA membership and have professional development requirements to foster industry knowledge and application to counselling within a compliance standard.

Further to this proposal, the Review considers that the legislation should set a clear standard that counselling should be undertaken by an ‘appropriately qualified counsellor’. However, the definition of an appropriately qualified counsellor would be best set in regulations or a compliance standard to provide flexibility to accommodate changes in professional practice over time. Currently however, there is broad consensus among key stakeholders, including ART providers, counsellors and the regulator, that an ‘appropriately qualified counsellor’ can be defined as a person who is eligible for membership of ANZICA and who has the relevant experience, skills and knowledge, including in key legislative requirements, appropriate to the counselling undertaken.

**Recommendation 35 Qualifications and eligibility to provide counselling**

It is recommended to remove the requirement in the Act that a counsellor must be providing services on behalf of an ART provider, so that patients may choose to seek counselling outside a clinic setting from a person who meets the definition of ‘appropriately qualified counsellor’. It is recommended that the Act be amended to state that counselling in respect of ART must be provided by an ‘appropriately qualified counsellor’.

The term ‘appropriately qualified counsellor’ should be defined in regulation or compliance standards as a person who is eligible for membership of ANZICA and has the relevant experience, skills and knowledge, including in respect of key legislative requirements, appropriate to the counselling undertaken.

### 4.4.6. Screening functions to be undertaken by the ART provider

The Review has also reflected on the most appropriate functions of counsellors, and notes that a range of stakeholders observed that counsellors’ responsibility for criminal record checks can give rise to tension in therapeutic relationships and has an adverse impact on their relationship with patients. Counsellors reported that patients frequently express concerns about the police check process during their initial appointments, and this discussion can frustrate the development of a therapeutic engagement with the client. The Review notes that counsellors themselves reported that they felt unqualified for this role and expressed concern that there was no clear source of legal advice to make a determination in these more complex cases. Moreover, counsellors noted that the requirement to undertake such checks puts them in a very difficult position, as patients and intended parents may perceive the counselling role as that of gatekeeper rather than an opportunity to provide support. This perception adversely impacts on the primary role of counsellors to support people. Clinics were similarly of the view that the counselling
function should be separated from the police checks. Clinics noted there have been cases of breaches of the Act in relation to decisions by counsellors on police checks, and that, if this legislative requirement were to remain, decisions should be made by an appropriate decision maker within the clinic, consistent with organisational policies and clinical governance arrangements.

It is recommended that the current requirement that the counsellors undertake a criminal record check be replaced by an obligation for the ART provider to ensure that this check is completed. The proposed change will provide more flexibility and enhanced certainty about the organisational responsibility for decision making on patient treatment. Feedback from patients indicates that this recommendation will be very welcome and will help ensure that counsellors can create a therapeutic space where emotional issues associated with treatment can be discussed in a safe environment separate from any practical or legal requirements. ART providers and counsellors were also supportive of this change, although some providers indicated that counsellors could still play a valuable role in explaining the process to help alleviate patient anxiety about undertaking these checks.

As a more general observation, stakeholders noted that it would be beneficial for better guidelines to be developed for clinics to follow in considering whether a presumption against treatment has been triggered. There was a view that it would be useful for the PRP to provide updated clear guidelines, and the Review agrees that to the extent that more and better information can be made available to clinic decision makers, the PRP should endeavour to provide such practical assistance.

**Recommendation 36 Assigning responsibility for screening to the ART provider**

It is recommended that the Act be amended to make it clear that the completion of mandated police and child protection checks is the responsibility of the ART provider rather than a counsellor.
5. Promoting inclusive practice for the diversity of those impacted by ART

Key points

- People from a range of different cultural or social groups experience barriers to accessing ART, and ART providers do not always respond appropriately to diverse needs.
- Inclusive practice should be improved for LGBTQ+ people, people with intersex variations, sole parents by choice, culturally and linguistically diverse people, Aboriginal people and people with disability.
- In addition to these groups, clinics do not always respond appropriately to the needs of single people accessing treatment, men facing infertility issues and people born of treatment.
- Further research is needed to understand the diverse needs of people accessing ART services, as well as the psychosocial challenges facing donor conceived individuals.
- The general principles of putting people at the centre of fertility care should apply, so that needs are understood, and care is person centred and responsive to the full diversity of ART users.

The terms of reference for the Review specifically ask whether the regulatory framework creates or enables unnecessary barriers to access for LGBTIQ+ people. This has been an area of high priority for the Review, and a focus in the consultations. The Review discussed these barriers to access in the Interim Report, with a focus on potentially discriminatory provisions in the legislation, and made recommendations that will remove these barriers.

Throughout the course of consultations, the Review heard that there are other social or cultural groups of people who face barriers to access in ART, or who have reported concerns to the Review about how well ART providers respond to the particular needs of their group. This chapter outlines the issues faced by these groups, and makes recommendations to improve their access, especially by promoting better understanding of the diversity of people’s needs and encouraging the development of inclusive practice in the ART sector. Inclusive practice is an extension of the Review’s general aim – to put people at the centre of fertility care – by ensuring care is person centred, and responsive to the full diversity of ART users.

Although this chapter focuses specifically on issues relating to diverse groups, these matters are discussed throughout the report, and feedback from consultations with people from these groups is reflected in many other chapters. The Review also recognises the intersectional nature of people’s lives – that is, that people can be both LGBTIQ+ and from a culturally diverse background, or a rurally located sole parent. Any approach to more diverse and inclusive practice must be implemented with an awareness of this intersectionality, and a commitment to deliver services in a way that is centred on individual needs of that person.

Although the Review understands that some clinics and those working in them work very hard to understand the perspective of their patients and meet their needs, the consultations revealed that this is not always the case. Some service users told the Review that clinics did not appropriately consider their individual needs and circumstances when managing their treatment. This included needs and circumstances related to sexuality, gender, sex, relationship status, family form, and culture. Additionally, the Review heard that some adult donor-conceived people believe their specific challenges of growing up with a different genetic parents and social parents are not fully considered by intended parents, clinics, and even ART regulators.
During the consultations for the review, clinics, clinicians and regulators displayed an interest to learn more about the experiences of those who feel excluded from current ART practices. To some extent, the Review initiated a dialogue between the ART sector and these interest groups that can be further developed over coming years, as part of the process of raising standards and expectations of ART so it is more responsive to the full diversity of ART users. The Review considers that this recent dialogue between the ART sector and these groups could form a strong platform for promoting greater understandings between the Regulator, ART providers and diversity of people impacted by ART. Therefore, the Review considers it appropriate that the Regulator facilitates research into the diverse experiences of people who use or are affected by ART, in order to identify improvements in clinical practice, communication with service users and approaches to implementing the regulatory framework.

**Recommendation 37 Research on diverse service user needs and experiences**

It is recommended that the Regulator facilitate research into the diverse experiences of people affected by ART in collaboration with research institutions, ART providers, community organisations, and service users. This research should include, but not be limited to:

- the diverse family forms of people accessing treatment
- the different needs of people accessing treatment, including people with intersex variations, people from culturally and linguistically diverse communities, Aboriginal people and people with disability
- the range of experiences of donor-conceived people and their families.

### 5.1.1. LGBTQ+ people accessing treatment

In the Interim Report, the Review recommended that all discriminatory and gendered language be removed from the Act. The Review considers that this approach should be reflected in the development of inclusive practice guidelines for Victorian ART, and that any new regulations be written with this in mind.

Consultation with the LGBTQ+ community revealed feedback relating to issues that are discussed specifically in other areas of this report, including:

- information about costs and success rates in Chapter 4
- donor issues, recruitment and access to gametes in Chapters 7 and 8
- the use of ‘known donor’ sperm outside ART clinic settings is discussed in relation to the sperm and egg bank in Chapter 7
- individualised and flexible emotional and mental health support in Chapters 4 and 9
- specific challenges for families formed through surrogacy in Chapter 9.

As mentioned in the Interim Report, consultations with LGBTIQ+ groups brought up the issue of birth certificates and the way that they represent families. Birth certificates are beyond the scope of this Review. Nevertheless, the Review consulted with Births, Deaths and Marriages Office during the Review, and informed them of the concerns raised by these groups throughout the Review’s consultations.

Additionally out of scope of the Review are the Medicare rebates for ART for people experiencing ‘medical infertility’. The Review has been advised that, in practice, access to rebates is provided, as with other MBS payments, on the assessment of the treating clinician, and that some LGBTQ+ and sole
intended parents are able access rebates. Nevertheless, many stakeholders, including clinics, professional organisations and patients, expressed frustration with the continued distinction between ‘social’ and ‘medical’ infertility in the MBS system, and its impact on patients.

*The current Medicare subsidy regime inappropriately discriminates against women without a diagnosed cause for medical infertility and should be abolished in order to support the further development of equitable access to ART.*

Submission – Royal Women’s Hospital

### 5.1.2. People with intersex variations accessing treatment

The terms of reference for the Review grouped people with intersex variations within the LGBTIQ+ community. However, the Review identified concerns from people with intersex variations that the issues they face differ to those of the broader LGBTQ+ community. The Review undertook specific consultations with the Victorian Government’s Intersex Expert Advisory Group to understand these issues. The consultations identified specific barriers to access, information and support faced by people with intersex variations.

A major barrier to access for intersex men identified through consultation was the lack of Medicare rebate for a procedure necessary for men with some intersex variations to have children – micro testicular sperm extraction (microTESE), the surgical removal of sperm directly from the testicles using an operating microscope. It requires some medical management in preparation for the procedure and attention to a range of potential complications that can arise (Flannigan 2017).

Currently, the procedure is classified within the Medicare Benefits Scheme (MBS) as a cosmetic procedure, and patients receive no rebate. Given the complex nature of the procedure, the costs are high, and the absence of a rebate leads to high out-of-pocket costs for people accessing this treatment. The Review has been told patients can expect to pay $10,000 to $15,000 for this procedure. The Intersex Expert Advisory Group also reports there can be long wait times to access the procedure.

While the MBS is outside the Review’s scope, the Review has noted that the MBS Review Taskforce has considered this issue as part of its review. The draft recommendations of the relevant Taskforce Committee propose a new MBS item to be created for surgical testicular sperm retrieval. If implemented, this would allow for people who require micro-TESE to claim rebates on their treatment, and classify the procedure as being reproductive health. This will also be beneficial to people without intersex variations who require the procedure.

The Review also heard that there could be improvements in the information available to both patients and clinicians on the physical effects of ART on people with intersex variations.
**Patient experience**

Kathleen has Swyers syndrome, an intersex variation that results in non-functioning ovaries. As a result, Kathleen was on hormone replacement therapy prior to accessing ART, in order to help regulate her body’s hormone production.

Kathleen’s clinician did not discuss with her the potential impacts of the hormones used in a stimulated cycle on her body, and did not acknowledge her intersex variation when discussing the treatment plan.

Kathleen found that her body reacted quite strongly to the medications prescribed by her clinician, resulting in depression, pain and cramping, heavy periods, and heightened pain sensitivity, among other effects. She did her own research online about her intersex variation, and then took that research back to her clinician to advise them on how they needed to treat her.

Kathleen did not feel supported through this process, and did not feel as though her clinician knew how to appropriately treat her. Due to the severity of the side effects, and the lack of support, Kathleen chose to end her treatment.

Stakeholders were also concerned about the potential deselection of embryos with some intersex variations. While the Act prohibits selection on the basis of sex, there were concerns that some intersex variations are classified as serious genetic abnormalities and screened out on that basis. While clinicians informed the Review that this deselection is not happening in practice, these concerns do highlight the need for more information regarding how and why embryos are chosen for implantation above others, to ensure that intended parents are fully informed about their fertility journey. Further consultation with people with intersex variations may be required to fully understand this issue.

The issues surrounding pre-implantation genetic testing, and perceived abnormalities, are discussed further in Chapter 10.

### 5.1.3. Culturally and linguistically diverse people accessing treatment

In earlier consultations, the Review identified that there may be some issues for culturally and linguistically diverse people in accessing gametes of a similar cultural heritage, and some specific challenges for some groups with social attitudes towards fertility. These issues are further discussed in Chapters 4, 6, 7 and 8.

Future consultations with service users and clinicians identified some further issues. It was reported that some people from culturally and linguistically diverse backgrounds may delay seeking ART for a range of issues related to cultural attitudes and awareness of services. Given the importance of maternal age to successful ART, these delays can reduce the likelihood of success for these groups. In addition, the Review heard from service users that people from culturally and linguistically diverse backgrounds can experience particular frustrations with the regulatory process of accessing gametes from overseas. Some service users reported that VARTA can place additional barriers on the use of gametes from non-English speaking countries. While some requirements may be intended to support communication between donors and donor conceived people, service users from culturally and linguistically diverse backgrounds are concerned. One Greek Australian intended mother objected to this practice as discriminatory.

The Review also sought out the views of the Ethnic Communities Council of Victoria, the multicultural Centre for Women’s Health and the Centre for Ethnicity and Health on any specific barriers faced by
people from culturally and linguistically diverse backgrounds. The primary issue identified during consultation regarding culturally and linguistically diverse people accessing services related to information about ART not being available in a wide variety of languages.

*Submission – Multicultural Centre for Women’s Health*

In response, the Review recommends that the Regulator, in consultation with appropriate groups, expand the range of translated materials available to ART service users. Spoken and written language barriers faced during treatment, and the need for interpreters, are discussed further in relation to public fertility services, in Chapter 6.

**Recommendation 38 Access to translated information resources on ART and fertility**

It is recommended that the Regulator work with ART providers and community organisations to expand the range of translated materials available to ART service users.

### 5.1.4. Aboriginal people accessing treatment

After the Interim Report, the Review reached out to the Victorian Aboriginal Community Controlled Health Organisation (VACCHO) for comment on some of the specific issues that may face Aboriginal people accessing ART. While VACCHO advised that more detailed and specific consultation would be needed to appropriately identify and tease out the issues, they did identify some specific issues for consideration.

*Submission – VACCHO*

The Review considers that the experiences of Aboriginal people accessing treatment should be considered, and included in the development of inclusive practice guidelines for Victorian ART.

The issue of sourcing culturally appropriate gametes for Aboriginal intended parents requires specific consultation with Aboriginal communities in Victoria. However, the Review has not identified any specific information on the demand for such gametes, or more broadly demand for ART from Aboriginal people in Victoria. Promoting self-determination is a priority for the Victorian Government, and the Regulator and ART providers may wish to consult further with Aboriginal communities over their specific needs in ART.

### 5.1.5. Sole parents by choice

Some of the key issues facing single people accessing treatment identified in consultation were:

- difficulties in accessing donated gametes – the Review discusses increasing access to local gametes in Chapter 8
- information and forms being targeted towards couples, and providing insufficient information as to how the experience of ART may be different for a single person
- the need to understand the different reasons single people may have for accessing ART

*Migration and refugee women may face barriers at the outset when seeking out information on ART if information is not available in their preferred language.*
comments from clinicians and counsellors that were interpreted as assuming a preference for a partner.

_The counsellor seemed to be trying to convince me not to go ahead. She kept asking “What happens if you meet a man and you’ve got a baby who isn’t his?” Everything was about some hypothetical man who might come into my life, rather than about how I was going to raise this child alone._

**Study response – Dr Fiona Kelly submission – La Trobe University**

The Review considers that the experiences of sole parents by choice should be included in the development of inclusive practice guidelines for Victorian ART. These guidelines could include advice on adapting consent documents and treatment information to meet the needs of single people, and advice on how to respectfully communicate with single people seeking ART.

### 5.1.6. People with disability accessing treatment

Consultations with people with disability were consistent with the responses provided in the Interim Report, specifically regarding feeling pressure to use pre- and post-implantation genetic testing and diagnosis, and the screening out of known donors with disability.

The Review considers that the experiences of people with disability accessing treatment should be considered and included in the development of inclusive practice guidelines for Victorian ART. These guidelines could include improving approaches to communicating the nature and criteria for genetic testing, including the importance of choice on the part of intended parents and known donors as to whether to proceed with testing.

### 5.1.7. Men as participants in treatment

In some consultations, the Review heard that some men experiencing infertility feel as though their needs are regarded as secondary to the treatment of the carrying partner. This feedback was also reported by some same-sex couples, where the couples felt the non-carrying partner was not provided sufficient support or information, or was not as fully engaged by the care team in the process. The Review heard of some cases where a carrying partner underwent multiple cycles before their male partner was even tested for infertility issues.

On the other hand, the Review also heard that ART clinicians are aware of male infertility issues. The contribution of male infertility is acknowledged in the sector, and there is growing awareness of specific issues with male reproductive health. ICSI is a specific procedure designed to respond to certain forms of male infertility. Victorian ART clinics have benefited for many years from the work of Andrology Australia and Australian researchers on male infertility. Some counsellors spoke to the Review about their extensive efforts to engage partners as participants in treatment.

The needs and preferences of men and non-carrying partners will vary, and the way partners are engaged in the ART process will vary significantly depending on the circumstances of the family and the nature of treatment. However, inclusive practice that supports as strong an engagement as possible with men and non-carrying partners is clearly to the benefit of all, including the people born as a result of treatment.
The Review considers that improving responsiveness to the experiences of men and non-carrying partners accessing ART should be considered and included in the development of inclusive practice guidelines for Victorian ART.

5.1.8. People born of treatment

The primary guiding principle of the ART Act is that

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

However, consultations with people born of treatment, particularly donor-conceived people, revealed that some of the impacts on their lives could be mitigated by regulatory changes. Feedback on the efficacy of these regulatory changes may need to wait until they are adults, and cannot be predicted with certainty at the time of making changes. In addition, the experiences, values and wishes of donor-conceived people are of course not all uniform and not all determined by the nature of ART regulation. Nonetheless, better research on the specific psychosocial challenges faced by donor-conceived people, and consultation with donor-conceived adults, can improve ART practice and regulation.

The Review heard that a particularly important issue for donor-conceived people is the number of donor-siblings they may have, and the ability to connect with their donors. These are both highly impacted by local donor supply, donation limits and importation of gametes, which are discussed in Chapter 8.

While out of scope of the Review, most donor-conceived people consulted provided feedback on the Donor Register. Specifically, they were concerned with the way the current Donor Register contacts donor-conceived people whose donors are seeking information, and the inability for donor-conceived people to contact their donor-siblings. The Review identifies these issues as matters the government may wish to further consider in responding to this Review.

5.1.9. Inclusive practice

A critical component of person-centred care is inclusive practice. Ensuring that the ART industry is responsive to the needs of all people accessing services, and that their diversity is acknowledged and respected, is fundamental to equitable access to ART.

In the Interim Report, the Review recommended that VARTA and the PRP should work together with the LGBTIQ+ community to develop embedded, regular inclusive practice and cultural competency training for ART industry members and staff. However, the Review acknowledges that inclusive practice in ART should encompass more than just LGBTIQ+ people, as outlined above.

Therefore, the Review recommends that clinical governance compliance standards for ART providers include the development of appropriate inclusive practice policies. The Review’s recommendations on establishing measures of patient experience and complaint handling should also ensure over time a stronger focus on diverse patient experiences, and more effective resolution within clinics of the range of concerns expressed to the Review. The success of these policies should form part of the conditions of registration.

To support the development of these inclusive practice policies, it is further recommended that the Regulator develop guidelines on inclusive practice, with the active involvement of service users,
community representatives, parents and intended parents, their families, surrogates, donors and donor-conceived people.

The Interim Report recommended that inclusive practice training for clinics be developed to promote inclusive practice for LGBTIQ+ service users, and that participation in this training be included as a requirement in conditions of registration. The Final Report broadens this proposal by recommending the development of inclusive practice guidelines for a broader range of groups. These guidelines would not be a regulatory instrument, but would support clinical governance compliance standards

**Recommendation 39 Inclusive practice in ART**

It is recommended that the proposed compliance standards on clinical governance (Recommendation 19) include a requirement for ART providers to develop inclusive practice policies. It is further recommended that the Regulator develop guidelines on inclusive practice with the active involvement of service users, community representatives, parents and intended parents, their families, surrogates, donors and donor-conceived people.

Additionally, the Review has heard that the publicly available information regarding access and success rates is not detailed enough, and does not include information such as sexuality, relationship status, cultural background, languages spoken, or variations in sex or gender. Therefore, the Review recommends that the data that intended parents, donors and surrogates can choose to provide is expanded to include sexuality, relationship status, cultural background, languages spoken, and variations in sex or gender. This will support services users and clinicians to better understand the experiences of diverse ART users.

The Department of Health and Human Services has considerable expertise in improving data collections in health and human services, and is currently undertaking work on improving data collections related to the LGBTIQ+ community. This expertise could assist the regulators and the ART sector to improve the sensitivity of ART data collections to diverse populations using these services.

*Including client information on gender identity status in data collection [will] maximise research and development opportunities [and] … enable improved reliability of success rates for the trans and gender diverse population as well as improving quality and safety in care provision.*

Submission – The Royal Children’s Hospital Gender Service

**Recommendation 40 Improving ART data collection on diverse user groups**

It is recommended that the Department of Health and Human Services work with the Regulator, RTAC, ART providers and the data custodians of the Australian and New Zealand Assisted Reproduction Database to improve the collection of ART data related to sexuality, relationship status, cultural background, languages spoken, and variations in sex or gender. Appropriate voluntary consent requirements and protections of privacy should be ensured as part of any data collection.
6. Improving access and affordability through public provision of ART

Key points

- Direct public provision of fertility services will allow careful redesign of the system to improve access, affordability and equity.
- A public provider would also be able to champion evidence-based practice, including person-centred care, research and training, and place these within the government’s reproductive health strategies.
- Risks to be considered in establishing public fertility services include balancing Commonwealth and state funding responsibilities, the cost of establishing public infrastructure, managing demand and the impact on private industry.
- Issues to consider as part of the business case for public IVF services include: improving access for disadvantaged groups; the model of care; how the proposed sperm and egg bank will affect the design of public fertility services; ensuring fair access in metropolitan and regional areas; the mix of capital and recurrent funding; patient fees; workforce; the management of laboratories and scientific practice; research capability and funding; opportunities for partnerships with universities and private sector firms; and the pace and scale of implementation.

6.1. Direct public provision of fertility services

Unlike most aspects of health care, ART has evolved in the private health system. This has caused considerable problems with equity, affordability and quality in reproductive health care. Consequently, government intervention should focus on systemic changes, rather than simply subsidising access to ART for particular services and particular groups. The Review strongly supports the provision of public fertility services, including ART, not only because of affordability and access, but because of the opportunity to make broad changes to the healthcare system, including highlighting fertility within both women’s and men’s health strategies and within reproductive health care more generally. This will potentially reduce the need for expensive, high-technology ART, while making it more widely available for Victorians who need it have children.

The Interim Report outlined the problems with the present model of private billing of ART services. Although The Royal Women’s Hospital does have an arrangement with Melbourne IVF, there is no option for purely public ART. ART has become so expensive that it is unaffordable for many Victorians, which reduces access for many already disadvantaged groups and heightens health inequity. In addition, Medicare rebates are available only to people who meet criteria of medical infertility, placing limitations on some LGBTIQ+ and single people.

In addition, the concerns discussed in previous chapters in relation to person-centred care, evidence-based medicine and the needs of diverse groups could be addressed in part by a public clinic that acts as a centre of excellence in these areas. Such a clinic could also address the lack of publicly available ART research in Australia, which leading stakeholders believe is in part due to the solely private sector nature of fertility services.

Presently, little ART training for doctors, nurses, allied health professionals and scientists takes place in the public hospital system – unlike almost every other area of medicine, ART training largely takes place in the private system. The Review considers that training and continuing professional development for
the many subspecialists working in the field should be free from the perceived influence of commercial interests, and focused on quality, safety and effectiveness.

The Review has formed the view that state-subsidised services that can augment Medicare funding would achieve significant improvements in access to ART for a wider variety of Victorians. This may involve the establishment of public clinic(s), public–private partnerships, or through subsidies to private clinics. The Review welcomes the government’s election commitment to establish public IVF services. In implementing this commitment, the review considers that the system should be designed with the future in mind, so it can be built on over the longer term to deliver high-quality fertility services. This chapter outlines some dimensions of that long-term vision.

The practicalities of such provision need to be addressed through the development of a business case, which would include an evaluation of similar interstate and overseas models.

Key elements when considering an appropriate model include:

- target groups
- access criteria
- scope of services
- model of care, including mix of public versus public-private service provision
- relationship to a public sperm and egg bank
- metropolitan and regional location(s)
- mix of capital and recurrent cost funding
- patient fees
- workforce recruitment, retention and continuing professional development
- management of laboratories and scientific practice
- research capability and funding
- pace and scale of implementation.

### 6.1.1. Models of public provision

The re-elected Victorian Government made a commitment during the recent state election campaign to establish public IVF services. A total of $32 million over five years has been committed for bulk-billed and subsidised public IVF services for low-income Victorians, which will operate in conjunction with a regional health service.

The financial and policy assumptions for the public IVF commitment are:

- $12 million for:
  - $2 million for a business case for a public IVF service
  - $10 million, split evenly over two years in grant funding (to treat an estimated 4,000 patients a year)

- $20 million capped capital fund for upgrades to facilities delivering services. Prioritisation of projects will be determined through the business case.

The Victorian Government will support the development of a comprehensive business case, and this will be informed by the Review’s Final Report. The Review has not undertaken a detailed cost modelling, but it has provided advice on key policy issues and design features around the issue of public ART provision more generally, for consideration as part of the business case.
The Review considered various models, including:

- wholly public provision using public facilities by means of Medicare and state subsidies, with no out-of-pocket expenses for any patients
- public provision using public facilities by means of Medicare and fixed state subsidies with fixed co-payments for some and no out-of-pocket expenses for low-income earners
- public provision using public facilities by means of Medicare and state subsidies with the option of varying level of subsidy and co-payment by target group
- public–private partnership decided by tender, to enable the use of the technical facilities and workforce of private industry, with subsidies for eligible recipients
- voucher system to subsidise care for eligible recipients wholly in the private sector.

After examining these issues, the Review considers that there are advantages and disadvantages for each option. For all of the options, the Review is of the opinion that full fertility services (including ART) should be provided, including treatments such as donor services that are not provided by existing low-cost private providers.

Public facilities could provide services using the philosophy of universal provision of care. However, unless specified target groups such as low-income earners are given priority, the high demand that public services are likely to experience will not significantly improve access for these groups. If a co-payment is charged, it would likely be more affordable than using a private fertility clinic. However, co-payments do put an administrative burden and cost on public services. People on low incomes, most easily means tested by whether they hold a Health Care Card, could access services at low or no cost. If state subsidies for all people were fixed, target groups not eligible for Medicare such as some same-sex couples and single people would still suffer differential disadvantage, because their out-of-pocket costs would be higher than other groups. Varying state subsidies and co-payments by target group would enable services to charge everyone the same out-of-pocket costs (low-income earners could be exempt).

For public–private partnerships, the main advantage is being able to use existing technical facilities such as laboratories, as well as scientific staff with their considerable levels of expertise. Such an arrangement could also use the skills of the private clinical staff in the public clinic. Patients from specified target groups, including low-income earners, could receive care at either much reduced or no cost. Such a model is probably most useful in regional areas that already have private fertility services but may not be able to sustain a public facility as well.

However, there are challenges to any commercial relationship, including a relative lack of control over the technical facilities and scientific staff for the public service. Working within the public system can be quite different for clinical staff and managers used to a private sector business model. In addition, contracts would need to be renegotiated periodically, with all the time, effort and tensions that this entails.

The main advantage of providing vouchers for target groups to use in the private sector is that no new infrastructure would be required, and it may even grow the existing private fertility industry. It can also use the existing range of geographical locations, which does include some regional areas.

The disadvantages to a voucher system are, however, significant. It is likely that providing further subsidies to the private health system in this way will simply exert upward pressure on prices, making ART even less accessible for the general community. Vouchers in the private system can also be an inefficient way of using public money, rather than directing that money to those most in need of it – any growth in the industry would not then be towards low-income earners nor regional areas without an existing service.

Determination of appropriate eligibility criteria for subsidies is critical to improving access to all those who are presently disadvantaged. If this is not done carefully, little will be gained. In addition, the private
system may still not be able to cater well for disadvantaged groups such as culturally and linguistically diverse communities and those with disability.

Service users have very little information to go on to make well-informed decisions about which clinic to use, and are likely to make decisions based solely on which has the lowest out-of-pocket expenses. People in low-income groups are especially price sensitive, regardless of the quality and safety of the health service offered – this is particularly an issue if the clinic has an excessively lean business model.

6.2. Benefits of public provision of ART

The Review considers that there are many possible advantages to public provision of ART, and many countries, such as New Zealand, the United Kingdom and Canada, already have some public ART provision. Perhaps the most persuasive reason for public provision of ART services is the opportunity to redesign the system and provide universal access to good-quality, evidence-based fertility support and advice. This would reduce health inequity by giving greater reproductive choice for a wider range of people. The present system is characterised by a significant amount of unmet need among certain groups of people, although this need is presently unquantified, and many people have their disadvantage magnified by falling into more than one group.

6.2.1. Reproductive public health

Public provision of ART would likely result in a much broader and better integrated reproductive health system for Victoria. It would also support the goals of *Women’s sexual and reproductive health: key priorities 2017–2020*, the Victorian Government’s first strategy and action plan to improve the sexual and reproductive health of all Victorian women. Specifically, wider availability of appropriate fertility support and advice contributes to the key priority areas of reducing stigma and improving knowledge of sexual and reproductive health, as well as improving the understanding and management of endometriosis, polycystic ovary syndrome and menopause, as these are all associated with fertility difficulties. Similarly, sexual and reproductive health is identified as a priority area for the government’s high-level men’s health strategy *Improving men’s health and wellbeing: strategic directions* (Department of Health and Human Services 2013.). Redesign of fertility services in Victoria would provide an excellent opportunity to enhance care in a neglected area of men’s health.

6.2.2. Impacting affordability

Not surprisingly, the Review heard that the issue of most concern to both ART recipients and the industry itself was the high out-of-pocket expenses – many people experience issues of affordability. Those in low socioeconomic groups have the most obvious, although unquantified, unmet need in the field of ART and should most benefit from targeted public ART provision. Although Australia’s public health system provides a safety net for most types of health care, the present ART funding model of private billing sees a large amount of public funding go into the private sector through Medicare rebates. These are not means tested and are not targeted to lower-income groups. The emergence of low-cost providers may appear to improve access for low-income groups, however they also do not appear to have increased per capita use of services. The current private clinics that are relatively low-cost do not cater for people with complex needs or who require donor services or surrogacy.
Some people resort to accessing their superannuation early on the grounds that ART is not readily accessible in the public system (Treasury 2018). However, such access is proposed to be tightened under a review of Australian Taxation Office rules, making the provision of affordable ART even more important for those who need it.

6.2.3. Rural and regional Victoria

Substantial parts of rural and regional Victoria are without any ART services – currently Ballarat, Warrnambool, Bendigo, Geelong, Sale and Mildura are the only regional centres with ART clinics, with more planned for Bacchus Marsh and Maryborough. The level of services offered at the various clinics varies. ART usually involves multiple visits to the clinic or procedure centre over what can be many months, and large amounts of travel and additional time off work make such treatment increasingly impractical and expensive for people outside metropolitan Melbourne.

Careful placement and coordination of appropriate public services could reduce the amount of unmet need for fertility services at various levels of care in regional and rural areas. This could be achieved by using community health centres, the eight existing and proposed Sexual and Reproductive Health Hubs, existing public hospitals or subsidies paid for services rendered at regional private fertility clinics, especially where demand at the regional area was insufficient to sustain a public clinic as well. It would also be advantageous to leverage existing expertise by developing reproductive health services in regional and rural areas in association with a large central public provider.

6.2.4. Disadvantaged people and/or people with specific needs

Public provision of fertility services could potentially better serve disadvantaged people, or those with specific needs, than the current system. Culturally and linguistically diverse communities may need special provision to meet their needs, and the stigma associated with infertility can be especially high in some communities. Public hospitals are already experienced in helping many in these groups with their health care, and staff usually have increased cultural understanding and familiarity with them as a result. Services routinely provided in public hospitals include provision of translated written information in community languages, and free interpreter services (including AUSLAN) where necessary.

The degree of unmet need among Aboriginal people is not clear, and the Review has found no evidence of particular consideration for them under the current system. It is likely that Aboriginal people are disproportionately affected by cost, geographic, cultural and other barriers to access, as in other areas of health. Public hospitals reduce these barriers through the provision of Aboriginal Liaison Officers (such as Monash Medical Centre’s Aboriginal Women’s and Children’s Health Team), for both direct support of Aboriginal patients and cultural advice for staff and the hospital. Culturally safe spaces may also be provided, improving the patient experience for Aboriginal patients.

Some single people and same-sex couples face differential financial impacts, as they do not qualify for Medicare benefits unless a medical need for ART can be shown or presumed (for example, by several failed IUI cycles). Members of the LGBTIQ+ community expressed concern with the additional costs involved in meeting these criteria. Public provision of services would result in much fairer access to ART services for those members of the LGBTIQ+ community who are currently unable to form a family because of cost constraints.

Public fertility services that include subsidised donor services should reduce the need for IVF. For instance, IUI is a cheaper and technologically much simpler technique, with very little risk to the patient if
their natural cycle is used. The current reliance on private industry and the Medicare subsidy regime results in perverse incentives to prematurely use IVF, rather than allowing longer for natural conception if appropriate for heterosexual couples or using IUI for a sufficient number of cycles where clinically indicated for other people. The situation is complicated by the lack of availability of sufficient quantities of donor sperm, as IUI requires many times the amount of sperm as IVF. The Review heard that this situation has a disproportionate impact on single women and lesbian couples, the main users of IUI.

Some public hospitals are particularly experienced in providing health care to trans and gender diverse people, which could provide a good basis for providing ART services to this group. Monash Medical Centre performs gender-affirming surgeries and The Royal Women’s Hospital provides gynaecology and andrology services after this. The Royal Children’s Hospital’s Gender Clinic provides advice and support to trans and gender diverse children and adolescents, and it is important that it can recommend and refer young people for fertility conservation where appropriate, prior to medical treatments such as puberty blockers or gender affirming hormones or surgeries. This should be able to occur regardless of the child’s socioeconomic background. Clearly, hospitals need to be appropriately resourced to provide these services.

These services also give these hospitals experience in providing healthcare to trans and gender diverse people. There are reports that trans and gender diverse people accessing ART in Australia have received inadequate care and support from private ART clinics, and as a result turn to informal networks and methods of ART (Charter et al 2018). A public health service that is experienced in providing health care to trans and gender diverse people may be best placed to provide respectful and inclusive ART to this group.

Fertility preservation is particularly important for people with intersex variations. As discussed in Chapter 5, the Review heard that people with intersex variations can be born infertile, but still wish to be parents – and that costs for ART are very high. For example, although microscopic testicular sperm extraction (micro-TESE) has finally been recommended for inclusion in the Medicare Benefits Schedule, it is not easily accessible in Victoria. A public clinic might be able to provide more accessible ART for people with intersex variations, both in terms of cost and range of services.

Presently, fertility preservation prior to medical treatment that is toxic to the ovaries or testes, particularly for cancer, is inadequately covered by Medicare. The Royal Women’s Hospital operates the only dedicated fertility preservation service in Australia in conjunction with its private contractor. However, for some patients, there are still some out-of-pocket expenses for using this highly specialised service, and storage fees are charged for the preservation of tissue, gametes and embryos in both paediatric and adult patients. Consequently, fertility preservation for medical reasons can be a significant expense for affected patients at a very difficult time, both psychologically and financially. Although the Review was assured that, at least in the Melbourne Metropolitan area, there is a 24-hour turnaround time to be seen by an ART specialist after an oncofertility (cancer-related) referral, it is uncertain what proportion of affected patients can afford to follow through with fertility preservation because of out-of-pocket expenses. More concerning, it is unknown what proportion of patients facing gonadotoxic therapy do not take up the offer of a referral to an ART specialist in the first place (or even if such an offer is made) due to financial concerns. It is unlikely that people in lower socioeconomic groups can give sufficient priority to the cryopreservation of their gametes in the face of a fertility-threatening cancer diagnosis. More extensive public provision of fertility preservation services, including outside the metropolitan area, would greatly reduce the emotional impact of such serious diagnoses.

The Review heard that some private clinics seemed to lack experience in working with people with disability and their potentially more complex needs. This may be because increased financial stress in this group contributes to their lack of access to ART. In contrast, larger public hospitals are more likely to have experience in the health care of people with disability, and may already have specialist staff and equipment (such as lifting machines) in consulting rooms as well as procedure rooms. For instance, the
Royal Women’s Hospital already provides midwifery and social work care for pregnant women who have a learning difficulty, acquired brain injury, or intellectual, physical or sensory disability, with longer appointments, AUSLAN interpreters where necessary, and linkage to appropriate community supports, appropriate equipment and outreach support after the birth. The aim is to help women care for their babies independently. Similarly, targeted public hospital clinics could take on the role of specialised care for people with disability who wish to access ART services, supporting their independent decision making. If such clinics are run using Medicare, state government subsidies are likely to be necessary to resource longer appointments, for instance.

It is likely that people with more complex medical conditions will have better coordination of care during infertility treatment at a tertiary care hospital due to improved access to multidisciplinary teams. This includes coordination with oncology services and referrals for medical fertility preservation. Similarly, ART clinics located in some public hospitals would be well placed for more seamless transition between their gynaecological services, as well as their midwifery services.

6.2.5. Whole-of-person care

Care of the whole person is particularly important in infertility management, as most people find it physically and emotionally stressful. Public hospitals often see people during stressful life events as well as joyful ones such as giving birth, and are usually large enough to have provisions for holistic care. For instance, The Royal Women’s Hospital has specialised grief support in a Reproductive Loss Service to support families after miscarriage, stillbirth or death of a baby (Royal Women’s Hospital 2019a). Larger public hospitals will also have more general counselling services provided by psychologists and social workers – this should be done at best practice levels, not limited by cost. In addition, pastoral care services that include access to ministers of a variety of faiths are usually provided, as well as multi-faith sacred spaces for personal reflection and prayer, and communal services (Royal Women’s Hospital 2019b; Monash Health 2019). Such care is important to the psychological and spiritual wellbeing of people who use these healthcare services, especially in the context of change, loss and grief that is part of the infertility journey for so many.

6.2.6. Centres of excellence – care, training and research

Another important consideration is that exclusively private provision of services does not encourage plentiful, good-quality research, which is needed in an area of medicine that so often pushes technical limits and is perceived to have commercial conflicts of interest. The long-term health of the ART sector in Victoria needs a strong culture of robust research to enable a more measured approach to the introduction of novel techniques, especially those that are insufficiently proven, unnecessary, expensive or ethically questionable.

In contrast, public hospitals often become centres of excellence in the provision of care, training of health professionals and the production of medical research, all of which can be consciously planned for, including for person-centred care outcomes. Freeing practice from commercial influence and the need to gain competitive advantage, combined with providing strong partnerships with universities, is a well-established way of contributing to a strong evidence base in medicine, including for appropriate novel therapies. Such an environment puts quality, safety and effectiveness first for patients. It is also likely to be cheaper when unproven and unnecessary medical adjuvants are not used. A reputation as a centre of excellence also makes a service a trusted source of public information. Good-quality information (or links
to other authoritative sources) on fertility challenges and treatment on a public hospital’s website may be an influential resource for both potential and current service users, as well as the wider community.

Partnerships with universities and appropriate postgraduate colleges that are free from commercial conflicts of interest are necessary to providing quality training and continuing professional development for both clinic staff and the wider ART workforce. Such training arrangements are standard in the public system for most aspects of undergraduate and postgraduate training, such as between the Royal Australian and New Zealand College of Obstetricians and Gynaecologists and major women’s hospitals. Notably, ratios for clinical educators to trainees and other staff tend to be lower in public hospitals, commensurate with their role as teaching facilities. The intellectual stimulation that comes from working in facilities that encourage evidence-based practice, research, training and teaching opportunities is likely to attract staff, especially doctors and scientists, even though wages at public services may not be as high as at private clinics.

6.3. Success criteria for public provision

It is important to consider what success would look like for public ART provision. At its heart, public health care provides good-quality care to a much wider variety of people than those who receive it in a purely private system. Evaluation strategies need to be designed to assess use of ART by target groups before the introduction of public services, and on an ongoing basis. Public services should aim for improved access to infertility advice, support and services for:

- low socioeconomic groups – these often overlap with the other groups
- regional and rural populations
- culturally and linguistically diverse populations
- Aboriginal and Torres Strait Islanders
- people with disability
- people who need fertility preservation for medical reasons
- people with more complex medical conditions or multimorbidity
- LGBTIQ+ people
- sole parents by choice.

Rigorous evaluation of person-centred outcomes should be integral to any fertility clinic, and public clinics should show leadership on this. A validated evaluation tool could be used throughout Victorian (and even Australian) clinics, allowing fair comparisons and benchmarking, and enabling all clinics to improve their services.

As with any fertility service, the number and rate of live births will be an important outcome measure. Statistical analyses will, however, need to consider patient factors likely to reduce the success rates at a public service, such as treating more complex patients.

The amount and type of subspecialist staff training, as well as continuing professional education given, will be important to assessing the development of centres of excellence.

Research output is another important measure – such research should ultimately also benefit the wider fertility industry.

The contribution of public provision to broad population health outcome measures, and specifically to those in women’s health, as well as links with the Department of Health and Human Services’ outcome measures framework, will also need to be considered.
### 6.4. Risks to be considered when selecting a model of public provision

Consideration needs to be given to financial, medical, social and intangible aspects of public ART provision for the various models, including those aspects that affect the person to be born.

#### 6.4.1. Commonwealth and state funding responsibilities

Provision of services will rely on funding from the state and federal governments. As with a number of public health services, provision of services would be covered by the use of Medicare rebates augmented by state government subsidies. Appropriate business rules would need to be defined.

#### 6.4.2. Cost of establishing public infrastructure to deliver ART

Some possible public providers already have suitable consulting and operating theatre facilities – The Royal Women’s Hospital, for instance, currently uses its facilities for clinical ART services, with a private fertility clinic providing the laboratory services. Laboratory facilities are expensive – despite this, it is important that public clinics should offer comparable technology to private laboratories, as this is standard care in ART. A public provider would also need to have the facilities to enable an appropriate level of research as part of a centre of excellence.

Victoria has many private ART services with established facilities, workforce and technical capabilities to deliver ART services. For the state to establish equivalent infrastructure to deliver these services is arguably a costly way to expand access. Alternatively, a voucher-subsidy system to private clinics or a low-cost public–private partnership model could be used, whereby public services make use of private infrastructure. However, the strengths and weaknesses of such an approach will need to be assessed as part of the planned business case. The private clinic in a partnership could either be an existing clinic (with its existing expertise) or a new private legal entity. Ultimately, it may still be cheaper for public fertility services to establish their own ART laboratory, as well as providing greater public control of governance, which is an important consideration.

#### 6.4.3. Managing access to fertility services

There is likely to be significant demand for subsidised public ART services, and this will create pressures to manage access criteria and waiting lists for services. In both Canada and the United Kingdom, public clinics have experienced difficulties managing demand. Improving early fertility advice and support in primary care should ultimately reduce demand for ART.

It is likely that more complex patients will shift towards using public services, as happens elsewhere in the healthcare system. Triaging service users to simple and complex streams at a secondary or tertiary healthcare level will reduce the chances of people with complex fertility issues causing waiting lists to lengthen unnecessarily. The issue of access criteria is explored below under ‘Design features of a public fertility service model’.

Current ATO rules on accessing superannuation early for medical treatment require that the treatment is not readily available in the public system, so it is possible that public ART provision could reduce the
personal funds that some people rely to access ART. However, the current ATO review is likely to also result in some tightening of eligibility criteria for early access to superannuation (Treasury 2018) – this emphasises the importance of making public fertility services as accessible as possible for people who need it.

6.4.4. Impact on private industry

The introduction of public clinics may have a significant impact on existing private providers. The amount of unmet need among low-income Victorians for ART services is uncertain, and the extent of this need will help to determine the impact of public ART services on the rest of the fertility industry. The response of those providers to the increased competition will have a direct effect on consumers of ART services, and there are several possible scenarios for the overall impact on the market. It is possible that public fertility services will simply grow the market through provision of care to people who presently do not access private services. Public clinics may also lead to pressure to reduce prices overall, and to increase standards of care. However, there is a risk that public clinics could lead to a reduction in the profitability or market share of some firms; private clinics may also raise prices for the remaining users of fertility services to compensate for their loss of revenue, although this will be moderated by other competitors. However, the response of companies and providers to this significant change in the market is uncertain.

6.5. Design features of a public fertility services model

It will take careful consideration to transform a publicly subsidised, privately provided system with high out-of-pocket expenses into equitable, direct public provision of fertility services within a quality framework that is appropriately targeted to those in greatest need. Public fertility services should be well thought out and designed as a system – not just as an access issue for specific groups to ART. Consultations with patients and practitioners also highlighted opportunities to co-design services to provide care that is specifically designed for their needs – this is consistent with modern healthcare system design. Such services should aspire to not just provide a basic level of care but leadership in the industry generally to improve health outcomes for people who need assistance having children.

6.5.1. Target groups

A broad cross-section of the community experiences geographic, social and cultural barriers to accessing fertility treatment, as well as difficulties with the cost of ART. Publicly funded services are ideally placed to service a wide range of consumers, including those with special or complex needs. The Review has considered the most appropriate target groups for public fertility funding to better plan service delivery.

Low-income earners are the largest group who are presently excluded from accessing ART due to the high cost of treatment. Many of those in other underserved groups are also on low incomes, so they may also be captured by measures to target low socioeconomic groups – but people in more than one underserved group experience double disadvantage. For this reason, the Review considers that those on low incomes should be a priority group for public ART provision. This group is specifically targeted by the Victorian Government’s public IVF commitment. Means testing could be done via a Health Care Card status, however there is a real risk that other middle- and low-income earners will still not be able to afford ART services, given the high out-of-pocket expenses.
In addition, there are other groups with specific needs that should receive particular consideration, including people with physical and intellectual disability, Aboriginal people and people from culturally and linguistically diverse backgrounds.

People in regional and rural Victoria do not presently have equitable access to ART, although the amount of unmet need is not known – this is further discussed under ‘Metropolitan and regional locations’. Regional health services are also specifically mentioned in the government’s election commitment.

Since oncofertility is presently inadequately covered by Medicare, and ART prior to other medical therapies that are toxic to the ovaries or testes is not reimbursed at all, a public provider would need to give serious consideration to targeting these patients and resourcing their care. Similarly, equitable access to fertility preservation for trans and gender-diverse people and people with intersex variations is vital, as gender affirming treatments can affect gametes, and people with intersex variations may have specific fertility needs.

Currently, some single people and people from the LGBTQ+ community cannot access Medicare subsidies unless medical reasons for infertility have been proven to their doctor’s satisfaction. Consequently, many pay more for ART. In the interests of equity, the Review considers that groups without medical causes for infertility should be targeted for access to the public clinic.

There are various options for appropriately targeting underserved groups. These include a clinical prioritisation score using an algorithm with clearly defined underlying assumptions, such as is used in New Zealand, which includes age, body mass index, smoking status and duration of infertility. Another approach would be to clearly define a set of groups, focusing on the order of priority of underserved groups. Having separate streams of service for people who require more complex treatment and those who have a good prognosis with relatively little intervention (such as IUI) is likely to increase throughput and maximise the number of successful outcomes. For people with more complex treatment needs such as IVF, prioritisation could be more rigorous and relate to underserved groups as well as agreed clinical criteria. Public providers may prefer a more flexible approach to prioritisation, consistent with the general approach in the Victorian health system, of responding appropriately to individual patient’s clinical need.

### 6.5.2. Access criteria

Depending on the model chosen for publicly funded ART services, demand for services is likely to be high, which may result in long waiting lists for access to clinics and treatment. The Review therefore considers that careful attention needs to be given to service demand projections, as far as can be ascertained (see ‘Metropolitan and regional locations’), and management of waiting lists. This includes whether access criteria will be applied and what these might be.

To better target people from low income groups who are presently unable to access ART in private clinics, attention should be given to the issue of means testing access to public clinics. If this is not done, waiting lists for public services will quickly grow, and people who can afford private clinics will likely use them. This could act as a de facto means test, however it is uncertain if this would be sufficiently targeted to be useful. Means testing also raises the possibility that many people would not be on a low enough income to be seen at a public clinic, yet would still be unable to afford treatment at a private clinic.

Consideration needs to be given to targeting other disadvantaged groups, especially people experiencing disadvantage magnified by being in more than one such group, often including poverty. Priority access could be given to groups with needs not presently well served by the current private system, including people with physical and intellectual disability, Aboriginal people and those from culturally and linguistically diverse backgrounds.
Oncofertility services must be delivered quickly after referral has taken place to allow patients to commence treatment for their cancers. Oncofertility patients need priority access to public provision of fertility specialists and treatment or else provision of such services is futile. This group of people perhaps fits most easily in a system where clinical urgency is used to prioritise access to medical care.

Another approach would be to restrict public ART funding to people with the best chance of success, such as by age and body mass index, as is done in other jurisdictions like the UK (NHS 2019) and New Zealand. In Australia, the recent Medicare Benefits Schedule review recommended that rebates for ART services be restricted to people under 44 years (Medicare Benefits Schedule Review Taskforce 2018). Decisions would need to be made for state-based public fertility services as to what any cut-offs would be. These criteria would need to be both evidence-based and much more cost-effective than providing ART to people with low chances of conceiving. It would enable many people to achieve a family with as little delay as practicable. However, in order for public fertility services to provide whole-of-person care, people with a body made index outside a defined range should be offered appropriate support to bring their weight into a healthier range. This would increase their chances of becoming pregnant naturally as well as by ART if required. For people suffering insurmountable barriers to conceiving, specialist advice and support also includes counselling towards acceptance of infertility and explorations of other options in forming families if appropriate.

In addition, different public providers could have different access criteria to better serve a wider range of people and needs. For instance, one provider could limit their services by age and body mass index to enable a greater number of people with fertility issues to use the service successfully. Another public provider could either simply see people in order of referral or prioritise other underserved groups including people with more complex medical and fertility issues. Overall, the combination of public providers would then give a much better service for a greater number and range of people than is possible under the present system. However, this approach could also be seen as inequitable, as access would vary with the service to which a patient had been referred, which is likely to depend at least partly on geography.

Recently, the Medicare Benefits Schedule Review made draft recommendations for an age limit of 45 years and six stimulated IVF cycles for Medicare rebates. These appear to be reasonable base-level access restrictions to apply to a public clinic. However, many countries that provide public access have stricter access criteria, for example an upper limit of 43 years of age or three stimulated cycles.

As previously mentioned, the Review heard that public hospitals feel strongly that only clinical criteria should determine eligibility for public ART services, and not means testing or any other non-clinical processes.

### 6.5.3. Scope of services

The government’s election commitment was to ‘establish public IVF services’. Although IVF is a commonly understood term, the Review is of the opinion that, to ensure cost-effectiveness and adherence with evidence-based practice, any public provision should incorporate a much broader range of fertility services, including other forms of ART. This is because many of these services are cheaper and less medically complex than IVF itself (for example, artificial insemination, including IUI). For many sub-fertile people, cheaper and less invasive fertility treatments are clinically more appropriate than IVF and make better use of resources overall. Making a broad spectrum of fertility services more widely accessible will help a larger number and range of people have children more quickly and safely using the minimum intervention required. This will make most efficient use of resources and ensure that only people who need invasive and expensive treatments such as IVF are offered it. In this way, public fertility
services can provide an exemplar to the industry in evidence-based practice with the aim of raising standards more generally.

The Victorian Government is currently investing in eight Sexual and Reproductive Health Hubs that will provide the opportunity to enhance fertility services at the primary healthcare level aimed at 'young people, women, men and couples', with education, advice, support and basic medical testing. This would be sufficient for many people, as well as being relatively cheap. However, the present focus for these hubs is on fertility control and sexually transmissible infections, especially for women, rather than fertility support, and there remains insufficient emphasis on men's reproductive health and public education. This is but one option for broadening the links of public fertility services to primary health care. Ideally, any public hospital-based fertility service should have strong links with primary health care, including community health services.

The range of evidence-based fertility treatments to be made available is particularly relevant to donor services, including IUI, as they are not as well reimbursed under Medicare as IVF, contributing to their underuse in the private system. However, to not provide these services would differentially disadvantage single and older people as well as same-sex couples. In addition, it would create incentives for the use of IVF or the more complex ICSI rather than the less costly and invasive IUI. Similarly, oncofertility is not yet funded by Medicare for egg collection and neither is fertility preservation for other reasons such as prior to gender affirming treatment. ART services related to surrogacy are similarly not covered by Medicare.

Patients value preimplantation genetic testing, but it comes at a considerable cost for them. Demand for testing can be partly driven by patients and partly by providers. Private providers are also investing significantly in other technologies (including artificial intelligence) to assist with selection of appropriate embryos. Although there is no persuasive evidence base for screening embryos for genetic disease in families not at higher risk, the situation is different for people with a higher risk of having an affected child. The Review heard convincing arguments that such people who are also on low incomes are differentially affected by not being able to access preimplantation genetic diagnosis should they wish to have it, as it is not covered by Medicare. Notably, the birth of children affected by serious genetic disease not only causes significant distress to the parents and children themselves, but also places a considerable financial burden on the healthcare system. As a result of all of these factors, there will need to be explicit assessment about the range, business rules and technology required for the diagnostic services offered by the public clinics. Equitable access to evidence-based technologies should receive careful consideration. It is the view of the Review that, where clinically appropriate, pre-implantation genetic diagnosis should be offered at public fertility services for people at higher risk.

At this stage there is a less persuasive argument for offering elective gamete freezing via public fertility services. It is recognised that this does disadvantage people requiring egg collection, as freezing sperm usually does not involve medical procedural costs and therefore could be done at a lower fee directly with a state-run gamete bank, for instance. However, elective egg freezing is not covered by Medicare, and the recent Medicare Benefit Schedule review of ART items did not propose it.

**Recommendation 41 Scope of public fertility services**

It is recommended that, in addition to IVF, public fertility services should provide general fertility advice and support and assisted reproductive treatments more broadly – this includes intra-uterine insemination and other donor services as well as offering preimplantation genetic diagnosis for those at higher risk.
**Recommendation 42 Policy and service design framework for public fertility services**

It is recommended that public fertility services should be developed within the framework of the existing Victorian Government strategy, *Women’s sexual and reproductive health: key priorities 2017–2020*. These priorities should be reviewed to increase the focus from 2020 on fertility services, fertility education and male reproductive health, and to provide a clear policy framework for the design and development of public fertility services and their relationship with community health and primary healthcare services.

### 6.5.4. Model of care

The groups targeted for services will help to determine the model of care offered.

A tiered approach to fertility support and education would be appropriate, and it could be delivered by leveraging existing facilities throughout the state such as community health centres and the new Sexual and Reproductive Health Hubs. Services at these sites would need to be appropriately resourced, including upskilling primary healthcare practitioners. For people requiring higher levels of care, these venues could then also provide convenient places for patients to consult specialist medical, nursing and counselling practitioners.

Service design will include how fertility services are staffed and patients are to be cared for – in a purely public hospital model, patients would see a doctor appointed by the hospital, with various aspects of their care handled by a team, including doctors at various levels of training. In a public–private arrangement, patients might primarily be seen by one doctor, to whom they may have been referred by their general practitioner, as in private practice. Although all patients undergoing ART are sure to have contact with specialist fertility nurses, this should be available to all people who need fertility advice and support. In addition, some target groups would especially benefit from consultation with allied health practitioners such as social workers and occupational therapists.

Victoria’s existing low-cost private clinic uses a simplified, streamlined model of service delivery to minimise costs. The Review considers that this would be inappropriate for public service provision. Some target groups are likely to require greater levels of intervention or to be at higher risk of complications of treatment. In addition, as in other areas of health, there is likely to be a shift of case complexity to public services.

There is an opportunity to develop public clinics as centres of excellence in the delivery of fertility services that are person centred and integrated with a wider range of health and social support services. Counselling and psychosocial care is a very important aspect of fertility services and consideration will need to be given as to how clinics in public hospitals can best deliver this type of support.

Training and continuing professional development of subspecialist staff of the full spectrum of disciplines is likely to be an important part of the role of public fertility services. It is important to consider how trainee subspecialists and scientists are incorporated into patient care.

### 6.5.5. Sperm and egg bank

The Review has found that a lack of access to donated eggs, sperm and embryos in Victoria is having multiple harmful outcomes – these particularly affect single women who need donated sperm, as well as older women as the largest users of donated eggs. It is also contributing to a limited genetic pool which
differentially impacts the LGBTIQ+ community. People who can afford it can import gametes (with some difficulty) or travel overseas to undergo IVF with donor gametes and embryos, at potentially greater risk to the health of themselves and their babies. Many people, however, can neither afford to import gametes nor travel overseas for treatment. As IVF, and especially ICSI, uses a fraction of the amount of sperm as IUI, the shortage of donated sperm creates incentives to inappropriately use IVF and ICSI instead, with greater risks to patients and costs to the taxpayer. The Review proposes establishing a Victorian sperm and egg bank as a solution to this problem – this is explored in greater depth in the next chapter.

I ovulate every month without fail but I respond extremely poorly to IVF medications. I am excluded from IUI due to sperm access issues so continue to spend money & receive medications that I respond poorly to. This is despite having no issues with ovulation and being under 40 years old.

Submission – recipient of assisted reproductive treatment

Notably, access to donated gametes differentially affects people with low incomes or who do not qualify for Medicare subsidies, and patients pay significant fees to access imported gametes. Consequently, the Review considers that a public sperm and egg bank would be integral to establishing public fertility services that prioritise evidence-based care.

6.5.6. Metropolitan and regional location(s)

Decisions will need to be made regarding locations for metropolitan and regional and rural public fertility services. Factors to be taken into account will include locations of existing expertise, public healthcare infrastructure, health service networks, private clinics and priority areas of unmet need. Unfortunately, the distribution of unmet need for ART services throughout Victoria is not yet documented. The aim should be to provide service to as wide an area of Victoria as possible and to leverage existing public health services provision.

Australian Bureau of Statistics data on the distribution of people in reproductive age categories in geographic areas could be used as a proxy measure for unmet ART need. Refining the data to also identify parts of Victoria with higher concentrations of low-income earners could be done by using Socioeconomic Index for Area (SEIFA) categories. Locations with high proportions of people both in reproductive age groups (especially those who are higher users of ART) and on low incomes are likely to be areas of high unmet need for ART services. These underserved areas are unlikely to attract investment from private fertility clinics. In addition, the Victorian Women’s Health Atlas provides useful information on birth and fertility rates and counts by local government area, using Australian Bureau of Statistics data.

Privately run regional clinics presently exist at Ballarat, Warrnambool, Bendigo, Geelong, Sale and Mildura with more planned for Bacchus Marsh and Maryborough – however, most are branch clinics of much larger providers. Not all ART services are available at all existing regional sites, and there are large areas of Victoria that do not have any ART services at all.

The Review’s Interim Report recommended relaxation of the laws around IUI to return to the previous arrangements where the procedure could be performed by a person under the direction of a medical practitioner, rather than only by a medical practitioner. As this greatly improves the financial sustainability of branch ART clinics, this of itself should make an important, relatively simple and cheap ART procedure more accessible to people in regional areas, albeit through the private clinic system.
All fertility clinics require consultation rooms and, as previously noted, primary health care, including community health centres and even Sexual and Reproductive Health Hubs may be suited to this. In addition, IUI only requires storage facilities for what would probably be a relatively small amount of sperm, although the sperm would need to be prepared in a laboratory elsewhere. Similarly, relatively little infrastructure would be required for locations where blood tests and ultrasounds are done and many existing facilities in rural areas could be used for this. A hub and spoke model can be used to provide a range of fertility advice and management services, even up to day procedures using local health services, such as diagnostic laparoscopies. However, the more invasive and technologically advanced ART procedures such as IVF, ICSI and associated techniques require infrastructure that includes procedure facilities for egg pick-ups as well as a properly equipped laboratory. For example, Ballarat IVF provides IVF and ICSI procedures only in Ballarat – however, a wide range of other fertility management, including preparation for and monitoring of IVF and ICSI, can be undertaken at their branch clinic in Warrnambool, where they ‘complement’ local women’s health services (Ballarat IVF 2019).

The need for greater infrastructure for advanced ART procedures is likely to be a limiting factor in deciding on regional location(s) for public provision, especially if economies are to be achieved by using existing medical procedure facilities, for instance. This will need to be weighed against the issue of equity in provision of ART services through a wider area of regional and rural Victoria.

6.5.7. The mix of capital and recurrent cost funding

The public commitment to ART services envisages that $20 million of capital funding will be provided to help establish public clinics and all necessary equipment and recurrent funding of $5 million a year.

Capital funding would be required to set up ART clinics, procedure facilities and expensive laboratories. The amount required will depend on the extent to which existing facilities can be used – for example, consultations could take place at community health centres and public hospital out-patient clinics and public hospital operating theatres could be used for procedures. Space availability at some sites may constrain what clinic space can be used. Appropriate equipment for disadvantaged groups such as people with physical disability may need to be purchased. If the public facility operates in partnership with a private fertility clinic, then existing ART laboratory facilities could be used (presumably at a cost), although the issue of adequate storage facilities for gametes and embryos would need to be resolved if a Victorian bank does not eventuate.

After set-up costs, significant recurrent funding will be required for the maintenance of equipment and facilities. Delivery of services requires, among other considerations, costs of staff recruitment, training and wages and clinic, operating and laboratory consumables as well as rebates available through Medicare. To include IUI and donor services, it may be necessary to either cross-subsidise them with services that receive a better Medicare rebate, or a co-payment could be charged. Recurrent funding could be allocated by case mix (Weighted Inlier Equivalent Separation) and an appropriate price set for services.

Consideration needs to be given to placing limits on the expenditure of public funds. Provision could be limited by the number of patients serviced, the number of public clinic consulting sessions available or the number of treatment cycles to be provided per person.

In this respect, forms of public–private partnerships may be considered. For example, the fertility clinic at the Royal Prince Alfred Hospital (Sydney) is a public–private partnership between the public health service and the private ART firm Genea. The private firm provides some of the technical equipment and infrastructure for the service as well as laboratory specialists. The public hospital provides clinical services on an outpatient basis at its central city campus. Patients are charged a discounted fee, and this income supports research and teaching activities at the hospital. Another model is the newly established
service at The Royal Hospital for Women in Sydney. This service was established, with new technical infrastructure, through contributions from the associated university, a philanthropic fund, and the New South Wales State Government. The service will cater for low-income patients, oncofertility patients as well as some patients who are participating in clinical trials.

One of the key benefits of these kinds of partnerships is to share the costs of infrastructure between public and private sectors. If the government wished to pursue such partnerships, it could consider funding mechanisms to allow publicly funded fertility services to be delivered by private clinics. For example, it could offer an open tender to both public hospitals and private clinics to offer public services.

An alternative to delivery of care through dedicated public clinics is the provision of subsidies to eligible patients to enable them to use the private infertility clinic system already in place. Such subsidies could be means tested and rationed if necessary to prioritise people in underserved groups. Potentially, this could include prioritising regional and rural areas, however this could encourage people to move to areas where they had a greater chance of qualifying for subsidised ART. Patients would also not be able to take advantage of the services available through large public hospitals. In regional areas with existing private fertility clinics that may not be able to sustain a public clinic as well, private clinics could be contracted to also provide public services. Purely public facilities could concurrently be used in other parts of the state without any current access to fertility services.

However, although it may appear cheaper, a voucher system would in reality subsidise the current private industry. Consequently, subsidies may exert upwards pressure on prices rather than reducing out-of-pocket expenses overall, leaving all service users worse off. Overall, the Review considers that Victoria should follow the model of many other countries and implement reforms to the system of delivery of fertility services with a larger component of public provision, rather than relying on public subsidies to private industry and patients.

### 6.5.8. Patient fees

State-subsidised services can play an important role in augmenting Medicare, but the delivery of public fertility services will need to consider what level of patient contribution is made. Currently the private provision of these services relies on out-of-pocket fees.

Thought will need to be given as to whether state-subsidised services should ensure that public fertility services are provided at no further cost to service users, or whether co-payments are necessary for them to run on a cost-recovery basis, as could be charged in a public–private partnership, with as many services as possible bulk billed. Not all services potentially offered as part of public provision are covered by Medicare item numbers, and some are reimbursed better than others. It is important that decisions about appropriate treatment for individuals or couples can be made on purely clinical grounds, as far as is practicable. Perverse incentives that encourage either service users or medical practitioners to opt for less appropriate treatments should be avoided if possible. This will contribute to good practice as a centre of excellence in fertility services.

Further significant costs of ART include the medications used during IVF to stimulate the maturation of multiple eggs. These are potentially unaffordable for low-income patients, but also a considerable cost if publicly funded.

Consideration will also need to be given as to whether people who do not qualify for Medicare rebates at all for their ART should be differentially charged a co-payment or if services to them should be cross-subsidised. This would particularly apply to single people and those from the LGBTQ+ community without a medical reason for infertility, as well as older women. It is the firm view of the Review that those
who are unable to form a family should receive equitable access to treatment through public fertility services, and that this should not be based on their eligibility for Medicare subsidies.

Some potential public providers have also considered the concept of a relatively low levy per patient or couple being charged in order to help fund research at a public fertility service on the grounds that research is necessary for ongoing practice improvement.

6.5.9. Workforce recruitment, retention and continuing professional development

Fertility services that are publicly funded will need to recruit quality staff. Private clinics are likely to be able to pay their staff more than publicly funded clinics, and staff will need to be attracted to working in a centre for fertility service excellence that practises evidence-based medicine and contributes to high-quality and needed research in the sector, as well as being free from perceptions of commercial influence. The appointment of key senior clinicians, scientists, nurses, and other staff with a clear vision to provide quality clinical care to underserved and/or disadvantaged groups and to achieve scientific excellence will be vital to attracting other like-minded staff.

Senior clinicians, scientists and laboratory managers, and others will need to recruit the rest of the workforce needed. It is not certain whether there is an adequate pool of appropriately qualified staff in Victoria. It would not benefit Victorians who use private clinics to have significant numbers of staff recruited from the private system, especially in a short space of time. At least some recruitment is likely to need to be done interstate, and possibly internationally for key senior positions. A phased introduction of public services may enable the training of new staff to keep pace with requirements in public fertility service provision.

Similarly, staff retention will depend not only on the intellectual stimulation of striving to achieve excellence in fertility services and research, but on providing them with a rewarding, collegiate and respectful working environment with reasonable expectations of staff.

Some staff may prefer to split their work between public and private fertility clinics. Combining public and private work is, of course, common in other areas of medicine, and enables doctors to balance gaining a higher income from private work with their often more intellectually stimulating and altruistic work in the public sector. The Review considers that care would have to be taken with employing staff under these circumstances that their contracts with private fertility clinics do not preclude employment at any another clinic, including a public one.

Being a rapidly changing field, continuing professional development for all staff is an important issue for ART clinics. Ongoing professional development should be part of the culture of public fertility provision, and ideally combined with training for subspecialists. For instance, presentations on recent scientific papers and management of difficult clinical situations could be part of a regular training and professional development program, with the option of webcasting to remote locations. This would also be part of the advantage of a sizeable clinical network.

6.5.10. Management of laboratories and scientific practice

The Interim Report identified some issues in the standards of laboratory management and incident reporting, despite the RTAC accreditation required of ART laboratories. A public ART facility would be required to have very high standards of laboratory management to fulfil its purpose and to prevent potentially devastating errors. National Association of Testing Authorities, Australia (NATA) accreditation
would be expected as a matter of course. High standards would need to be maintained across multiple locations, if applicable.

Decisions will also need to be made regarding the purchase of appropriate equipment and technology for the various locations. In order to future-proof technology as far as possible, the equipment purchased will also need to reflect developments in ART, such as the move towards the use of artificial intelligence algorithms in embryo selection, if appropriate. The technology acquired should also be suitable for engaging in projected research projects.

The Review considers that the training and development of specialist scientists and technicians should be an important part of the role of public ART facilities – providers could build on existing strong roles in this area. There are additional costs associated with the provision of training that need to be factored in the design of a public model — this is much safer than relying on trainees as an undertrained workforce.

### 6.5.11. Research capability and funding

The Review believes that an active research program to contribute to the evidence base of ART is integral to the role of public fertility services. High-quality scientific evidence of clinical appropriateness and success will encourage services that maximise the efficiency and effectiveness of the funding allocated.

Ideally, public fertility clinics would have a working relationship with universities and research institutes, which would then be well positioned to access research grants. Senior clinicians and scientists should have joint academic appointments that formalise the requirement for them to be actively involved in research. Such relationships with other institutions should include those that promote ongoing research into the health of all fertility service users, including the resulting children from birth through to adulthood and thence to their own reproductive lives. Information on children beyond birth is presently not collected in the ANZARD database owned by the FSA. In contrast, research on the health of children born from assisted conception continues to be done through cooperation between the Murdoch Children’s Research Institute, the Royal Children’s Hospital, the Royal Women’s Hospital, the University of Melbourne, the Hudson Institute of Medical Research and Monash University (Amor et al. 2017). Although Melbourne and Monash IVF clinics are also involved, the data they can provide will become progressively less useful as they no longer cover all ART in Victoria. Ongoing production of high-quality scientific evidence, including more extensive long-term datasets, is necessary to inform the provision of ethical, effective, and efficient fertility services.

The resources available for research will vary depending on the funding model chosen for public fertility services overall and how often external sources may be available, such as National Health and Medical Research Council or Australian Research Council grants. Such grants are, however, highly competitive to obtain and it would be wise for a research facility not to rely on them. The model used should consider how to fund research consistently and reliably, including a specific allocation for set-up costs. A low levy on a per patient or couple basis (such as used in one New South Wales clinic) to provide a reliable funding stream for ongoing research could be used – this model received favourable feedback during consultation.

The Review considers that leadership in research at public fertility services should not only be confined to the technological aspects of ART. There is great scope for improvements in the evaluation of person-centred care in Victoria, including psychosocial support, through the development of a new survey tool or validation of an existing one for local use. Such a tool could then be used throughout the state for comparisons between clinics.
6.5.12. **Pace and scale of implementation**

It will take time to set up quality public fertility services – this will depend on the number of providers and locations, the degree of difficulty in obtaining a suitable number of qualified staff, as well as key appointments of senior staff. The extent to which existing facilities will be able to be used, along with how long it will take to set up any new clinics and laboratories, will need to be considered. There may be legal considerations for facilities and staff wishing to switch from private to public services, or simply moving from their existing private employers.

The business case will need to assess the phasing of service introduction – if a provider with existing facilities and staff can be used, operations may well be able to be commenced earlier than promised in the election commitment. A provider that requires an entirely new service to be set up will take longer but may have other benefits.

Notably, the election commitment represents a significant proportion of the nearly 13,000 women treated in 2016 in Victoria, and could therefore cause a significant disruption to the ART market. The commitment is aimed at low-income Victorians and a regional service – it will depend on the access criteria for a public fertility service as to what proportion of those currently accessing ART privately, if any, will qualify for public provision. The alternative would be a more gently phased introduction, taking into account market demand and the benefits to public fertility services of building their capabilities gradually.

**Recommendation 43 Model for delivery of public fertility services**

It is recommended that public fertility services should be progressively developed over time to be a high-quality system to ensure better health outcomes for a broad range of service users and families, not just low-income earners. This should be achieved through provision of a comprehensive range of person-centred, evidence-based services, including care for people with complex medical needs and a specific focus on the needs of LGBTIQ+ people, culturally and linguistically diverse people, Aboriginal people, people with disability, single women, rural and regional Victorians, and other relevant groups who have difficulty accessing ART.
Recommendation 44  Issues to assess in the business case for public fertility services

It is recommended that the business case for public fertility services should consider the following key design features:

- elements of co-design with consumers and practitioners with a view to improving person-centred care
- improving access for underserved groups
- model of care, including mix of public and/or public-private service provision
- consideration of any links with the proposed sperm and egg bank
- mix of capital and recurrent funding
- patient fees
- workforce recruitment, retention and continuing professional development
- management of laboratories and scientific practice
- research capability and funding
- opportunities for partnerships with universities and private sector firms
- the pace and scale of implementation, including the phasing of service development subject to both resources and demand.
7. Establishing a public sperm and egg bank

Key points
- There is a serious shortage of donated gametes in Victoria, which causes delays in treatment and constrains treatment options.
- To help address this, a public sperm and egg bank should be established.
- The work of the sperm and egg bank should be combined with public fertility services to ensure that donated gametes are available, and personal gametes and embryos can be stored appropriately until needed, including for fertility perseveration.
- The sperm and egg bank will also deliver education and awareness programs about the need for donations, and it will recruit local donors proactively, and if necessary import gametes into Victoria to meet local shortfall.
- The bank could also offer a screening service for gametes where the donor and recipient know each other but wish to undertake proper medical checks before attempting conception through home insemination.

The Interim Report highlighted that increasing the supply of donor gametes and embryos in Victoria would improve accessibility and alleviate some of the existing costs and risks associated with sourcing gametes and embryos. The Review noted that in 2017–18, there were only 246 egg donors and 424 sperm donors in Victoria, a slight decline from the previous year. There were 2,151 recipients treated with donated gametes (VARTA 2018). The Review has heard that the demand for donated gametes continues to grow, particularly as more single women and same-sex couples seek donations to help form a family.

Stakeholders, including patients, industry experts and VARTA, raised concerns about the serious shortage of donated gametes in Victoria and the adverse consequences this has for those seeking ART, including additional costs, delays in treatment or constraints in treatment choices. Feedback indicates that the scarcity of donor gametes, in particular donor eggs, means that it is not uncommon for people to seek donors through informal channels such as social media forums. This approach is unregulated and can put people at risk. It may lack proper screening processes and other protections, and may result in complications and inferior health outcomes. Alternatively, donations may be sourced by individuals through friends; however, such eggs may be of lower quality, as the donors themselves are generally older. This can result in poorer overall outcomes and higher treatment costs as numerous treatment cycles may be necessary.

The Review also heard that many Victorians now access donated gametes overseas. While some people report positive experiences of treatment outside Victoria, others highlight the significant costs, time commitment and risks associated with this option. Less rigorous regulation and processes abroad may also result in health complications for Victorians receiving treatment. For example, overseas clinics may favour practices likely to result in multiple pregnancies, with the attendant health risks and expenses borne by the Victorian healthcare system when patients return home to deliver. There are also ethical concerns about the potential exploitation of vulnerable people for donations in some environments with less regulatory oversight. Feedback to the Review also highlighted that donor-conceived people can view the use of anonymous overseas gametes as a practical obstacle to accessing information about their genetic heritage and ultimately connect with their donors.

Stakeholders furthermore highlight the need for less restrictive regulation regarding access to donors in Victoria. Some of the main barriers identified related to a lack of public awareness about the need for donors and information about donor programs, limited scope for financial compensation of donors,
restrictions on advertising and barriers to the importation of gametes. It was also suggested that a more proactive approach to addressing these key issues, including active recruitment of potential donors, would enable better access to treatment for people who need donor gametes or embryos to create a family. The Interim Report indicated that the Review would explore opportunities to establish a public sperm and egg bank, as well as areas for regulatory reform. A range of overseas jurisdictions have well-established donor sperm and egg banks. However, no such entity exists in Victoria, or elsewhere in Australia. While some Victorian ART providers have donor sperm and egg stores, these supplies fluctuate and are available only to patients using those providers.

The Review observed in its Interim Report that a dedicated sperm and egg bank in Victoria may increase supply by having a strong focus on recruitment of donors and ensuring more equitable access to donor gametes and embryos. The creation of a sperm and egg bank requires consideration of a range of issues, including:

- the nature and regulation of the bank
- the types of services to be offered
- preferred funding model
- approaches to sourcing donations
- promoting the wellbeing of donors
- ensuring fair access to donated gametes for individuals and ART providers
- identifying appropriate success criteria for the bank.

In addition to these matters, Chapter 8 will explore additional opportunities to improve access to gametes and embryos in Victoria through appropriate legislative reform.

7.1 Nature and regulation of a sperm and egg bank

The Review considers that some of the potential options for establishing a donor sperm and egg bank include a publicly run bank attached to a hospital or public fertility services, facilities made available through a commercial operator, or by way of a public–private collaboration. Over time, Victoria may see the emergence of a combination of these services to help increase access to gametes. The Review notes in particular that commercial egg and sperm banks are common overseas. A private model in Victoria could involve an ART provider that specialises in ART expanding its business to source and process donated gametes locally and/or from overseas, and making them available to their own patients as well as others. ART providers may already have much of the necessary infrastructure, equipment and trained staff to undertake this function, and the Review encourages providers to explore options on how they can best meet the needs of their patients and the community.

7.1.1. A public sperm and egg bank in Victoria

Separate to any private initiatives, the Review considers that a public sperm and egg bank would provide a valuable service to the Victorian community and many patients concerned about costs and difficulties in sourcing gametes. Options that could be offered by the public sperm and egg bank are explored below. The Review anticipates that the work of the Victorian sperm and egg bank could be effectively combined with public fertility services, noting that sourcing gamete stocks will be integral to the success of public fertility services, with donated gametes available for patients when needed.

The services offered by the bank could reasonably comprise:
sourcing and storage of donated gametes and embryos through the development and delivery of suitable education and awareness programs in the community about the need for donations

- proactive recruitment of local donors
- importation of gametes into Victoria to meet local shortfall in supply.

It is envisaged that the bank would be responsible for providing information and counselling services for donors and recipients of gametes or embryos who are not receiving treatment through an ART provider, and developing and implementing appropriate access and matching criteria for people seeking gametes and embryos.

*Sperm donor access – I have now got to move Victorian clinics (likely states) purely to access donors. Where is my autonomy in this state to stay with my chosen specialist given donors are quarantined to clinics? Arbitrary obstruction to access currently.*

Submission – recipient of assisted reproductive treatment

The bank would also play an important role in storing gametes for personal use to support the work undertaken by public fertility services. The Review considers that the provision of storage options for elective fertility preservation, in collaboration with public fertility service, is a further area where the bank could play an important role. This area of work is particularly important, as it may yield a source of future donations if stored gametes are ultimately surplus to an individual’s requirements.

In addition, the bank could offer a screening service for gametes where the donor and recipient know each other but wish to undertake proper medical checks before attempting conception through home insemination. Rainbow Families was particularly supportive of such a service, and recommended the development of an LGBTIQ+ specific program within the bank to allow for referrals and support in a culturally sensitive manner. The Review considers that a service of this type would be desirable not only from a public health perspective but also to address cost barriers in accessing safe and affordable screening options. Finally, the sperm and egg bank may also offer some fee for service components where appropriate, including access to donated gametes by ART providers on a cost recovery basis.

**Feasibility assessment of the sperm and egg bank**

The Review commissioned Deloitte Access Economics to undertake a feasibility assessment of the public sperm and egg bank, and the findings of this assessment are reported here.
Deloitte Access Economics feasibility assessment of public sperm and egg bank

Given the Victorian Government’s intent to establish a public fertility service, it is timely to consider how the donation needs of this service will be met. At the same time, it is timely to consider whether the same mechanism may serve as an opportunity to address some of the broader market failures observed in the local donation market.

Some of the factors that drive the shortage in local donations will need to be addressed through regulatory change. Others are the result of deliberate policy choices, and it is not appropriate to change them – for example, restrictions on payments to donors.

Some factors, however, can be addressed through appropriate changes to support the market, which could include the establishment of a public sperm and egg bank. For example, a market mechanism could be designed to enable access for providers that do not operate local donor programs.

The purpose of this feasibility assessment is to consider whether there is a feasible model which a public provider could operate to address some of the identified challenges, including the possibility of a public sperm and egg bank. A number of options have been considered including:

- increase local donor gamete supply across the state by a government-funded social marketing campaign to improve public awareness and understanding, in order to change attitudes towards donation
- facilitate patients’ access to donated gametes (both local and imported), particularly for patients who access providers without existing donor programs and those who choose to access the public fertility service
- increase choice for patients across the domains of provider (irrespective of whether they operate a donor program), portability (gamete supply is independent of provider) and potentially across a wider pool of donors.

The need for public investment

First, it is unlikely a private bank solution will service the needs of the public fertility service. As such, there will necessarily be some level of investment in a public banking service, either as part of the public fertility service or separate to it.

The question becomes whether there is an opportunity for this public investment to do more to improve access and supply issues more broadly.

By opening access to providers beyond just the public fertility service, the investment in the public sperm and egg bank has the potential to address broader access issues.

Critical to the success of the public sperm and egg bank will be its capacity to grow the donor pool in Victoria. Private providers that currently operate local donation centres already make substantial investments to recruit donors. Any work the government does to increase awareness and donation above this will need to build on these existing efforts, strengthening and creating a more stable local donation supply across the board.

A public provider is well placed to orchestrate a social marketing campaign that speaks to the value of donation and seeks to influence social views on donation. This is demonstrated through the success of numerous social marketing campaigns such as in blood donation, plasma donation, organ donation and breastmilk donation. However, achieving change in community attitudes and behaviours can take time and the results are uncertain.
A feasible model

There different models that could be adopted for a public sperm and egg bank. Both the functionality and scope of the public bank should be developed to respond to known market challenges. It also needs to be appropriately proportioned, taking into account the level of public investment required.

Five optional model formats were put forward, with three models assessed in detail.

1. a social marketing campaign in isolation
2. a virtual bank with no collection facilities that would simply facilitate trade of gametes between providers
3a. a public sperm and egg bank focused on servicing the needs of a public fertility service
3b. a public sperm and egg bank focused on servicing the needs of a public fertility service, enabling access to locally donated and imported gametes to providers without local donation programs and to providers with donation programs with insufficient quantities of donated gametes to meet demand
3c. a model where a public sperm and egg bank replaces all local donation collection centres across the state (fully centralised)

Only 3a, 3b and 3c were considered, because these are the only options that also provide a solution for the public fertility service.

Specifically, the three options were assessed against the following feasibility criteria:

- market failure – does the option address existing failures in the market?
- appropriateness – is the model aligned with government priorities and the regulatory framework?
- supply of gametes – does the proposed option have the capacity to safely and positively impact the quantum of supply?
- demand for gametes – can the proposed option meet demand – not only in terms of quantum but also in terms of specific characteristics like ethnicity?
- viable within stakeholder environment – is the proposed option likely to be met with acceptance from key stakeholders?
- minimise public outlay – does the option minimise public outlay through cost recovery and by maximising benefits from existing investments?
- enablers – is the option feasible from the perspective of investment enablers (capital, workforce, technology)?

The option in which the public sperm and egg bank supplemented the existing donor collection market (3b) was considered the most feasible when assessed against these criteria.

This model met the core objective of providing supply for the public fertility service, but also addressed other market failures without unnecessarily disrupting the activity of existing donation collecting providers.

The capacity for the bank to not disrupt local collection activities is entirely contingent on its capacity to increase the donor pool across Victoria through information and marketing rather than simply dividing the existing pool into smaller pieces.

Key lessons

While the Victorian legislative, regulatory and cultural environment is in many ways unique, there are lessons from banking experiences in other jurisdictions/sectors and countries that are of direct relevance to the implementation of a public sperm and egg bank in Victoria.
First, the failed and poorly funded national sperm bank in the United Kingdom in 2014 serves to show the importance of adequately resourcing a service operating on this scale.

Second, awareness and social attitudes are key driving factors in donor response rates – even in countries with no scope for donor payment beyond reimbursement for time and costs, as in Australia.

Third, while some countries allow donor anonymity and payment for donation – and Australia and Victoria do not have any intention to do so – there are structural changes that can be adopted to improve donor rates. This can include simple design features such as offering out-of-hours services or simplified booking systems. Such lessons may be adopted from Spain or California, where banks are known for creating positive experiences for donors.

**Limitations of this analysis and next steps**

This paper considered what a feasible public banking solution would comprise in order to acceptably and practically improve access to locally donated gametes in Victoria.

The model proposed is one that extends beyond the needs of the public fertility service, but does not seek to impede the business operations of existing private donation centres.

The critical success factor underlying this model is the capacity for the proposed agency to increase and maintain a stable donor pool within Victoria. While the nature of a social marketing campaign to do this has been considered at a high level in this paper, the exact design and realistic market impact of such a campaign would need to be considered in greater detail beyond this study.

Further steps beyond this feasibility study will include the design of a full business case for the public facility. Further, the interaction between this proposed facility and the public fertility service – which is proposed to be a related but independent public function – will need to be considered in the business case for the public fertility service.

The Review considers this feasibility assessment demonstrates a strong case for public investment in a sperm and egg bank, and shows how there are a number of viable models for such a bank. Service users expressed strong support for the sperm and egg bank as a practical solution to a major difficulty in accessing ART – the costs, delays and frustrations of sourcing appropriate gametes. Clinics and clinicians also expressed support, although there are some business issues to be worked through. Clearly, the government has several options to consider, including education and awareness and donor recruitment programs without a bank. However, the Review considers any such programs are likely to be more effective when paired with a dedicated service such as outlined in the feasibility assessment.
**Recommendation 45 Establishment of a public sperm and egg bank**

It is recommended that a public sperm and egg bank be established to increase access to donor gametes. The work of the sperm and egg bank should be combined with the provision of public fertility services, as an integral component in ensuring that donated gametes are available where needed. The services offered by the public sperm and egg bank could reasonably include:

- sourcing and storage of donated gametes and embryos through the development and delivery of suitable education and awareness programs in the community about the need for donations
- proactive recruitment of local donors
- importation of gametes into Victoria to address any local shortfall in supply
- storage of gametes and embryos for personal use by individuals seeking treatment through public fertility services
- provision of storage options for elective fertility preservation, in collaboration with public fertility services
- testing of donated gametes where the donor and recipient know each other but wish to undertake screening of the gametes through the bank
- some fee for service components where appropriate (for example, access to donated gametes by ART providers).

7.1.2. Regulation of the bank

While the Act regulates the use of ART and artificial insemination procedures (other than self-insemination), it does not envisage, or directly address, matters relating to the storage of gametes or embryos outside a clinic setting. The Review notes that elective fertility preservation also falls outside the scope of the Act and will need to be clearly addressed, given the increasing prevalence of this type of treatment in Victoria. As indicated above, the bank would likely offer storage options for fertility preservation, in collaboration with a public fertility service.

The Review considers that many aspects of the work of a sperm and egg bank in Victoria, including issues relating to donor consent, counselling and information provision, record keeping and reporting requirements, as well as the storage and use of gametes, are already captured within the existing regulatory framework. Nevertheless, the Act will need to be amended to clearly articulate that these obligations will apply to the proposed sperm and egg bank and any other storage-focused facility that may be established privately. The Review considers that additional issues specific to the function and operation of a dedicated sperm and egg bank could generally be developed through best practice guidelines and standard operating procedures.
**Recommendation 46 Legislative and regulatory requirements for sperm and egg bank**

It is recommended that the Act be amended to include provisions for the storage of gametes and embryos which may occur independently of the provision of ART, and clearly articulate that regulatory obligations will apply to the sperm and egg bank or any other private storage facility. These obligations include matters such as donor consent, relevant counselling, information provision, prohibition on commercial incentive or reward for donation, record keeping, reporting requirements, and the storage and use of gametes.

**7.1.3. Ownership and consent issues**

The Review does not envisage that the bank would have any ownership of the gametes or embryos held in storage. Consistent with Recommendation 12 of the Interim Report, a donor would provide consent for the use of their gametes, but could modify or revoke such consent until the time the gamete is used, either for insemination or to create an embryo. The donors of an embryo could withdraw consent until it is used in treatment. Otherwise, as discussed in Chapter 8, a prescribed donor age cut-off should apply to the storage and use of donated gametes, and any embryos created from such gametes, to ensure that there is a realistic prospect for a donor-conceived person to connect with their biological donor. In the absence of donor intervention, it is not anticipated that consent for the use of donated gametes or embryos could ‘lapse’ under the arrangement. The Review considers it appropriate that the consent process at the time of donation canvasses the fate of any gametes or embryos that may still be in storage when the statutory time limit for storage is reached. The default option offered should authorise use of surplus gametes or embryos for scientific research, with an opt-out alternative allowing gametes and embryos to succumb naturally.

Any gametes or embryos held by the bank for personal use by an individual would be stored in accordance with the arrangement put in place between that person and the bank at the commencement of the storage period, including any time limit specified by the bank. In circumstances where individuals store gametes or embryos for personal use, the original consent and counselling process should discuss the option of allowing the gametes or embryos to be donated for treatment or research, with additional information and counselling made available in an appropriate format as the completion of the agreed storage period draws closer. Surplus gametes or embryos stored for personal use with the bank would be eligible for donation and use for treatment until the person reaches the prescribed age limit. The Review understands that there are many emotional issues associated with donating stored gametes, and people will need to be approached with appropriate sensitivity and care to discuss the options open to them, particularly if their own fertility journey was not ultimately successful.

**7.1.4. Proposed funding model for the sperm and egg bank**

The Review considers that the establishment of a suitable sperm and egg bank would likely require both capital and ongoing funding. This may include requirement for some public funding to help secure suitable physical space and equipment, recruit appropriately trained staff, and develop a governance and policy framework for the operation of the bank. The Review notes that the Victorian Government has committed $32 million for the establishment of public fertility services. The government may wish to consider allocating some of this funding to set up a bank to complement the work of the public fertility services and help, as part of its work, to meet the anticipated increase in demand for donated gametes and embryos which will likely result.
Although a comprehensive business case will be required prior to the establishment of a public sperm and egg bank, it is anticipated that ongoing costs are likely to include expenses relating to running the bank including staff costs, appropriate training programs, community education, marketing, donor recruitment and screening processes, importation of gametes where necessary, and liaison with ART providers and individuals seeking gametes. The feasibility assessment by Deloitte Access Economics of the sperm and egg bank estimated the operating costs of the bank in the range of $750,000 to $1.5 million. This estimate includes a significant component for marketing and community education programs to support donor recruitment, which could also be undertaken separately to the bank. These estimates are preliminary, and final costings will depend on a preferred model and phasing of implementation.

In the course of consultations, ART providers expressed a willingness to contribute financially to a public sperm and egg bank on a cost-recovery basis, but have stressed that this would be contingent on equitable access for all patients irrespective of their treating ART provider, whether public or private. The Review considers that it would be appropriate for the ongoing cost of the sperm and egg bank to be funded directly by ART providers and individuals accessing the bank.

**Recommendation 47** Resourcing the sperm and egg bank

It is recommended that consideration be given to appropriate funding to establish a sperm and egg bank. Funding requirements and appropriate phasing of these services should be assessed through a comprehensive business case assessment. The ongoing cost of the sperm and egg bank could be, in full or in part, funded directly by fees for both ART providers and individuals accessing the bank.

### 7.2 Need for better community education and proactive donor recruitment

During consultations, the Review heard that demystifying the need and process for donation would help to address widespread misinformation and a lack of understanding of the process and legalities involved. The Review considers that one of the roles of the bank would be to develop and deliver suitable education and awareness programs in the community about the need for donations. There is broad stakeholder agreement that community education and awareness is often lacking and needs to be more effectively addressed. Anecdotal evidence from ART providers suggests that human interest stories on donor issues on mainstream media programs have been particularly effective in awareness raising and increasing donor interest and activity.

The bank would also be responsible for undertaking proactive recruitment of donors through a sophisticated information and marketing campaign to reach out to suitable donor target groups, including by working collaboratively with other entities and charities with an aligned focus where appropriate. In particular, the Review heard that there is some confusion within the LGBTIQ+ community about whether gay and bisexual men are permitted to make sperm donations, and how screening for such donations differs from the approach for blood donations. Rainbow Families has suggested that a successful education and awareness program would need to include LGBTIQ+ community consultation and co-design, as well as legal, medical, and related information. In addition, some cultural and religious groups hold beliefs that prevent donation of gametes. Community attitudes towards contact between donors and donor-conceived children may also be a barrier to donation in some cases. It is difficult for individual ART providers to respond to these underlying social attitudes that limit donor recruitment. A public agency may be best placed to adopt community education approaches that increase the pool of donors.
In addition to reaching out to the wider public through communication campaigns, in many cases it may be possible to more effectively engage with people who are already accessing ART by encouraging them to donate surplus gametes or embryos if they are willing to do so. As noted above, an increase in elective egg freezing, including from medical tourists, may in the coming years yield a surplus of eggs. This may occur, for example, where women do not use eggs they have frozen because they conceive naturally or complete their family with less than the total number of eggs in storage. It is envisaged that educating this cohort of women about the value of egg donations, both around the time of the egg freezing procedure and when storage limits approach, could provide a much-needed boost to egg stocks.

The Review anticipates that a targeted approach to education and sourcing donations by the bank will likely require dedicated staff, appropriate training and a budget for community engagement and donor recruitment. There may be scope for the sperm and egg bank and ART providers to work collaboratively to achieve objectives around better education and dissemination of information in the community.

**Recommendation 48 Education and donor recruitment functions of the bank**

It is recommended that the Victorian Government and, if established, the sperm and egg bank develop and deliver education and awareness programs in the community about the need for donations, and undertake proactive recruitment of donors to increase the local supply of gametes in Victoria.

### 7.3 Ensuring the wellbeing of donors

The Review considers that ensuring the wellbeing and health of donors needs to be an important priority for the sperm and egg bank. In particular, potential donors should be provided with information on the donation process, including screening, medical risks associated with donation, the legal and emotional aspects of donating, the discomfort or possible psychological implications of their donation, and expected outcomes of donation. The bank would address these matters by developing and publishing appropriate donor support policies, guidelines and information packs.

Careful consideration also needs to be given to assessing suitability of donors through screening processes that strike the appropriate balance between obtaining information required without excluding people unnecessarily. The Review notes, for example, that some commercial sperm and egg banks overseas appear to take an unduly invasive or interrogative approach to assessing the suitability of a donor, including detailed medical background of the applicant and their family, assessment of their physical, social, personality and educational attributes, as well as physical examinations and genetic testing. While such an approach may cater to the preferences of some intended parents, it can easily lead to discriminatory practices and should not be promoted in Victoria. The Review considers that a public Victorian bank should operate on a best practice model that focuses on donor wellbeing and avoids these questionable practices of overseas banks. Stakeholders agreed that donors should have discretion on the information they choose to share beyond basic biographic, physical and health characteristics.

Consistent with feedback provided by a number of stakeholders, the Review considers it essential that the donation process be made available in a streamlined and flexible format to minimise the impact on donors’ time. Among other things, the bank should ensure that donation can occur at key central locations, out of business hours, and in a way that imposes the least on donors (for example, undertaking counselling and medical tests at the same time). Donors have also indicated that they appreciate ongoing communication about their donation, particularly if children are ultimately born as a
result of their donation. The bank should ensure that donors are kept informed in a timely and sensitive manner on all relevant ongoing matters.

**Recommendation 49 Promoting the wellbeing of donors and donor-conceived people**

It is recommended that the sperm and egg bank develop appropriate donor support policies, guidelines and information packs to ensure that it operates on a best practice model that prioritises the wellbeing of donors and donor-conceived people in Victoria.

### 7.4 Fair access to donated gametes and embryos

Given that demand for donated gametes and embryos may outstrip supply, at least in the early stages of establishing the bank, fair access to gamete and embryos will require the development of appropriate guidance and policies by the bank to effectively prioritise recipients. When a person becomes eligible to access to bank stocks, the bank would have processes to ensure that some gametes could be set aside for future use if the recipient wishes to have biologically related children from the same donor.

Beyond the initial criteria for accessing gametes, a review of overseas sperm and egg banks reveals a variety of models for matching donors and recipients. Options range from selection for suitability by bank staff for basic physical characteristics only, through to individuals choosing gametes from a catalogue of donors based on a range of physical, health and personality characteristics via large commercial banks. The Review anticipates that the desire for information and choice by recipients regarding potential donors will need to be carefully balanced against making unreasonable demands for personal information, which may discourage donations. The bank will need to manage user expectations through effective information and education campaigns on its policies and practices. The Review also notes that it will be important for the bank to avoid practices that may be discriminatory generally, or in breach of antidiscrimination law in particular. To this end, donations made on conditions relating to race, religion, sexuality and other similar bases should not be permitted.

The Review suggests that initially, the bank would support access to gametes for people undergoing treatment through the public fertility services. As the supply of gametes increases, the bank should also explore opportunities to support people seeking gametes through private ART providers, or a general practitioner for the purposes of undergoing artificial insemination. The Review notes that the provision of artificial insemination will be supported by the implementation of Recommendation 3 of the Interim Report, which proposed that the Act be amended to allow for a properly trained health professional acting under supervision to carry out artificial insemination, in addition to a doctor. Given that artificial insemination requires a higher volume of sperm than other forms of treatment, however, access under this model may be dependent on the availability of suitable quantities of donated gametes.

**Recommendation 50 Access to gametes and embryos supplied by the bank**

It is recommended that the sperm and egg bank develop appropriate guidance and policies to ensure fair access to gametes and embryos by potential recipients. Recipients should be eligible to access gametes through the sperm and egg bank irrespective of whether they wish to do so via public fertility services, an ART provider or general practitioner.
7.5 Provision of a screening service by the bank for known donors

Given the Act currently excludes self-insemination from the definition of ‘treatment procedure’, the Review considers it may be appropriate to amend the legislation to specifically cater for the scenario where individuals access the bank to screen gametes from a known donor. This may allow people who may not require clinical intervention to conceive to benefit from some of the services and supports available through clinics. This may be particularly beneficial for same-sex couples and sole intended parents who favour self-insemination. The Review considers that a new Division of the Act should set out the ‘General requirements for known donor gamete screening’, including:

- provision of appropriate information to the donor and recipient seeking to screen known donor gametes, including the existence and function of the central and voluntary registers
- counselling requirements
- acknowledgement by the donor and recipient that they have been provided with the relevant information and counselling to make an informed decision about using known donor gametes.

Each of these requirements could be satisfied and/or completed remotely, using appropriate communication methods including online platforms. The Review does not consider that a presumption against treatment should apply for this class of people. Given the sensitivities associated with the presumption in the community, the Review is concerned that this requirement may discourage individuals from accessing gametes through safe and controlled channels, in favour of informal, undocumented and unscreened donations in the case of self-insemination.

Consequential amendments will be required to Part 2, Division 3 of the Act in respect of consent requirements for donors, to ensure that consent can be provided not only for ‘treatment procedures’ as defined in the Act, but also self-insemination by individuals in the circumstances under discussion.

Recommendation 51 Regulation of known donor screening by the bank

It is recommended that the sperm and egg bank provide a service for known donor screening and the government establish appropriate legislative or regulatory requirements for known donor gamete screening by the bank, including:

- provision of appropriate information to the donor and recipient seeking to screen known donor gametes, including the existence and function of the Central and Voluntary Registers
- supportive counselling required for donors and recipients of donated gametes
- acknowledgement by the donor and recipient that they have been provided with the relevant information and counselling to make an informed decision about using known donor gametes.

7.6 Success criteria for the bank

The Review considers it important to identify what success will look like for an effective public sperm and egg bank, and to ensure that establishment and ongoing costs are outweighed by the benefits of the proposed public service. Some of the markers of success for an effective public sperm and egg bank include:
- appropriate processes to identify existing and future demand for donor gametes in Victoria
- ability to take pro-active steps to ensure that gametes are sourced in sufficient numbers, either locally or internationally (with a preference for local services)
- delivery of public education, awareness and recruitment campaigns resulting in increased local supply of donated gametes and embryos
- regular assessment of public understanding and support for the bank
- establishment of appropriate global partnerships and arrangements to meet local shortfall in supply
- fair access to donated gametes and embryos based on a clearly articulated set of eligibility and prioritisation criteria, available to people either through a public or private ART provider or directly where appropriate
- reduced number of Victorians sourcing gametes through informal channels, or travelling overseas for donor gametes and embryos
- reduced waiting times for donated gametes
- appropriate record-keeping and data management processes in place for donors, recipients and donor-conceived people
- increased genetic diversity in locally sourced gametes, including for culturally and linguistically diverse groups
- increase in the number of live births resulting from donated gametes or embryos (reviewed both for overall increase in births to ensure that donations are going to recipients most likely to have a baby, and as a benchmark to ensure that ART providers are keeping up with best techniques)
- trusted as a quality service provider within the industry with services in demand by a broad cross-section of users.

It is envisaged that ongoing evaluation of the bank will help ensure that relevant objectives are being achieved and the work of the bank can be adjusted to meet community needs.
8. Removing barriers to accessing donated gametes and embryos

Key points

- Access to donated gametes and embryos can be improved by removing legislative and other barriers, including: clarifying reimbursement of donors; developing clear guidelines for donor eligibility; reducing advertising barriers; developing moderated online forums for better communication between parties; simplifying the importation of overseas gametes into Victoria; and providing straightforward rules around the storage and use of gametes and embryos.
- As the supply of donor gametes increases, existing statutory limits on the use of gametes should be reduced. This should be reassessed after five years in light of evidence on the supply of donated gametes.
- Donations within Victoria should be more effectively monitored via mandatory reporting of all donations.
- The PRP should have the power to determine applications to use donated gametes above the statutory limit in exceptional circumstances.

8.1. Reasonable reimbursement of donors

The Review is of the view that better recognition of donors, and interventions to remove barriers and disincentives to donation, are likely to play an important role in increasing the supply of gametes. Under Commonwealth and 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. 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, the Guidelines allow for the 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 earnings\(^\text{19}\)
- insurance

\(^{19}\) The Guidelines advise 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.
- childcare costs when needed to allow for the donor’s attendance at donation related appointments and procedures
- legal advice.

RTAC also released a Technical bulletin on donor issues 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
- receiving any legal advice associated with donation.²⁰

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.

During consultations, the Review heard concerns from ART providers that the current model for reimbursement does not sufficiently acknowledge the time, inconvenience, risk and discomfort associated with donation, particularly egg donation. Stakeholders also indicated that the rules around reimbursement and what constitutes reasonable donor expenses are vague and open to interpretation, and that this lack of clarity has resulted in inconsistent levels of compensation paid by ART providers within Victoria.

To help ensure a more harmonised approach to compensation for donations, the Review considers that it would be appropriate for the Regulator to publish guidance on a suitable reimbursement amount for donors. It is envisaged that such guidance on costs would be based on stakeholder consultation, reflect data collected on actual costs incurred by donors, and be subject to ongoing review and adjustment as necessary. Information should also be published for circumstances where higher expenses may be reimbursed to recognise additional costs in exceptional cases. It will be up to the Regulator to determine the nature and detail to be included in its guidance, including whether it publishes a global figure for reimbursement or an itemised breakdown of available costs (acceptable calculations for loss of earnings, travel etc). Some stakeholders flagged that the financial compensation of egg donors should also reflect the risk and personal time invested in the donation process, as well as recovery time for postoperative procedures.

The Review notes that the proposed approach to specifying reimbursement amounts is not novel and has been effective in other countries with similar principles regarding gamete donations as Victoria. Notably, the Interim Report observed that, in order to avoid similar uncertainty about the appropriate level of compensation, the UK HFEA sets guidelines for appropriate reimbursement of costs. Whereas sperm donors can receive up to £35 per clinic visit to cover their expenses, egg donors can receive up to £750 per donation cycle. In both cases, the HFEA leaves open the possibility to claim more for higher expenses such as travel, accommodation and childcare. The HFEA figures are based broadly on comparators within the EU and acknowledge the generous act people perform through donation.

The proposal to create a uniform approach to the reimbursement of donor expenses was met with broad support during consultations with stakeholder groups. While a small minority raised concerns that reimbursements would be inconsistent with the altruistic nature of donation, the majority of stakeholders recognised this as a respectful gesture and a means of ensuring that a donor was no worse off for coming forward to donate. In particular, they welcomed more specific guidance on the value of

²⁰ 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.
reimbursements they could offer donors. VARTA considered that the UK model is working well and noted that a uniform approach would also be appropriate in Victoria, provided that the amounts prescribed did not provide an undue incentive to donors. VARTA also commented that clear guidelines on reimbursement would greatly simplify the administrative processes for approval of imported gametes, reducing regulatory costs for both VARTA and clinics. Apart from facilitating local donations, a set reimbursement amount would also make consideration of importation applications clear and more straightforward.

The Review also considers that it would be reasonable to reimburse certain costs incurred by people who may be willing to donate gametes or embryos they no longer need for personal use. Such gametes might become available, for example, where eggs frozen electively are ultimately not used, or a couple have completed their family and need to decide the fate of any remaining embryos in storage. Similar to the reimbursement of donors, there was broad stakeholder support for the proposal that the Regulator should offer guidance on the reasonable range of costs that could be covered in such circumstances, including those associated with undergoing the necessary donor counselling, medical appointments or tests, and reimbursement of storage fees incurred after a decision to donate has been made. ART providers indicated that it is already common practice to waive storage fees in certain circumstances on compassionate grounds, and this may also be an appropriate option where a person decides to donate gametes they had placed in storage for personal use.

To achieve greater clarity on reimbursement, the Review considers it appropriate that Victorian legislation be amended to expressly authorise the Regulator to publish guidance on appropriate reimbursement amounts for costs incurred by donors and people willing to donate gametes and embryos that become surplus to their personal needs. The Review considers that the publication of such guidance would be consistent with current Victorian and Commonwealth legislation. However, if the government takes a different view, the operation of the current laws on commercial trading in human eggs, sperm and embryos should be reviewed through appropriate state and national forums to ensure they do not create an unreasonable barrier to the reimbursement of legitimate costs incurred by altruistic donors.

Recommendation 52 Regulatory guidance on donor reimbursement

It is recommended that Victorian legislation authorise the Regulator to publish guidance on acceptable reimbursement amounts for costs incurred by donors, and storage and other costs incurred after a decision has been made by people to donate gametes and embryos that become surplus to their personal needs.

8.2. Development of guidelines for donor eligibility and handling of disqualifying medical conditions

Stakeholders agreed it would be useful for the Regulator to develop guidelines, in collaboration with ART providers and industry experts, on matters relating to donor eligibility, including in respect of medical history or known conditions. While donors should be medically screened for relevant infectious diseases and serious genetic diseases through medical history and suitable tests, the Review considers that a good evidence base is needed for all exclusions. Medical exclusion criteria should be transparent and published, for the benefit of both potential donors and recipients.

Where medical screening processes disqualify a person from donating gametes, the Regulator should develop, in consultation with the relevant stakeholders, appropriate guidelines for the sperm and egg bank and ART providers to facilitate the appropriate care of the individual concerned, including through timely referral for treatment of infectious diseases, or genetic or other counselling. If significant hereditary
medical conditions are diagnosed in a donor later in life, it is recommended that processes be put in place for the matter to be reported to the Regulator, to ensure that any donor-conceived offspring can be proactively provided with information and options for managing the medical condition.

**Recommendation 53 Regulatory guidance on donor screening**

It is recommended that the Regulator develop appropriate guidelines for donor eligibility in Victoria in consultation with relevant stakeholders, to ensure a consistent and streamlined approach to the recruitment and screening of donors. The Regulator should also develop guidelines for the handling of disqualifying medical conditions when they are identified, to ensure the timely referral of the individual concerned for treatment of infectious diseases, or genetic or other counselling. Where a donor’s medical condition becomes known after the birth of donor-conceived offspring, the individual(s) concerned should be notified through appropriate reporting to the Regulator, and proactively provided with information and options for managing the condition. Guidelines developed by the Regulator should apply to ART providers and to any sperm and egg bank that is established.

### 8.3. Advertising for donor gametes

The Interim Report identified that restrictions on the advertising for donations of eggs and embryos is a significant barrier to access in Victoria and makes it difficult for ART providers or individuals to connect with potential donors. Accordingly, the Review considered whether amendments should be made to remove or ease current advertising restrictions on seeking gamete donors.

Currently, advertising for donation of gametes and embryos in Victoria is strictly regulated under s. 40 of the Human Tissue Act, and Ministerial approval is required before a person may advertise for a donor. The Minister of Health is able to delegate the power for the approval of advertisements for eggs to the Regulator but has not done so. There does not appear to be scope to delegate approval of advertisements for donation of sperm or embryos. The Review heard that approaching the Minister directly can be intimidating and time consuming, with advertising approvals sometimes taking months to be processed.

The Review notes that other jurisdictions have a range of policy options regarding advertising for donor gametes. Western Australia completely bans advertising relating to the buying of human tissue. New South Wales, South Australia and Tasmania do not require Ministerial or any other form of approval to advertise for a gamete donor. Similar to Victoria, it is an offence to provide money or other inducements, other than reasonable expenses, to the donor in each of these jurisdictions.

The Review is concerned that the current model of Ministerial oversight is not only cumbersome for users, but also ill-suited to the task of monitoring and guiding advertising activity, which could be more effectively handled by the Regulator. Noting the concerns raised by stakeholders, and the approach in a number of other jurisdictions, the Review favours removing the existing advertising restrictions and requirement for Ministerial approval.

In place of the current approach, the Review considers the Regulator should be given powers to develop and publish guidelines on advertising to help inform interested parties about acceptable ways to contact potential donors. Advertising guidelines should apply to individuals and equally to all providers, whether public or private. The Regulator would furthermore be given powers to oversee advertising activity in Victoria, and to request the removal or amendment of material that is inconsistent with the guidelines, with a graduated set of regulatory powers to address repeat offenders or serious breaches. Any
decisions by the Regulator in respect of a breach of these guidelines would need to follow clear and transparent processes, provide written reasons for the decision and be reviewable.

The recommended approach received broad support from stakeholders as an important step to help facilitate better channels of communication, which is integral to raising community awareness and increasing donor numbers in Victoria. ART providers noted the importance of appropriate consultation with the industry in developing the guidelines, and the Review supports an inclusive approach by the Regulator in progressing this work.

### Recommendation 54 Advertising for donated gametes

It is recommended that the existing advertising restrictions and requirement for Ministerial approval be removed from s. 40 of the *Human Tissue Act 1982*. In place of these restrictions, the Regulator should be given powers to:

- develop and publish guidelines on advertising
- monitor advertising for donated gametes in Victoria and require the removal or amendment of material which is inconsistent with the guidelines.

### 8.4. Online communication between donors and recipients

Stakeholder feedback highlights that some potential donors and recipients of gametes or embryos wish to get to know each other before reaching a private arrangement for donation. The Review has heard that unmoderated online forums and discussion groups connecting donors and recipients have become common over recent years. There is significant but undocumented use of these forums, with participants reporting mixed experiences in their engagement with such sites. The Review heard, for example, that there is a potential for bullying or other undesirable conduct to occur on existing forums, and stakeholders urged that a safe and regulated alternative be offered to fill the current gap. In some cases, women have been encouraged to conceive ‘naturally’ when responding to ads for donor sperm.

The Interim Report contemplated the establishment of a statewide service to facilitate connections between donors and recipients to help improve access to donated gametes and embryos. It is envisaged 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. The forum could facilitate direct communication between potential donors and recipients, as well as to provide appropriate information packages or webinars prepared and hosted by experts to help educate and support service users. Individuals who wish to source gametes through this forum would be strongly encouraged to access appropriate counselling and screening services through the sperm and egg bank or another provider. As discussed further in Chapter 9, the Review recommends that a similar forum be established to facilitate online communication between surrogates and intended parents.
**Recommendation 55 Supporting safe communication between donors and intended parents**

It is recommended that the Victorian Government consider facilitating the operation of a community-led moderated online forum in Victoria, to allow safe channels of communication between potential donors and recipients of donated gametes or embryos, and people who are contemplating entering into a surrogacy arrangement as a surrogate or as intended parents.

### 8.5. Importing donated gametes from overseas

The Review heard a range of divergent views on the issue of the importation of donated gametes and embryos. ART providers and some potential recipients called for the relaxing of restrictions on the importation of donated gametes to help address issues of supply shortages, noting that the current approach restricts ART providers’ ability to resource their donor programs with imported gametes. Some stakeholders perceive the time taken for approvals is too long, and that there is inconsistency or lack of clarity as to how VARTA makes decisions under the Act. They have also noted that patients can and will access treatment outside Victoria if they are unable to source gametes locally. Other stakeholders have supported the existing 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. The Review acknowledges that donor-conceived people favour local donations wherever possible, to ensure that there is a realistic prospect of future contact between the person born and their donor. The use of overseas donors undoubtedly makes it more difficult for donor-conceived people to connect with biological relatives, even if contact information is correct and kept up-to-date.

The NHMRC Ethical Guidelines provide that treatment in Australia using gametes donated by persons living in another country must not take place unless it can be established that the gametes were obtained in a manner consistent with any Commonwealth legislation and any relevant state or territory legislation, accreditation body guidelines and these Ethical Guidelines. Relevantly, s. 36 of the Act requires written approval from VARTA for the importation of gametes into Victoria. The Act does not offer guidance on the matters to which VARTA must have regard in making decisions about whether to approve gametes or embryos being imported into Victoria. Section 37 of the Act envisages that if a person has obtained approval under s. 36 to bring gametes or embryos into Victoria, VARTA may exempt the person from compliance with certain consent, counselling, information provision, maintenance of register and other prescribed provisions of the Act or the regulations, provided that similar procedures have taken place outside Victoria and there are special circumstances that warrant the exemption.

Guidelines for the importation of donor gametes and embryos are set out by VARTA, and generally require strict compliance with all Victorian legislative requirements in Part 1, Division 3 of the Act relating to donor information, consent and counselling undertaken by a Victorian counsellor to domestic standards. The Review understands that, as a matter of practice, additional information may be sought from applicants in relation to the identity of the intended recipient of the donated gamete or embryo. It is not clear from the guidelines how or when the exemptions envisaged in s. 37 of the Act might apply to an importation application.
The import of donated gametes from overseas could be subject to additional oversight however the current process of ‘approving a recipient’ serves no purpose. This clinic recommends a more streamlined approach with the approval of the overall program e.g. [the gametes provider] and regulator oversight through regulator reporting of donor use. This would further improve the patient experience as feedback from patients indicates they feel judged by having to apply to import gametes.

Submission – Victorian fertility clinic

Having reflected on the issues raised by stakeholders, the Review considers that the current legislative and regulatory guidelines on importation arrangements for donated gametes could be clarified to ensure they are not a barrier to access for Victorians who seek to use imported gametes or embryos as part of their treatment. Given current gamete shortages, and the time likely to be required to build up local donor numbers, the Review anticipates that ART providers, as well as a future sperm and egg bank, may reasonably wish to enter into arrangements with overseas banks to access additional gamete stocks through global channels. This can be particularly useful for people sourcing gametes that match their cultural heritage. Such activities need to be better supported. It is envisaged that as local donor supply increases, there will be less need for imported gametes.

To this end, the Review is of the view that it would be appropriate to specify in legislation or the regulations the criteria that need to be satisfied in order to import gametes into Victoria. These requirements should be clear, comprehensive and consistent with the principles of the Act, and facilitate reasonable access to overseas gametes. The Review envisages that a more balanced approach could be struck between ensuring that overseas donors have received appropriate information and counselling to provide informed consent and making sure that the importation conditions are clear and practical. This could be achieved by amending the Act to create clear legislative guidance in respect of the importation of gametes and embryos into Victoria, where the following importation conditions would need to be satisfied:

- the donation is altruistic, and any payments made to the donor are consistent with the Victorian approach to reimbursement
- best efforts have been made to ensure that use of the donation will not result in more than 10 families being treated with gametes or embryos obtained from a single donor
- the donor has received appropriate counselling about their donation and provided written consent for the use of their gametes
- the donor has been given written information and advice about the Central and Voluntary Registers in Victoria and the rights of individuals to apply to those registers
- the donor has provided sufficient information to enable the registration of that information on the Victorian Central Register.

The Review considers it would be sufficient to provide information to the Regulator about how donor gametes and embryos are used, and the name of recipients, at the time that ART is provided, rather than at the time of importation. Arrangements between the sperm and egg bank or ART providers with overseas banks should require that all sperm stock from a donor be imported to Victoria, to ensure compliance with local family limits.

Some stakeholders provided feedback that it would be preferable to replace the requirement for the Regulator to approve an importation application with audit powers to review the practice of the sperm and egg bank and ART providers if necessary. The Review supports this approach and recommends the introduction of a certification process that attests that the prescribed matters for importation have been satisfied. Failure to comply with the requirements relating to the importation of gametes would be an
offence and could engage the relevant compliance and enforcement powers of the Regulator. It would also be an offence to make a false attestation.

**Recommendation 56 Simpler process to approve the importing of gametes**

It is recommended that the current legislative and regulatory guidelines on importation arrangements for donated gametes be amended to ensure they are not a barrier to access for those Victorians who seek to use imported gametes or embryos as part of their treatment. Accordingly, the Act should be amended to set out the criteria that need to be satisfied in order to import gametes and embryos into Victoria, through a certification process that attests, to the Regulator, that the following matters have been satisfied:

- the donation is altruistic, and any payments made to the donor are consistent with the Victorian approach to reimbursement
- best efforts have been made to ensure that use of the donation will not result in more than 10 families being treated with gametes or embryos obtained from a single donor
- the donor has received appropriate counselling in respect of their donation and provided written consent for the use of their gametes
- the donor has been given written information and advice about the Central and Voluntary Registers in Victoria and the rights of individuals to apply to those registers
- the donor has provided sufficient information to enable registration on the Victorian Central Register.

**8.6. New provisions relating to storage and use of gametes and embryos**

**8.6.1. Storage of gametes and embryos for personal use**

The Interim Report highlighted that the provisions set out in Part 3, Division 2 of the Act relating to the storage of gametes and embryos are complex, outdated and potentially confusing. Storage limits in Victoria are set at 10 years for gametes and five years for embryos, subject to extensions that may be available upon application to the PRP. These limits are the most conservative in Australia. Further, they do not reflect current scientific knowledge on the storage of gametes and embryos, the period of time that an individual may realistically want to store their gametes for future use, and represent an access barrier for those who need more time to complete their families.

The Review notes that New South Wales sets a storage period of 15 years for donated gametes and embryos, with no time limit for the storage of gametes for personal use, while Western Australia sets a storage limit of 15 years for gametes and 10 for embryos. Both jurisdictions allow for extensions upon application. Other jurisdictions rely on the NHMRC Ethical Guidelines, which 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 considers that the current storage and extension processes in Victoria are overly complicated and onerous. They are furthermore out of step with the approach to storage elsewhere in
Australia. The Review notes that there may be a range of reasons why longer storage periods could be appropriate, including, for example, where people store their gametes as teenagers due to gender affirmation or cancer treatments. Stakeholders were generally supportive of extending current storage periods, however some highlighted that a prescribed limit appropriately encourages people to actively engage in discussions and decisions about their personal ART plans and opportunities to donate unwanted gametes for treatment or research. While the Review accepts these points, on balance, it takes the view that decisions around storage for personal use are most effectively and sensitively made between the individual and the ART provider or bank concerned, and should not be the subject of strict and standardised storage timelines prescribed by legislation. In the course of consultations, a number of ART providers agreed that they were well placed to determine the maximum storage periods that could be made available to patients, and supported removing the current limits.

The Review thus proposes that the Act be amended to authorise the storage of gametes or embryos for personal use for any period of time agreed between the ART provider or storage facility and the person concerned. The Review considers it would be prudent for entities that provide storage of gametes and embryos to have appropriate policies in place to ensure that the removal of statutory storage limits does not result in a stockpile of unused gametes that could have been donated or discarded. There should also be appropriate information and counselling offered to people who have completed their ART journey to discuss the options for any unused gametes or embryos in storage, including the possibility of donating them for the purposes of treatment or research.

8.6.2. Storage and use of donated gametes or embryos created from such gametes

With respect to the storage and use of donated gametes, or embryos created from donated gametes, the Review considers that the current time limit should be increased but not left entirely to the discretion of ART providers or storage facilities. During consultations, donor-conceived people told the Review that they highly value having an opportunity to connect with their donor, and this may be hindered where older gamete stock is used. Moreover, some stakeholders observed that the presence of time limits encourages service providers to maintain robust records and actively manage stored gametes and embryos. Accordingly, while the Review considers there needs to be greater flexibility for the storage of gametes and embryos for personal use, as discussed above, it also recognises the need for some clear parameters around the use of donated gametes and embryos.

The Review notes that the New South Wales legislation specifically provides that an ART provider must not offer 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. This appears to be a useful approach to help minimise the age gap between a donor and their donor-conceived offspring, and ensure that people born as a result of a donation have a reasonable prospect of contacting their donor. A recent review of the Western Australian legislation (Allan Review) recommended that a similar time period be adopted there, with the additional caveat that gametes should not be used if the donor has reached the age of 50 or is deceased (Allan 2019).

The Review notes that while there was broad support for extending the time limit for storage and use from stakeholders, there were some concerns that a 15-year limit was arbitrary, particularly if the donor was young and there are reasonable prospects for contact with any offspring. The Review considers that the adoption of the proposed Western Australian approach of setting an upper age limit for use of a donor’s gametes would be sensible and appropriate to help ensure that there is a realistic prospect for a donor-conceived person to connect with their biological donor. It is recommended that the specified age cut-off should be prescribed following appropriate stakeholder consultation, and by reference to data
on average life expectancies and age at which donor-conceived people will generally seek to connect with their donor. The Review recognises that the appropriate period of storage and use of donated gametes will require ongoing monitoring to ensure that statutory limits continue to align with the needs and expectations of key stakeholders generally and donor-conceived people in particular.

Having reflected on stakeholder feedback, the Review does not consider it necessary to otherwise set a maximum time limit for storage, provided that the donor is prompted to renew their consent at reasonable time intervals of at least every 10 years. It is recommended that the PRP should have the power to authorise an extension to the storage and use of gametes and embryos beyond the prescribed donor age cut-off where it is considered appropriate to do so in the circumstances, for example, to allow the recipient to complete a family with biologically related siblings.

**Recommendation 57 Storage period for personal and donated gametes or embryos**

It is recommended that the Act is amended to authorise the storage of a person’s own gametes or embryos for any period of time agreed between the person concerned and the provider.

The storage and use of donated gametes, and any embryos created from such gametes, should be authorised until the donor reaches a prescribed age cut-off, to ensure there is a realistic prospect for a donor-conceived person to connect with their donor.

The Patient Review Panel should have the power to authorise storage and use beyond this limit, if it is considered appropriate to do so in the circumstances.

The Act should state that a donor may only consent to a storage period of up to 10 years, and should be prompted to renew their consent at reasonable time intervals of at least every 10 years.

### 8.7. Posthumous use of gametes or embryos

The Review notes that the Act currently prohibits the posthumous use of gametes unless they are to be used by the deceased person’s partner and provided certain conditions have been satisfied. One of the conditions is that the deceased person has provided written consent for the use of their gametes or embryos in an ART procedure. The Review considers this to be a high threshold to satisfy and is of the view that it would be preferable to allow the PRP to determine such applications by reference to all available information about whether the deceased person had provided consent for the posthumous use of their gametes.

There is moreover currently no scope under the Act for the use of donated gametes, or embryos created from such gametes, after the death of a donor. Some stakeholders have argued that the Act should be amended to allow for the posthumous use of donated gametes, provided this is consistent with the wishes of the donor, to give greater certainty to recipients who may be partway through treatment when a donor dies. As noted above, donor-conceived people observed to the Review that they have a strong interest in connecting with their biological donor, and as such consider the posthumous use of donated gametes or embryos to be undesirable.

Having regard to these interests, the Review considers that as a general rule, the posthumous use of donated gametes, or any embryos created from such gametes, should be prohibited by the Act unless the PRP approves such cases where there is evidence the donor has consented to such use, and the gametes will be used to complete a family with biologically related siblings where at least one child has
already been born using the donated gametes, or other exceptional circumstances apply. Exceptional circumstances may include, for example, situations where the donated gametes have already been used to create an embryo, and the use of the embryo is a 'last resort' option for the recipient hoping to form a family.

As a final point, the Review considers it appropriate that the Act make it clear that the posthumous use of gametes for research purposes is permitted, provided this is consistent with the wishes of the donor or person storing the gametes for personal use, as recorded in their consent form.

**Recommendation 58 Posthumous use of gametes or embryos**

Further to Recommendation 7 of the Interim Report, it is recommended that s. 46(b) of the Act be amended to remove the requirement that the deceased person must have provided ‘written consent’ for the posthumous use of their gametes in a treatment procedure by their partner. The Patient Review Panel should determine each application by reference to all available information about whether the deceased person had provided consent to support the posthumous use of their gametes.

The Act should furthermore be amended to state that the posthumous use of donated gametes, or any embryos created from such gametes, is prohibited except if the Patient Review Panel approves such cases where:

- there is evidence that the donor has consented to such use, and
- the gametes will be used to complete a family with biologically related siblings where at least one child has already been born using the donated gametes, or
- other exceptional circumstances apply.

The Act should make it clear that the posthumous use of gametes for research purposes is permitted, provided this is consistent with the wishes of the donor or person storing the gametes for personal use, as recorded in their consent form.

8.8. **Review of the current limits on the number of families formed from donated gametes**

Currently, s. 29 of the Act restricts the number of people who may conceive a child using gametes donated by the one person to 10 women. The limit imposed is intended to reduce donor fatigue, resulting from contact from numerous offspring and the risk of donor-conceived people unknowingly forming consanguineous relationships. The Review recommended in its Interim Report that the limit should be applied to families, rather than women, to avoid discrimination against same-sex couples where both partners may wish to have children using gametes from the same donor. Having reflected on the issues further, the Review considers that it would be appropriate to reduce the limit from 10 to five families as the supply of donated gametes increases, and to introduce discretion for the PRP to authorise use above the limit in exceptional circumstances.

The Review understands that donor-conceived people and their parents may have an expectation that donors will be open to future contact. However, this may be an unrealistic hope if high numbers of children have been conceived from a donation, and anecdotal evidence suggests that donor fatigue can set in after several linkages through the register. With the increase in direct consumer access to DNA
testing, it is now also possible for people to independently find their donor or siblings and initiate contact directly. These developments raise concerns for the emotional wellbeing of donors and their families, who may be contacted by numerous offspring. The Review has heard that donor-conceived people can also find it challenging and confronting to discover that they have a large number of donor siblings they do not know. For these reasons, both donor-conceived people and donors have said they would prefer lowering 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. Whereas the Guidelines state that ‘gametes from a single donor must be used to create only a limited number of families’, the relevant RTAC technical bulletin advises that ‘a maximum of 10 donor families per sperm donor’ is acceptable.

While a broad range of stakeholders were generally in favour of reducing the current family limit, ART providers stated that the current shortage of gamete stocks does not make it feasible to make such a change in the short term without adversely affecting those who rely on donor gametes to form a family. The Review supports lowering the current limit and recommends that the Victorian Government continue to monitor the feasibility of doing so in the coming years. As the supply of donations grows in Victoria with legislative amendments to enhance supply and the establishment of a dedicated sperm and egg bank, it would be desirable to make the changes sought. It may be appropriate to reduce the limit incrementally, as evidence of increased donor supply becomes available, with a view to bringing Victoria in line with the five-family limit in New South Wales and Western Australia by 2025. Noting stakeholder feedback on this proposal, the Review considers it appropriate that any decrease in the limit should be prospective and ensure that appropriate transitional arrangements are in place for the use of existing donor stock, particularly where the gametes have already been allocated for use by recipients. The Review has heard feedback that the current drafting of s. 29 is confusing in so far as it relates to the inclusion of the donor’s own children in the 10 family limit. To address this concern, it would be appropriate to resolve any ambiguity when s. 29 is reviewed, or to simply exclude any children of the donor when a future five-family limit is introduced in Victoria.

Whereas the law in Victoria and New South Wales is silent on the geographic reach of the donor limit, Western Australia issued directions stipulating that the five-family limit includes families that may be outside Australia. While a global limit is favoured by some stakeholders, and attractive in theory, the Review considers that the practical difficulties in monitoring the activities of donors outside Victoria make it unrealistic to entrench this requirement in legislation. Nevertheless, best efforts should be made to ensure that donors are vetted appropriately and excluded where they have made significant interstate or overseas donations.

**Recommendation 59 Review of 10 family limit after addressing gametes shortage**

Further to Recommendation 10 of the Interim Report, which proposed the amendment of s. 29 of the Act to ensure that the limit on the use of donated gametes applies to ‘families’ rather than ‘women’, it is recommended that the proposed 10 family limit be reviewed after five years with a view to reducing the limit to five families if increased donor supply becomes available. The review will need to consider harmonising arrangements with other jurisdictions, ensuring that any changes are prospective only, and that appropriate transitional arrangements for the use of existing donor gametes and embryos are in place.

### 8.9. Effectively monitoring donor activity within Victoria

The Review has heard of instances where a donor may have concealed information about previous donations, causing significant distress to recipients. The recipients were subsequently unable to use...
gametes or embryos created from such gametes under the current Act because the statutory 10 family limit for use had been reached. To help more effectively monitor donor activity within Victoria and prevent these situations from arising, the Review considers that the Regulator should develop and manage a Central Register of donations made at Victorian ART providers and the future sperm and egg bank.

It is envisaged that the details of every donor would be reported to the Regulator by Victorian ART providers or the future sperm and egg bank on a mandatory and contemporaneous basis. As part of a general background check on a prospective donor, ART providers or the bank would be expected to undertake a search of the register to determine if donation limits have been reached. These measures would be in addition to the current reporting requirements for live births. The Review recommends that the donor database should be accessible, on a confidential basis, to both Victorian and interstate providers.

Recommendation 60 Mandatory and contemporaneous reporting of all donations

It is recommended that the Act be amended to require the mandatory and contemporaneous reporting of all donations to the Regulator by ART providers and any sperm and egg bank. The Act should authorise the sharing of relevant donor information by the Regulator with providers for the purpose of determining if donation limits have been reached.

Feedback from stakeholders on this proposal was met with support from both VARTA and ART providers. Some ART providers noted that a national approach would offer even greater benefits, for example, if a database could be managed through the FSA. While the Review agrees that such an approach would be useful, it is also cognisant of the time and complexity which may be involved in developing a suitable national scheme. Accordingly, it is appropriate that the Regulator take steps to implement a local donor register as described, while also staying open to supporting any future national efforts to monitor and manage donor activity.

While it is rare for donors to provide misleading information about previous donations, the Review considers it appropriate that such activity be strongly discouraged through legislation. To this end, the Review recommends that a new offence be created if a person knowingly conceals from, or fails to disclose previous donations to, the sperm and egg bank or provider where they wish to register as a donor.

Excessive ‘donation’ activity undertaken through personal arrangements by individuals in Victoria should also be discouraged, and the Victorian Government may wish to consider whether it is feasible and appropriate to create an offence for a person who knowingly donates gametes in excess of the prescribed family limit in a private capacity outside a regulated setting. However, such a rule would be extremely difficult to police, and may have negative consequences in driving such behaviour underground. A preventive approach is more likely to deal with this problem. Many of the recommendations made by the Review in this chapter are aimed at removing existing barriers to accessing gametes in Victoria, and thereby reducing the demand for unsafe and unregulated means of donation.

Recommendation 61 Offence for knowingly donating in excess of the family limit

It is recommended that the Act create an offence for a person to knowingly conceal or fail to disclose previous donations to an ART provider or any sperm and egg bank where they wish to register as a donor.

Finally, the Review believes there should be a capacity to authorise the use of donated gametes in addition to the prescribed 10 family limit set out in s. 29 of the Act, where exceptional circumstances
apply, and it is considered appropriate to do so. It is envisaged that these powers would be used only rarely and as a measure of last resort, where the applicant finds out that for reasons beyond their control, the use of donated gametes, or embryos formed from such gametes, would exceed the statutory limit imposed, and there is no reasonable alternative available to that person. Since the approval powers currently rest with the PRP, the Act should provide for an appropriate residual power to respond justly to exceptional circumstances.

**Recommendation 62 Authorising use of donated gametes in exceptional circumstances**

It is recommended that the Patient Review Panel be given residual powers under the Act to determine an application to authorise use of donated gametes above the statutory limit set out in s. 29, where exceptional circumstances apply, and it is considered appropriate to do so.

### 8.10. Partner consent for donation

There is currently no requirement for a donor’s partner to consent to a donation under the Act. Some stakeholders provided feedback to the Review about the significant impact of donation on not only the donor but also their partner and family, and suggested that the Act should be amended to require partner consent for donation. Donor-conceived people noted, for example, that donors are less likely to engage in contact or liaise with VARTA if their partner or children are unaware of the donation, and this may have adverse consequences for understanding their family background.

While the Review agrees that the sperm and egg bank and ART providers should make best efforts to ensure that the partner of a person intending to donate gametes receives appropriate information and counselling about the process and its implications, introducing a legal requirement to obtain consent from a partner is likely to add an unreasonable burden to existing processes. In circumstances where the bank or ART provider becomes aware that a potential donor’s partner is unaware of the intention to donate, or does not support the donation, the donor may be appropriately counselled and, if necessary, deemed unsuitable to provide gametes to the sperm and egg bank or an ART provider.

### 8.11. Access to information for donor-conceived people

The Interim Report highlighted the strong desire of donor-conceived people to connect with their donor siblings. While this group is currently entitled to access identifying information about their donor under the Act, they cannot obtain details in respect of genetically related half-siblings also born as a result of donation by the same person. The Interim Report noted that with technological advances, many people are connecting with donor siblings via DNA testing websites, and recent media features have also highlighted that informal contact is becoming increasingly prevalent.

The importance of accessing information about genetic relatives, especially donor siblings, has been stressed to the Review in subsequent consultations with donor-conceived individuals. Given the high-priority status of this issue to the donor-conceived community, the Review recommends that consideration be given to amending the Act to allow donor-conceived people to connect with their biological siblings through the Regulator. The Review notes that any efforts to bring sibling contact within a clear and supportive framework was endorsed by a broad range of stakeholders, including VARTA.
While this issue is outside the terms of reference of this Review, the Government may wish to consider changes that would allow for access to identifying information donor siblings on a similar basis to the existing process for accessing information about a donor. Such a change would help meet the needs of donor-conceived people.
9. Supporting altruistic surrogacy arrangements

**Key points**

- Altruistic surrogacy arrangements need to be better supported and more accessible in Victoria.
- The existing regime fails to provide appropriate protections for the parties to a surrogacy arrangement, and does not offer enough clarity and certainty about legal rights and obligations.
- Reforms should aim to increase opportunities for people to pursue surrogacy arrangements in Victoria, within a safe and properly regulated environment.
- In addition to the existing safeguards that currently exist and will remain, these reforms will strengthen support and protections for the surrogate and provide greater clarity for all parties.

As observed in the Interim Report, the Review considers that surrogacy arrangements would benefit from clearer and more comprehensive treatment within the legislation. While surrogacy provides a way for people to have children if they are not otherwise able to do so, it also raises a complex set of legal and ethical issues that need to be carefully addressed to ensure that the interests of all parties, including the child to be born, are considered and protected.

Feedback to the Review has made it clear 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 these and other matters. While Queensland, New South Wales, Western Australia and Tasmania have specific legislation on surrogacy, other jurisdictions manage surrogacy through parentage orders that specify the conditions of surrogacy arrangements. A recent review by the South Australian Law Reform Institute Review into surrogacy (SALRI Review, 2018) also recommended that a dedicated Surrogacy Act be adopted in that jurisdiction, to promote the clarity, comprehension and accessibility of the law. However, these jurisdictions have less comprehensive ART legislation.

The Review considers that the current gaps could be addressed either through a dedicated piece of legislation, or by way of an expanded Part on surrogacy in the existing Act. However, there are certain aspects of surrogacy that do not naturally fall within the scope of an Act focused on ART, and may be better suited for treatment in a standalone legislation. The Review also notes that standalone surrogacy legislation may make it easier for surrogates and intended parents to find and familiarise themselves with Victoria’s surrogacy laws. On the other hand, there are only approximately 50 surrogacy arrangements approved annually in Victoria, so embedding surrogacy within more widely used legislation has many benefits. Similar to ART more broadly, the surrogacy environment is changing rapidly, and the legislative and policy framework needs to be reviewed regularly by government to ensure that it keeps pace with relevant developments and continues to offer appropriate protection and support for surrogates, intended parents and the children born as a result of surrogacy arrangements in Victoria. This issue is explored further Chapter 12.

9.1. Moving towards national harmonisation

The Review heard that inconsistent laws and policies between jurisdictions makes surrogacy difficult to navigate and may result in 'jurisdiction shopping' by intended parents. The Commonwealth House of Representatives Standing Committee on Social Policy and Legal Affairs observed in its 2016 report, *Surrogacy matters: inquiry into the regulatory and legislative aspects of international and domestic*
surrogacy arrangements (Surrogacy matters), that disparity in legislative regimes around Australia causes a range of inequities for people choosing to pursue domestic altruistic surrogacy. To address these concerns, it was recommended that the Commonwealth Government, in conjunction with the Council of Australian Governments, consider the development of a model national law that facilitates altruistic surrogacy in Australia. The Commonwealth’s response to the report agreed in principle with this proposal, noting that that state and territory laws should, as far as possible, be consistent in their approach to the regulation of domestic altruistic surrogacy arrangements. To this end, the Commonwealth undertook to seek the views of states and territories about progressing consistency in the regulation of domestic altruistic surrogacy arrangements.

Other recent reviews into surrogacy, including in New South Wales, South Australia and Western Australia, have similarly called for a consistent national approach. Given these developments, the Review considers it appropriate that future reforms to Victorian legislation also explore opportunities to move towards a nationally harmonised approach to surrogacy laws and policies, consistent with efforts in other Australian jurisdictions. At the same time, the Review notes that developing a national approach is likely to be a prolonged process, and as such, the Victorian Government will need to be prepared to progress reforms independently if necessary, to ensure that a clear and comprehensive surrogacy framework can be established in this state within a reasonable timeframe.

9.2. New Guiding principles tailored to surrogacy arrangements

While a set of Guiding principles creates a useful framework for the provision of treatment procedures under s. 5 of the Act, the Review does not consider that this is sufficiently tailored to assist with the interpretation of the law relating to surrogacy arrangements in Victoria.

Surrogacy matters recommended a model national law that facilitates altruistic surrogacy in Australia, which would have regard to a number of guiding principles:

- The best interests of the child should be protected (including the child’s safety and wellbeing and the child’s right to know about their origins).
- The surrogate mother is able to make a free and informed decision about whether to act as a surrogate.
- Sufficient regulatory protections are in place to protect the surrogate mother from exploitation.
- There is legal clarity about the parent–child relationships that result from the arrangement.

The current approach in other jurisdictions varies in terms of the level of detail provided in the Guiding principles to help decision makers interpret and implement the legislation. A recent statutory review into the New South Wales Surrogacy Act noted that the three policy objectives of that legislation are to protect the interests of children born of surrogacy arrangements, provide legal certainty and prevent commercial surrogacy arrangements. The Act itself provides that it is to be administered by reference to the principle that, in relation to any surrogacy arrangement, the best interests of the child of the surrogacy arrangement are paramount. The Western Australian Act offers minimal guidance, stating only that a decision concerning parentage orders in respect of a child born under a surrogacy arrangement must have regard to the best interests of the child as a paramount consideration.

Surrogacy legislation in Queensland and Tasmanian sets out considerably more detailed Guiding principles, stating in identical terms that:

1. This Act is to be administered according to the principle that the wellbeing and best interests of a child born as a result of a surrogacy arrangement, both through childhood and for the rest of his or her life, are paramount.
2. Subject to subsection (1), this Act is to be administered according to the following principles—
   (a) a child born as a result of a surrogacy arrangement should be cared for in a way that—
      (i) ensures a safe, stable and nurturing family and home life; and
      (ii) promotes openness and honesty about the child’s birth parentage; and
      (iii) promotes the development of the child’s emotional, mental, physical and social wellbeing;
   (b) the same status, protection and support should be available to a child born as a result of a surrogacy arrangement regardless of—
      (i) how the child was conceived under the arrangement; or
      (ii) whether there is a genetic relationship between the child and any of the parties to the arrangement; or
      (iii) the relationship status of the persons who become the child’s parents as a result of a transfer of parentage;
   (c) the long-term health and wellbeing of parties to a surrogacy arrangement and their families should be promoted;
   (d) the autonomy of consenting adults in their private lives should be respected.

Following extensive consultation regarding the South Australian surrogacy laws, the SALRI Review outlined a comprehensive set of statutory guiding principles:

- That the best interests of the child are paramount and should be protected (including the child’s safety and well-being and the child’s right to know about their family and origins).
- That the surrogate mother is able to make a free and informed decision about whether to act as a surrogate.
- That sufficient regulatory protections are in place to protect the surrogate mother and the intending parents from exploitation.
- That there is legal clarity about the parent-child relationships that result from the arrangement.
- The intervention of the law and the State in people’s private lives, with regards to surrogacy, should be kept to a minimum.
- Any model should ensure that, at the outset, all parties are fully aware of their rights and responsibilities (particularly in relation to the child) and such a model should seek to avoid and resolve any legal dispute (if arising) between the parties.
- That the surrogate mother has the same rights to manage her pregnancy and birth as any other pregnant woman.

In relation to the reimbursement of costs, the SALRI Review furthermore stated that guiding principles should provide that:

- No valuable consideration should be provided for the act of becoming pregnant and carrying a child for another person; and
- A surrogate mother should not be financially disadvantaged as a result of taking part in a surrogacy arrangement and should be able to recover any costs actually incurred as a direct result of the pregnancy and birth.

The Review considers it appropriate that the Victorian legislation on surrogacy, whether included within the current ART Act or developed as a separate piece of legislation, include more comprehensive Guiding principles to help distil the primary policy objectives and provide meaningful assistance in the interpretation of the law.
Recommendation 63 Legislative guiding principles tailored to surrogacy

It is recommended that Guiding principles specifically tailored to articulating the policy objectives of surrogacy legislation be developed. At a minimum, the Guiding principles should articulate the following key ideas:

- The welfare and best interests of the child to be born as a result of a surrogacy arrangement, both through childhood and for the rest of life, are paramount.
- Commercial surrogacy is prohibited in Victoria.
- The regulation of surrogacy should promote positive relationships of trust between the parties to a surrogacy arrangement.
- The parties to a surrogacy arrangement should have certainty and clarity about their rights and obligations.
- The surrogate should be able to make a free and informed decision about becoming a surrogate and be protected from exploitation.
- The bodily autonomy of the surrogate should be protected throughout the surrogacy process.
- The autonomy of consenting adults in their private lives should be respected.
- A surrogate should not be financially disadvantaged as a result of acting as a surrogate and should be able to recover any costs incurred as a result of the pregnancy and birth, including in respect of any unforeseen medical complications and income foregone.

9.3. Bringing traditional surrogacy arrangements within scope for ART

The Interim Report noted that while traditional surrogacy arrangements are not prohibited by the Act, a registered ART provider may carry out a treatment procedure on a woman under a surrogacy arrangement only if the surrogacy arrangement has been approved by the PRP. 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 (s. 40(1)(ab)). The Review heard that the current restriction is unique in Australia and is problematic because it denies access to ART services that would be beneficial for traditional surrogacy arrangements, including screening, ovulation tracking and expert assistance with IUI or IVF procedures.

Given the complexity and sensitivities involved in surrogacy, the Review considers that the legislation should ensure that all surrogacy arrangements be the subject of proper oversight through the PRP approval process. The Review recommends that both traditional and gestational surrogacy arrangements should require PRP approval, irrespective of how the pregnancy is achieved. It is proposed that the Act be amended to remove the restriction that the PRP may only approve a surrogacy arrangement if it is satisfied that a surrogate’s oocyte will not be used in the conception of the child. This approach will bring traditional surrogacy within a clear and supportive regulatory framework. It will also allow individuals to access ART provider services, if they so require or desire. While stakeholders were supportive of providing a legal framework to protect all parties to a traditional surrogacy arrangement, they cautioned,
sensibly, against making the process so onerous that it would drive these arrangements underground. In particular, there were concerns that the PRP is already under considerable resource pressures, noting that currently it can take up to three months for surrogacy arrangements to be heard once an application is submitted, and review of traditional surrogacy applications will further increase this burden. The Review agrees that it will be important for the PRP to reduce these delays and resolve these additional applications in a timely manner.

The Review notes that the proposed amendment in respect of traditional surrogacy will likely necessitate consequential amendments to the Status of Children Act in respect of the making of parentage orders. Whereas this Act currently draws a distinction between surrogacy arrangements commissioned with and without the assistance of an ART provider (ss. 22 and 23 respectively), a more consistent legislative approach may be appropriate and beneficial if all surrogacy arrangements are subject to PRP oversight and approval. Further, the Review is aware that in some circumstances, the parties to a traditional surrogacy arrangement have found it difficult to obtain a parentage order as a result of a relatively minor shortcoming in satisfying the prescribed requirements for the order (for example in relation to the nature of counselling). To help safeguard the wellbeing of a child born as a result of a surrogacy arrangement and ensure the appropriate resolution of applications, the Review considers that it may be appropriate for the relevant provision(s) of the Status of Children Act to explicitly allow the court to dispense with certain prescribed requirements in making a parentage order, if exceptional circumstances apply and the making of the order would serve the best interests of the child.

**Recommendation 64 Ensuring access to ART services for traditional surrogates**

It is recommended that treatment by an ART provider is available to the parties of all surrogacy arrangements, including where the surrogate’s own egg is used. The Act should be amended to require all surrogacy arrangements (including these ‘traditional’ surrogacy arrangements) to be the subject of appropriate oversight through mandatory Patient Review Panel approval. Treatment by an ART provider would be available to support all surrogacy arrangements which have received Patient Review Panel approval.

Part IV of the *Status of Children Act 1974* may need to be revised to ensure a consistent and streamlined approach in the consideration of parentage orders arising from all surrogacy arrangements. There should be a residual discretion for the court to grant a parentage order if exceptional circumstances apply and the making of the order would serve the best interests of the child.

### 9.4. Counselling for surrogates and intended parents

#### 9.4.1. Counselling requirements for surrogacy arrangements

The Interim Report observed that good counselling is essential for positive outcomes in surrogacy arrangements. Currently, 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, as set out in the ART Regulations (r. 9). Unlike a number of other jurisdictions, however, there is no requirement for additional counselling to take place following the birth of the child and prior to the making of any parentage orders in favour of the intended parents. The Victorian legislation is also out of step with the NHMRC Ethical Guidelines, which provide that individuals and couples involved in surrogacy
arrangements must undergo counselling on a broad range of matters before, during and after ART, because of the complex nature of the issues involved.

Legislation in Queensland, New South Wales, Western Australian and Tasmania mandates that, in addition to counselling prior to entering into a surrogacy arrangement, the parties must also have received further counselling after the birth of the child and before an application for parentage order is made. Queensland and New South Wales set out the most detailed provisions in respect of counselling. These jurisdictions require that an application for a parentage order must be supported by a report prepared by an independent counsellor, which sets out a range of matters including the counsellor’s opinion as to whether the parentage order is in the best interests of the child and their assessment of each affected party’s understanding of the social and psychological implications of the making of the order. Western Australia and Tasmania do not require the preparation of a report by a counsellor but state that the relevant parties to the surrogacy arrangement must receive counselling about the effects of the proposed parentage order.

Submissions to the Review favoured the approach taken in these jurisdictions over the current Victorian model, to better recognise the unique circumstances and support needs of parties to a surrogacy arrangement. The SALRI Review into surrogacy also recommended that the legislation in that jurisdiction be amended to provide that it is mandatory for the surrogate to undergo one session of counselling after the birth of a child (with costs to be met by the intended parents). It was proposed that the counsellor would prepare a short post-birth report to assist the court in the making of a parentage order. The court would have an express power to order a more detailed report if it considers this appropriate and/or in the best interests of the child. The Allan Review similarly observed that counselling should be provided at key stages of the surrogacy process, including prior to the arrangement taking place, at least once during each trimester if a pregnancy has been achieved, and after miscarriage or the birth of a child.

In line with the preliminary views expressed in the Interim Report, and consistent with the approach in other jurisdictions and the NHMRC Ethical Guidelines, the Review considers that counselling should be provided not only before the parties enter into a surrogacy arrangement but also following the birth of a child and prior to the finalisation of parentage orders resulting from a surrogacy arrangement in Victoria. The Review has heard that it is not uncommon for disputes to arise between the parties to a surrogacy arrangement during the pregnancy, and considers that the surrogate and intended parents should be encouraged to schedule regular check-ins with their counsellor to ensure that any problems can be resolved before they escalate. The proposed additional counselling will help ensure that a parentage order is underpinned by informed consent by the surrogate, and her partner, if any, in respect of the transfer of parentage. Moreover, it will be a valuable opportunity to provide emotional and psychological support to the surrogate following the birth of the child. In addition to undertaking counselling at these two key stages of the surrogacy process, parties to a surrogacy arrangement should be encouraged to seek out additional counselling as needed. Stakeholder feedback indicated broad support for the two-stage counselling model. ANZICA also noted the importance of ongoing counselling for surrogates and intended parents during the pregnancy to ensure that any issues can be resolved before they are exacerbated, and the relationship is damaged irretrievably.

The Review notes that the PRP’s guidance note no. 1: Approval of surrogacy arrangements in Victoria states that a counsellor’s report must make it clear that each issue prescribed for counselling in the Regulations has been specifically discussed and addressed in the counsellor’s report under separate headings. This Guidance also notes that while an independent psychological assessment is not mandatory, the Panel is greatly assisted by these reports in satisfying itself that the parties to the surrogacy arrangement understand the social and psychological implications of entering the proposed arrangement. The Review considers that the current requirements are quite onerous and investigative in nature. A more streamlined approach preferred by the Review is that the legislation clarify that a counsellor is required to prepare a brief report to help guide the PRP in considering an application to approve a surrogacy arrangement.
In the case of counselling after the birth of a child, it should generally be sufficient that an appropriately qualified counsellor certifies that appropriate counselling has been provided to the parties, and that the PRP and court have powers to seek a more detailed information where appropriate to protect the surrogate, intended parents and the interests of the child in line.

It is envisaged that a more detailed report may be sought from the counsellor, or any other relevant expert, in those cases where this is considered necessary and appropriate by the decision maker.

**Recommendation 65 Supportive counselling for surrogacy**

It is recommended that the Act be amended to expand the current counselling requirements relating to surrogacy. Specifically, the legislation should mandate appropriate counselling for parties to a surrogacy arrangement at two distinct points during the surrogacy process, namely:

- before the parties enter into a surrogacy arrangement and seek Patient Review Panel approval
- following the birth of the child and prior to the making of any parentage orders.

Reporting to the Patient Review Panel on these counselling requirements should be less detailed than current arrangements.

Following counselling after the birth of the child, the relevant counsellor should certify that appropriate counselling has been provided to the parties. Both the Patient Review Panel and the court should be given express powers to seek a more detailed report from a counsellor, or any other relevant expert, if this is considered necessary and appropriate in the circumstances to help aid the decision-making process.

**9.4.2. Qualifications and role of counsellors**

The Interim Report highlighted stakeholder concern that the current requirements for counselling in the legislation lack flexibility and are not sufficiently tailored to meet the needs of participants. There was also a perception that the blending of screening and counselling functions currently undertaken by counsellors made it difficult to build rapport with those involved in a surrogacy process.

The Review considers that it would be useful for the legislation to clearly articulate the relevant qualifications and skills that a counsellor is required to have in order to offer counselling to parties to a surrogacy arrangement. Consistent with the approach to defining the meaning of ‘appropriately qualified counsellor’ within the Act for counselling more generally as outlined in Chapter 4, the Review considers that a useful and practical provision would define an ‘appropriately qualified counsellor’ as a person who is eligible for membership of ANZICA and has the relevant experience, skills and knowledge, including of key legislative requirements, appropriate to the counselling undertaken. The Review considers that there should be no requirement that the counsellor be providing services on behalf of an ART provider, as currently stated in s. 43 of the Act. It is envisaged that this amendment will open up counselling options to provide parties to a surrogacy arrangement with greater flexibility in choosing a counsellor who best meets their circumstances and support needs.

In order to preserve impartiality and objectivity in formulating a view on whether a parentage order is appropriate and the best interests of the child, the Review recommends that the Act mandate that a counsellor offering counselling for the purposes of an application to obtain a parentage order should be
independent of any ART provider or medical professional involved in the conception of the child born. This approach is consistent with the requirement for independent counselling established in a number of other jurisdictions, including Queensland and New South Wales.

**Recommendation 66 Qualifications and eligibility to provide surrogacy counselling**

It is recommended that the Act be amended to state that counselling in respect of surrogacy arrangements must be provided by an ‘appropriately qualified counsellor’. Consistent with Recommendation 35, the term ‘appropriately qualified counsellor’ should be defined in regulation or compliance standards as a person who is eligible for membership of ANZICA and has the relevant experience, skills and knowledge, including in respect of key legislative requirements, appropriate to the counselling undertaken.

The Act should be amended to allow for the counselling required before parties enter into a surrogacy arrangement, and seek Patient Review Panel approval, to be provided either by a counsellor providing services on behalf of an ART provider or by an independent counsellor who meets the definition of ‘appropriately qualified counsellor’.

In order to preserve impartiality and objectivity, the Act should state that counselling provided following the birth of a child and prior to the making of a parentage order must be undertaken by a person who meets the definition of an ‘appropriately qualified counsellor’ and who is independent of any ART provider or medical professional involved in the conception of the child born.

9.4.3. Nature and scope of surrogacy counselling

Current legislative requirements mandate that the surrogate (and their partner, if any), and the intended parents, explore a broad range of issues prior to the commencement of any treatment with the support of an appropriately qualified counsellor. The matters prescribed for surrogacy counselling in the Regulations (r. 9) are as follows:

(a) the implications of surrogacy for the relationship between—

i. if there are 2 commissioning parents, the commissioning parents, and

ii. if the surrogate mother has a partner, the surrogate mother and her partner, and

iii. the commissioning parent and the surrogate mother, and

iv. all parties to the surrogacy, and

v. if donor gametes or embryos are to be used, the donor and the donor’s partner, if any, and all parties to the surrogacy,

(b) the implications of surrogacy for any existing children of the surrogate mother or the commissioning parent

(c) the possibility of medical complications for the surrogate mother or the child
(d) the possibility of any party deciding not to proceed with the surrogacy

(e) the attitudes of all parties towards the conduct of the pregnancy

(f) the attitudes of all parties to investigation of a genetic abnormality, the possibility of termination of pregnancy or other complications

(g) the need for the parties to agree on a process for resolving disputes—
   i. relating to the pregnancy, or
   ii. arising during the pregnancy,

(h) if there are 2 commissioning parents, the commissioning parents' intentions for care of the child if one of them dies

(i) possible grief reactions on the part of the surrogate mother and her partner, if any

(j) ways of telling the child about surrogacy, and

(k) attitudes toward an ongoing relationship between the surrogate mother, her family and the child.

The Review considers that this list of issues is a useful starting point to help guide discussions prior to the relevant parties entering into a surrogacy arrangement. However, it would be appropriate to expand the list of topics that should be covered. The Review notes that NHMRC Ethical Guidelines provide that surrogacy counselling should address:

- the potential long-term psychosocial implications for each individual and each family involved, including the person who may be born and any other child within the family unit(s) who may be affected by that birth
- the reason(s) why the potential surrogate wants to become involved in a surrogacy program
- the surrogate's right to make informed decisions about their own medical care, including before and during the pregnancy and birth
- the possibility that the surrogate may need medical and/or psychological assistance following the birth and that the pregnancy may affect the surrogate's own health
- the potential significance of the gestational connection and the right of persons born to know the details of their birth, and the benefits of early disclosure
- the possibility that persons born may learn about their birth from other sources (for example from other family members) and may independently access information about their birth
- the possibility that persons born may attempt to make contact with the surrogate in the future.

The SALRI Review also offers a comprehensive list of matters that should be the focus of surrogacy counselling in South Australia, which could also sensibly inform reforms in this area in Victoria.

The Review furthermore recommends that regulations should be developed to prescribe the matters that should form the basis of counselling following the birth of the child and prior to the making of any parentage orders, consistent with the approach taken in other jurisdictions including Queensland and New South Wales.
Recommendation 67 Matters to be discussed in surrogacy counselling

It is recommended that the regulations be amended such that, prior to parties entering into a surrogacy arrangement, counselling must be given in relation to all the matters currently prescribed under the Act, and:

- the social and psychological implications of the surrogacy arrangement on the child and relevant persons
- the surrogate’s motivation for entering into an arrangement with the intended parents
- an assessment of the parties’ mental and physical health in the context of ability to cope with the stress of treatment, pregnancy and parenting
- the need for the surrogate and their partner, if any, to provide free and informed consent to enter such an arrangement
- the surrogate’s right to bodily autonomy and to make informed decisions about their medical treatment in respect of the pregnancy and birth
- the potential significance of the gestational connection, the right of the child born to know the details of their birth and background, and the benefits of early disclosure
- any implications where it is proposed that the surrogate will provide their own ovum for use within a surrogacy arrangement.

It is recommended that the required counselling following the birth of the child under a surrogacy arrangement and prior to the making of any parentage order should, at a minimum include discussion 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
- openness and honesty about the child’s birth parentage being for the wellbeing, and in the best interests, of the child
- the care arrangements that the intended parent(s) have proposed for the child
- expectations in respect of any future contact arrangements between the child and the surrogate
- whether any consent to the parentage order is informed consent, freely and voluntarily given
- whether the making of a parentage order would be for the wellbeing, and in the best interests, of the child.

Finally, as noted in respect of counselling arrangements more generally in Chapter 4, the Review considers that the screening and counselling functions are currently too closely connected in the Act, and this has an adverse effect on the therapeutic effectiveness of counselling. To address this concern, the Review recommends that the current requirement for counsellors to undertake criminal record checks be replaced by an obligation for the ART provider to ensure that this check is completed.

9.5. Providing information to surrogates and intended parents

As the Review has observed in Chapter 4, access to clear and timely information is important to help inform decision making by parties contemplating entering into a surrogacy arrangement. Both surrogates
and intended parents reported that they found it difficult to gain adequate information about surrogacy and the costs involved through formal channels, and individuals generally rely on information gathered through surrogacy community support groups. The Review has made a number of recommendations aimed at ensuring that participants in ART, including surrogates and intended parents, have access to better information about relevant treatments, laws, impacts and costs.

A number of other reviews have recommended the development of a national website that provides advice and information for Australians considering entering into a domestic surrogacy arrangement. For example, the Commonwealth’s Surrogacy matters recommended that such a website should be established to provide advice on:

- the role of Commonwealth Government support and service provision for intended parents, surrogates and children including Medicare, social security and welfare payments, child support, paid parental leave
- surrogacy legislation in each Australian State and Territory
- the support and services funded and provided for by each Australian State and Territory including relevant health, counselling and legal services available.

The SALRI Review also highlighted the benefits of a national website or portal to provide reliable and impartial material on the various legal, ethical and medical issues and implications to all parties either contemplating or taking part in surrogacy. In the event that the Commonwealth does not set up such a website, SALRI recommended that such information be made available at the state level in South Australia by an appropriate party or agency.

Consistent with these views, the Review considers that Victoria should support and contribute to the development and provision of appropriate information at the national level on surrogacy related matters. Noting the complexity and prolonged timelines that may be involved, the Review considers that appropriate information should be offered in Victoria through the Regulator, in addition to any future dissemination of information through a national website. The Review notes that VARTA already plays a role in providing information to surrogates and intended parents, and encourages this work to continue, with a view to developing further tailored content to reflect the legislative amendments and supportive elements proposed.


9.6.1. Requirement to enter into a written arrangement

Unlike a number of other jurisdictions in Australia, including Queensland, New South Wales, Western Australia and Tasmania, there is currently no requirement in Victoria for a surrogacy arrangement to be set out in the form of a written document signed by all of the relevant parties. While the legislation interstate makes it clear that written surrogacy arrangements are not legally enforceable, except in so far as they relate to the reimbursement of the surrogate, they nevertheless offer a clear and detailed record of the parties’ expectations and intentions.

The Review notes that in considering the desirable features of a model law on surrogacy in 2016, the Commonwealth’s Surrogacy matters expressed support for an approach where the parties enter into an agreement that sets out shared expectations, including how disputes will be resolved and by whom, particularly where it is a matter concerning the best interests of the child. The Committee was also of the view that agreements should recognise the surrogate’s right to make decisions about their own health and that of the child. The recent SALRI Review similarly noted the benefits of a written surrogacy
arrangement entered into by the parties following appropriate legal advice about its effects. Consistent with the approach recommended by the Allan Review in Western Australia, it is recommended that appropriate templates for written surrogacy arrangements should be developed by the PRP and made available for use by interested parties.

In the interest of greater certainty and transparency, the Review considers it appropriate that the Victorian legislation be amended to require that a surrogacy arrangement be evidenced in writing and signed by the surrogate, and their partner, if any, and the intended parents, following appropriate independent legal advice about the effect and implications of the arrangement. Among other things, it is proposed that the content of the arrangement should include detail on:

- the expected reimbursement of surrogate’s costs associated with the pregnancy
- a shared understanding that protects the surrogate’s right to bodily autonomy in managing their pregnancy and the birth of the child
- the parties’ expectations in respect of applying for a substitute parentage order
- arrangements in the event that there is a medical emergency for the child prior to the making of a parentage order
- provisions for dispute resolution should disagreement arise between the parties.

The Review envisages that the arrangement would be seen by the PRP, with any appropriate modifications included as part of the existing surrogacy application process.

Feedback to the Review from key stakeholders highlighted that the introduction of the requirement for a written agreement would be a useful means of documenting intentions and confirming discussions and decisions between parties. The Review agrees with stakeholder advice that it would be valuable for the PRP to develop and publish a readily accessible template that parties to a surrogacy arrangement could adapt to their particular circumstances.
**Recommendation 68 Requirements for surrogacy arrangements**

It is recommended that the Act be amended to include requirements in respect of a surrogacy arrangement, namely that the arrangement:

- is evidenced in writing and signed by the surrogate, and their partner, if any, and the intended parents
- is entered into by the parties after they have obtained independent legal advice about the effect and implications of the arrangement
- sets out the reimbursement of the surrogate’s costs associated with the pregnancy, subject to any subsequent revisions which may become necessary if costs change
- protects the surrogate’s right to bodily autonomy in managing their pregnancy and the birth of the child
- is clear about the parties’ expectations in respect of applying for a substitute parentage order
- makes arrangements in the event that there is a medical emergency for the child prior to the making of a parentage order
- includes provisions for dispute resolution
- has been seen by the Patient Review Panel as part of the surrogacy application process.

### 9.6.2. Legal advice to surrogates and intended parents

Section 43 of the Act provides that before a surrogacy arrangement is entered into, the relevant parties must obtain information about the legal consequences of the arrangement. The PRP’s guidance note no. 1, *Approval of surrogacy arrangements in Victoria*, provides that independent legal advice should address the following matters:

- legal status of the child when born
- need for the commissioning parent(s) to apply to the court for a substitute parentage order
- timelines for making an application
- arrangements in the event there is a medical emergency for the child prior to the making of a parentage order.

In circumstances where a surrogacy arrangement involves donated gametes, the PRP requires that the legal advice address issues specified in relation to this situation. The PRP guidance states that the Panel expects that the provision of legal advice should occur through a face-to-face meeting with a lawyer, and that the surrogate and the intended parents obtain such advice from different lawyers to avoid the potential for a conflict of interest. Further, the PRP requires that all legal advice provided to the parties is included as attachments to the surrogacy application.

The Review notes the SALRI Review’s recommendation to amend the legislation in South Australia to indicate that legal advice should include information dealing with the rights and responsibilities for the child, particularly regarding the authority to make decisions about health care (both pre- and post-birth),
and, upon the making of a parentage order, the effects of the agreement on succession and estate planning, and the categories of costs recoverable.

The Review considers the issues that need to be addressed by legal advice provided to the parties to a surrogacy arrangement should be set out within the Act or prescribed in the Regulations. The matters that would form an appropriate basis for legal advice should include the topics set out in the PRP guidance, as well as the following topics:

- the legal effect of the proposed surrogacy arrangement
- the categories of costs recoverable by the surrogate under the arrangement
- the legal effect of making a substitute parentage order.

It is appropriate that the surrogate, and their partner, if any, and intended parents obtain independent legal advice from separate legal practitioners in relation to these matters, and this requirement should be clearly prescribed in the Act. While the Review anticipates the parties would ordinarily speak to their legal practitioner in person, it should also be open to the parties seeking appropriate advice electronically, for example, through Skype.

The Review believes it is unnecessary for the parties to the surrogacy arrangement to be required to provide all legal advice as attachments to their surrogacy application to the PRP. Instead, the Review proposes the legal practitioners acting for the parties should prepare a certificate in an approved form, which states that legal advice has been provided on the relevant matters. This certificate could be presented to the PRP as evidence that the legislative requirement has been satisfied.
Recommendation 69 Legal advice on surrogacy arrangements

It is recommended that the content of legal advice provided to the parties to a surrogacy arrangement under the Act focus, at a minimum, on the:

- legal effect of the proposed surrogacy arrangement
- categories of costs recoverable by the surrogate under the arrangement
- legal status of the child when born
- process and timelines for making an application for a substitute parentage order
- legal effect of making a substitute parentage order
- proposed arrangements in the event that there is a medical emergency for the child prior to the making of a parentage order.

The Act should make it clear that the legal advice provided must be independent, and, as such, a legal practitioner acting for the surrogate, and their partner, if any, cannot also be acting for the intended parents.

The Act should require that the legal practitioners acting for the respective parties prepare a certificate in a form approved by the Regulator, which states that legal advice has been provided on the relevant matters. This certificate could be presented to the Patient Review Panel as evidence that the legislative requirement has been satisfied.

There should be no requirement either in the Act or any supplementary guidelines for the parties to present written legal advice to the Patient Review Panel, either in part or full.

9.6.3. Reimbursement of reasonable costs incurred by a surrogate

In the course of consultations, the Review heard concerns that Victoria’s restrictive approach to reimbursement fails to ensure a fair outcome for surrogates and may discourage people to become surrogates in Victoria. As noted in the Interim Report, 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).

The Review formed the view that the category of surrogacy expenses currently eligible for reimbursement in Victoria is overly restrictive and inconsistent with interstate practice and the NHMRC Ethical Guidelines. Accordingly, the Interim Report called for the amendment of Victoria’s legislation to allow for the payment or reimbursement of reasonable costs that are incurred by a surrogate. It was recommended that the costs to 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

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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 would be disclosed to the PRP as part of the application for approval. Costs listed on the application could be amended if gaps were subsequently identified by the parties.

Consistent with the approach proposed in respect of the reimbursement of donors, the Review considers that it would be appropriate for the Regulator to publish guidance on reasonable surrogacy cost categories and amounts. This would help surrogates and intended parents negotiate an appropriate basis for reimbursement of costs. The Review anticipates that such guidance would be based on stakeholder consultation and reflect data on actual costs incurred by surrogates. It would also be subject to ongoing monitoring and review as necessary. Published costs should be treated as illustrative rather than prescriptive in nature, to recognise that every surrogacy journey is different. The legislation should in general be drafted to ensure there is sufficient flexibility in the reimbursement of surrogates to reflect the unique circumstances of the individuals involved.

The SALRI Review recommended a similar approach, observing that there should be public information relevant parties can access that sets out the typical range of costs recoverable under a lawful surrogacy agreement. This could be, for example, in the form of a table or schedule of surrogacy costs, or as a questionnaire, to prompt potential parties to surrogacy agreements to turn their mind to the full range of potential costs recoverable under a lawful surrogacy agreement. The Allan Review also noted that clearer information needs to be provided to people concerning surrogacy costs that may be reimbursed. To the extent possible, the Review considers it appropriate to harmonise these arrangements with similar provisions in other jurisdictions.

The Review supports the recommendation in the Allan Review that clearer information should be provided to parties contemplating entering a surrogacy arrangement about the expected costs of required counselling and legal advice. To this end, it is recommended that the Regulator develop and publish guidance on reasonable range of costs for these services in Victoria, to bring greater transparency and consistency to the fees which are charged.

Recommendation 70 Regulatory guidance on altruistic surrogacy reimbursement

Further to Recommendation 14 of the Interim Report that proposed expanding the range of costs for which surrogates can be reimbursed, it is recommended that the Regulator publish guidance on reasonable surrogacy cost categories and amounts, to help surrogates and intended parents negotiate an appropriate basis for the reimbursement of costs. To the extent possible, it would be appropriate to harmonise these arrangements with similar provisions in Australian jurisdictions. The Regulator should publish guidance on the reasonable range of costs for the counselling and legal advice services which need to be satisfied by parties who enter into a surrogacy arrangement in Victoria.

Unlike 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 SALRI Review recommended South Australian legislation be amended to ensure that the part of a surrogacy agreement relating to costs is legally enforceable.
Given the feedback received about the physical, emotional and financial vulnerability of surrogates, including examples where the intended parents have refused to pay for some or all of the agreed expenses incurred by a surrogate, the Review considers it would be desirable to make clear in legislation that surrogacy arrangements to pay or reimburse costs are enforceable. This amendment would have no impact on the general principle that a surrogacy arrangement is not enforceable.

Having considered the current approach in other jurisdictions, the Review recommends that a provision relating to the enforcement of surrogacy arrangements should state that a surrogacy arrangement is not enforceable. However, an obligation under a surrogacy arrangement to pay or reimburse costs incurred by a surrogate is enforceable, and costs incurred should be paid or reimbursed where a surrogate has tried to become pregnant, irrespective of whether a child is ultimately born as a result of the surrogacy arrangement. The Review recommends that an exception to the enforcement of costs should apply where the surrogate fails to relinquish the child to the intended parent(s) or consent to the making of a parentage order in relation to the child, unless there are reasonable grounds for doing so.

The Review considers that these amendments will help strike an appropriate balance in protecting the interests of both the surrogate and the intended parent(s) in so far as ensuring certainty about the financial aspects of the surrogacy arrangement are concerned.

**Recommendation 71 Enforceability of surrogacy reimbursement**

It is recommended that a provision be included in the Act to clarify that:

- a surrogacy arrangement is not enforceable
- an obligation under a surrogacy arrangement to pay or reimburse costs incurred by a surrogate is enforceable
- costs incurred should be paid or reimbursed where a surrogate has tried to become pregnant, irrespective of whether a child is ultimately born as a result of the surrogacy arrangement
- the surrogacy agreement may include an exception to the enforcement of costs, where the surrogate, without reasonable grounds, fails to relinquish the child to the intended parent(s) or fails to consent to the making of a parentage order in relation to the child.

A further concern raised by surrogates was that negotiating payment directly with the intended parents can have a negative effect on the relationship. In particular, feedback to the Review indicated that some stakeholders felt that it would be preferable for payment to be managed through a third party to bring greater transparency and independent oversight to the process.

While the Review appreciates these concerns, it is of the view that introducing an intermediary into surrogacy arrangements is likely to bring an additional layer of complexity to the process. Given the range of relationships and circumstances that may arise in the surrogacy context, it is important the parties are given some independence and flexibility to manage the process in a way that best suits their needs. The Review anticipates that the proposed PRP oversight of the original surrogacy arrangement, including costs to be paid, will help protect the interests of relevant parties. Further, in deciding whether to make a substitute parentage order under the Status of Children Act, the court may take into account any other considerations it thinks relevant (s. 22(4)). To the extent that there are outstanding costs payable following the birth of the child, this could be a relevant consideration in a court making a parentage order sought by the intended parents.
9.6.4. Protecting the surrogate’s bodily autonomy

Anecdotal evidence indicates that surrogates may feel pressured to undergo certain medical treatments or screening procedures requested by intended parents, who may have strong views or preferences about aspects of the pregnancy or birth. The Review heard, for example, that some surrogates in Victoria felt that they had to comply with the demands for more invasive forms of treatment because the intended parents were paying for the medical expenses involved. Others reported that personal medical records or test results had been made available to the intended parents by medical professionals or clinics without their prior consent.

The Review notes that the NHMRC Ethical Guidelines provide that ART providers must respect the autonomy of surrogates to make informed decisions about their own medical care. Moreover, the Queensland and Tasmanian surrogacy laws expressly protect the right of the surrogate to manage the pregnancy and birth of a child, which prevail despite any agreement by the parties in respect of the surrogacy arrangement, whether orally or in writing. The SALRI Review has also highlighted the need to protect the rights, wellbeing and physical autonomy of surrogates, including autonomy over their bodies and medical treatment, and recommended that these rights should explicitly feature in a surrogacy framework. Feedback to the Review from one legal practitioner highlighted that a provision protecting the surrogate’s bodily autonomy offers peace of mind to surrogates, and the inclusion of such a clause in surrogacy arrangements was generally strongly supported by the parties to a surrogacy arrangement.

Having reflected on the importance of protecting the surrogate’s bodily autonomy, the Review considers that the Victorian legislation should clearly articulate and protect the surrogate’s rights in managing their pregnancy and birth. It is intended that this principle will prevail over anything that the parties to the surrogacy arrangement may have agreed, whether or not in writing.

**Recommendation 72 Right of surrogate to manage pregnancy**

It is recommended that a provision be included in the Act to make it clear that a surrogate has the same rights to manage their pregnancy and the birth of the child as any other pregnant person. This principle prevails over anything that the parties to the surrogacy arrangement may have agreed, whether or not in writing.

9.7. Advertisements and publications regarding surrogacy arrangements

9.7.1. Targeting existing prohibitions on advertising to commercial activity

During consultations, the Review heard from a range of stakeholders that the current restriction on publication makes it extremely difficult to source a surrogate in Victoria. Stakeholders noted that this often drives intended parents to seek surrogacy arrangements overseas, where clinical standards and industry regulation may be of a lower standard. Feedback to the Review highlighted it is in the best interests of a child that their donor and surrogate are within Australia, with clear 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. Intended parents would also prefer to access surrogacy arrangements locally rather than overseas, particularly in light of the minimal regulatory oversight or protection for surrogates and intended parents in some of the
developing countries where such arrangements may be pursued. Rapidly changing laws relating to surrogacy in some overseas jurisdictions have also created uncertainty for Australian intended parents.

Section 45 of the Act provides that it is 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. The provision relating to publication is interpreted strictly and poses a real barrier for people seeking to find a surrogate in Victoria, as they are unable to share their stories on online forums to seek a surrogate within Australia. The Review understands that people have been threatened with prosecution for publishing their desire to find a surrogate on such forums. A number of stakeholders observed 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.

There are a range of approaches to the regulation of advertising in other jurisdictions. Queensland and Tasmania have a general prohibition on publications or advertising material that 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; or demonstrates a willingness to enter into a surrogacy arrangement. By contrast, Western Australia prohibits the advertising of surrogacy arrangements ‘for reward’, but does not otherwise prevent the publication of material relating to altruistic surrogacy. Similarly, there are no specific prohibitions in respect of advertising a willingness to enter into a surrogacy arrangement in South Australian legislation; however, brokerage of a surrogacy contract or inducement of another to enter into surrogacy contract, for valuable consideration, is an offence.

While New South Wales prohibits the publication of advertisements relating to surrogacy, the legislation also states that an exception applies where a) the surrogacy arrangement is not a commercial arrangement, and b) no fee has been paid for the advertisement, statement, notice or other material. A recent review of the New South Wales legislation recommended that the latter requirement be repealed, permitting the payment of fees for an advertisement, statement, notice or other material if it is clear that any advertised arrangement is not a commercial surrogacy arrangement and any advertisement does not seek or offer rewards or other inducements (NSW Department of Health 2018). The SALRI Review agreed with the approach proposed in NSW, and recommended that legislation capture commercial introduction and brokerage and commercial advertising within the scope of prohibited conduct, but not frustrate non-commercial communication and negotiation between the parties.

The Review considers that the current prohibition on advertising creates a significant barrier to access for people seeking to have a child by entering into a lawful surrogacy arrangement in Victoria. Having reflected on the issues raised by stakeholders, and recent recommendations for reform interstate, the Review is of the view that the needs of people who wish to connect with an altruistic surrogate in Victoria should be met through a more balanced approach to the regulation of the advertising environment. While it is appropriate that legislation continue to prohibit advertising commercial surrogacy arrangements, the Review considers that advertising for the purpose of entering into an altruistic surrogacy arrangement should be permitted within clearly defined parameters. The Review considers it appropriate that the legislation should expressly state a general prohibition on commercial surrogacy in Victoria. A payment of reasonable advertising fees would not fall foul of this rule.

Consistent with the current approach, commercial brokerage of any surrogacy arrangement, whether commercial or altruistic, should be prohibited. The Review considers that it would be inappropriate for any third party to profit from introducing intended parents and surrogates for the purposes of entering into a surrogacy arrangement. Consistent with the approach recommended in the Allan Review, the legislation should clearly indicate that such prohibitions are not intended to capture the work of non-profit
groups providing information and support to people contemplating entering into a surrogacy arrangement.

It is envisaged that relevant guidelines for advertising would be developed by the Regulator in consultation with relevant stakeholders, to help inform the public about acceptable ways to contact potential surrogates or intended parents. Consistent with the proposed approach to advertising for donated gametes, the Review recommends that the legislation should authorise the Regulator to oversee advertising activity in Victoria relating to altruistic surrogacy arrangements, and to request the removal or amendment of material it considers to be inconsistent with the advertising guidelines. Any decisions by the Regulator in respect of a breach of the guidelines would be reviewable.

**Recommendation 73 Permitting advertising of altruistic surrogacy arrangements**

It is recommended that the current prohibition on certain publications in connection with surrogacy arrangements be revised to provide that:

- it is an offence for a person to enter into, or offer to enter into, a commercial surrogacy arrangement
- it is an offence for a person to induce, or seek to induce, another person to enter into a commercial surrogacy arrangement
- commercial brokerage of any surrogacy arrangement, whether commercial or altruistic, is prohibited
- advertising relating to a commercial surrogacy arrangement is prohibited
- advertising relating to an altruistic surrogacy arrangement is permitted, provided that it is consistent with guidelines developed and published by the Regulator
- the Regulator has the power to oversee advertising activity in Victoria relating to altruistic surrogacy arrangements, and to require the removal or amendment of material which is inconsistent with the advertising guidelines
- any decision by the Regulator in respect of a breach of these guidelines is reviewable.

**9.7.2. Online communication between surrogates and intended parents**

Many intended parents and surrogates currently connect through online surrogacy social media forums and discussion groups. As discussed in Chapter 8 in relation to online communication between gamete donors and recipients, there are anecdotal reports that these forums and discussions groups may, on occasion, expose people to risk or misleading information. As with Recommendation 55, the government may wish to consider facilitating the operation of community-led safe channels of communication between people contemplating entering into a surrogacy arrangement.
9.8. Clarifying the role of the PRP in approving surrogacy arrangements

Section 39 of the Act provides that a registered ART provider may carry out a treatment procedure on a woman under a surrogacy arrangement only if the surrogacy arrangement has been approved by the PRP. In making its determinations, the Panel must 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 [the child] are paramount’.

The Interim Report noted stakeholder concerns that the current requirement to have surrogacy arrangements approved by the PRP deters people from pursuing surrogacy in Victoria. In particular, feedback highlighted that hearings before the PRP can be confronting and stressful for people seeking approval for a surrogacy arrangement, as they are perceived to be overly formal and legalistic. Others stated there is a lack of transparency surrounding PRP 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.

The Review notes that the PRP’s guidance note no. 1, Approval of surrogacy arrangements in Victoria, appears to be highly prescriptive and sets out a broad range of documentary evidence the PRP may seek from parties to support a surrogacy arrangement application. The panel advised the Review that to ensure the welfare and interests of the potential child to be born are properly considered, it may have to ask probing personal questions of the adult applicants and may not always be able to give them what they seek.

While it is appropriate for the PRP to maintain an oversight role in approving surrogacy arrangements as envisaged in the legislation, the Panel appears to interpret its role as requiring an investigative approach to reviewing applications. This is undesirable, and the Review considers that there should be a presumption in favour of approving an arrangement if the matters set out in s. 40 are satisfied. Consistent with the proposed Guiding principles to promote positive relationships of trust between the parties to a surrogacy arrangement, the Panel should avoid undertaking intrusive additional interrogation of matters such as the precise nature and content of legal advice or counselling received by the parties, unless this is reasonably appropriate in the circumstances.

While the PRP is outside the terms of reference of this Review, the government may wish to consider requesting the PRP to review its guidance and policies on the approval of surrogacy arrangements in Victoria to avoid an investigative approach to the process. The government may also wish to ensure that the Panel provides accessible information about the approval process to better prepare parties who wish to enter into a surrogacy arrangement.

9.9. Addressing overseas commercial surrogacy

While commercial surrogacy is prohibited in Victoria, the offence does not have extraterritorial application, and as such, intended parents may enter into commercial surrogacy arrangements overseas. This is in contrast to the situation in Queensland, New South Wales and the Australian Capital Territory, where it is an offence for intended parents who ordinarily reside or are domiciled in those jurisdictions to enter into commercial surrogacy arrangements either at home or abroad. The key objective of the extraterritorial offence for commercial surrogacy in these jurisdictions is to protect vulnerable women from exploitation in countries where the regulation of surrogacy is less developed than in Australia. The Review notes that intended parents also expose themselves to a range of risks when they enter into
surrogacy arrangements abroad, including sudden changes to surrogacy laws relating to foreigners, unexpected additional costs, and inferior health outcomes for children born in countries where substandard medical practices may prevail.

The introduction of extraterritorial provisions is not universally welcome in Australia. Critics note that there have been no prosecutions of people pursuing international commercial surrogacy arrangements, and thus deem the provisions to be ineffective. For this reason, while the SALRI Review accepted the concerns about international commercial surrogacy, it ultimately concluded that a specific offence of this nature would be inappropriate and ineffectual in South Australia. By contrast, having undertaken a careful and thorough review of the extraterritorial provisions currently in place in Queensland, New South Wales and the Australian Capital Territory, the Allan Review recommended that the Western Australian Government amend the surrogacy laws in that state to ‘provide for the extraterritorial application of the law … which would make it an offence to enter into, or engage in, other practices related to commercial surrogacy arrangements abroad’ (Allan, 2019).

Central to this recommendation was the finding that ‘it would not be appropriate for a State [which criminalises commercial surrogacy domestically] to then endorse practices elsewhere that do not meet the standards agreed upon for citizens within that state or by those who choose to uphold the law rather than circumvent or breach it’. As part of its analysis, the Allan Review noted the value of a clearly articulated policy position on the issue of overseas commercial surrogacy, and highlighted the importance of a harmonised approach across jurisdictions, noting in particular stakeholder feedback that some people living in jurisdictions where overseas commercial surrogacy is prohibited are advised to move address, or make it appear that they were resident in a state such as Victoria, to circumvent such prohibitions. While accepting that there have been no prosecutions to date in the states that have introduced the extraterritorial offence, the Allan Review pointed to the strong deterrent effect that such laws have both on individuals contemplating overseas commercial surrogacy and ART providers or other medical practitioners who might encourage or advise the use of such services.

The Review acknowledges the arguments and expertise set out in the Allan Review in respect of overseas commercial surrogacy. This Review however has treated commercial surrogacy as outside the scope of its terms of reference, and has not examined the complex legal, international and moral issues. It has not assessed the potential impact of a criminal offence on those Victorians who do use commercial surrogacy services. The Review notes that many of the recommendations in this Chapter are aimed at making altruistic surrogacy arrangements more accessible locally, by clarifying the rights and obligations of the parties concerned, and removing existing barriers including opportunities for intended parents to connect with people who may be willing to act as surrogates, and making it possible to offer fair reimbursement of reasonable costs incurred. As such, the package of reforms as proposed will allow intended parents to have more and better opportunities to find a suitable altruistic surrogacy arrangement locally in Victoria. Nevertheless, the Review also acknowledges the benefits of a national harmonised approach to surrogacy laws, and that there may be interests in developing a common national approach on this specific issue. Efforts to harmonise surrogacy laws among key jurisdictions will likely require Victoria to review its position on introducing an extraterritorial offence for an individual or corporation to enter into, or engage in, practices related to commercial surrogacy arrangements outside Victoria.
10. Early preparation for emerging issues in reproductive medicine

**Key points**
- ART is a rapidly changing field, with novel therapies that challenge social norms and have other ethical implications.
- Ethical issues need to be debated by the community well in advance of their clinical use.
- Australia has no routine mechanism to consult with the community over forthcoming ethical and social challenges in ART.
- Ongoing and early national leadership is needed for dialogue with the community to avoid unnecessary delays to the introduction of novel ART techniques – and also to avoid the introduction of techniques that the community ultimately finds unacceptable.
- National harmonisation of ART and related laws and regulations is needed, with five-yearly review.

ART is a rapidly changing field which by its very nature may attracts a small number of doctors and scientists who wish to push scientific boundaries, encouraged by demand from people who desperately want children and commercial pressures on the various private clinics to distinguish their offerings. Emerging ART techniques bring with them ethical challenges that should not be ignored until novel methods are already in clinical practice. It is important to have proper community debate before moving forward with ART techniques that challenge accepted social norms, and presently Australia does not have a mechanism to do this routinely. The ethical dilemmas posed by new ART techniques were demonstrated in late 2018 when Dr He Jianku genetically edited two embryos that were then transferred to their mother’s uterus and became twin girls with heritable genetic changes. He Jianku’s actions caused worldwide outrage. Although there is no suggestion that anyone in Australia is attempting clinical application of heritable gene editing, it is clear that further dramatic scientific and clinical developments will occur over the next 10 years. This case has highlighted the sensitivities around new technology and the creation of human life, and appropriate regulation of the scientific and ethical challenges of ART.

10.1. Pushing scientific boundaries: ART and community norms

While IVF and associated techniques are now widely accepted by the general community, new developments and sometimes unrealistic expectations are cause for both awe and concern.

Mechanisms are needed to continually encourage community dialogue about novel therapies that are likely to significantly challenge societal norms and values or where changes to laws are required, and to assess the scientific and ethical merits of such techniques. This should be done before such treatments are used to result in pregnancies and certainly before being introduced into wider clinical practice. The understanding of the science behind new technologies is likely to be difficult for communities, requiring careful explanation and communication of the risks. It is also important to hear and understand community concerns, addressing them wherever possible. This will be challenging without unnecessarily slowing access to improved infertility treatments. However, a proactive approach could encourage timely community dialogue. Importantly, community dialogue should not be avoided in order to hasten the introduction of novel techniques into clinical practice, and instead should be used as a means to provide genuine social consensus regarding these treatments.
The science behind ART is moving forward quickly, and globally there are cases where this may be occurring without adequate scrutiny especially in less regulated jurisdictions (Schandera and Mackey 2016). There are several new technologies already being used to varying extents throughout the world that would benefit from greater community understanding and debate. These include uterine transplants, the use of artificial intelligence in embryo selection, genomics, and making new gametes from other cells. A better community understanding of these techniques would expedite consultation on further scientific developments such as other types of heritable gene editing.

10.1.1. Uterine transplants

For those women who are born without a uterus, have malformations of the uterus preventing pregnancy, or have had to have their uterus removed before having children, there are few options if they wish to have their own biological children. Gestational surrogacy is an established method, but it does not give the opportunity to experience pregnancy and birth oneself, which may be desired. The new option of a uterine transplant is already happening overseas. This is where the uterus from a donor, usually a living family member or close friend, is transplanted temporarily into the person without a uterus. Immunosuppressant drugs must be taken to stop the transplant being rejected, once surgeons are satisfied that the body is not rejecting the uterus, pregnancy is attempted using the recipient's own embryos, which are created and frozen using IVF prior to the surgery. Immunosuppressive drugs must be taken throughout the pregnancy, as rejection of the transplanted uterus remains a risk – and the uterus therefore needs to be removed after the baby is delivered.

There are many ethical questions about uterine transplants that need to be worked through (Mitchell 2019). For instance, at this stage, the procedure is experimental, and only produces a live birth in a minority of cases, causing risks for both the donor and recipient that may not be outweighed by a positive result. Notably, it is not life-saving for the recipient and is undertaken only to satisfy the strongly felt desire to have a child. A live donor takes risks in undertaking significant surgery to have her uterus removed, although this may be able to be mitigated – at least one baby has now been born successfully after uterine transplantation from a deceased donor (Aubusson 2018). It is unknown what effect exposing the baby to immunosuppressive drugs during the pregnancy will have, although initial results appear promising.

It is possible this procedure could lead to pressure on family members and friends to donate their uteruses. In addition, impoverished women could be exploited, as has already happened with commercial surrogacy, given the uterus is not essential to life. This type of treatment may also go beyond what is beneficial for the recipient, despite the fact that the uterus is not essential for life. For some, the desire to carry and give birth to their own baby is so deep that they are willing to take all the attendant risks. Uterine transplants push the ethical and scientific boundaries of assisted reproduction, and discussing the procedure is a conversation that the community needs to engage in sooner rather than later, as there are people already waiting for this treatment in Australia (Aubusson 2018).

10.1.2. Artificial intelligence for selecting embryos

A novel technology that is becoming common practice in Victorian clinics is the use of artificial intelligence for assessing the likelihood of viability of embryos. The ethical considerations surrounding the use of machine learning and artificial intelligence in medicine more generally are starting to receive more attention, such as the recent draft guidelines from the Royal Australian and New Zealand College of Radiologists (The Ethics Centre 2019). For instance, such a technology should be safe, care should
be taken to avoid bias – and machine learning is prone to this – and decisions should be transparent and explainable. Machines should not take the final decision on treatment (or in the case of ART laboratories, selection of embryos), the responsibility for which remains principally with the scientist, although scientists who use large systems may ultimately share liability, such as with the fertility clinic and the manufacturer. Humanitarian values should be applied in their use and an appropriate governance system should be in place to ensure adherence to ethical and humanitarian frameworks.

A new technology already in use is the EmbryoScope+, a combination incubator that takes and analyses many more time-lapse photos of the developing embryo than can be done using standard techniques, potentially allowing increased accuracy in the selection of the embryos most likely to result in a pregnancy. Melbourne IVF identifies that its use provides a ‘wide range of clinical, workflow and data management advantages over traditional methods’ (Melbourne IVF n.d.). Its use is not covered by Medicare and is presently being sold as an expensive extra in Victorian ART clinics – at the time of writing this was $495. However, Melbourne IVF also acknowledges there is a need to establish robust evidence on the benefits of artificial intelligence for embryo selection, and has established a prospective multicentre randomised clinical trial into the use of analysis of time-lapse photography of the early embryo by artificial intelligence.

The Review is pleased that a large clinical trial of apparently good design will be undertaken before artificial intelligence technology is added to time-lapse photography as part of usual clinical practice at this network of clinics. However, the use of artificial intelligence in the selection of potential human beings involves ethical issues that the wider community has not been given much opportunity to explore. The NHMRC Ethical Guidelines on the use of assisted reproductive technology are silent on the use of artificial intelligence (NHMRC 2017a). Practically, it makes sense to have a computer trawl through large amounts of data to identify embryonic characteristics most likely to be associated with the later development of a fetal heartbeat, and by extrapolation, the probability of a live birth. However, the practice raises many questions. Will it be known on what features the decision algorithms are actually based? What protections are there against the computer learning how to select for irrelevant, or worse, deleterious characteristics? Some properties may not become obvious until much later than the study end-point chosen. In this research, it would appear that the study end-point is an early one: a fetal heartbeat – it would take a much longer trial to identify resulting issues in the health of pregnancies and children as they grow. Such long-term studies are of vital importance to our overall understanding of ART interventions, but are expensive and time-consuming to perform.

Of more immediate concern, given its cost, is the fact that only people with greater financial resources will be able to use it, potentially giving them a greater likelihood of success. Less well-off people are more likely to experience greater financial hardship, exacerbating the psychological distress that attends most fertility treatment. Consequently, the use of artificial intelligence in ART may exacerbate pre-existing socioeconomic disparities in health.

10.1.3. Genetic testing in ART

The community needs a wider debate about genomic testing in general. Genomic testing is the process to prevent, diagnose, treat or monitor disease. Genomic testing involves analysis of a person’s DNA to provide information about a person’s genes and chromosomes. This information can be used to better understand the biology of human disease. It is not genetic treatment as such, although it may later lead to treatment of perceived genetic defects.

Genomic testing or screening of people not known to have, or to be at higher risk of, the diseases being tested comes with risks. These risks include misdiagnosis or overdiagnosis, which involves detection of conditions that will never develop into overt illness during the person’s lifetime. This can burden people

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with information they may not adequately understand, or worse, cause them to undertake unnecessary or possibly harmful treatments. Screening is different to diagnostic testing, where the person being tested already has the disease of interest, or has a higher risk of it, and the results are more likely to be accurate and relevant. It is important that in each case, the advantages of testing outweigh the disadvantages, and that genomic testing does not cause harm unnecessarily and inadvisably to people using ART services, including to their gametes.

Despite how much is known about the human genome and the sophistication of diagnostic tests, there is a great deal more to be learnt – including the degree to which the interaction between the environment and the genome influences the eventual development of disease.

Notably, genomic sequencing is now easily available directly to the public, and in the UK the NHS plans to offer genome sequencing without clinical need to individuals interested and prepared to pay for it, as well as subsidised for those who are not. While this effort ultimately aims to increase data and subsequent research on the human genome, it is uncertain how significant the findings will be for asymptomatic individuals, and it is likely to place an additional burden on publicly funded health services. People are likely to present to general practitioners for interpretation of their genomic results, and, for a significant proportion, this will lead to further investigation of risk and referral for genetic counselling. There are also ethical and legal implications for the sensitivity of personal genomic data and the uses to which it can be put. These practices also contribute to a culture where genomic screening is normalised without a general community understanding of the normal variation of the human genome, its complex relationship with disease manifestation, and due consideration of the risks of genomic screening.

Social acceptance and even demand for genomic screening has implications for ART. Donors of gametes undergo genetic screening for a range of diseases, with the potential for the number of conditions tested for to increase exponentially with increasingly high and even unrealistic expectations on the part of recipient parents. The proportion of donors considered medically, socially and legally acceptable for providing gamete donations is likely to shrink in these circumstances. As the number of genetic diseases that are tested for increases, so does the problem of donors being diagnosed with genetic problems many years after their gametes have been used to create children. When the clinic and donor registry are notified of these occurrences, a painstaking and expensive task of tracing donor children through their parents ensues, followed by genetic counselling and testing. The donor and recipient families will be burdened with knowledge about potential ramifications for their health over which they may or may not be able to take action, depending on the disease in question.

In addition, screening of embryos for genetic defects leads to an acceptance of routine testing of embryos for apparent genetic defects, even though no specific disease runs in the family concerned – this is known as preimplantation genetic screening. Embryos that are deemed not to have passed the screening testing are discarded. It is now becoming clear that testing embryos that are not at higher risk of genetic disease has resulted in lower pregnancy and live birth rates – that is, many embryos that would likely have resulted in normal babies were discarded (Mastenbroek et al. 2011). This is an example of a novel technique being offered for wide clinical use before an appropriate amount of evidence as to its safety has been assessed. While for parents and clinics it may be appealing to use only embryos that appear to have a good chance of success, the science behind preimplantation genetic screening is still developing, and the practice may cause adverse effects, including lengthening the time to pregnancy and increasing costs of treatment. It is hoped that advances in cell-free testing will improve testing accuracy and live birth rates.

In addition, it is concerning that routine preimplantation screening has become almost routine without sufficient public debate on the ethical and clinical issues involved. There may be ramifications for discarding embryos with perceived abnormalities, including an underlying assumption that no parent would choose to have a child with an apparent genetic abnormality. The Review heard that some parents felt pressured to have genetic testing of their embryos, especially if they had a disability, which they
experienced as an intolerance of difference related to disability. There may also be risks in the use of screening where it is not clinically indicated. The Review is encouraged, however, that the major ART clinics have reported significant change in clinical practice over the last year that reduced the rate of screening of embryos. Nonetheless, genetic screening of embryos remains in need of greater scientific and ethical scrutiny.

In addition, the widespread use of direct-to-consumer DNA testing by companies such as 23andMe and similar websites may have unintended effects for donors, donor conceived people and their families (23andMe n.d.). These tests expose not only potential issues with the health of the person who has consented to the test, but also members of their family, who have not. This can lead to misinterpretation of the test and lack of understanding of its limitations.

Furthermore, the linking of DNA testing with family trees, for example by 23andMe and ancestry.com, may bring with it many unanticipated issues for wider families. In the case of sperm donation, people may find out that the person who raised them is not their biological parent, and may then make contact with the donor regardless of their wishes. This has impacts for donors, donor-conceived people and their respective families, and it is unlikely that the full implications of these genetic tests (which can even be given as a gift) are appreciated beforehand by those undertaking them.

10.1.4. Mitochondrial replacement therapy and mitochondrial donation

Mitochondria are located in most cells in the body and produce energy, akin to cellular ‘batteries’. They are coded for by a small amount of DNA separate to the main DNA in cells and inherited only from the mother. Defects in mitochondria can cause a wide range of diseases that have symptoms, severity and age of onset which vary vastly even within the one family. Some manifestations of these diseases are fatal from an early age, and the nature of mitochondrial inheritance means that every child of that mother will have the disease.

Mitochondrial replacement therapy, also known as mitochondrial donation, for treatment of disease in embryos is now technically possible and has resulted in a handful of births internationally. Mitochondrial replacement therapy does not alter the main genetic (nuclear) material of an embryo, but does require a small amount of mitochondrial DNA from a donated egg. Consequently, babies born from this technique have popularly been referred to as having three parents. In reality, the vast majority of the DNA in the embryo thus created comes from the intended parents, and any visible resemblance will be with their families. Without such treatment, some women are unable to produce healthy, genetically related children. However, mitochondrial replacement therapy changes not just the DNA of the embryos treated, but also that of the baby’s descendants – that is, it is heritable. Consequently, the use of mitochondrial replacement therapy has sparked international debate.

International law around mitochondrial replacement therapy varies, and is now legal in UK under the auspices of the HFEA (Schandera and Mackey 2016). There, its use is strictly controlled, and requires individual approval, with the first permissions only just having been issued and no pregnancies yet having been announced. Some countries do not specifically ban it (for example, Ukraine and Northern Cyprus), while many including Mexico insufficiently regulate it, and others, such as Australia, ban it all together.

A recent Australian Senate Community Affairs References Committee report recommended interim measures be developed for Australians to access mitochondrial replacement therapy in the UK. The Australian government has responded to this report and initiated a broad community consultation, including state and territory governments, on this issue. The NHMRC has been tasked with further advising the government on whether new information from the UK could inform decisions here regarding the safety of introducing mitochondrial replacement therapy to Australia under controlled conditions.
Such advice would include the legal, regulatory, scientific and ethical issues, as well as the production of a plan for consultation with community. Such broad consultation is an important and necessary step to the introduction of mitochondrial replacement therapy for certain devastating diseases.

### 10.1.5. Other types of gene editing

Progress on editing the main DNA in the human genome is progressing much faster than anticipated, with use of CRISPR-Cas9, which allows much more precise editing. This includes making changes to embryos, which then become heritable. Although gene-editing research on early embryos is ongoing, the scientific consensus is that the current knowledge of gene function is not advanced enough to allow altered embryos to be used in ART, even in the case of preventing fatal genetic diseases – the risk of unintended consequences is presently thought to be too great. For this reason an influential international scientific summit in 2015 declared that the creation of genetically modified children was inappropriate, and should not proceed until safety, community consensus and ethical issues were resolved (Baltimore et al. 2015). Despite this, in November 2018 gene editing has apparently been used to modify the genomes of two embryos in China, resulting in the birth of twin girls (The He Lab n.d.). These changes are heritable and may reduce the chances of at least one of the girls contracting HIV, but the other possible effects on the immune system of altering the gene concerned are not well understood, exposing the girls to risks for uncertain benefit. Although there has been near universal scientific denouncement of Dr He Jianku’s premature work and his apparent research misconduct, it is clear that therapeutic, heritable gene editing is close (Begley 2018). While the scientific community is proposing a new international moratorium on germ-line editing, this is only a temporary measure to allow further ethical debate, as well as improving the scientific understanding of genes, their functions and the effects of editing them (Lander et al. 2019). The social and ethical implications of therapeutic gene editing of embryos are potentially profound, and a considered, community-wide ethical debate for Australia needs to start now.

Currently, Australia’s federal Prohibition of Human Cloning for Reproduction Act prevents gene editing of any kind that will result in pregnancies. However, a recent article by prominent legal experts argues that the law lacks clarity in the area and is in need of revision – this has become more urgent since the advent of CRISPR-Cas9 (Taylor-Sands and Gyngell 2018). It is appropriate and important that issues that challenge social norms to this extent are tackled at a national rather than state level. In addition, it is necessary to move towards a medical, scientific and social consensus regarding this area of gene editing, which would inform a regulatory framework for appropriate research and clinical trials. Much needs to be considered when deciding how much, if any, heritable gene editing will be allowed in Australia.

Nonetheless, heritable gene editing promises a genuine reduction in human suffering. Some people are unable to have genetically related children without a medium to high risk of major genetic abnormalities, whereas for others only a proportion of their children are likely to be affected. To avoid these potentially devastating diseases, people must make difficult choices in forming a family, and different people will come to different decisions, depending on their ethical beliefs, the relative ease and availability to them of the various options as well as their financial resources.

Affected people may choose not to have children, to adopt (not an easy option in Australia), foster children, or to use donor gametes. This would involve using IUI for sperm and IVF for eggs with the attendant difficulties of insufficient gamete supply, medical risks due to the invasive nature of IVF, and potentially other issues for donor children as they mature.
Some people whose children are at risk of specific genetic diseases, but who also have a chance of having unaffected children choose to undergo IVF, even if they do not have problems conceiving. This is so that any embryos created can then undergo preimplantation genetic diagnosis for specific genetic abnormalities, with only apparently normal embryos then transferred to the uterus. Any embryo found to be abnormal will not be transferred and are allowed to succumb. Preimplantation genetic diagnosis is currently not rebated by Medicare, and combined with the need for IVF, access to this option is differentially reduced for people with limited financial resources.

Another option that is currently more frequently used involves natural conception that is then followed by prenatal testing at a later stage of pregnancy, allowing prospective parents to either terminate affected pregnancies or to prepare themselves mentally and physically for the birth of baby with disability or specific needs. For most people, the idea of terminating a pregnancy at a later stage is more distressing than allowing a few-days-old embryo to succumb, precious though each created embryo may be to them.

However, some people are presently not able to have children who are in anyway genetically related to them without them suffering from a potentially devastating genetic illness. The only option available to them is presently illegal in Australia – to edit the main genetic material of the embryo. Such editing would need to be done before the fertilised embryo had divided from a single cell, so that all genetic changes would be likely to found in all cells of the body and thus would become heritable.

Current European and many international laws do not disallow genetic manipulation of embryos. In Australia, research on embryos requires an NHMRC licence, and embryos with edited, heritable genomes cannot be implanted, and cannot progress to pregnancy. According to both Commonwealth (2002) and Victorian (2008) Prohibition of Human Cloning for Reproduction Acts, embryos used in research must be allowed to succumb after 14 days. Both of these Acts are quite old and lack clarity in this area, and there is no mechanism for ongoing revision of the law as a consequence of changes in community attitudes with advances in science and medicine. It is clear that the ability to make heritable changes to the human genome is upon us, yet there is no adequate formal and ongoing process to engage the community in a dialogue about it.

10.1.6. In vitro gametogenesis

More than a decade ago, it was discovered that skin or blood cells could be made to revert to stem cells in the laboratory, with the potential to change into any cell in the body. Since then, mouse tail cells have been used to create egg cells, that have been fertilised to become viable pups. More recently, researchers have caused human blood cells to revert to stem cells, and then to differentiate into very early egg cells – the early stages of in vitro gametogenesis (Yamashiro et al. 2018). While there is still much scientific work to be done, it is clear that the prospect of human gametes produced from other bodily cells is on the horizon, and that it is time to work through the attendant ethical issues.

There are multiple pressures likely to encourage the use of in vitro gametogenesis, the most obvious being the lack of donor gametes currently available in Australia. A woman could potentially even use her own cells to have sperm created to fertilise her own eggs. Presumably this would come with an increased risk of genetic disease through a lack of genetic diversity, although it is likely that attempts would be made to mitigate this through the use of preimplantation genetic testing and attendant selection processes. Allowing women to use their own cells would give them more control over the genetic heritage of their children, and many other species do successfully reproduce asexually, so this problem is clearly not insurmountable. Most donor sperm in Victoria is currently used by single women (52 per cent), so they represent a significant market for this technique (VARTA 2018).

Same-sex couples who wish to have a child who is genetically related to both of them would also be an important market for in vitro gametogenesis. Women in same-sex couples use approximately a third of
donor sperm in Victoria (VARTA 2018), and could have sperm made from one partner's bodily cells. Male same-sex couples could potentially have eggs made, although they would also need to use a gestational surrogate.

The ability to create eggs from easily obtained tissue such as blood could significantly reduce the risks to the donor of obtaining eggs by stimulating ovarian cycles, as is done currently. In such a situation, there would then be concerns as to when it would be appropriate to use 'natural' donor eggs versus in vitro gametogenesis (Carter-Walshaw 2018).

It is also possible that bodily cells taken for a different purpose could be used to create gametes without the permission of the person concerned.

There are social, legal, and ethical concerns with each of these scenarios, many of which are similar to previous debates in ART. Some include the ‘unnaturalness’ of the process, psychosocial and physical effects on the resulting child, and ‘eugenic’ implications of heritable manipulations of the genome and usage of preimplantation and prenatal testing (Suter 2015).

All of these technologies bring with them challenges which require a national community dialogue, such as that proposed for mitochondrial replacement therapy. The recent report of the Nuffield Council on Bioethics (2018) noted that the interactions between the interests of parents, their children, the wider ART industry and wider society affect what comes to be considered an acceptable community norm. Ethical issues to be considered when deciding if a new technology is appropriate include whether the disease being treated or prevented is life-threatening, or if people are otherwise unable to have children who are genetically related. The scientific understanding of the disease needs to be well understood with appropriately solid research experience before it should even be considered for introduction into clinical practice. It is also important to protect social justice and not to create or exacerbate social divisions by reducing the prevalence of genetic disease. For example, it is possible that societal intolerance of genetic disease could be exacerbated, and allowances need to be made for differences in opinion and values in decision-making by potential parents. Clearly it would be better to develop a proactive national mechanism to decide when new technologies are appropriate to be introduced that takes into account the relevant medical, scientific and social issues, rather than the current ad hoc approach.

The Victorian Government may wish to consider what actions it may take to contribute to that community dialogue. There are clearly some immediate opportunities, such as those presented by the discussion of mitochondrial replacement therapy, although they directly affect a relatively small number of people. Some of the other technologies and medical techniques discussed in this chapter do affect many more people and over coming years are likely to interest patients, clinicians and researchers, and be the subject of ethical debates in the community. However, this community dialogue is best conducted at a national level and in a responsible way informed by all perspectives. For that reason, the Review does not make any specific recommendations on these topics. However, at the least the Victorian Government should regularly monitor these developments, and ensure its regulatory framework is “future-proofed.” It should also ensure that the state regulator scans these developments, and engages effectively with national, and indeed global, leaders in these fields of scientific and medical research to prepare the Victorian community to respond to these emerging issues in reproductive medicine.

10.2. Risks of pushing scientific boundaries

There are scientific risks associated with pushing the boundaries of ART. The techniques themselves may not progress as hoped, and gene editing, for instance, is only now recovering from the disappointment of overly high early expectations (Crossley n.d.). It is certain, however, that the current knowledge of complex inherited characteristics means that such characteristics are unlikely to be able to
be changed in way that is reliably heritable. Certainly, the concept of so-called ‘designer babies’ is beyond what is currently believed to be possible. While mitochondrial replacement therapy is transitioning to clinical use in other countries, it is very unlikely that the editing of non-mitochondrial DNA would be licensed in Australia until its risks were mitigated. However, less regulated jurisdictions have no such protection. In the case of China, it would appear that He Jianku was able to break even his own country’s laws and engage in more general research misconduct. The Chinese Government has since announced stronger laws, regulations and enforcement in this area.

For genome editing, there are other risks – there may be ‘off-target effects’, whereby fixing one genetic problem creates others, tempering its great potential to relieve human suffering. This is what is feared for the twin girls whose genes were edited by He Jianku (Lander et al. 2019). The attempt to reduce their susceptibility to the HIV virus may or may not have been successful, but changing the gene in question is then likely to have increased the risk of contracting West Nile virus and influenza or worse effects, as the gene is not yet well-enough studied. Many gene sequences have multiple functions and changes may have unintended consequences. It is not yet known if other genes been inadvertently affected by the editing. The CRISPR-Cas9 technology used is known to not necessarily be as precise as originally thought (Kosicki et al. 2018). The girls could have an increased risk of cancer through reduced suppression of the body’s ability to fight it. The level of such risks is unknown (Nuffield Council on Bioethics 2018).

Although altering the genetic code of an embryo at its earliest one cell stage might be expected to result in all its cells that develop afterwards having the same change, this is not necessarily the case. Mosaicism can occur, where different cells in the body have different sets of genes due to the vagaries of inheritance, genetic mutations and embryonic developmental issues. However, if only some of the resulting person’s genes have been successfully edited, this is likely to result in improved clinical outcomes with less severe disease (if any) than may have been the case.

Until the ability to do cell-free genetic testing of the earliest embryos is better developed, successful gene editing in the whole embryo must be inferred by removing and testing a cell from the early embryo (Kuznyetsov 2018). Most embryos continue to develop successfully, but those cells are currently unable to be directly tested, and mosaicism is always possible.

It may also eventually be possible to make changes to the early embryo that only alter the effects of its genes – so-called epigenetic modification. Such changes might then affect the next generation (intergenerational) but not following generations (transgenerational) and this could be considered more acceptable to the community.

It is important to bear in mind that even if these and many more ART techniques can be reliably developed, other scientific techniques may be developed which may make ethically controversial techniques redundant. Gene editing, for instance, is likely to only be an alternative to other available methods because of the inherent risks to the resulting children and their descendants.

There is always the risk of ‘function creep’, whereby the original uses to which the technology are put are gradually added to without adequate consideration of the full scientific and ethical considerations. If there is no mechanism to prevent the slide, descent down the slippery slope is inevitable once the initial application of the technology becomes acceptable (Nuffield Council on Bioethics 2018, p. 55). Importantly, however, public morality may evolve, and what was once difficult and problematic for the community (like ART in general) may come to be generally accepted.
10.3. Possible social developments

The potential social ramifications of emerging ART technologies need to be carefully considered. We already live in an unfair society, and it would be unwise to produce or exacerbate further social division and increase societal inequity through the use of new ART technologies. The generations to be born must be protected, and wariness of creating divisions between those who have and those who have not had a new ART technique used on them as an embryo is vital. This may be through exacerbating pre-existing socioeconomic differences in health, as the financially advantaged are more able to afford ART techniques that reduce ill-health in their offspring. Another risk is that it may become less socially acceptable to allow a child to be born with a condition that could have been alleviated with gene editing or screened out through the use of artificial intelligence for embryo selection. There may be a lack of tolerance for affected individuals and their parents and a reduction in tolerance more generally for people with any kind of disease, disability, or difference. It is also not surprising that there is a deep-seated discomfort and even fear of anything resembling ‘eugenics’, with its sinister historical overtones, and lack of understanding of the complex interaction between genetic inheritance and environment in the development of human disease and behaviour (Jones n.d.). It is for this reason that the Nuffield Council on Bioethics recommended that controls of human gene editing be guided by a principle of avoiding any damage to social solidarity.

It is also clear that different communities and jurisdictions may reach different conclusions on acceptance of emerging ART technologies such as gene editing in different circumstances. This is an issue that has ramifications not just a national level, but also internationally.

10.4. Path forward

Scientific change in ART is likely to accelerate, and it is important to have ways to manage this. Australia needs a system to provide ongoing leadership to broad consultations across the community on the social, ethical, and scientific possibilities emerging with gene editing, artificial intelligence, and other scientific advances relevant to reproductive medicine. It is clear that debate on ethical and social implications needs to be stimulated well before a technology is used clinically.

Such a process of community consultation has recently been approved by the Commonwealth Government in response to the recent Senate Community Affairs References Committee report into mitochondrial replacement therapy (Commonwealth Government of Australia 2019). The response recognises that, although only a small amount of genetic material is being changed, it is heritable, so bringing this relatively developed technique into clinical practice is not to be undertaken lightly. A wide consultation process is planned, including state and territory governments with community consultation and expert advice overseen by the NHMRC (Commonwealth Government of Australia 2019).

While outside the terms of reference of this Review, it is observed that the Victorian Government – through both the Department of Health and Human Services and VARTA – is well positioned to play a role in the community consultation process over mitochondrial replacement therapy.

Notably, this consultation process about a novel technique that challenges community norms is restricted only to the issue of mitochondrial replacement therapy. The consultation process is time limited and reactive – there is no ongoing and proactive process for assessing either the appropriateness or scientific readiness of other ART techniques for introduction, nor informing and consulting with the community over ethical issues in a meaningful way. It should not be left to the consciences of individual scientists and medical practitioners to decide if it is appropriate to move novel techniques into clinical practice, even less so for their routine use. The NHMRC should play an active role in this space, as it is
well placed to provide clear, regular guidelines on clinical issues relevant to ART, as well as reviewing ethical issues (including community engagement) in a way that is readily understandable to clinical, scientific and lay audiences.

Nationwide communication and consultation takes time, especially so where changes to laws may be necessary. Social norms and ethical standards around ART are influenced by familiarity with the technology as well as existing legal frameworks, and the community needs time to become acquainted with the issues surrounding emerging technologies. An early national conversation is preferable for community consultations about novel ART techniques. There are challenges for the current regulatory framework that already need to be addressed, and this would be best achieved by harmonisation across Commonwealth and state and territory lines, flowing through to all regulations, accreditation for clinics under RTAC, codes of conduct and clinical and Ethical Guidelines for practitioners. For Victoria, in addition to the ART Act, key related Acts would need to be reviewed, including the Human Tissue and the Status of Children Acts. Notably, it is unusual for Acts to be reviewed more often than 10-yearly, which in ART is unlikely to be adequate; five-yearly review is a more sensible target.

With heritable human genome editing focusing international attention on emerging technologies in ART, now would be an ideal time to take better control of how Australia as a nation manages current and emerging issues in ART.

The Review observes that there may well be benefit in the Victorian Government supporting greater discussion of national approaches to ART, especially the emerging challenges discussed in this chapter. Depending on the interests of other jurisdictions, there may be value in:

- supporting a community dialogue about emerging ART issues, including heritable gene editing, well in advance of the technologies being available for clinical use
- supporting the NHMRC to broaden its ART guidelines from ethical issues to include clinical guidelines, and for these to be regularly reviewed
- regular review of key Acts and NHMRC guidelines relevant to ART.

However, the most pressing issue facing this field is developing an effective response to the challenges of gene editing, following the world’s first gene-edited babies.

Recommendation 74 Review of laws on human embryo research and gene editing

It is recommended that the Victorian Government propose to COAG Health Council a joint Commonwealth–state review of national laws related to human embryo research and human somatic and germline gene editing. This is particularly important for the Prohibition of Human Cloning for Reproduction Act 2002 (Cth), given current developments in heritable gene editing. The review should establish an appropriate framework for the control of these technologies and related research that is consistent with community standards. The review should include consideration of the work of the World Health Organization Advisory Committee on Human Genome Editing over the next 18 months, and consider a governance framework for this field of scientific research and its application to clinical trials.
11. Designing a contemporary regulatory framework for ART

Key points

- Regulation should target the core risks and harms associated with ART, and contribute to raising standards of person-centred care in ART.
- Reforms should eliminate discriminatory features of the Act and unnecessarily restrictive regulation, as well as improving access and affordability.
- Further recommendations are made to support a more effective co-regulatory system in which the industry self-regulatory bodies, primarily the Fertility Society of Australia and the Reproductive Technology Accreditation Committee, can work in effective partnership with the state regulator to raise standards in this industry.
- Requirements of providers should be strengthened, and compliance standards should be included as a condition of registration for ART providers.
- Reporting requirements should be enhanced and streamlined and the Regulator provided with more extensive and graduated compliance and enforcement powers to be used as a last resort in response to ongoing areas of risk or non-compliance that are not adequately dealt with through the self-regulatory approach.
- There should also be a specific provision for review of administrative decisions, as well as stronger requirements for reporting on the performance of statutory functions.

As discussed in Chapter 2, the Review believes ongoing state regulation of ART is required. However, there is scope to streamline and to refocus regulation to ensure it is targeted at addressing the most significant risks, and contributes more effectively to improving clinical care.

The Interim Report made recommendations aimed at addressing immediate issues in the regulation of ART. In particular, recommendations sought to eliminate unnecessary barriers to access and discriminatory features of the Victorian legislation. Others aimed to increase affordability and access by removing unnecessarily restrictive regulation.

In its second stage, the Review has identified a range of additional changes needed to ensure regulation is targeted to address the core risks and harms associated with ART.

This includes removing unnecessary regulatory barriers such as restrictions on advertising and the payment of compensation for donors and surrogates; some overly prescriptive approaches to counselling; and statutory storage limit for gametes and embryos stored for personal use.

It also includes the clarification of some regulatory requirements or how these requirements are to be applied in particular circumstances, for example through providing a clear legislative regime for egg freezing and through changes to the Guiding principles of the Act.

This chapter considers the design of the regulatory framework to best articulate requirements and support effective oversight and compliance. The Review considers that this framework should employ regulatory instruments and establish regulatory bodies that:

- avoid unnecessary duplication of regulation and burden on providers
- allow sufficient flexibility to accommodate changes in technology, markets, risks and community views
• provide clarity and certainty for providers, users and the community about their rights and obligations and the role of relevant regulators in ensuring these are met
• establish a basis for risk-based, outcomes-focused and transparent regulation, by a regulator with an appropriate range of tools to promote and enforce compliance as required
• ensure that formal regulatory powers are a ‘last resort’, preferring guidance, education and engagement as first approaches.

11.1. Regulatory instruments

11.1.1. Legislation

Throughout the course of the Review it was proposed that duplication of regulation could be minimised by bringing Victorian regulation of ART under the broader umbrella of health services regulation more generally, for example by regulating ART through the Health Services Act 1988. The Review has identified advantages and disadvantages to this approach.

On the one hand, such an approach may streamline some requirements for providers. It may also lead to a more consolidated and streamlined approach to regulation by bringing closely related regulation of health services together under one umbrella.

On the other hand, the purpose of the ART Act differs, at least in part, to that of other health service regulation. While legislation such as the Health Services Act primarily regulates how services are provided to individuals, much of the ART Act directly regulates the actions of individuals. For example, a number of provisions in Part 4 of the Act, which relates to surrogacy, prohibit individuals from certain actions such as the advertising or seeking to gain material benefit from a surrogacy arrangement. Similarly, Part 6 of the Act, which relates to registers and access to information, includes a number of offences that apply to individuals, for example, offences related to disclosing certain information or making contact with a person in contravention of an undertaking to comply with a no contact preference. This difference can be seen in the objectives of the Health Services Act (s. 9), which relate to the ways in which services are provided, organised and funded. This is in contrast to the Guiding principles of the Act, which set out the principles to be followed by all those carrying out functions and activities under the Act.

Feedback to the Review has also identified the complexity of the Health Services Act, and stakeholders have expressed concern that any move to include an additional Part or Parts in that Act to cover ART would only add to that complexity. This is also likely to raise many practical implementation issues for such an approach, and may require a larger and more complex review of the underpinning principles of the Health Services Act, which is beyond the scope of this Review.

Furthermore, the Review noted at a number of points the desirability of moving towards national harmonisation of ART regulation. There has been recognition in some recent national reports (for example, the Senate Committee report on mitochondrial replacement therapy) of some of the advantages for Victoria of having a specific regulatory regime for ART, and perhaps a growing need for such approaches with recent scientific advances in this field. A move to national harmonisation in this field is already very complex. To add to that complexity, harmonisation of all states’ health services regulations would make it practically impossible.

On balance, the Review considers that standalone ART legislation should be retained in Victoria.

It will be for the government to decide if changes to the legislation proposed by this Review, if accepted, are best implemented through amendment of the existing Act or if that Act should be repealed and new
legislation made in its place. The Review does observe, however, that the Act is now over a decade old and reflects drafting practices that may now be out of date. It has also been subject to a number of substantive amendments over that time, and as such, further substantive amendment may compromise ease of interpretation.

Whatever approach is taken, it will be important that legislation keeps pace with the changing ways in which ART services are delivered and the multidisciplinary nature of that service provision. Since the Act was drafted, the model of care has moved from services predominantly owned and run by specialists to clinics that provide counselling, nursing and scientific services, to specialist treating doctors who may be external to the clinic. It is critical that legislation is drafted in a way to ensure that regulatory requirements and the capacity for oversight apply to all relevant parties – treating doctors, owners of clinics, employees/contractors (such as nurses, counsellors and embryologists) working in clinics – and to all registered providers, be they private or public in nature.

The Review heard that the current Act may give rise to confusion or different interpretations about where obligations rest and the capacity for the Regulator to provide oversight of various actors within the ART industry. For example, s. 14(3) of the Act prohibits a registered ART provider from carrying out a treatment procedure where a presumption against treatment applies. Section 7 refers to a doctor who is carrying out the treatment on behalf of a registered ART provider. Any amendments to the Act or any new legislation should ensure a consistent and inclusive approach to identifying responsibility for regulatory compliance and oversight.

### 11.1.2. Compliance standards and conditions of registration

Throughout this report, the Review has identified a need for strengthened requirements, greater clarity of standards or improved oversight in relation to a number of matters, including:

- clinical governance
- complaint handling
- public information and advertising – including public reporting of success rates and costs
- patient information
- counselling

Many of these areas are already subject to some existing requirements (including under the national self-regulatory scheme and general health and non-health regulation). The Review found, however, that these requirements are not sufficiently robust, of sufficient scope or subject to sufficient oversight and enforcement. Nonetheless, it is not desirable to add an additional layer of regulation that is inconsistent with existing requirements, or unable to be changed to reflect changes made by other regulators.

The Review therefore recommends that new requirements should not be prescribed in the Act or in regulations, but rather should be addressed through compliance standards that are included as conditions of registration for all providers. The proposed compliance standards would be reviewed, revised or revoked over time if the risk they are designed to mitigate diminishes, or in response to changes in the broader regulatory environment. It may be, for example, that future revisions of the RTAC Code of Practice address some of the issues identified above in a more comprehensive manner that removes the need for a specific additional requirement in a Victorian compliance standard. The Review would be strongly supportive of any move by RTAC to strengthen the obligations of ART providers across these domains.

The Review considers that the compliance standards should be developed by the Regulator, in consultation with relevant stakeholders (including patients, the ART industry, professional organisations,
RTAC and, where appropriate, certifying bodies under the RTAC scheme) and kept under regular review.

To facilitate this, and ensure that there is sufficient clarity for ART providers and transparency and accountability of the Regulator in undertaking this function, the Review recommends that explicit legislative provision should be made for the Regulator to make compliance standards for a range of matters. This provision should include requirements for consultation, review and public reporting, and should require that the compliance standards articulate specific measures to allow objective assessment of compliance. As is current practice, the Regulator should be obliged to publish all conditions of registration (including compliance standards) on the Regulator’s website. The Regulator should also be required to report to the Secretary of the Department of Health and Human Services at the time of making or reviewing any compliance standards.

The Review notes that the Act (s. 75) provides for the Regulator to impose conditions on an ART provider’s registration if the Regulator considers it necessary in the public interest. Indeed, VARTA has used this provision to impose both general and provider specific conditions on registration. For example, in response to concerns about widespread promotion and use of unproven adjuvant treatments, VARTA included conditions on the registration of all providers that VARTA be informed of adjuvant therapies and new treatments used and that patients and the public are provided with accessible and easily understood information about the benefits and risks of these treatments. Some ART providers have expressed concerns to the Review that VARTA’s use of this power has lacked transparency, or has led to conditions that impose an unnecessary burden.

The Review considers that the proposed compliance standards, and the requirements for consultation and reporting, will support greater ownership and acceptance by the sector, as well as improved public confidence in the oversight of ART providers.

The Review considers that the Regulator should retain a power to impose conditions in addition to those contained in compliance standards, where necessary and in the public interest. This power enables the Regulator to respond to specific risk relevant to an ART provider or providers, and to immediate or imminent risk relevant to all registered ART providers. In determining whether to use this power, the Regulator would be required to consider whether the public interest is best served by imposing conditions in this manner, or through the more consultative and transparent approach of making or revising compliance standards.

Inclusion of compliance standards within conditions of registration will provide a mechanism for the Regulator to oversee compliance with the standards, investigate potential failures to comply and to impose a range of regulatory responses, depending on the nature and extent of the issue identified. The nature of these compliance and enforcement activities is discussed later in this chapter.

To avoid unnecessary duplication for ART providers, it is proposed that the RTAC Code of Practice be adopted, with or without appropriate modification, as a condition of registration with additional compliance standards only addressing matters not already covered in that document.

Furthermore, where existing regulatory requirements exist, and, following appropriate consideration and consultation, these requirements are considered appropriate to address some or all of the risks to be mitigated (for example, requirements under the National Law regarding the advertising of regulated health services), the Review believes that the Regulator should adopt, with or without modification, these existing requirements within the compliance standards. This will ensure that ART providers are not subject to duplicative or inconsistent regulatory requirements. In these circumstances, the value of the compliance standard will be in clarifying the obligations of ART providers, and allowing for effective oversight and, where necessary, enforcement activities.

Consideration should be given to whether it would be appropriate and desirable to exempt these compliance standards from being legislative instruments for the purposes of the Subordinate Legislation
Act 1994, on the basis that there will be explicit processes for consultation under the Act and to support the intended flexibility and responsiveness of the approach.

The Review has given careful consideration as to how compliance with these new standards should be overseen. It is not desirable that ART providers be subject to duplicative accreditation processes, and therefore it is not intended that the Regulator routinely audit compliance. Rather, it is proposed that RTAC accreditation continue to be a precondition of registration, and that ART providers also attest, on the basis of self-assessment, that policies and procedures are in place to conform with all conditions of registration, including any compliance standards. As outlined later in this chapter, it will be desirable for the Regulator to have powers to require additional audits or monitoring where the Regulator believes that an ART provider may have failed to comply, or where there are concerns about some aspect of a provider’s practice.

**Recommendation 75 Compliance standards**

It is recommended that provision be made for the Regulator to make compliance standards that articulate specific measures of compliance, in respect to a range of matters, which may include, but not be limited to:

- clinical governance
- complaint handling
- public information and advertising – including public reporting of success rates and costs
- patient information
- counselling
- reporting requirements.

The Regulator should be required to keep compliance standards under review and consult with relevant stakeholders (including patients, the ART industry, professional organisations, RTAC and, where appropriate, certifying bodies under the RTAC scheme) in the making and review of the standards.

It is recommended that compliance standards form part of the conditions of registration, with failure to comply grounds for a range of regulatory responses.
**Recommendation 76** Conditions of registration

All conditions of registration of each ART provider, including all compliance standards, should be published on the Regulator’s website and the Regulator should report on the making and review of compliance standards to the Secretary of the Department of Health and Human Services. It is recommended that the RTAC Code of Practice, as modified by the Regulator, form part of the conditions of registration.

It is recommended that the Regulator retain the power to impose conditions on registration in addition to those contained in compliance standards where necessary, in the public interest, to respond to specific risk relevant to an individual ART provider (or providers) or immediate or imminent risk relevant to all registered ART providers.

It is recommended that, prior to registration in Victoria, an ART provider be required to:

- achieve RTAC accreditation
- undertake a self-assessment in order to make a declaration that the ART provider complies with all conditions of registration, including any relevant compliance standards made by the Regulator.

11.2. Ensuring the regulator is equipped with the tools required to identify risks and support compliance

The Review has made a number of recommendations that seek to address gaps in the regulatory requirements for ART providers, or provide greater clarity about the minimum standards that should be met. However, many of the serious issues identified in this report and the Interim Report actually represent a failure to comply with obligations that are already in place. Others stem from a failure, by ART providers and/or relevant regulators, to identify or respond proactively to indicators of risk.

Consistent with the finding that there is a need for clearer and more comprehensive regulatory requirements in regard to some aspects of ART provision, the Review has concluded there is a need for ongoing and strengthened regulatory oversight of ART, with greater capacity to identify risk and support compliance.

As highlighted in *Targeting zero*, strong oversight, monitoring and support for continuous improvement is critical to ensure that patients are protected from failures of local safety and quality systems, and to facilitate a culture of learning and shared knowledge within a sector.

The Review has already noted in this paper and in the Interim Report that the introduction of the current Act resulted in the removal of a number of the regulatory oversight functions and powers that had been exercised by the Infertility Treatment Authority under the previous ART legislation. This included the shift away from the initial assessment of application for licences by clinics and from approving practitioners working in those clinics, towards a greater focus on support for those involved in donor conception, public education and the promotion of research.

As the industry has evolved, the Review believes these changes have swung the pendulum too far, and resulted in a system where state-based regulatory oversight is insufficient to support effective co-regulation and provide assurance to the government and the community that service provision is safe, of high quality and occurring in accordance with the provisions of the Act.
The intent of this judgement is not to make comment on the performance of VARTA in undertaking its regulatory role. Nor is it intended to deny or discount the very significant improvements in practice that RTAC and VARTA have contributed to over the years. However, with a larger, more diverse industry, and with higher expectations of the quality of care from both patients and government, more needs to be done. This will require reconsideration of the framework for monitoring and identifying risk, and for supporting compliance. This should ensure effective operation of the Victorian legislation and the co-regulatory scheme, and effective partnerships with other relevant regulators such as AHPRA, the ACCC and the Health Complaints Commissioner.

The diagram at Figure 1 illustrates the Review’s proposed approach to co-regulation of ART services in Victoria. The proposed approach recognises the role of RTAC in setting standards at the national level, identifying risks and areas of non-compliance and working with providers to address these concerns and support ongoing quality improvement. The Victorian Regulator will adopt the RTAC Code of Practice as a compliance standard included as a condition of registration in Victoria, where necessary this will be supplemented by additional compliance standards to address identified areas of concern. The Victorian Regulator will not actively audit compliance with the compliance standards, instead will accept RTAC accreditation and provider self-assessment of compliance with additional standards. The Victorian Regulator will have access to a graduated set of compliance and enforcement tools to be used as a last resort in response to ongoing areas of risk or non-compliance that are not adequately dealt with through the self-regulatory approach.

The question of which entity or entities should be responsible for regulatory oversight of ART is discussed later in this chapter.
11.2.1. Monitoring and identifying risk

Effective regulation requires the capacity to monitor activities and identify risks as they emerge in a proactive and responsive manner. The Department of Health and Human Services’ Better regulatory practice framework (Department of Health and Human Services 2018a) recognises three key ways risks can be identified – non-compliance reported by members of the community, collaboration with other agencies, and proactively identifying risks through the analysis of intelligence.

The Interim Report made two recommendations aimed at ensuring there is no barrier to the Regulator receiving information from the community (including patients and staff of services) that may indicate a possible risk to the safety or wellbeing of people using ART service. Recommendation 1 of the Interim Report aimed to ensure that recipients of treatment, staff of clinics or others with knowledge of potential breaches or non-compliance with conditions of registration suffered no detriment for reporting concerns to the Regulator.
Interim Report 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.

The Review understands that increasingly VARTA and RTAC have been working together to identify and respond to issues. Recommendation 2 of the Interim Report aimed to facilitate the sharing of information between relevant regulators and other bodies to support the identification of emerging risks. In particular, a capacity for the Health Complaints Commissioner to share information about complaints received regarding ART services will be critical to ensure the Regulator is able to identify, assess and appropriately respond to risks.

Interim Report 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 PRP, AHPRA, the Health Complaints Commissioner, Safer Care Victoria, the Department of Health and Human Services and the Minister for Health.

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

The Review has formed the opinion that the regulatory changes made when the Act was introduced, as described above, have limited the capacity of VARTA, as the regulator, to proactively identify risk in ART service provision.

The ‘deemed registration’ system, whereby a provider that has been accredited against the RTAC Code of Practice will, on application, receive registration in Victoria means that there is little if any systemic oversight by the statutory Regulator of the processes and systems of an ART provider. This affords little opportunity, at the state level, to assess providers’ approaches to preventing adverse incidents and/or breaches of the legislation.

The Review has identified a number of ways in which the Regulator’s capacity to gather and analyse intelligence to identify risks associated with non-compliance and other issues may be improved.

Data reporting requirements – ART providers

Targeting zero described information as ‘the “lifeblood” of a continuously improving system’ (Duckett et al. 2016). 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 Review understands that the current data reporting obligations of ART clinics are significant. Clinics must report to:

- RTAC on all serious notifiable adverse events
- the Australia and New Zealand Assisted Reproduction Database (ANZARD)\(^\text{22}\) on specified data relating to treatments and outcomes

\(^\text{22}\) The Australia and New Zealand Assisted Reproduction Database (ANZARD) is an initiative of the Fertility Society of Australia (FSA) to provide a joint data collection for both the National Perinatal Epidemiology and Statistics Unit (NPESU) and the
• VARTA on any incidents reported to RTAC and on any breaches of the Act, Regulations or conditions of registration, matters that VARTA is required to report annually to the Minister under s. 114 of the Act (including information about treatment programs, participants in treatment procedures conducted, embryos formed, and embryos and gametes stored), as well as the use of adjuvant therapies.

Despite these significant reporting obligations, there are concerns about the extent to which data that is collected and reported is used to identify service-level risks and opportunities for improvement.

Some providers also expressed concern that the decision criteria for what constitutes a reportable event under the RTAC scheme are unclear, and require further definition and clarification.

As noted in the Interim Report, the definition of serious notifiable events required to be reported to RTAC sets a high threshold. In particular, it was noted that guidance as to when instances of OHSS are to be reported are limited to the most serious of circumstances, that is when OHSS results in hospitalisation that included paracentesis or draining of pleural effusions or permanent disability (hospitalisation for observation and fluids after symptoms of OHSS is specifically excluded). The Review agrees that the requirement for the immediate reporting of events might reasonably be restricted to the most serious. However, it has been suggested that the regular reporting, for example on a quarterly basis, of a broader set of adverse events (such as all instances of diagnosed OHSS) and rates of use of adjuvant therapies, may assist both providers and the Regulator to identify areas of risk and better target efforts to improve practice. The Review proposes that appropriate requirements for the reporting of such information be included within a compliance standard. As described earlier in this chapter, such a compliance standard would form part of the conditions of registration.

The Review wishes to ensure that any increased requirements for reporting, as proposed above, do not represent an unreasonable additional burden on providers. One proposal to address the current reporting burden is to align requirements for routine reporting to the Regulator with requirements to report to ANZARD. Currently, providers must:

• provide the Regulator with information on treatment programs, participants in treatment procedures conducted, embryos formed, and embryos and gametes stored in the preceding financial year by around the third week of August. This timeframe is to allow VARTA to comply with the requirement under s. 114 to provide a report to the Minister by 30 September each year.
• provide ANZARD with similar information in respect to the proceeding calendar year during October each year. It is understood that this timing is to allow information about the outcomes of any pregnancies achieved to be included.

The Review considers that in developing compliance standards for reporting, it would be valuable to streamline the reporting requirements of ART providers, such that the timing and format of reports to the Regulator align with those of reports to ANZARD. This would require amendment of the requirements of s. 114 to allow the Regulator’s report on the activities of the ART sector in Victoria activities of the ART sector in Victoria to be provided to the Minister by the end of the calendar year. Requirements for the Regulator to report to the Minister on the Regulators operations are discussed in section 11.2.3).

The Review has heard that this approach would allow for more meaningful analysis of the information collected, as well as more ready comparison of Victorian and national data regarding activity and outcomes of treatment.

Reproductive Technology Accreditation Committee (RTAC) of the FSA. The purpose of the ANZARD collection is to monitor the perinatal outcomes of assisted reproduction and to assess the effectiveness of ART.
The Review further notes that the collection of data alone is of no value unless that data is interrogated to allow for variations in practice or outcomes to be identified and understood. Given the particular expertise of Safer Care Victoria, there is an opportunity to involve that body in assisting the Regulator to interpret trends, and to target quality improvement activities to areas where they will be of most benefit.

**Recommendation 77 Reporting to the Regulator of adverse events, treatment and outcome data**

It is recommended that the Regulator develop compliance standards in relation to reporting requirements, including requirements for the reporting of adverse events, and the use of adjuvant therapies. The adverse events reported should include, but not be limited to, the reporting, by ART providers, of all diagnosed cases of OHSS (whether mild, moderate or severe) to the Regulator. The compliance standards should, as far as possible, align the timing and format for reporting to the Regulator with existing requirements for reporting to ANZARD, and form part of the conditions of registration.

To facilitate this, it is recommended that the requirement (s. 114 of the Act) for the Regulator to report to the Minister on the activities of the ART sector in Victoria be amended to allow for the report to be made by the end of the calendar year.

**Data reporting requirements – hospitals**

The Review has also heard from professionals in other areas of the health sector that there is additional information available, but not currently routinely collected, that might assist the Regulator to identify areas of risk associated with clinical practice. In particular, it has been suggested that the collection and reporting of presentations at hospital for OHSS might assist the Regulator to identify rates of this complication that are outside the expected range, and may also assist in assessing providers’ compliance with requirements for reporting adverse events.

The Review considers there may be merit in Safer Care Victoria leading the development of a system for hospitals to report all presentations to emergency departments and/or admissions to hospital that involve OHSS. Safer Care Victoria could also have a role in assisting the Regulator to interpret trends identified through this data and consider quality improvement activities that might be implemented in response. However, since the costs and benefits of such a system will need to be assessed fully, the Review only observes that the government may wish to consider asking Safer Care Victoria to investigate a system for the reporting by hospitals of all presentations to emergency departments and/or admissions that involve OHSS or other defined events.

**11.2.2. Tools to support improvement and compliance**

Good regulatory practice dictates that regulators make use of a range of interventions, taking into account both the level and likelihood of the risks to be ameliorated, and the willingness and capacity of the regulated entity to work with the regulator to improve performance and comply with regulated requirements. The compliance tools that may be used are often described as forming pyramid of possible interventions. Figure 2 shows the possible tools, ranging from low-level interventions such as education, advice and guidance materials for low-level risks, to higher-level interventions, such as the revocation of registration or criminal prosecutions available to respond to serious risks.

Not all regulators will have access to each of these tools, but it is important that a range of options, proportionate to the risks, are available. Regulators should aim to use lower-level interventions, wherever
possible, to achieve the desired outcomes. Higher-level interventions are reserved for circumstances where an entity is deliberately non-compliant or has repeatedly failed to comply, and the potential harms arising from this non-compliance are significant.

**Figure 2: Pyramid of possible regulatory interventions**

Source: Department of Health and Human Services 2018

The Review has observed that changes to regulatory oversight of ART brought about by the Act, coupled with an apparent preference communicated by the government in statements of expectations for VARTA and other means, have resulted in VARTA taking ‘light touch’ to system oversight. This is especially so when compared with its predecessor, the Infertility Treatment Authority. Regulatory activity has been predominantly at the lower end of the pyramid of regulatory tools. Some stakeholders expressed the view that this approach has, at times, not been proportionate to the risks and that stronger responses may have been more appropriate in some instances where there were clear breaches of the Act.

The Review notes, however, that the Act provides the Regulator with only very blunt instruments to respond to more significant instances of non-compliance of ART providers in Victoria, and may not offer an adequate suite of graduated compliance tools to support improvement and proportionately respond to risk. In particular:

- The circumstances under the Act in which the Regulator may exercise its investigatory and inspection powers are narrowly defined to determining compliance with a registration, and they do not extend to allowing the Regulator to compel doctors and others (who are not employees of clinics) to cooperate. These limitations can hinder the capacity for full investigation of issues that arise, and thereby affect the response to these issues. The lack of provision for delegation of these powers also means that they may be exercised only when a member of the VARTA board is present. This can restrict flexibility and responsiveness.
The range of sanctions under the Act is limited and, in the opinion of the Review, not sufficiently graduated or nuanced to allow for effective and responsive regulatory practice. For example, the Act provides for conditions to be placed on a provider’s registration. However, there is no penalty specified in the Act for a breach of conditions. The Act does provide for suspension of registration (ss. 76 and 77), but the use of such a strong power would have significant consequences for patients that would only be warranted in extreme circumstances. As such, this power has never been used.

The Review heard there is a lack of clarity regarding the role of VARTA in responding to and prosecuting breaches of the Act.

The Review believes a more comprehensive, graduated set of compliance tools should be available to the Regulator. Working within the co-regulatory scheme it is anticipated that the Victorian Regulator will make use of these powers only when RTAC is not taking action or when action under the self-regulatory scheme has failed to address issues or risks. Where low-level intervention is required, this might include a range of functions, already available to the Regulator, such as education, the provision of guidance materials or official warning letters alerting the provider to compliance concerns. With appropriate information-sharing powers, it may also be possible for the Regulator to facilitate clinical support, including through the Department of Health and Human Services and Safer Care Victoria to address specific risks identified with some clinical practices.

However, when the risks are greater, or the Regulator believes that a provider is not willing to work collaboratively, a stronger set of powers is required. These are likely to be exercised only infrequently, and should include:

- strengthened inspection/investigation powers for the Regulator (including unannounced inspections carried out within usual business hours) to monitor compliance with the Act or conditions of registration (including any relevant compliance standards). This should include appropriate powers for the Regulator to collect information from any person, not just a registered ART provider. This would allow for doctors or patients, where relevant, to be interviewed. It should be made clear that the powers of the Regulator in relation to inspection and seizure of documents and other things extend to doctors working as agents of a registered ART provider, regardless of whether they are employees of the provider or not
- a power to impose periodic audits on an ART provider where the provider has been found to have failed to comply with conditions of registration, or where there are concerns about some aspect of a provider’s practice. The purpose of such audits would be to ensure compliance issues are remedied
- powers to require undertakings from providers or issue compliance notices in response to identified instances of non-compliance with conditions of registration or breaches of the Act
- a capacity to impose monetary penalties on ART providers where there are repeated, significant breaches of conditions of registration or where undertakings are not complied with
- powers to suspend or withdraw registration both generally and/or for the provision of specific service types.

These powers would be limited to circumstances in which the Regulator is satisfied there is a significant risk to the health and safety of an individual or individuals, or where there is evidence of a significant breach of the Act or registration conditions, or where lower level compliance activities have failed to remedy identified issues. The use of any of these powers should be subject to appropriate procedural fairness requirements, with ART providers afforded a formal opportunity to respond to any alleged breaches or failures to comply and to any proposed action by the Regulator, such as the imposition of a penalty, additional conditions on registration or proposed suspension or withdrawal of registration. The Act should provide for immediate suspension of registration in circumstances where the Regulator is satisfied that there is an immediate and serious risk to the health or safety of an individual or individuals.
The Regulator should be required to notify RTAC and the Secretary of the Department of Health and Human Services in relation to the use of these significant powers and in relation to any serious breaches or instances of non-compliance.

The Review also considers that the Act should set out a clear process for the initiation of prosecutions under the Act.

However the Regulator is constituted, it will also be important to ensure that the legislation provides sufficient protections for people exercising these powers, as well as scope to delegate the powers as necessary to facilitate the Regulator fulfilling its functions.

**Recommendation 78 Comprehensive, graduated compliance and enforcement powers**

It is recommended that provision be made for a more extensive and graduated set of compliance and enforcement powers to be available to the Regulator to respond to significant issues of non-compliance or where lower level compliance activities have been unsuccessful. This should include:

- strengthened inspection and investigation powers
- a power to impose periodic audits on ART providers to ensure compliance issues are remedied
- powers to require undertakings or issue compliance notices
- powers to impose monetary penalties and to suspend or withdraw registration both generally and/or for the provision of specific service types.

It is recommended that the Regulator be required to notify RTAC and the Secretary of the Department of Health and Human Services in relation to the use of these more significant powers and any serious breaches or instances of non-compliance.

There should be a clear process for the initiation of prosecution under the Act.

### 11.2.3 Transparency and accountability of the regulator

This Review has focused on the regulatory framework, rather than the performance of VARTA. Nevertheless, during the Review’s consultations, some criticisms have been made by industry representatives of VARTA’s performance, governance, capability and interpretation of key legislative provisions. Effective regulation is well served by open scrutiny of public institutions, and it is important that a regulator such as VARTA is responsive to the concerns of regulated entities about its performance.

**Review of administrative decisions of the Regulator**

The Review heard concerns that the basis for administrative decisions under the Act are not always clear and that there is no capacity for appeal in relation to a number of administrative decisions made by VARTA. Transparency and accountability of the Regulator and its decisions are critical to support public confidence and to gain the acceptance and compliance of the regulated sector.

The Review suggests that the functions of the Regulator should adequately reflect its role to provide oversight of the sector and to support regulatory compliance. The Review further believes that a clear avenue to review the decisions of the Regulator is required. The Review proposes that the Regulator
should be required to have in place, and communicate to affected parties, an internal process for review of all decisions. It is further proposed that in the case of significant decisions, review by a court or tribunal would be appropriate. This will be particularly critical if recommendations regarding additional compliance and enforcement tools are implemented.

**Requirements for reporting on the Regulator’s activities**

The Regulator must report to the Minister annually under s. 114 of the Act. The matters set out in this section relate exclusively to the activities of the sector rather than the performance of the Regulator itself. The Review notes that the Regulator is also subject to reporting requirements with respect to its operations and finances under the *Financial Management Act 1994*. VARTA’s practice has been to prepare an annual report that addresses the matters set out in s 114 and meets these reporting obligations. As outlined earlier in this chapter and addressed in Recommendation 77, the Review considers that there is value in separating the requirements for the Regulator to report on the activities of the sector from the requirements to report on the operations of the Regulator. The Review further considers that it may be appropriate to require in the Act, inclusion in the Regulator’s annual report information about the exercise of any significant enforcement powers.

**Recommendation 79 Accountability and administrative review of the Regulator**

It is recommended that specific provision be made for review of the administrative decisions of the Regulator.

It is recommended that the Regulator be required to provide an annual report to the Minister by 30 September each year on the performance of the Regulator’s statutory functions, including the use of significant enforcement or compliance powers.

**11.3. Establishing an effective regulator to support safety and quality in ART**

The Review has made a significant number of recommendations about the framework required for the regulation of ART in Victoria, and is clear that there is an ongoing need for an identified state-based Regulator. However, the Review has not formed a view, and is not making any recommendations, as to which entity or entities should take on this role, and is not making any recommendations on the specific Victorian Government organisations that should implement this new framework. That decision is best made by government in the context of resource constraints and reforms in the broader health and human services portfolios in Victoria.  

In making that decision, consideration will need to be given to the full range of statutory functions established by the Act and the role of the identified Regulator in relation to these functions. This includes:

- the functions of the PRP under s. 85 of the Act, including consideration of applications in relation to surrogacy, posthumous use of gametes and embryos, storage extensions, and treatment where an individual does not meet criteria or where there is a presumption against treatment in place

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23 For example, work is currently underway within the Department of Health and Human Services to strengthen the practice of departmental regulators, and the support to external regulatory agencies. This was a driver behind the development of the department’s *Better regulatory practice framework* (2018) and the establishment of a dedicated Regulation, Health Protection and Emergency Management division to bring together regulatory expertise to better identify and mitigate existing and emerging risks.
- registration of providers and monitoring of activities under the Act
- management of the donor conception registers, donor linking and the release of information from the registers
- provision of counselling and support services for donors and donor-conceived people
- approval of importation and exportation of gametes or embryos
- a range of other functions currently carried out by VARTA under s. 100 of the Act, including promotion of research and public education.

Other functions undertaken in Victoria under other legislation are also relevant and include the capacity for the Minister to approve the advertising for sperm donation under the Human Tissue Act 1982, the receipt and resolution of complaints about health services (including ART service) by the Health Complaints Commissioner, the registration of day procedure centres and private hospitals by the Department of Health and Human Services, and the regulation of health practitioners through AHPRA.

The recommendations of this Review may also lead to some additional functions such as oversight of an sperm and egg bank, broader programs of education and service design in reproductive health, and changes in relationship with Commonwealth Government entities such as the NHMRC.

The Review considers there are currently two realistic options for the Victorian Regulator of ART:

1. An independent statutory Regulator is established – either a refocused VARTA or a new entity that takes over similar regulatory functions of VARTA.

2. The Department of Health and Human Services, or an office within the department, assumes responsibility for the regulatory oversight functions and embeds them within broader regulatory oversight. The non-regulatory functions currently carried out by VARTA could either remain with VARTA or be taken over by the department.

Notionally, a third possibility is that the regulatory functions could be embedded within a general consumer protection function within Consumer Affairs Victoria. However, given current priorities and capabilities, the Review does not consider this to be a feasible option.

The Review does not consider that it would be desirable or appropriate for the Department of Health and Human Services to take on all of the functions currently performed by VARTA. Functions such as the management of the donor conception registers and the provision of support and counselling to people making applications for information from the registers may not align with the functions of the department’s health service regulators, and splitting these functions into another part of the department may not serve VARTA’s clients well. Some stakeholders may be concerned about these functions being carried out by a government department, rather than at arm’s length through a statutory authority. Another possibility is to transfer these functions to Births, Deaths and Marriages, but this would reverse a recent policy change.

Both options are viable, and both may have advantages and disadvantages. The preferred approach will need to reflect practical judgements about which can best deliver an authoritative, capable, fit-for-purpose and adequately resourced regulator.

To support government’s decision making, the Review has identified a number of desirable features of the Regulator,24 and considered how well the two main options for the regulation of ART align with these features.

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24 These characteristics have been informed by literature regarding good regulatory practice, in particular the OECD Best Practice Principles for Regulatory Policy: The Governance of Regulators: (2014), as well as an understanding of the particular challenges and context of the regulation of ART.
11.3.1. Desirable features of the Regulator

11.3.1.1. Clarity of role and purpose

Clarity as to role and purpose is essential for the Regulator to effectively fulfil its role. The objectives and functions of the Regulator should be clear to providers, patients (and potential patients), others involved in ART (such as donors and surrogates), donor-conceived people, other regulators and the community more generally. This is critical both to establish the appropriate priorities and boundaries for the Regulator’s work, and also to ensure that the Regulator can be held to account for performance across the range of its functions. These objectives should not be in conflict with each other.

As outlined above, there is a range of statutory functions under the Act, currently undertaken by a number of different bodies, and, if implemented, the recommendations of this Review may refocus some of these functions or necessitate the allocation of some new responsibilities to one or more entities.

The regulatory framework should be clear as to the priorities and considerations a regulator must be guided by in managing its range of functions, and it is critical that no single function limits or compromises the Regulator’s capacity to undertake its core regulatory role. For example, it would be inappropriate for the Regulator of ART to be charged with functions related to the development or promotion of the ART industry in Victoria. It is also not desirable that there is a perception that the Regulator is ‘captured’ by one group of stakeholders where there are strong service delivery ties.

Furthermore, in the context of limited resources, there is also a risk of resources being diverted from regulatory oversight functions to address pressing service delivery demands.

However, that is not to say that the Regulator cannot perform a range of different functions where they are not in conflict. For example, the Regulator might provide both service delivery functions (such as providing public education or managing the donor conception registers and providing information and support to applicants) and regulatory functions (such as the registration and oversight of providers).

Indeed, the Review considers that service delivery activities can valuably support regulatory functions, for example through building critical relationships and generating expertise and an intelligence base. The Review considers that the consolidated range of functions undertaken by VARTA has assisted in promoting community awareness about the role of the Regulator and assisted in the identification of issues that may have been missed were service delivery functions managed separately to the regulatory oversight role.

It will also be critical that the role of the Victorian Regulator acting within a co-regulatory framework is clear. As outlined earlier the approach is one that respects the role of the national bodies while providing the state Regulator with strengthened powers to act where the self-regulation has not been able to ensure that appropriate standards are met and retained. Achieving this will require clear delineation of roles between the FSA/RTAC and the state regulator with clear processes for sharing information and making decisions about which body should most appropriately take action in relation to specific incidents or risks.
Case study: cooperation between VARTA and RTAC

In 2017, a clinician raised an issue with VARTA, RTAC and other peak bodies about the rate of Ovarian Hyperstimulation Syndrome (OHSS) and ectopic pregnancies at a registered ART provider in Victoria.

VARTA, in consultation with RTAC led a coordinated approach to managing these issues. The ART provider submitted a report of their investigation process to RTAC and VARTA, after which RTAC organised a special audit of complaints handling policies and processes at the clinic two months later.

When RTAC conducted their scheduled annual audit three months later, a six-month licence was granted, instead of the usual 12-month licence, so that the provider could make improvements to leadership and oversight of work in all areas, including addressing VARTA’s concerns about clinical governance and clinical adverse incidents. VARTA also obtained documentation directly from the provider about complaints handling, medical supervision and clinical governance for monitoring purposes.

VARTA maintained regular liaison with RTAC and the clinic to monitor the progress and changes in clinical practices and governance. A third RTAC audit of the same provider was conducted prior to the expiry of the six months accreditation licence revealing significant changes to clinical governance and the organisational management structure. These improvements included quality and patient services management and included site-based clinical supervision. VARTA facilitated access to independent advice on quality assurance.

In early 2019, VARTA received a final detailed report that analysed the root cause and corrective actions taken by the ART provider relating to these adverse incidents. VARTA was satisfied that the significant changes made to clinical governance, organisational structure and clinical practices would now mitigate risks.

Subsequent information reported to VARTA suggested the changes made have had a beneficial impact on outcomes.

Submission - VARTA

11.3.1.2. Knowledgeable and capable

An effective Regulator requires strong regulatory capability. In addition to being able to work collaboratively with providers to support improvements in practice, the Regulator must have the skills to interrogate available evidence to identify risk and to investigate and gather necessary, admissible evidence to support more significant regulatory action, including prosecutions and other enforcement actions under the Act, when required. The capacity to respond capably and authoritatively to incidents will become more critical if the increased oversight powers proposed in this review are realised. The Review heard some concerns about the regulatory capacity of VARTA. On the one hand, VARTA has been criticised for failing to take decisive action in response to identified breaches of the Act. On the other, stakeholders have suggested that VARTA has acted too assertively and has been unduly intrusive in the operation of the clinics. The Review observes, however, that these criticisms, at least in part, may arise from the way in which regulatory functions have been established, and that the new regulatory powers and approach to co-regulation proposed by this Review may address some of these concerns.
The Review also notes that there may be a range of ways to ensure that regulatory capability is sufficient. This would be achieved through assigning regulatory functions to an existing strong regulator, such as the Department of Health and Human Services. It could, however, also be achieved through establishing strong ties between the Regulator and another organisation, such as the department, to allow the Regulator to access or leverage expertise as required.

The Review has also heard differing views about whether the community would best be served by a general health services regulator or by a standalone regulator with a specific focus on ART.

On balance, the Review is persuaded that the characteristics of this field, including its increasing complexity, the multifaceted social and ethical issues involved, and the need to sensitively balance divergent views on those fundamental ethical issues, means that this is an area best serviced by a regulator with specific knowledge and expertise in relation to ART. This is especially so given the prospect of rapid scientific and technological developments in reproductive medicine (including genome editing) over the next 10 years.

This view echoes the conclusion reached by a recent review of HFEA, the UK independent ART regulator. This review was charged with determining if a need remained for the specific regulator, and found widespread support for the retention of ‘a regulatory body with substantial expertise of operating in a specialised area of medical science that also raises complex moral and ethical issues’ (HFEA 2017).

While this specialist focus could be achieved through the establishment of a specialist unit within the Department of Health and Human Services, the Review considers that a dedicated, industry-specific regulator would best be able to build specialised knowledge that may assist it to practice outcome-focused, responsive regulation.

More difficult to influence through regulation and organisational design, but equally important, is the organisational culture of the Regulator. While this can be shaped in part by establishing clarity of purpose and mission, it is also heavily influenced by key personnel, particularly those in leadership roles, and through central agencies or government using formal and informal mechanisms to reinforce favourable cultures in regulatory bodies. The Review makes a number of observations towards the end of this chapter on some approaches to refocusing the Regulator that may be adopted in the short term.

11.3.1.3. Able to command the confidence of the sector and the public

It is critical that the Regulator has the confidence of the sector, the government and the public. Given the concerns the Review heard about the perceived conflict of interest of the self-regulatory model in this highly commercialised and competitive industry, establishing this confidence requires that the Regulator be independent of the sector, and is not seen to be ‘captured’ by any particular interest group or set of stakeholders. The Regulator should engage individuals with appropriate skills, expertise and experience to ensure that it is able to undertake its role and functions effectively.

The Victorian Government’s recent commitment to establish public IVF services means that some private providers may be concerned about the impartiality of the Regulator if, for example, regulatory functions were moved to within the Department of Health and Human Services. Although the Review does not accept that the department would act in a way to warrant such concerns, it is possible that some elements of the sector may perceive a conflict in this approach, if public clinics were seen to be in direct competition with private providers.

Strong, capable governance is a key means of ensuring that confidence in the Regulator can be achieved. Where an independent regulator is established, this can often be achieved through the establishment of a board with appropriate skills, experience and expertise to support core regulatory objectives. The government needs to ensure that board appointments to VARTA or any independent
Regulator include people, in particular, with authoritative expertise in this field of medical science. Such appointments are essential for the authority of the Regulator with its regulated entities, especially if the Regulator refocuses on improving patient care. Indeed the Review has heard strong criticism that VARTA’s current board may not include enough people able to provide strong clinical or scientific expertise to support decision making. There are well-established methods for managing conflicts of interest for such board appointments, and current or prior involvement with one or other regulated entity should not by itself prevent such appointments. Appropriate public reporting of the Regulator’s activities and performance is also critical.

11.3.1.4. Resources and sustainability

In identifying the most appropriate entity/entities to undertake regulatory functions in relation to ART, consideration will have to be given to the sustainability of the relevant bodies and the available resources.

Whatever entity is ultimately charged with the regulatory oversight of ART, adequate resourcing will be critical to ensure the aims of improving the quality, safety and experience of services can be achieved. Consideration should be given to how efficiency can be optimised.

It has been suggested that there are costs associated with small stand-alone entities that can be more efficiently managed by larger agencies with a greater breadth of roles. Larger agencies also have the capacity to more easily attract and retain skilled staff.

The Review notes that the introduction of the Act in 2008 saw the establishment of multiple new bodies with statutory responsibilities in relation to ART. Alongside VARTA, the Act established the PRP, and gave functions related to the donor registers to for the Register of Births, Deaths and Marriages (BDM). While the functions formerly undertaken by BDM were transferred to VARTA through the legislative amendments of 2016, the PRP still exists as a small separate statutory entity.

While some economies of scale can be achieved through combining multiple functions within one organisation, some stakeholders cautioned that often the only savings achieved are in back-office functions as the core regulatory activities for each function remain. Therefore, any decision to consolidate functions should be taken because that approach offers other benefits beyond simply the anticipated cost savings. Similarly, it should not be assumed that moving regulatory functions for ART into the Department of Health and Human Services would necessarily result in a reduction of costs. This Review recommends a greater focus on regulatory oversight, and whichever entity is chosen will require appropriate resources to deliver on these expectations.

Consideration may also be given to whether there is any capacity for some cost recovery to offset government funding requirements (for example, through the imposition of registration fees). The requirement to regulate the activities of private ART providers imposes a cost on the community, and therefore it may be appropriate that these organisations contribute to these costs. Furthermore, the Review considers that effective regulation will benefit the sector through mitigating against reputational damage, providing clarity of responsibility and supporting system-side quality improvement.

Cost recovery is unlikely to be an appropriate way to fund other statutory functions related to ART, for example activities associated with the donor registers or public fertility education. Ongoing government investment will therefore remain important.
Recommendation 80 Institutional design of the state Regulator

It is recommended that the Victorian Government identifies and resources a Regulator that:

- has clarity of role and purpose and a complementary balance of functions
- is knowledgeable about practices relevant to the provision of ART and related science
- is capable of engaging the community in dialogue on ethical, social, medical and scientific issues
- has strong regulatory capacity
- is able to command the confidence of the sector and the public.

11.3.2. Related organisational issues

Clarity about how the Regulator interacts and coordinates with other relevant entities is also critical given that the regulation of ART occurs within a crowded space.

Establishment of the Regulator should ensure that its functions complement other bodies, rather than duplicates or conflicts with them. As described earlier in this report, the Review has already made a recommendation aimed to facilitate the sharing of information between relevant regulators and other relevant bodies to support this aim.

The Review has identified significant confusion among stakeholders about the governance and independence of the PRP. Some stakeholders expressed a belief that the PRP is a part of the Department of Health and Human Services and is therefore subject to the direction of the Secretary of the department. This perception arises from the fact that administrative support functions for the PRP are delivered from within the department. The Review also considers that this may be an inefficient allocation of resources, which have the result of isolating the PRP and its staff from broader issues in relation to ART service provision in Victoria. While the PRP is outside the terms of reference for this Review, the Review observes that the government may wish to consider providing the administrative support functions for the PRP through the Regulator in order to strengthen the connection between the PRP and the Regulator and to facilitate appropriate information sharing.

The Review has also heard that the current requirements under the Act for the PRP to hold formal hearings in relation to all applications and to provide written reasons for all decisions represent a significant administrative burden. The Review considers the PRP should have the power to approve some applications on paper, without the need for a hearing. This may be appropriate, for example, where the application is straightforward and does not give rise to any significant issues that warrant further investigation. Similarly, while the Review believes that written reasons should be provided in cases where an application is denied or where requested by the applicant, there does not seem to be a compelling reason to require written reasons to be prepared where an application is approved. The government may wish to consider changing the expectations of the PRP so that the Panel provides written reasons for a decision where an application is denied, but is not required to provide reasons where an approval is given, unless the applicant requests it.

The Review notes that any legislative reform and institutional reorganisation arising from this Review will take time to achieve. It is noted, however, that there may be scope to support VARTA to ensure it is meeting the regulatory expectations of government in the short to medium term. The Review has
observed that the legislative changes made in 2016 significantly increased the workload of VARTA and in so doing may have skewed the organisational focus towards management of the donor registers and donor linking activities. The Review has not been privy to information about the resources allocated to VARTA at this time, but it may be that a modest additional investment may assist the organisation to balance its various statutory functions.

The Ministerial Statement of Expectations (SOE) also provides opportunity to focus the effort of the Regulator. For example, in developing the next SOE, the Minister may consider highlighting one of the areas of risk identified in this report as an area for particular focus of VARTA over the coming years.

Finally, the Review considers that as vacancies on the VARTA board arise, consideration may be given to ensuring that the board’s composition is adjusted to ensure the range of skills and experiences are those necessary to meet its priorities. It may be appropriate to appoint an individual with a strong regulatory background, for example, and, critically, someone who can bring authoritative clinical expertise to guide the regulator’s response to the emerging scientific or medical challenges facing the industry.
12. Conclusion

This Review set out to assess whether Victoria’s regulatory framework for ART was fit-for-purpose, and how well it responds to the key concerns Victorians have about ART – access, affordability, quality of care and support, understanding of infertility and treatments, respect for diverse family preferences, and the need for the highest standards of ethical practices in this field.

It has been the first major review since the introduction of the 2008 Act, based on the 2007 Victorian Law Reform Commission report, which focused on reform to the legal rules for who can access ART. Arguably, this Review has taken a more comprehensive approach to assessing the regulatory framework for ART. It has assessed the specific Victorian legislation and regulation, but also examined the effectiveness of the national self-regulatory scheme and related national laws on reproductive medicine. Unlike the Victorian Law Reform Commission, it examined the provision of health care and psychosocial support to patients, surrogates, donors and donor-conceived people. It has also considered the regulatory framework in the broader context of other government interventions to support people who need medical help to form a family, and has proposed both regulatory and non-regulatory interventions to address concerns about ART.

The response of the Review to those two core questions is clear. Victoria’s regulatory framework for ART is no longer fit-for-purpose, and the system for delivering ART is not adequately putting people at the centre of fertility care, nor providing the solutions that Victorians expect regarding access, affordability or quality of care and support.

This conclusion does not imply that all is wrong with the Victoria’s ART industry or its regulatory institutions, VARTA, RTAC, the Department of Health and Human Services and other relevant regulators. Both the industry and its regulators have much to be proud of. The industry has supported tens of thousands of Victorians to create families. It has led the country on many technical and clinical improvements to fertility care and supported world-leading research on IVF practices and health outcomes for IVF conceived children. It has taken its own initiative to implement many measures to improve patient care and protect safety. The state regulator is respected nationally for its expertise and contribution to public education on fertility issues, and it has acted effectively and prudently in response to public concerns with practices in the industry. It has also led the introduction of Victoria’s unique and supportive legal regime of donor linking.

But the verdict of the users of ART and many ART practitioners, as reported in the wide-ranging consultations of this Review, is clear – the 2008 framework no longer meets the standards of today. As documented in both the Interim Report and this Final Report, there has been a growing chorus of patient concerns with IVF and its regulation over the last 10 years: high costs, unclear success rates, misleading information, limited psychosocial support for patients, intrusive legal requirements on patients, unproven treatments, and a small number of cases of unethical practices.

In addition, since 2008 much has changed in social attitudes, reproductive medicine, health regulation and the ART industry itself. Those changes have exposed flaws in the design of the 2008 Act, and led to many frustrations with the limitations of the regulatory framework across the board – for patients, surrogates, donors, donor-conceived people, clinics, doctors, counsellors and regulators. Those changes have brought to light a new set of risks and harms related to ART, and this Review has set out an understanding of those risks to underpin government policies and regulatory strategies. The changes in society, health care and the market have also led to new and higher aspirations from patients, clinicians and governments for the quality of fertility care. Together, these frustrations and aspirations demand a renovation of both the regulatory framework for ART and how fertility services are delivered in Victoria.
This Final Report sets out a renovation plan. It does not propose a radical overhaul or complete rebuild. In practical terms, given the complex arrangements involving Commonwealth and state governments, government and industry regulators, and sensitive ethical issues, a complete rebuild is simply not feasible. Starting from the fresh assessment of the risks and harms of ART and public expectations for fertility care, the plan sets out:

- the components of the regulatory framework for ART
- system changes in the delivery of fertility services
- the design of the regulatory institutions responsible for co-regulation of these services.

Together with the recommendations of the Interim Report, this Final Report provides a comprehensive set of recommendations for the Victorian Government to redesign the regulatory framework in this state, improve access to quality fertility care, and to raise the standards for this industry nationally.

The recommendations of the Interim Report related especially to the Review’s terms of reference to remove unnecessary or discriminatory barriers to access, especially for LGBTIQ+ people, the adequacy of safeguards and improving access and affordability more generally. These recommendations would remove discriminatory or outdated provisions from the Act. They are expected to have an impact on strengthening capacity for the timely identification of potential quality and safety risks by facilitating reports of breaches of the Act or non-compliance, and information sharing between regulators. They will improve access to low-cost services by allowing fertility nurses to perform artificial insemination procedures again. They will reduce unintended discrimination resulting in barriers to access for some women and members of the LGBTIQ+ community, and they will improve access to donors and surrogates for people who need them.

The recommendations on improving experience, quality and safety (Chapter 3) will refocus the regulatory framework and the ART industry on the highest standards of person-centred care. They will reframe Victorian legislation on ART to reflect contemporary approaches to managing quality and safety in health care, and establish systems for the measurement and continuous improvement of quality, safety and patient experience.

The recommendations on providing clear information and supportive counselling (Chapter 4) will establish a new approach in Victoria to ensuring all users of ART provide informed consent and receive supportive counselling. Victoria’s distinctive approach to mandatory counselling has brought many benefits to patients over the years, but it has become too prescriptive and inflexible. The Review’s reforms will clarify the responsibility of the treating doctor for ensuring the patient’s informed consent with the plan of care and support. They will ensure patients are better informed about fertility issues and the likely outcomes of treatment for them as individuals. They will ensure more patients receive the counselling support they need – before, during and after treatment – and in a way that is tailored to their individual needs, not dictated by government regulations.

The recommendations on delivering inclusive practice for LGBTIQ+ and other disadvantaged groups (Chapter 5) applies these general principles of person-centred care, informed consent and supportive counselling to the specific needs of LGBTIQ+, culturally and linguistically diverse people, Aboriginal people and people with disability. The process of this Review has made the industry aware that it must constantly adapt its practice to the diverse needs of Victorians, and guidance on inclusive practice will provide a means for practitioners to engage with patients to improve the responsiveness of clinics to these needs.

The recommendations on the public provision of ART services (Chapter 6) provides guidance on how to establish public fertility services, following the government’s pledge of $32 million to establish public IVF services, and to undertake a full business case assessment of the model. The establishment of public fertility services is among the most significant outcomes of this Review, and is strongly supported by the Review and many stakeholders. The design and development of these services has the potential to
change fundamentally the system for delivery of fertility care through a model of excellence in public health services that is co-designed around the needs of users.

The recommendations on establishing a public sperm and egg bank (Chapter 7) set out the Review’s assessment of the proposal to establish a public sperm and egg bank to deal with the current shortage of donated gametes in Victoria. The Review has conducted a preliminary feasibility assessment of this proposal, and recommends the government include a comprehensive assessment as part of the business case for public IVF services. This proposal is the most effective way to deal with the shortage of donated gametes in Victoria that is adding to costs, delays and access difficulties for many Victorians.

The Review also proposes to deal with the shortage of donated gametes by removing legislative barriers to the donation of gametes (Chapter 8). The review proposes to reduce the regulatory burden on both clinics and individuals in relation to the donation of gametes, and other changes to improve the processes related to donation for donors, patients and donor-conceived people. Together with the establishment of the sperm and egg bank, the Review has proposed recommendations to improve reimbursement for donors, simplify storage and importation of gametes, and prevent unethical donations, to promote a stronger culture of local donation of sperm and eggs in Victoria. These will simplify the process of donation, improve access, and preserve Victoria’s model of ethical donation that prioritises the interests of donor-conceived individuals.

Victoria’s legislative and regulatory framework for surrogacy (Chapter 9) needs to be more comprehensive and truly supportive of altruistic surrogacy. These changes in no way support commercial surrogacy. They will build on the Interim Report’s recommendations to improve reimbursement for surrogacy, and reorient the legal and support processes to be supportive of both surrogates and intended parents. Importantly, by including traditional surrogacy within the regulatory framework, it will ensure all altruistic surrogates receive the support and access to treatments they need. These changes will also support the gradual harmonisation of Australian surrogacy laws over time, and are broadly consistent with key provisions in New South Wales and Queensland law, and recent major reviews of surrogacy laws in South Australia and Western Australia.

Victoria’s regulatory framework for ART also needs to be future-proofed, given the major, ethically challenging scientific developments that are likely to occur over the next 10 years. The announcement on the world’s first gene-edited baby in late 2018 shocked the world, and has stimulated a global effort to establish global standards for the governance and oversight of human genome editing. Victoria is well positioned with its strengths in national medical and health research and the regulation of ART to play a leading role in the community debate on how to respond to these emerging challenges of reproductive medicine (Chapter 10) – including mitochondrial replacement therapy, reviewing national laws and research frameworks related to human embryo research and ART, and responding to the specific challenges of human somatic and germline gene editing.

The final set of recommendations of this Review concerns the design of the regulatory institutions for ART (Chapter 11). The aim of these recommendations is to design a more effective co-regulatory system in which the industry’s self-regulatory bodies, primarily the Fertility Society of Australia and RTAC, can work in effective partnership with the state Regulator to raise standards and improve the experience for patients, donors, surrogates, donor-conceived individuals and the families they all belong to.

The impact of these changes to the regulatory framework is positive for all key groups involved in ART. The Review commissioned Deloitte Access Economics to undertake a preliminary impact assessment of the regulatory changes proposed in this report. This assessment found that the proposed changes appear well-targeted and are likely to drive a net positive impact. The assessment considered the impact of the proposed regulatory changes from a range of stakeholder perspectives including: ART users, donor-conceived people, donors, ART providers and the Regulator. The assessment is summarised in Appendix 4 and the impact of proposed changes on the regulator is outlined in Appendix 5.
The greatest potential benefits of the proposed regulatory changes are likely to flow to ART users, whereas the greatest likely costs are expected to be borne by the Regulator and ART providers. However, these additional costs are moderate and offset by other proposed regulatory changes that will lead to reduced regulatory burden for both the Regulator and ART providers. The highest impact regulatory changes identified by Deloitte Access Economics were:

- inclusion of fertility preservation in the regulatory framework – this recommendation addresses a large gap in the current regulations and is expected to create a large positive benefit for people who wish to preserve their fertility
- the package of reforms to increase access to gametes – these recommendations will include removing some restrictions around advertising, clarifying reimbursements and reducing regulatory barriers to importation of gametes. They will lead to reduced regulatory burden for ART users, ART providers and the Regulator
- reporting of clinic success rates and costs – this recommendation benefits ART users by enabling better decision making, and will need to be implemented in way to prevent the presentation of misleading information or perverse incentives through the creation of league tables of patient success rates that are not adjusted appropriately for factors such as age or medical complexity.
- changing the role of the counsellor in the ART process – these recommendations are expected to create a large benefit in terms of the experience of the intended parent, with a relatively small administrative burden for ART providers to comply.

Prior to implementing any of the proposed regulatory changes, the government would need to develop a full Regulatory Impact Statement. This will require a detailed consideration of impacts and costs across stakeholder groups, and there are some limitations in the available data to assess some costs in detail. The Review has given the full Deloitte Access Economics report to the Department of Health and Human Services to facilitate this more detailed assessment. However, the Review considers that the package of reforms will bring many benefits to providers, the regulator and patients, and ought not lead to any increase in patient costs.

More broadly, the government will need to consider its approach to amending current ART legislation. This Final Report has presented an extensive set of recommendations that, if adopted, will require substantial revisions to the current Act, changes in priorities for some Victorian Government institutions, and potentially additional resources. The Review focused its recommendations on the outcome sought and on ensuring flexibility for co-design to find the best approach to implementation. It recognises that the government will need to consider other matters before making final decisions on the best approach to implementing some of these recommendations. For example, the government may also wish to consider aspects of the Health Complaints Commissioner’s Investigation into IVF and ART practices. The Review also encourages ongoing consultation with industry, health practitioners, legal professionals, researchers, RTAC, and service users on the implementation of this report’s recommendations.

Given the scale of changes and some of the complications in the existing legislation, however, it is likely that the government, if it accepts these recommendations, will need to make extensive changes to the Assisted Reproductive Treatment Act 2008, and some other Acts. The Review does not make any recommendations as to how the government might best do that. However, it is likely that in effect a comprehensive new Act may need to be prepared.

**Issues outside the terms of reference**

If the government were to make broad legislative changes, there are two major issues, excluded from the terms of reference of this review, that it may wish to consider as part of a comprehensive rewriting of this Act. These include presumptions against treatment and access to information from the donor register for donor-conceived people.
Presumptions against treatment

In terms of presumptions against treatment, many responses to the Review’s consultations suggested that Victoria’s system of conducting police and child protection checks for all people undergoing ART and establishing a presumption against treatment could be reconsidered. As reported in the Review’s Interim Report, this requirement received more comment during the public consultations and survey conducted in 2018 than any other issue with the exception of cost. In later consultations with stakeholders, including clinics, patients and service users, this issue continued to be raised. The Review has heard many reports of the cost, burden, delay and distress caused by this requirement. The Review has not heard any evidence of the effectiveness of this system in preventing the abuse of children. The system could be dismantled without creating significant risk to children, or revised to better target the risks of family violence and the risks to children. Such a reform would be welcomed across the board by ART users, health and legal practitioners, and ART providers.

Access to information from the donor register

In terms of access to information from the donor register, the Review heard from many stakeholders who supported the aims of Victoria’s admirable legislative framework that enables donors and donor-conceived people to access information about each other, and to connect where they wish to. The Review heard many stories of the positive impact this legislation has had on many Victorians. Many responses to the Review supported further changes to enable adult donor-conceived people to access information and potentially make contact with their donor siblings. Currently, donor-conceived people can only find out about their donor siblings through their donor. In circumstances where a donor does not wish to have contact with their donor offspring or where a donor is deceased, a donor-conceived person may have no avenue to find out about or attempt to connect with their donor siblings.

The Review also heard of issues and concerns with the implementation of the framework for access to information from the donor registers. It appears that there has been a greater-than-anticipated number of requests from donors for information from the donor registers about their donor offspring. This has led to some testing of the prescribed legal requirements and administrative procedures for managing this highly sensitive and personal situation. The Review has heard of the difficulties encountered by some families, where a young donor-conceived adult has learned of their genetic origins for the first time through an administrative agency of government, rather than their own parents. The Review has also heard that some of the legislative requirements of this process are needlessly complex. This can create difficulties for VARTA in administering the processes in a sensitive way that can be adapted flexibly to the variety of family situations. Consideration could be given to changes to the legal processes, communication protocols and support services for donor linking that could support the intent of this Review to ensure that all people who participate in, or are born as a result of, ART are supported and protected in a way that is sensitive to the needs of diverse families, including their emotional and mental health.

Amongst all of the emotions from finding out about being DC, I felt incredibly let down by the system ... if someone was going to find out that they are DC, it could at least come from their family – rather than randomly receiving a letter in the mail and subsequently being told something life changing from a stranger.

Submission – donor-conceived person

These additional changes in relation to presumptions against treatment and access to information from the donor register may be considered by the government as part of any major legislative amendments. However, they are supplementary to the main reforms proposed in this report. Those reforms aim to
reinstate people at the centre of fertility care. They aim to make substantial system reforms and innovations in the delivery of fertility services.

Final summary

For the first time, public health services will play a significant role in the delivery of public fertility services. Victoria will back its support for a system of altruistic and identifiable sperm and egg donation with a serious effort to recruit and support local donors and to coordinate the distribution of gametes equitably through a local sperm and egg bank. Access to gametes and domestic altruistic surrogacy will be improved. The regulatory framework will be overhauled to focus more centrally on person-centred care, quality, safety and patient experience, truly informed consent and supportive counselling. The state Regulator will raise the bar for the national co-regulatory system on patient care issues – improving standards of information, emotional and mental health support, reporting of success rates, the use of evidence-based treatments, and adapting to the ethical and scientific challenges of the next decade in reproductive medicine. Finally, the state Regulator itself will be redesigned to be effective, authoritative and equipped with the necessary tools to act decisively, but not intrusively, to protect the public from the key risks and harms of ART.
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 Partitioner 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.

GIFT
Gamete intrafallopian transfer – a procedure where the ovaries are stimulated to produce eggs which are then retrieved in the same way as IVF, but the sperm and egg are placed back inside the fallopian tube for conception to occur. This procedure was previously commonly done when the intended parents did not wish conception to occur outside the body, but is rarely done these days as it is much less effective than IVF.

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 person 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 Patient Review Panel 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 person 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 providers
- 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**

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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.

Appendix 2: Overview of regulatory environment for assisted reproductive treatment in Victoria
Appendix 3: Key regulatory and quasi regulatory bodies of relevance to ART provision in Victoria

Patient Review Panel

The PRP is established under s. 82 of the Act to consider applications by people who wish to access assisted reproductive treatment where the Act requires they have permission to do so. This includes hearing applications in relation to surrogacy arrangements, posthumous use of gametes and embryos, issues related to the ongoing storage of gametes and embryos, the use of PGD for the purpose of sex selection, and where there is a presumption against treatment on the basis of the results of a criminal record check or a child protection check.

Department of Health and Human Services Victoria

The Department of Health and Human Services is responsible for the registration, performance monitoring and oversight of private hospitals (including day procedure centres). Under the Health Services Act 1988 and associated Regulations, oocyte collection may only occur within a registered private health service establishment (day procedure centre). While ART providers will access day procedure centres for these procedures, only two providers currently operate their own day procedure centres to which these regulations would apply. The registration requirements and oversight of private hospitals does not apply to ART service provision more generally.

Australian Health Practitioner Regulation Agency and the National Boards

The Australian Health Practitioner Regulation Agency (AHPRA) works in partnership with National Boards for each of fifteen registered health professions (including medical practitioners, nurses or psychologists who may be involved in ART service provision). Under the Health practitioner Regulation National Law (Victoria) Act 2009 (the National Law) National Boards set standards and codes of conduct for each profession, and set requirements for entry into the professions (for example qualifications and competencies) and requirements for ongoing professional development.

AHPRA investigates notifications about unprofessional conduct, unsatisfactory professional performance and impairment where this is placing the public at risk. Serious matters may result in restriction of a practitioner’s registration.

Health Complaints Commissioner

The Health Complaints Commissioner is an independent statutory body established under the Health Complaints Act 2016. The Commissioner receives and resolves complaints about a wide range of health service providers, including providers of ART. The Health Complaints Commissioner advised the review that a total of 28 complaints regarding ART providers were received between February 2017 (with the Health Complaints Act commenced) and July 2018, however it was noted that, due to the way in which data is collected and recorded, this includes only includes complaints where the registered clinic is named as the respondent. It does not capture complaints where the complaint is lodged in relation to an individual practitioner working within a clinic.
The Health Complaints Commissioner issues complaints handling standards for health service providers, these standards would apply to ART clinics.

The Commissioner also has powers to investigate providers who pose a serious risk to the health, safety and welfare of the public (or conduct an investigation on referral by the Minister). The Commissioner issue an order prohibiting an unregistered health service provider (including an organisation) from providing service, or impose conditions on the provision of services, and can also issue public warning statements under certain circumstances.

Under s. 103 of the Health Complaints Act 2016, on referral from a House of the Parliament or a Parliamentary Committee; or the Minister for health, the Commissioner may inquire into any health service matter.

In announcing the intention to provide public ART services during the 2018 state election, the government also committed to tasking the Health Complaints Commissioner lead an investigation into the ‘dodgy, dangerous and unethical practices by IVF providers including those who fail to be upfront about success rates or costs’.

Australian Competition and Consumer Commission (ACCC) and Consumer Affairs Victoria (CAV)

The Australian Competition and Consumer Commission (ACCC) and Consumer Affairs Victoria (CAV) each have a role to play in investigating breaches of the national consumer law (the Competition and Consumer Act 2010), including matters related to false or misleading representation. In 2016, the ACCC undertook an investigation of the claims made by assisted reproductive treatment services about their rates of success. The investigation found that some clinics made claims and comparisons without adequate disclosure, or explanation of the data, and that some used technical terms which may be misleading to consumers. The ACCC cited for example, the use of ‘clinical pregnancy rate’ data to compare success rates. ‘Clinical pregnancy’ data reflects a clinic’s success in achieving a pregnancy, regardless of length, rather than achieving a live birth. The ACCC noted that this data was frequently accompanied by photographs of newborn babies, which it considered was likely to lead potential clients to form an inaccurate impression about the rate of successful pregnancies achieved by the clinic. It is understood that this investigation was instrumental in bringing about improved practice in reporting success rates, however the ACCC and CAV have indicated to the Review that this matter is unlikely to be the focus of further sustained effort.

National Health and Medical Research Council – Embryo Research Licensing Committee

The National Health and Medical Research Council (NHMRC) Embryo Research Licensing Committee is established by the Research Involving Human Embryos Act 2002 (Cth) and is a Principal Committee of the NHMRC. The Licensing Committee oversees the Research Involving Human Embryos Act 2002 (RIHE Act) and the Prohibition of Human Cloning for Reproduction Act 2002 (Cth). It regulates research activities that involve the use of human embryos created by assisted reproductive technology (ART) or by other means. The legislation also prohibits human cloning for reproductive purposes and a range of other practices relating to reproductive technology.

National Association of Testing Authorities (NATA)

The National Association of Testing Authorities, Australia (NATA) is the national accreditation body for the accreditation of laboratories. ART clinic laboratories comply with the relevant standards established by NATA.
Therapeutic Goods Administration (TGA)

As part of the Commonwealth Department of Health, under the *Therapeutic Goods ACT 1989* (Cth), the TGA regulates the supply, manufacture and advertising of therapeutic goods, including medications as used in ART.
Appendix 4: Preliminary assessment of regulatory impact by Deloitte Access Economics

Purpose of the report

The Interim Report and the Final Report of the Independent Review of Assisted Reproductive Treatment (ART) in Victoria (2018), proposed a number of areas where regulations should be reconsidered. The purpose of this report was to assess the impact in terms of potential benefits and likely costs of the 23 proposed regulatory changes to ART.

Our approach

The assessment of impacts was based on review and analysis of existing data and literature, materials provided by the DHHS ART Review Team and targeted stakeholder consultation with private ART providers, an ART regulator and a public hospital.

The assessment considered the impact of the proposed regulatory changes from a range of stakeholder perspectives including: ART users, donor-conceived people, donors, ART providers and the Regulator.

A summary of the 23 proposed regulatory changes, the estimated direction of regulatory burden and the net impact to the identified stakeholder groups is presented in the tables on the following two slides. In addition, a detailed assessment of the impact of the 23 proposed regulatory changes including an indication of the magnitude of the change and considerations for implementation are presented individually. Indication of the magnitude has been quantified where possible, however overall assessment of the proposed regulatory changes have not been quantified at this stage.

The next step towards implementation of the proposed regulatory changes would be development of a full Regulatory Impact Statement (RIS). This will require a detailed consideration of impacts and costs across the stakeholder groups that are noted across this report. This report proposes potential data collection and analysis which could inform this.

Expected magnitude of impact

The greatest potential benefits of the proposed regulatory changes are estimated to accrue to ART users, whereas the greatest likely costs are expected to be borne by the Regulator and ART providers. Of note, however, a number of the proposed regulatory changes also imply reduced regulatory burden for both the Regulator and ART providers.

Proposed regulatory changes of note include:

- Inclusion of fertility preservation in the regulatory framework. This recommendation addresses a large gap in the current regulations and is expected to create a large positive benefit for people who wish to preserve their fertility.
- The significant package of reforms involved around increasing access to gametes. These recommendations include removing some restrictions around advertising, clarifying reimbursements and reducing regulatory barriers to importation of gametes.
- Reporting of clinic success rates and costs. This recommendation has a large potential benefit for ART users in terms of enabling better decision making. However, this recommendation risks incentivising ART providers to ‘cherry pick’ low risk patients if public league tables of success rates are not risk adjusted, for example by ensuring that success rates clearly indicate the age...

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of person receiving treatment and the level of treatment / health complexity involved. This risk is unlikely to materialise from public reporting of clinic costs.

- Changing the role of the counsellor in the ART process. These recommendations are expected to create a large benefit in terms of the experience of the intended parent, with a relatively small administrative burden for ART providers to comply.
Appendix 5: Impact of recommendations on the Regulator

Establishment of a Regulator equipped to provide effective oversight of the ART sector

The Review recommends (Recommendation 80) that the government identifies and resources a Regulator that:

- has clarity of role and purpose and a complementary balance of functions
  - is knowledgeable about practices relevant to the provision of ART and related science
  - is capable of engaging the community in dialogue on ethical, social, medical scientific issues
  - has strong regulatory capacity
  - is able to command the confidence of the sector and the public.

To support the Regulator to undertake its role, the Review further recommends that:

- legislation be amended to facilitate the sharing of information between relevant regulators and other bodies (Recommendation 2)
- provision be made for a more extensive and graduated set of compliance and enforcement powers to be available to the Regulator (Recommendation 78)
- there should be a clear process for the initiation of prosecution under the Act (Recommendation 78).

Transparency and accountability of the Regulator

To support enhanced transparency and accountability of the Regulator the Review recommends that:

- the requirements for the Regulator to report to the Minister be amended so an annual report on the operations of the Regulator is prepared for the Minister by 30 September each year in respect to the previous financial year, and a separate report on the activities of the sector by the end of December in respect to the previous calendar year (Recommendation 77)
- the Regulator be required to notify RTAC and the Secretary of the Department of Health and Human Services in relation to the use of the more significant compliance/enforcement powers and any serious breaches or instances of non-compliance (Recommendation 78)
- specific provision be made for review of the administrative decisions of the Regulator (Recommendation 79).

- that legislative requirements for annual reporting by the Regulator include a clear focus on the Regulator’s performance of its legislative functions. (Recommendation 79).

Recommendations for new or expanded functions/activities to be undertaken by the Regulator

The Review has also made a number of recommendations that propose new or expanded functions or activities to be undertaken by the Regulator. It is envisaged that these activities could form a program of work for the Regulator to be undertaken over a number of years.

Compliance standards and conditions of registration

The Review recommends (Recommendation 75) that the Regulator develop, in consultation with relevant stakeholders, a range of compliance standards for ART providers which articulate specific measures of compliance, in respect to a range of matters. These compliance standards will form part of the conditions of registration with failure to comply grounds for a range of regulatory responses. Compliance standards are to be made in relation to:
• clinical governance (Recommendation 19) including a requirement for providers to develop inclusive practice policies (Recommendation 39)
• complaint handling (Recommendation 22)
• reporting of ART provider success rates and costs (Recommendation 26)
• advertising (Recommendation 27)
• the provision of information in relation to adjuvant treatments (Recommendation 30)
• the provision of counselling (Recommendation 33)
• reporting requirements (Recommendation 77).

The Review also recommends (Recommendation 76) that:

• the Regulator publish the conditions of registration of each provider on its website and report on the making and review of compliance standards to the Secretary of the Department of Health and Human Services
• the Regulator retain the power to impose conditions on registration in addition to those contained in compliance standards where necessary, in the public interest, to respond to specific risk relevant to a provider (or providers) or immediate/imminent risk relevant to all providers.

Development of regulatory guidance

The Review recommends that the Regulator be given the function to develop and publish regulatory guidance on a range of matters including guidance in relation to:

• acceptable reimbursement amounts for cost incurred by donors and surrogates (Recommendations 52 and 70)
• advertising for donation of gametes and altruistic surrogates. The Regulator will have a role in monitoring this advertising and may require the removal or amendment of material which is inconsistent with the guidelines. (Recommendation 54 and 73)
• donor eligibility in Victoria and the handling of identified disqualifying medical conditions (Recommendation 53)

Development of training, guidelines and resources

The Review recommends (Recommendation 11) that the Regulator (along with the PRP) should work together with the LGBTIQ+ community to develop inclusive practice and cultural competency training for ART providers and should amend the conditions of registration to require clinics to ensure staff are trained in LGBTIQ+ inclusive practice.

The Review has made a number of recommendations for the Regulator to develop or contribute to the development of a range of guidelines and information resources, including:

• guidelines for person-centred care in ART (Recommendation 20)
• guidelines on inclusive practice (Recommendation 39).
• resources advising patients and clinicians on the evidence base, risks and benefits of adjuvant treatments and complementary health treatments offered to support fertility. (Recommendation 30)
• information materials on the range of social and emotional impacts of infertility and ART (Recommendation 31)
• an expanded range of translated materials available to ART service users (Recommendation 38).
Research, data collection and measures of patient experience
The Review has recommended that the Regulator be involved in the development of person-centred measures of patient experience (Recommendation 21).

It is also recommended that the Regulator:

- facilitate research into the diverse experiences of people impacted by ART. (Recommendation 37)
- work with the Department of Health and Human Services, providers and the data custodians of the ANZARD database to improve the collection of ART data related to sexuality, relationship status, cultural background, languages spoken, and variations in sex or gender (Recommendation 40).

Donor register

It is recommended that the Act be amended to require the mandatory and contemporaneous reporting of all donations to the Regulator and that the Regulator be authorised to share relevant donor information with providers to determine if donation limits have been reached. (Recommendation 60)

Recommendations that may reduce burden on the Regulator

In addition to the new and refocused functions of the Regulator, the Review has made recommendations which, if implemented, will directly reduce burden on the Regulator, freeing up some resources for other activities. For example, Recommendation 56 aims to simplify the process for approving the importation of gametes. Rather than having to consider each application, anyone seeking to import gametes would need to attest to the Regulator that a specified set of matters are satisfied. Furthermore, Recommendation 2 (Interim Report), which aims to facilitate the sharing of information between relevant regulators, should lead to some efficiencies for the Regulator.