

# INQUIRY INTO

# ASSISTED REPRODUCTIVE TREATMENT

# PRACTICES IN VICTORIA

Final Report

3 March 2020



## **ACKNOWLEDGEMENT OF TRADITIONAL OWNERS**

The Health Complaints Commissioner respectfully acknowledges the Aboriginal and Torres Strait Islander peoples as the Traditional Owners of our land, recognises their ongoing connection to land, waters and community and pays respect to their Elders, past, present and emerging.

# FOREWORD BY THE HEALTH COMPLAINTS COMMISSIONER

In March 2019, the Minister for Health, the Hon Jenny Mikakos MP, referred to me for inquiry under s.103 of the *Health Complaints Act 2016* the matter of the provision of assisted reproductive treatment (ART) services and unsafe and unethical practices by in-vitro fertilisation (IVF) and ART providers in Victoria.

In June 2019, I released a Discussion Paper, seeking submissions from people who had undergone or were receiving ART, from providers of ART services and their staff, and from other key stakeholders. I received 121 submissions from past and current ART patients (including family members and friends), ART providers and their staff (former and current), and other interested stakeholders or advocacy bodies. In addition, I held public consultation forums throughout September 2019 in Melbourne and Ballarat, attended by ART consumers, providers and other stakeholders. These submissions and consultation forums form the basis of this report.

This inquiry followed on from Michael Gorton AM's 2019 Independent Review of Assisted Reproductive Treatment, which looked into the legislative and regulatory framework underpinning the ART industry in Victoria.

While the Gorton Review focused on needed reforms in Victoria's legislative and regulatory environment regarding ART, this inquiry brings to light the voices of ART consumers and providers – both past and present – and looks at ART services from the perspective of those providing and receiving treatment. References to the Gorton Review are made throughout this report, however they are not intended to duplicate that work. Where submissions and public consultation indicated support for recommendations in the Gorton Review, I have noted this but not made further recommendations.

At the start of this inquiry, there was concern that the ART industry was preying on the vulnerability of Victorians desperate to have children but unable to do so. What we found was an industry that is driven by a desire to assist but could improve the ART experience for consumers. There may be 'outliers', but with inquiries such as this one, added scrutiny forces change. We will continue to monitor the complaints we receive to ensure the ART industry is the best it can be for all Victorians.

I am extremely grateful to the Victorian community for its interest in this inquiry and to those who provided submissions and participated in consultation forums. In many cases, speaking openly was a highly emotional and stressful experience for ART consumers and partners and I particularly thank them for having the courage to share their stories.

I am also grateful for the time taken by ART providers in both making submissions and attending a consultation forum. The discussion was productive and showed the great intent of those present in continuously improving the way in which they provide ART services to Victorians.

I would also like to thank my staff – Dr Rosalind Hearder, Ruth Morgan and Sarah Jade Besim – for their empathy, commitment and outstanding research skills. They have worked tirelessly on this inquiry.

Pursuant to s.103 of the Health Complaints Act, on completing the inquiry I may make recommendations about the health service matter in the inquiry to the Minister for Health. Based on the findings of this inquiry, I submit my report, which makes several recommendations regarding ART service provision in Victoria, including relating to ART providers' communication, counselling, adjuvant treatments and complaint handling.

**Karen Cusack**  
**Health Complaints Commissioner**  
3 March 2020

**Vale – Emeritus Professor Louis Waller, AO, 10/02/1935 – 08/10/2019**

In the early 1980s Emeritus Professor Louis Waller, AO, was instrumental in bringing about laws to guide the new and then-controversial procedures surrounding in-vitro fertilisation (IVF). He was appointed as the first chairman of the Law Reform Commission, chairman of Victoria's IVF Committee, the inaugural chairman of the Statutory Standing Review and Advisory Committee on Infertility, and the first chairman of the Infertility Treatment Authority.

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# 1. INTRODUCTION

## 1.1 The Assisted Reproductive Treatment inquiry

In March 2019, under s.103 of the *Health Complaints Act 2016*, the Minister for Health, the Hon Jenny Mikakos MP, referred for inquiry the matter of the provision of assisted reproductive treatment (ART) services to the Health Complaints Commissioner (HCC), Ms Karen Cusack (the Commissioner).<sup>1</sup> The inquiry focuses on two main areas:

- the current state of the provision of ART services in Victoria
- the lived patient experience of ART.

On 25 June 2019, the Commissioner released a discussion paper (see **Appendix 1**) including the Minister's terms of reference, and invited public submissions about Victorians' experiences of ART. This issue attracted considerable interest. By the closing date of 20 September 2019, the Commissioner had received 121 submissions from both individuals and organisations, either as personal statements or information given through a semi-structured survey available on the HCC website (see **Appendix 2**).

Submissions were categorised into three areas:

- A. ART consumers or family members (past and present)
- B. ART providers and staff (past and present)
- C. other stakeholders.

Almost 80 per cent of submissions were from ART consumers. All participants were able to remain anonymous if they chose.

This inquiry also included consultation and community engagement with ART users, ART providers and other interested stakeholders. The Commissioner hosted three consultation sessions, two for the public and one for providers, in both metropolitan Melbourne and Ballarat throughout September 2019.

The inquiry complements Michael Gorton AM's *Helping Victorians create families with assisted reproductive treatment: Final Report of the Independent Review of Assisted Reproductive Treatment (the Gorton Review)*, which focused on necessary reforms in Victoria's legislative and regulatory environment regarding ART.<sup>2</sup> Where the Gorton Review made recommendations regarding broader system reforms, this inquiry brings to light the voices of ART consumers and providers – both past and present. The Commissioner is grateful to the Victorian community for its interest in this inquiry and to those who provided submissions and participated in consultation sessions.

<sup>1</sup> Minister for Health, 2019, 'Media Release: Making IVF Fairer, More Affordable And Easier To Access' <https://www.premier.vic.gov.au/making-ivf-fairer-more-affordable-and-easier-to-access/> accessed 10 July 2019.

<sup>2</sup> Gorton, M, 2019, *Helping Victorians create families with assisted reproductive treatment: Final Report of the Independent Review of Assisted Reproductive Treatment*, Melbourne.

## 1.2 The Assisted Reproductive Industry in Victoria

*A diagnosis of infertility often comes as a shock. It is unexpected and unwelcome and emotionally challenging. Unlike other adverse life events, which may have a clear resolution, infertility is uniquely distressing because it can last for many years and the outcome is uncertain.<sup>3</sup>*

*This is one of few medical treatments where thousands of hours and dollars may be invested with little to no guarantee of a result, where disparate and conflicting information is available to patients, where medical professionals have a vested interest in secrecy and obfuscation, and a particular financial interest in providing a service that fails.<sup>4</sup>*

Infertility affects people of all genders, ethnicities and socioeconomic backgrounds. ART is a unique field in medicine, strongly tied to social and scientific changes. Only 30 years ago the industry was in its beginnings: the regulatory framework of the time had to consider changing social mores, clinical advances and legal and ethical issues. Since then, social attitudes have continued to change and scientific and clinical advances have continued to evolve.

The range of available ART services has expanded from artificial insemination and in-vitro fertilisation (IVF) to the development of intracytoplasmic sperm injection (ICSI) for male factor infertility, genetic testing of embryos and egg freezing.<sup>5</sup> ICSI was introduced in the 1990s, where one sperm is injected into each egg before being implanted in the uterus.<sup>6</sup> The growing field of fertility preservation, such as for children and adults undergoing cancer treatment or pre-surgery transgender patients, is increasingly important.

Today, one in 20 Victorian children is born through ART, and the industry generates approximately \$550 million nationally each year, predicted to rise to \$630 million by 2022.<sup>7</sup> ART can be accessed by single people, LGBTQ individuals and couples, people seeking to freeze their gametes (eggs and sperm), and people seeking donated gametes or surrogacy. As Monash IVF's website states: 'Take a look in any classroom today and at least one child is an IVF baby.'<sup>8</sup>

Being an early worldwide leader in the ART field and considered a 'mature and established market', it is not surprising that Victoria is responsible for around 30 per cent of treatment cycles annually in Australia.<sup>9</sup> Many Victorians enter ART expecting a positive outcome, but not all are successful. It is only once they have experienced one or two or more failed cycles or procedures that they realise it can be a long, arduous journey. As noted in the Gorton Review, '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.'<sup>10</sup>

<sup>3</sup> VARTA, 'Suspecting infertility' <https://www.varta.org.au/information-support/fertility-and-infertility/suspecting-infertility> accessed 15 August 2019.

<sup>4</sup> Submission 2019/06737

<sup>5</sup> Gorton (n2) 12.

<sup>6</sup> Better Health, 'Infertility in women', <https://www.betterhealth.vic.gov.au/health/conditionsandtreatments/infertility-in-women> accessed 3 July 2019.

<sup>7</sup> Gorton (n2) 12.

<sup>8</sup> Monash IVF, 'IVF - In Vitro Fertilisation', <https://monashivf.com/fertility-treatments/fertility-treatments/ivf-in-vitro-fertilisation/> accessed 22 December 2019.

<sup>9</sup> Gorton (n2) 12.

<sup>10</sup> Gorton (n2) 1.

This inquiry found disparities between the policies and procedures of ART providers and what some consumers face during their ART journey. Most consumers who provided evidence told the Commissioner that their experience of ART was negative. Many were quick to point out the positive aspects, or particular specialists or staff who provided excellent service, but there were common themes throughout the submissions of similar consumer experiences – across different providers.

2020 marks four decades since the birth of Australia’s first IVF baby, Candice Reed. In 2017, 13,752 babies were born in Australia as a result of ART.<sup>11</sup> The ART industry gives the gift of children to many people who otherwise may never have that experience. Technological advances have occurred so rapidly that ART is often seen as a fix-all final solution for infertile individuals and couples.

While many individuals and couples are successful in having a child or children with ART, many more go through ART without success, having spent thousands of dollars and potentially incurring long-term physical and psychological tolls. Others cannot access ART because they simply cannot afford the costs involved.

Together, the Gorton Review and this inquiry provide a comprehensive review of today’s ART industry in Victoria, and the impact on those who provide it and access it, uncovering several areas where improvements could be made for ART consumers while including the voices of providers and their frustrations with their industry. The findings and recommendations of this inquiry will play a part in ensuring Victoria’s continued reputation as an international leader and pioneer in ART delivery.

## 1.3 Findings and recommendations

A summary of the key findings and recommendations are provided below and set out in more detail throughout the report. Where the Gorton Review made recommendations that are consistent with and supported by the findings of this inquiry, it is noted, but separate recommendations have not been made here. Many of the recommendations by the Gorton Review considered the need for legislative change and this inquiry supports those proposals, but the nature of legislative change was outside this inquiry’s scope.

### Findings

#### 5.1 Communication

- The information provided to ART consumers varies between ART providers. There needs to be a minimum, consistent approach to the information provided by all ART providers.
- Overall, communication by many ART providers – including fertility specialists, nurses and administrative staff – is either poorly delivered or is ineffective. This can occur at various stages of the ART journey and by different people within ART providers and clinics.
- ART providers and consumers acknowledge the need for information sharing at all stages of ART treatment, but poor, insufficient and ineffective communication continues to exist, making informed decision-making difficult.
- Consumers highlighted the importance of good provider communication in feeling supported and well informed, leading to a more positive patient experience.

<sup>11</sup> Newman, JE, Fitzgerald, O, Paul, RC and Chambers, GM, 2019, *Assisted reproductive technology in Australia and New Zealand 2017*, National Perinatal Epidemiology and Statistics Unit, University of New South Wales, Sydney, 4.

## 5.2 Advertising

- Providers, while complying with the Reproductive Technology Accreditation Committee Code of Practice, advertise 'success rates' in a way that makes comparison between providers difficult for consumers.
- ART providers' advertising and promotional information can be difficult to interpret, potentially confusing, and in some cases, misleading consumers.

## 5.3 Counselling

- Mandatory counselling for potential ART consumers does not provide a therapeutic and supportive role and is often seen as a 'tick box' exercise.
- Currently, supportive counselling is not always offered or proactively encouraged by ART providers throughout treatment. If consumers do not seek out additional counselling beyond what is mandated in legislation, they are often without the support needed.
- The timing of counselling currently does not provide the emotional and psychological support consumers need. Consumers want supportive counselling provided throughout their treatment, particularly following a failed cycle or procedure, and at the end of treatment.

## 5.4 Adjuvant ('add-on') treatments

- There is widespread use of adjuvant or 'add-on' treatments as part of ART. These treatments are without a clear evidence base and consumers have a poor understanding of their efficacy or benefit.
- There is little agreement among fertility specialists as to the efficacy of many adjuvant treatments or what is classified as an adjuvant treatment.
- Many ART providers claim not to use adjuvant treatments or employ them only at the insistence of patients, despite their widespread use by ART providers.

## 5.5 Adverse events

- ART patients may experience higher numbers of adverse events during their treatment than is reported, particularly ovarian hyperstimulation syndrome.
- There is a lack of transparency by ART providers in the reporting of adverse events to patients.

## 5.6 Complaint handling

- ART providers who made submissions consider their complaint handling processes to be robust and patients' grievances are dealt with promptly and comprehensively.
- Consumers making submissions were largely unaware of their ART providers' complaint handling procedures.
- Some consumers expressed fear of repercussions if they made a complaint while undergoing ART.

## 5.7 Costs

- Costs are a significant issue for consumers accessing ART, and the information relating to the costs of treatment and the rebates available is poorly communicated by ART providers.

## 5.9 Criminal record and child protection order checks

- There is strong opposition from both ART providers and consumers to the required criminal record and child protection order checks for potential ART patients.

It is noted this issue is currently being considered by the Victorian Government.

## Recommendations

### 5.1 Communication

- It is recommended that ART providers, in consultation with ART stakeholders, develop an online 'consumer reference guide to ART', allowing consumers to access consistent and verified information to make better informed choices about their treatment.
- In supporting the development of Individual Plans of Support, it is recommended that ART providers better understand the communication needs of their patients, including the frequency of contact, by whom and to whom.
- It is recommended that ART providers deliver regular training to all staff employed within an ART clinic, including fertility specialists, nursing, counselling and administrative staff, both on the need for clear, timely communication with ART consumers, and the need for effective communication between clinic staff.
- It is recommended that ART providers ensure timely and accurate coordination of information between fertility specialists, nurses and counsellors.
- It is recommended that where ART services are to be provided by more than one fertility specialist or by different fertility specialists at different stages, this must be disclosed to consumers at the time of developing an Individual Plan of Support.
- It is recommended that ART providers give written information to consumers at the beginning of treatment regarding how and where to access emergency care out of hours, including telephone numbers and contact names.

### 5.2 Advertising

- The findings of this inquiry support Recommendations 26 and 27 of the Gorton Review regarding compliance standards for published public information forming part of ART providers' registration.

### 5.3 Counselling

- The findings of this inquiry support Recommendations 33–35 of the Gorton Review relating to:
  - qualifications and eligibility of counsellors;
  - freedom of choice of counsellor by consumers.

#### 5.4 Adjuvant ('add-on') treatment

- It is recommended that ART providers obtain written consent from consumers before each use of any adjuvant treatment.
- It is recommended that regulatory bodies, in consultation with ART providers, develop comprehensive written materials on current commonly used 'add-ons' or adjuvant treatments including:
  - identifying the treatment as an adjuvant treatment
  - informing consumers of the current evidence base for the efficacy of adjuvant treatments and where there is no evidence base or the efficacy is not established, clearly stating this
  - informing consumers of the possible risks or side effects of adjuvant treatments.

This should be provided to consumers before beginning ART.

#### 5.5 Adverse events

- The findings of this inquiry support Recommendation 77 of the Gorton Review relating to the development of compliance standards in relation to ART providers' reporting requirements.
- It is recommended that regulatory bodies work with ART providers in improving reporting of adverse events, particularly cases of ovarian hyperstimulation syndrome, regardless of the severity of the diagnosis.

#### 5.6 Complaint handling

- It is recommended that ART providers adhere to the minimum complaint handling standards set out in the Health Complaints Act 2016.
- It is recommended that ART providers ensure that consumers are made aware of the provider's own complaint handling standards and that a consumer has the right to make a complaint to the Health Complaints Commissioner.
- It is recommended that ART providers ensure that no ART patient shall experience reprisals because of providing feedback or making a complaint to a health service provider.
- It is recommended that ART providers access the training and events offered by the Health Complaints Commissioner in how to manage complaints, and information on implementing the complaint handling standards to create a culture where feedback and complaints are seen as leading to continuous improvement of the quality of their service.

#### 5.8 Inclusivity and access

- The findings of this inquiry note and support the recommendations of the Gorton Review relating to inclusivity and access.

## 2. BACKGROUND

### 2.1 Role of the Health Complaints Commissioner

The office of the Health Complaints Commissioner (HCC) was established on 1 February 2017 under the *Health Complaints Act 2016*. This legislation repealed the previous governing *Health Services (Conciliation and Review) Act 1987* and the functions of the Health Services Commissioner.

The inaugural HCC, Ms Karen Cusack (the Commissioner), resolves complaints about health care and the handling of health information in Victoria under both the *Health Complaints Act 2016* and the *Health Records Act 2001*. She can also investigate matters and review complaints data to help health service providers improve the quality of their service. The HCC acts independently and impartially.

Under the *Health Complaints Act 2016* the Minister for Health may refer any health service matter to the Commissioner for inquiry.

### 2.2 Scope of the inquiry

While the Gorton Review primarily examined barriers to accessing ART (including discriminatory, financial and geographical) within Victoria's legislative and regulatory environment, this inquiry focuses on two main areas:

- the current state of ART services in Victoria
- the lived patient experience of ART.

The inquiry does this by examining and analysing:

- the information and personal viewpoints given across 121 public submissions
- public and provider consultation forums
- literature reviews
- ART-related complaints to the HCC since January 2017
- previous reports and studies of the ART industry.

#### **Anonymity**

To carry out the inquiry, it was vital that as much information as possible relating to ART services was available. Importantly, that meant that anyone wishing to remain anonymous could do so. All submitters were given the choice of remaining anonymous. Throughout the inquiry, everyone making a submission was assured that anonymity would be respected and safeguarded.

As a result, all information has been de-identified in this report. Those who made submissions are referred to in the following manner:

- **ART consumers** are identified by the letter '**C**' followed by a number unique to each.
- **Fertility specialists** are identified by the letters '**FS**' followed by a number unique to each.
- **Provider staff** such as ART clinic nurses and embryologists are identified by the letter '**PS**' followed by a number unique to each.

- **Individual stakeholders** are identified by the letter ‘S’ followed by a number unique to each.

Where information was obtained from publicly available sources such as websites and publications, ART provider groups and public stakeholder groups are identified by name in the report.

A list of de-identified inquiry submissions is provided at **Appendix 3**.

## Bias

It is important to note that submissions to any public health inquiry will carry biases; these must be considered when weighing presented information. Bias is defined as ‘any tendency which prevents unprejudiced consideration of a question’.<sup>12</sup> For consumers, these include the following:

- Self-reporting bias – a person’s reported experience carries no corroborating evidence, meaning it can only be taken at face value. Some information may be erroneous, misleading or false – even unintentionally. Despite this, ‘self-reporting data can be valuable in obtaining subjects’ perspectives, views, and opinions’.<sup>13</sup>
- Self-selection bias – the inquiry was open to all members of the Victorian public, but those consumers who made submissions do not represent a ‘cross-section’ of either Victorians or ART patients.<sup>14</sup>
- Negativity bias – people generally have better recall of negative experiences, potentially disproportionately weighting the information given by consumers, due to ‘the tendency for humans to pay more attention, or give more weight to negative experiences over neutral or positive experiences’.<sup>15</sup>

Most of the current Victorian ART providers made submissions to this inquiry, and several attended the provider consultation forum. Submissions tended to focus on the positive aspects of their services and their successes and did not address any negative experiences of consumers.

While it is important to acknowledge these caveats to the information presented in this report, there are some key trends that have come out of this inquiry and through the complaints received by the HCC that can and should form a basis for quality improvement.

Victorian ART providers perform a vital role in helping infertile individuals and couples and preserving fertility for those who need it. But, as the Gorton Review noted, and this inquiry found, there is room for improvement.

## Recent **media** attention

In recent months, there has been considerable Australian media about a perceived lack of oversight of the ART industry, its predatory nature over vulnerable people and its potentially

<sup>12</sup> Pannucci, CJ and Wilkins, EG, 2010, ‘Identifying and Avoiding Bias in Research’, *Plastic and Reconstructive Surgery* <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2917255/> accessed 15 August 2019.

<sup>13</sup> Althubaiti, A, 2016, ‘Information bias in health research: definition, pitfalls, and adjustment methods’, *Journal of Multidisciplinary Healthcare* <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4862344/> accessed 15 August 2019.

<sup>14</sup> Lavrakas, PJ, 2008, ‘Self-Selection Bias’, *Encyclopedia of Survey Research Methods* <https://methods.sagepub.com/reference/encyclopedia-of-survey-research-methods/n526.xml> accessed 15 August 2019.

<sup>15</sup> Loranger, H, 2016, ‘The Negativity Bias in User Experience’, Nielsen Norman Group <https://www.nngroup.com/articles/negativity-bias-ux/> accessed 15 August 2019.

unscrupulous practices. The media environment in which the Gorton Review and this inquiry took place is one where providers feel their industry is being unnecessarily – and negatively – targeted.

At the most recent meeting of the Fertility Society Australia (FSA) in September 2019, Professor David Molloy, clinical director of the Queensland Fertility Group, stated: ‘The last 12 months have seen an explosion in bad media. We’ve never had a worse year in terms of the media’.<sup>16</sup> He noted an analysis of 2000 media stories on IVF showed 73 per cent of the ‘seriously negative stories’ came from Victoria.<sup>17</sup>

In the case of ‘add-on’ or adjuvant treatments, S5 notes that recent media coverage had not been balanced, ‘prompting some staff from providers to comment that the industry as a whole has been vilified’.<sup>18</sup>

FS20 noted that recent media coverage of the ART industry is almost entirely negative. He stated: ‘We have the lowest single-use embryo transfers in the world, all through self-regulation, why doesn’t anyone comment on that?’<sup>19</sup>

[ART provider] expressed frustration that despite their best efforts, ART:

*is a complex and emotional experience for our patients and their support networks, with no guarantee of success, despite the financial outlay required. The emotive nature of ART treatment can lead to increased levels of frustration as the expectation of what treatment can achieve may not meet the reality. With the development of the internet (and reliance on Dr Google) and the introduction of social media and blogs, patients are increasingly informed. Further, as social attitudes to ART change, patients are increasingly sharing their experiences and details of their treatment more widely. Unfortunately, this can lead to misinformation and perception that the treatment they have received was ‘inadequate’ or ‘inappropriate’, especially if their friend achieves a pregnancy and they don’t.*

*We further acknowledge that no two patients are the same, there is a large amount of information that needs to be conveyed and many decisions need to be made at the start of treatment. [ART provider] work with our patient groups to identify how and when to best to convey this information to support their decision-making process – but don’t always get it right for everyone and we strive to continuously improve this process.<sup>20</sup>*

<sup>16</sup> Salleh, A, 2019, ‘Fertility expert criticises ‘explosion in bad media’ about IVF in speech to industry’, ABC <https://www.abc.net.au/news/2019-09-19/fertility-doctor-criticises-bad-media-about-ivf-in-speech/11523054> accessed 2 December 2019.

<sup>17</sup> Ibid.

<sup>18</sup> Submission 2019/06639

<sup>19</sup> Provider consultation forum, Melbourne, 12 September 2019.

<sup>20</sup> Submission 2019/06547

## 2.3 Summary of submissions

Of the 121 submissions the inquiry received, the majority were from consumers (see Table 1).

**Table 1: Number of inquiry submissions by category**

Category of submitter	Number of submissions	Percentage
A. ART consumers or family members	93	77%
B. ART providers/staff	18	15%
C. Other stakeholders	10	8%
<b>Total</b>	<b>121</b>	<b>100%</b>

Most consumer submissions shared personal experiences of undergoing ART – both positive and negative – or those of spouses and other family members.

An analysis of the 93 consumer submissions showed half (50.5 per cent) found their ART experience negative, followed by a large group that found their experience both positive and negative, and a small group that reported a positive experience, as set out in Table 2. While a positive experience often related to whether the consumer had a successful live birth, this was not always the case, and the converse was true: some submitters reported positive experiences without having had a live birth.

**Table 2: Consumers' responses to their overall ART experience**

Experience overall	Number of consumers	Percentage
Negative	47	50.5%
Both positive and negative	38	41%
Positive	7	8.5%
N/A	1	1%
<b>Total</b>	<b>93</b>	<b>100%</b>

Considering the submissions further, Table 3 shows the breakdown of specific issues that led to their negative experience, equally led by adverse events and poor communication from specialists. Where consumers discussed a secondary issue, this was again led by poor communication from specialists and costs associated with ART.

**Table 3: Reasons for a primarily negative ART experience (47 consumers)**

Main issue	Number of consumers	Percentage	Secondary issue	Number of consumers	Percentage
Adverse event	13	27.5	Poor communication from specialists	20	43
Poor communication from specialists	13	27.5	Costs	7	15
Unsuccessful treatment	7	15	Counselling	3	6
Access to services	3	6	Unsuccessful treatment	3	6
Costs	3	6	Treatment not by specialist	3	6
Counselling	2	4	Adverse event	2	4.5
Lack of treatment consent	2	4	Other testing	2	4.5
Error made	2	4	Poor communication	2	4.5

Main issue	Number of consumers	Percentage	Secondary issue	Number of consumers	Percentage
			from other staff		
Add-on procedure	1	2	Error made	2	4.5
Other testing	1	2	Lack of treatment consent	1	2
<b>Total</b>	<b>47</b>	<b>100%</b>	Discrimination	1	2
			Add-on procedures	1	2
			<b>Total</b>	<b>47</b>	<b>100%</b>

Where consumers indicated both positive and negative aspects in their experience, they spoke about poor communication and counselling as negative components of the overall experience, while a live birth provided a positive experience. Table 4 shows the main reasons given.

**Table 4: Reasons for a positive and negative ART experience (38 consumers)**

Main reason for negative experience	Number	%	Main reason for positive experience	Number	%
Communication with specialists	9	24%	Live birth(s)	17	44.5%
Counselling	8	21%	Good provider communication	11	29%
Costs	6	16%	Treatment by specialist	6	16%
Error made	4	10.5%	Unstated	3	8%
Police checks	3	8%	Counselling	1	2.5%
Adverse event	3	8%	<b>Total</b>	<b>38</b>	<b>100%</b>
Communication with other ART staff	2	5%			
Storage problem	1	2.5%			
Lack of treatment consent	1	2.5%			
Unsuccessful treatments	1	2.5%			
<b>Total</b>	<b>38</b>	<b>100%</b>			

Further findings from consumers' submissions revealed:

- 95 per cent of consumers spoke from their personal experience; the remainder were partners or family members of ART patients.
- While several consumers sought treatment from more than one provider, the inquiry recorded the provider from whom the consumer had their main or most significant ART experience. Table 5 shows where consumers received treatment.

**Table 5: ART providers where consumers sought treatment**

Provider	Number of consumers	Percentage
Melbourne IVF	40	44%
Monash IVF	31	33%
Unstated	8	9%
Ballarat IVF	4	4%
City Fertility Centre	3	3%
Adora Fertility	2	2%
Number One Fertility	2	2%
City Babies	1	1%
Individual practitioner	1	1%
Reproductive Services Unit (Royal Women's Hospital)	1	1%
<b>Total</b>	<b>93</b>	<b>100%</b>

## 2.4 Related complaints to the HCC

Between February 2017 and August 2019 there were 53 relevant complaints made to the HCC about ART services. An analysis of these complaints is shown in Table 6. It should be noted that there will often be more than one issue raised in a complaint and so, while 53 complaints were dealt with during the period, the total number of issues is greater than 53.

**Table 6: Primary and secondary reasons (where stated) behind each ART-related HCC complaint**

Main issue	No. of issues	Secondary issue	No. of issues
Communication with specialist	12	Costs	12
Costs	7	Lack of treatment consent	5
Error made	7	Communication with specialist	4
Adverse event	5	Communication with staff	4
Other testing (genetic, etc.)	4	Add-on procedures	2
Unsuccessful treatments	3	Discrimination	2
Discrimination	3	Error made	2
Other	3	Other testing (genetic, etc.)	2
Lack of financial consent	2	Unsuccessful treatment	2
Access to treatment	2	Counselling	1
Communication with clinic staff	2	Treatment not by specialist	1
Add-on procedures	1	Lack of financial consent	1
Provider – other	1	Storage problems	1
Storage problems	1		

One of the most common threads in all complaints received by our office relates to poor communication. Similarly, in relation to ART complaints, communication was the primary cause for making a complaint, followed by the cost of treatment and adverse events. These issues mirror the most prevalent themes from submissions made to this inquiry.

### 3. ASSISTED REPRODUCTIVE TREATMENT

ART is an umbrella term for procedures that involve medical intervention to conceive a child or to preserve fertility for the future. This includes: intrauterine insemination (IUI); IVF; ICSI; fertilisation preservation such as egg freezing; gamete and embryo donation; and altruistic surrogacy.

In Australia, despite its relative youth as a medical specialisation, ART is a well-known field for infertile individuals and couples and for same-sex couples who wish to use donated gametes and/or surrogates to have a child. The most common ART process for conception is still IVF, which pioneered in London in 1978 with the birth of Louise Brown, the world's first IVF-conceived baby. Victoria's Monash IVF group produced the third IVF baby in the world, and Australia's first, Candice Reed, two years later.<sup>21</sup>

#### 3.1 Infertility today

An estimated one in six Australian couples experience fertility problems.<sup>22</sup> While the World Health Organization notes global infertility prevalence rates are difficult to determine 'due to the presence of both male and female factors which complicate any estimate which may only address the woman and an outcome of a pregnancy diagnosis or live birth',<sup>23</sup> statistics are similar. Across the developed world, including Australia:

- Around one-third of infertility problems are male-related.
- Around one-third of infertility problems are female-related.
- Around one-third of infertility problems may be with both partners or are idiopathic and cannot be identified.<sup>24</sup>

Of the 80,669 initiated autologous (using one's own eggs) and recipient (using a donor's eggs and/or sperm) cycles across Australia and New Zealand in 2017, 31.5 per cent reported only female infertility factors; 11.1 per cent reported male infertility factors as the only cause of infertility; 9.5 per cent reported combined male-female factors; 21 per cent reported unexplained infertility; and 25.6 per cent were not stated.<sup>25</sup>

VARTA notes, '[a]s more couples delay childbearing age-related infertility is becoming more common'.<sup>26</sup> Women who are in their 30s are generally half as fertile as they were in their 20s, and the chances of conceiving naturally declines significantly after age 35. While teenage pregnancy and birth rates remain high among Aboriginal and Torres Strait Islander peoples and Australian women in disadvantaged communities, more women are waiting longer to have children, 'often to first establish a position in the workforce and achieve material security'.<sup>27</sup> By the time they feel ready to start a family, their fertility may have declined significantly.<sup>28</sup> The most recent national

<sup>21</sup> Monash IVF (n8).

<sup>22</sup> Fertility Society of Australia, 'Media Release 10 September 2019' <https://www.fertileysociety.com.au/> accessed 22 November 2019.

<sup>23</sup> World Health Organization, 'Global prevalence of infertility, infecundity and childlessness' <https://www.who.int/reproductivehealth/topics/infertility/burden/en/> accessed 20 September 2019.

<sup>24</sup> VARTA (n3).

<sup>25</sup> Newman et al (n11) 7.

<sup>26</sup> VARTA (n3).

<sup>27</sup> Department of Health, 'Fertility and infertility'

<https://www1.health.gov.au/internet/publications/publishing.nsf/Content/womens-health-policy-toc-womens-health-policy-experiences-womens-health-policy-experiences-reproductive-womens-health-policy-experiences-reproductive-maternal-womens-health-policy-experiences-reproductive-maternal-fert> accessed 13 September 2019.

<sup>28</sup> Ibid.

estimates indicate that 4.7 per cent of all women who gave birth in Australia in 2017 received some form of ART.<sup>29</sup>

Other factors such as increasing obesity rates and the effects of 'increased exposure to man-made environmental toxicants' such as endocrine disrupting chemicals are also believed to be decreasing fertility.<sup>30</sup> Studies show that certain chemicals found in today's plastics, pesticides and heavy metals can mimic or block endocrine actions in adult females, 'causing fertility abnormalities in both humans and animals'.<sup>31</sup>

As reported by the National Perinatal Epidemiology and Statistics Unit, University of NSW in its most recent Annual Report for 2017, the Australia and New Zealand Assisted Reproduction Database (ANZARD) states:

In Australia:

- Across Australian fertility clinics, there were 74,942 ART cycles reported, representing an increase of 0.8 per cent from 2016.
- 36,463 women underwent autologous fresh and/or thaw IVF cycles in 2017.
- There were 13,944 babies born (including 13,752 liveborn babies) following ART in 2017.

Across Australia and New Zealand:

- The average age of women undergoing autologous and oocyte/embryo recipient cycles was 35.9 years.
- Women aged 35–39 were the largest age group undertaking autologous cycles between 2013 and 2017.
- For women aged 45 or older, only one live delivery resulted from every 175 initiated cycles compared with one live delivery from every five initiated cycles in women aged between 23 and 24.<sup>32</sup>

While scientific developments continue to improve ART technology, so too do the expectations of infertile single and coupled people who want children. A Human Fertilisation and Embryology Authority (HFEA) report noted in the UK, some studies have found that 'patients have unrealistically high expectations of success. Even though birth rates with frozen eggs are increasing, in 2016, only around one in four egg thaw cycles resulted in a birth.'<sup>33</sup>

Similarly in Victoria, the Gorton Review noted:

*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*

<sup>29</sup> Newman et al (n11) 1.

<sup>30</sup> Green, M, 2019, 'A GP guide to endocrine disrupting chemicals and fertility' <http://online.isentialink.com/ausdoc.com.au/2019/09/24/e6752206-9b26-411d-a74a-90bff2c7fe61.html> accessed 30 September 2019.

<sup>31</sup> Rattan S, Zhou, C, et al. 2017, 'Exposure to endocrine disruptors during adulthood: Consequences for female fertility', *Journal of Endocrinology* <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5479690/> accessed 13 July 2019.

<sup>32</sup> Newman et al (n11).

<sup>33</sup> Human Fertilisation and Embryology Authority, 2016, *Egg freezing in fertility treatment: Trends and figures: 2010-2016* <https://www.hfea.gov.uk/media/2656/egg-freezing-in-fertility-treatment-trends-and-figures-2010-2016-final.pdf> accessed 25 November 2019.

*effectiveness. Success rates are hard to calculate, and many people proceed with treatment despite a very low statistical likelihood of having a baby.*<sup>34</sup>

## Male infertility

Male factor infertility is poorly understood among the Australian community and ‘carries considerable individual and community burden and cost’.<sup>35</sup> Approximately one in 20 men have low numbers of sperm and about one in every 100 men have azoospermia (produce no sperm),<sup>36</sup> yet ‘[t]here’s still a common but incorrect belief that infertility is a woman’s problem. So men are often unprepared when they’re told there is a complication with their sperm. Fertility problems can affect a man’s sense of masculinity, sexuality and potency.’<sup>37</sup> As the *National Men’s Health Strategy 2020–2030* states, reproductive health conditions, including infertility, ‘are common among Australian males and represent a high economic and social cost’.<sup>38</sup>

A 2017 study revealed between 1973 and 2011, the concentration of sperm in the ejaculate of men in western countries has fallen by an average of 1.4 per cent a year, with an overall drop of just over 52 per cent.<sup>39</sup> Despite these findings, men may have no idea that they have fertility problems until they see a specialist and undergo tests, unlike women who may have a range of symptoms alerting them to potential complications with fertility such as polycystic ovarian syndrome, endometriosis or amenorrhea (lack of menstruation).

Male infertility causes may relate to: undescended testes at birth; Klinefelter’s syndrome; exposure to cancer treatments, heat, testicular trauma and infections; blockages in the tubes of the reproductive system; sperm autoantibodies; congenital defects; hormone deficiencies; erectile dysfunction; retrograde ejaculation; inadequate diet; azoospermia, low sperm numbers; or problems with sperm motility (movement) or morphology (form and structure).<sup>40</sup>

The *National Men’s Health Strategy 2020–2030* states:

*Fatherhood is a key life stage for many Australian men and requires a stronger emphasis within health strategy, to ensure better experiences and health outcomes for men and their children. Preconception health promotion, fertility and reproductive health issues warrant increased attention across primary care.*<sup>41</sup>

Healthy Male (formerly Andrology Australia) states, ‘men rarely have a proper health assessment when there are fertility issues’ and ‘[a]s ART programmes are largely directed by gynaecologists, we have long been concerned that review of male partners is not universally undertaken’.<sup>42</sup> As an example, Healthy Male noted the lobbying undertaken to include male factor evaluation as a critical criterion for an ART clinic to be accredited by the Reproductive Technology Accreditation Committee (RTAC). Previously where ANZARD gathered statistics on infertility, clinics were asked

<sup>34</sup> Gorton (n2) 2.

<sup>35</sup> Submission 2019/06410

<sup>36</sup> Healthy Male, ‘Male Infertility’, <https://www.healthymale.org.au/mens-health/male-infertility> accessed 31 January 2020.

<sup>37</sup> Ibid.

<sup>38</sup> Department of Health, 2019, *National Men’s Health Strategy 2020–2030*, Commonwealth of Australia, Canberra, 8.

<sup>39</sup> Davis, N, 2017, ‘Sperm counts among western men have halved in last 40 years – study’, *The Guardian* <https://www.theguardian.com/lifeandstyle/2017/jul/25/sperm-counts-among-western-men-have-halved-in-last-40-years-study> accessed 2 December 2019.

<sup>40</sup> Department of Health (n43) 21; see also Better Health, ‘Infertility in men’

<https://www.betterhealth.vic.gov.au/health/ConditionsAndTreatments/infertility-in-men> accessed 5 September 2019.

<sup>41</sup> Department of Health (n43) 21.

<sup>42</sup> Submission 2019/06410

only if there was a male factor, with an option to choose 'yes' or 'no', without any accompanying information. While the RTAC Code of Practice (**the RTAC Code**) now requires clinicians to provide more detailed criteria relating to male infertility factors, Healthy Male notes there is no audit to check whether clinicians are capturing these data. ANZARD is working on revised standards for 2020 that Healthy Male hopes will better capture specific male factor infertility statistics.<sup>43</sup> In doing so, 'you will have to meet the man'.<sup>44</sup>

## 3.2 The growth of ART services

Medical and technological advancements continue to find new ways for ART services to be used. While as recently as 20 years ago ART mostly meant IVF, today it encompasses a range of services. Fertility treatment expert Dr Karin Hammarberg, is reported as saying that Australian children born of ART have 'gone from nothing to about 5 per cent within a generation'.<sup>45</sup>

The range of people accessing ART continues to evolve from heterosexual married couples to same-sex couples, single patients, those using donated genetic material and transgender people seeking to have children.<sup>46</sup> Accordingly, the need for ART services is rising, while the legislative and regulatory environments struggle to remain in step with social and technological changes.

The market for fertility preservation is also increasing for a variety of reasons and non-medical purposes. For example, women may freeze their eggs at a younger age to ensure healthy eggs should they want to have children later in life – a choice that has been on the rise in recent years.<sup>47</sup> A recent article profiled Genea Horizon, a dedicated egg freezing clinic, that claimed a 78 per cent rise in women accessing the procedure.<sup>48</sup> VARTA reports IVF treatment cycles using a patient's own thawed eggs has grown from 77 in 2015–16 to 163 in 2017–18.<sup>49</sup> Egg and sperm freezing are also used to preserve future fertility where individuals are undergoing cancer treatment, a consequence of which may be infertility.<sup>50</sup>

In a newer application of ART, Melbourne's Royal Children's Hospital Fertility Preservation Service's mandate is to pioneer the new field of paediatric oncofertility 'to improve health and wellbeing of young people who have medical treatments or conditions that can affect fertility'.<sup>51</sup> Australia has a high global incidence of childhood cancer.<sup>52</sup> With technological developments in ART, fertility preservation for these patients is now possible to try to ensure their cancer treatment does not render them infertile.

<sup>43</sup> Ibid.

<sup>44</sup> Public consultation forum, Melbourne, 11 September 2019.

<sup>45</sup> Heffernan, M, 2019, "It's not something that was commonly talked about at all": families, fertility and ART', *The Age* <https://www.theage.com.au/national/victoria/it-s-not-something-that-was-commonly-talked-about-at-all-families-fertility-and-art-20190709-p525lv.html> accessed 30 July 2019.

<sup>46</sup> Human Fertilisation and Embryology Authority, *Fertility treatment 2017: trends and figures* <https://www.hfea.gov.uk/media/2894/fertility-treatment-2017-trends-and-figures-may-2019.pdf> accessed 7 December 2019, 43.

<sup>47</sup> VARTA, 'Fertility and infertility', <https://www.varta.org.au/information-and-support/fertility-and-infertility> accessed 15 August 2019.

<sup>48</sup> Le Messurier, D, 2019, 'More eggs in the basket', *Herald Sun*, 3.

<sup>49</sup> VARTA, 'Frozen egg use in IVF doubled in two years in Victoria', <https://www.varta.org.au/resources/news/frozen-egg-use-ivf-doubled-two-years-victoria> accessed 15 August 2019.

<sup>50</sup> Kato, K, 2016, 'Vitrification of embryos and oocytes for fertility preservation in cancer patients' *Reproductive Medicine and Biology* <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5715860/> accessed 15 August 2019.

<sup>51</sup> Submission 2019/08067

<sup>52</sup> Ibid.

In girls, cancer treatment can deplete ovarian follicles and the overall risk of later adult infertility is 16 per cent, reaching 40 per cent by 30 years of age.<sup>53</sup> In boys, cancer treatment can deplete sperm and affect sperm production in adulthood. Infertility in male survivors of childhood cancer is increased by nearly 40 per cent. Boys whose treatment involves 'ionizing radiation, high dose alkylating agents and conditioning prior to bone marrow transplantation' have a later infertility rate of 60–100 per cent.<sup>54</sup> Fertility preservation can also be extended to children with other medical conditions that threaten long-term fertility, as well as to gender diverse children and young adults.<sup>55</sup>

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<sup>53</sup> Ibid.

<sup>54</sup> Ibid.

<sup>55</sup> Ibid.

## 4. THE REGULATORY AND LEGISLATIVE ENVIRONMENT

There is no Commonwealth legislation that directly regulates ART in Australia, and there is variation among the states and territories regarding ART regulation.<sup>56</sup> Only the *Family Law Act 1975* (Cth), the *Prohibition of Human Cloning for Reproduction Act 2002* (Cth) and the *Research Involving Human Embryos Act 2002* (Cth) intersect with aspects of Victorian law.<sup>57</sup>

In terms of legislation governing ART, Victoria is considered an international pioneer with several Acts of Parliament enacted over time, including the following:

- The *Status of Children Act 1974* regulated early understandings of parentage in relation to ART procedures including donor treatment procedures, same-sex relationships, single women and posthumous use of gametes.<sup>58</sup>
- The *Infertility (Medical Procedures) Act 1984* and *Infertility (Medical Procedures) Regulations 1988* were the world's first legislation to regulate ART and human embryo research.<sup>59</sup>
- The *Human Tissue Act 1982* made it illegal to buy or sell unauthorised human tissue including eggs, sperm and embryos.<sup>60</sup>
- The *Births, Deaths and Marriages Registration Act 1996* outlined the requirements for birth registration of a child conceived as the result of a donor treatment procedure.<sup>61</sup>

Subsequent legislation has tried to match the rapid pace of the ART industry's technological growth and expansion. Significant legislative change for Victorians came with the *Assisted Reproductive Treatment Act 2008* (**the ART Act**). Before its introduction, many Victorians could not access ART, 'either by excluding certain categories of people from accessing ART services to enable them to have children or by failing to recognise the relationships existing within certain families'.<sup>62</sup>

The ART Act is still the primary legislation governing ART in Victoria, including rules regarding eligibility for ART and the types of services that can be provided by registered and accredited ART providers. The *Assisted Reproductive Treatment Regulations 2009* accompanied the Act, outlining 'requirements for counselling, consent, expenses that may be reimbursed to a surrogate, and information that must be recorded by clinics and with donor registers'.<sup>63</sup>

<sup>56</sup> VARTA, 'Legislation and guideline overview', <https://www.varta.org.au/regulation/legislation-and-guideline-overview> accessed 1 October 2019.

<sup>57</sup> Ibid.

<sup>58</sup> Ibid.

<sup>59</sup> VARTA, 'History of Victorian ART regulation', <https://www.varta.org.au/regulation/history-victorian-art-regulation> accessed 1 October 2019.

<sup>60</sup> VARTA (n56).

<sup>61</sup> Ibid.

<sup>62</sup> Victorian Law Reform Commission, 2007, *Assisted Reproductive Technology and Adoption: Final Report*, Melbourne, 6.

<sup>63</sup> VARTA (n56).

## 4.1 Gorton Review 2019

*[T]he verdict of the users of ART on the 2008 regulatory framework is clear: it does not meet the standards of today [...] Victorians expect better of this industry, which has such a proud record of delivering world-class fertility care to so many.<sup>64</sup>*

As the ART industry continues to grow, so does the need to ensure regulation and legislation remains relevant to the industry's practices. The Gorton Review, published in May 2019, directly addressed many of the concerns raised since passing the ART Act. Its 80 recommendations propose reform in the following areas:

- expanding the ART system to more diverse groups of consumers and removing remaining barriers to access
- making ART more streamlined and patient-focused
- enacting stronger regulation of ART providers, applying tougher penalties for breaches and giving governments increased enforcement powers
- more effective oversight of an industry that has had very little
- exploring a small number of cases of unethical practices.<sup>65</sup>

The Gorton Review concluded that today's ART industry needs updated legislation and accompanying reforms to better reflect the diversity of who ART patients are now and what they experience. The reforms address the 'serious shortcomings' of the ART 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 [...] 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.<sup>66</sup>*

The Gorton Review also commented on VARTA's role as the Victorian ART regulator, noting the ART Act weakened VARTA's authority from its previous powers as the Infertility Treatment Authority (under the previous *Infertility Treatment Act 1995*) and 'reducing its regulatory functions and powers and relying more on the national industry self-regulatory body'.<sup>67</sup> Significantly, this occurred 'just before major changes in commercial and clinical practices in the industry'.<sup>68</sup>

The Gorton Review was clear that its recommendations would take time to enact and would 'require an overhaul of Victoria's ART legislation' and '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'.<sup>69</sup>

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<sup>64</sup> Gorton (n2) i-ii.

<sup>65</sup> Ibid, v.

<sup>66</sup> Ibid, i.

<sup>67</sup> Ibid.

<sup>68</sup> Ibid.

<sup>69</sup> Ibid, xlv.

## 4.2 ART industry regulators

In Victoria, several bodies co-regulate the ART industry.<sup>70</sup> VARTA is the statutory authority for ART, guided by the ART Act and the Minister for Health. VARTA's functions include oversight and administration of the ART registration system.<sup>71</sup> Under the ART Act, VARTA grants registration in Victoria to a person who holds RTAC accreditation.<sup>72</sup> If VARTA considers a condition necessary in the public interest it may impose conditions on the registration of a person as a registered ART provider.<sup>73</sup>

The Commonwealth *Research Involving Human Embryos Act 2002* defines an accredited ART centre as a person or body accredited to carry out ART by RTAC (a committee of the Fertility Society of Australia – FSA). The FSA is the peak industry body representing scientists, doctors, researchers, nurses and counsellors in reproductive medicine in Australia and New Zealand.<sup>74</sup> Its board comprises representatives of ART clinics, professions, consumer groups and specific interest groups.<sup>75</sup> All ART services are subjected to the national self-regulatory accreditation model established by the FSA.<sup>76</sup>

RTAC reports directly to the FSA board and is responsible for setting ART standards and accreditation requirements at the national level.<sup>77</sup> These standards are regulated through the audited RTAC Code and the granting of licences to practise ART within Australia.<sup>78</sup> An ART provider's compliance with the RTAC Code is assessed via an audit undertaken by an independent certification body that is approved by the Joint Accreditation System of Australia and New Zealand.<sup>79</sup> Under the *Research Involving Human Embryos Act 2002* it is an offence to use human embryos without RTAC licensing.<sup>80</sup> Australian accreditation with RTAC is a required prerequisite for providers to receive Medicare rebates.<sup>81</sup>

Compliance with the RTAC Code and the National Health and Medical Research Council's (NHMRC) *Ethical guidelines on the use of assisted reproductive technology in clinical practice and research (the NHMRC guidelines)* is mandatory for all clinics involved in ART.<sup>82</sup> In conjunction with relevant federal and state legislation, the NHMRC guidelines provide an overarching framework for ART clinical practice and research.<sup>83</sup> As part of their accreditation, all clinics are required to report all ART and donor insemination cycles undertaken to ANZARD.<sup>84</sup> ANZARD works with the National Perinatal Epidemiology and Statistics Unit, the FSA and all 83 fertility clinics in Australia and eight fertility clinics in New Zealand.<sup>85</sup>

In submissions to this inquiry, Victorian ART providers referred to what they see as an already

<sup>70</sup> VARTA (n56).

<sup>71</sup> s.100(a) *Assisted Reproductive Treatment Act 2008* (Vic).

<sup>72</sup> *Ibid*, s.74.

<sup>73</sup> *Ibid*, s.75[1].

<sup>74</sup> Gorton (n2) 7.

<sup>75</sup> *Ibid*, 8.

<sup>76</sup> *Ibid*, 56.

<sup>77</sup> Fertility Society of Australia, 'RTAC', <https://www.fertilitysociety.com.au/rtac/> accessed 20 November 2019.

<sup>78</sup> *Ibid*.

<sup>79</sup> Fertility Society of Australia, 2017, *Code of Practice for Assisted Reproductive Technology Units*, Melbourne, 5.

<sup>80</sup> *Ibid*.

<sup>81</sup> Gorton (n2) 7.

<sup>82</sup> National Health and Medical Research Council, 2017, *Ethical guidelines on the use of assisted reproductive technology in clinical practice and research*, Canberra.

<sup>83</sup> VARTA (n56).

<sup>84</sup> Newman et al (n11) iv.

<sup>85</sup> *Ibid*, 3.

over-regulated industry. In its submission, [ART provider] made the point that with the regulation of ART in Victoria spread across different agencies:

*It is also important to ensure that the role of regulators in the review of complaints and adverse events is clear and minimises unnecessary administrative burden on clinics. At present, Victorian clinics are required to report to both RTAC and VARTA – with different information requested and differing responses possible. This does not seem to drive improvements to patient safety and indeed risks resources being diverted to reporting rather than addressing issues.<sup>86</sup>*

Providers told the Commissioner they feel there could be a more productive relationship between ART regulators and providers, particularly in the drafting of future legislation governing ART.

### 4.3 ART legislation and regulation in other Australian jurisdictions

Victoria, South Australia, Western Australia and New South Wales are the only states to have dedicated legislation for ART. The current governing ART legislation in Australian states is as follows:

**NSW:** *Assisted Reproductive Technology Act 2007* and Assisted Reproductive Technology Regulations 2014

**SA:** *Assisted Reproductive Treatment Act 1988* and Assisted Reproductive Treatment Regulations 2010

**WA:** *Human Reproductive Technology Act 1991* and Human Reproductive Technology Act Directions 2004.

The Northern Territory is guided by South Australia's legislation. Queensland, Tasmania and the Australian Capital Territory require ART providers to have national accreditation with RTAC and adhere to the NHMRC guidelines. Only those states with dedicated ART legislation have laws governing donor conception.

All Australian ART practitioners must be registered with the National Registration and Accreditation Scheme, adhere to the Code of Conduct relevant to their profession and abide by Health Practitioner Regulation National Law. The Australian Health Practitioner Regulation Agency (AHPRA) works with the National Health Practitioner Boards in implementing the national scheme.<sup>87</sup>

Surrogacy in Australia is regulated in each state, with no nationally uniform law; the Northern Territory has no laws regarding surrogacy. The Gorton Review noted this 'disparity in legislative regimes around Australia causes a range of inequities for people choosing to pursue domestic altruistic surrogacy'<sup>88</sup> and called for a consistent national approach.

Regarding other provisions such as counselling for ART patients or requiring criminal record and child protection order checks, states again vary. In New South Wales, s.12 of the Assisted Reproductive Technology Act stipulates that counselling services are available to any ART patients

<sup>86</sup> Submission 2019/06547

<sup>87</sup> AHPRA, 'National Boards', <https://www.ahpra.gov.au/National-Boards.aspx> accessed 20 November 2019.

<sup>88</sup> Gorton (n2) 119.

and offered prior to treatment, but it is not mandatory. There are no other screening requirements in New South Wales.

In South Australia, before 1 September 2010, the *Reproductive Technology (Clinical Practices) Act 1988* and the *Reproductive Technology (Code of Ethical Clinical Practice) Regulations 1995* required ART applicants to undergo counselling before accessing ART.<sup>89</sup> In addition, the female patient and her partner, if any, had to sign a statutory declaration stating: they were not subject to a term of imprisonment or to outstanding charges for an offence for which imprisonment may be imposed; that neither had been found guilty of a sexual offence involving a child; that neither had been found guilty of a violent offence; and/or had a child permanently removed from his or her guardianship.<sup>90</sup> If any of the above applied, ART was not to be provided.

In 2009, these requirements were removed as part of significant changes made to the *South Australian Assisted Reproductive Treatment Act*. A 2017 review of this Act argued:

- *The paramountcy of the welfare of the child principle, and the involvement of third parties such as the state and health professionals in the provision of A.R.T., supports the requirement for a level of assessment of people wishing to access A.R.T. regarding any risks of physical and/or psychological harm that may exist for a child born as a result of providing treatment.*
- *The removal of prior uniform requirements for screening applicants for A.R.T. for risk pursuant to the welfare principle, and the lack of guidance under the current Act and regulations, has led to inconsistent practices across clinics in South Australia. Inconsistency and some such practices do not serve to uphold the paramountcy of the welfare of the child principle.<sup>91</sup>*

Subsequently there has been some discussion about reintroducing the provisions for mandated screening in South Australia.

Western Australian ART clinics must provide access to counselling to all individuals/couples undergoing ART, but it is not mandatory. There are no screening criteria in the *Human Reproductive Technology Act*, but s.4(1)(d)(iv) requires that the prospective welfare of any child to be born through ART be taken into consideration.

This highlights two unique requirements of potential ART patients in Victoria: a requirement for mandated counselling prior to the providing ART; and a requirement to produce criminal and child protection order checks. These are discussed later in this report.

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<sup>89</sup> *Reproductive Technology (Code of Ethical Clinical Practice) Regulations 1995 (SA)*, 8–9.

<sup>90</sup> *Ibid*, 7.

<sup>91</sup> Allan, S, 2017, *Report on the Review of the Assisted Reproductive Treatment Act 1988 (SA)*, Adelaide, xxi.

## 5. PROVISION OF ART SERVICES IN VICTORIA

*[T]he distorted and misinforming message we are receiving from media and fertility service providers is that with IVF, you don't need to concern yourself with biological reality, because medicine has the means to cure your infertility. What is not known is that IVF can be a humiliating, demeaning process that can consume years of your life, cost thousands of dollars, cause you very high medical risks and will definitely increase experience of pain, both physical and emotional – and may not lead to a live, healthy baby.<sup>92</sup>*

### 5.1 Communication

SUMMARY OF FINDINGS 1-4
The information provided to ART consumers varies between ART providers. There needs to be a minimum, consistent approach to the information provided by all ART providers.
Overall, communication by many ART providers – including fertility specialists, nurses and administrative staff – is either poorly delivered or is ineffective. This can occur at various stages of the ART journey and by different people within ART providers and clinics.
ART providers and consumers acknowledge the need for information sharing at all stages of ART treatment, but poor, insufficient and ineffective communication continues to exist, making informed decision-making difficult.
Consumers highlighted the importance of good provider communication in feeling supported and well informed, leading to a more positive patient experience.

*Individual hopeful parents become hunter-gatherers of facts, anecdotes and maybes, family and friend stories, internet posts, all the while trying and failing. With more time passing.<sup>93</sup>*

The *Australian Charter of Healthcare Rights in Victoria* states health care providers 'should give you the opportunity to ask questions' and 'should give you all the information you need to make informed decisions, the opportunity to ask questions, and time to talk to your carers, family and friends before making decisions'.<sup>94</sup> Yet despite claims by providers that open and constant communication is key to their practices, this was perhaps the clearest area of divergence between what ART providers and consumers told this inquiry.

The Gorton Review found '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'.<sup>95</sup> Others concur there exists a disconnect between what ART patients believe will happen during their treatment and what they experience regarding communication from providers.

Complaints to the HCC reveal that poor service descriptions and ineffective communication are common in health care. ART services are no different. From evidence given to this inquiry, most negative consumer experiences related to poor communication and the struggles to obtain information from specialists and other ART provider staff. This included basic information about:

<sup>92</sup> Submission 2019/06737

<sup>93</sup> Ibid.

<sup>94</sup> Victorian Government, 2017, *The Australian Charter of Healthcare Rights in Victoria*, Melbourne, 11-13.

<sup>95</sup> Gorton (n2) xiii.

investigation and diagnoses of conditions possibly contributing to infertility; treatment protocols, procedures and possible side effects; and the provision of aftercare.

Providers acknowledged the importance of information sharing in ART, and noted in their submissions statements such as:

*There is [sic] extensive consultations, counselling, written information and also consents given to patients to help them understand the risks benefits and outcomes expected based on their personal circumstances.<sup>96</sup>*

*Fertility treatment is not just about IVF, as a fertility specialist, I only want my patient to be pregnant, I form a close relationship with them and are as delighted if they are successful with cycle tracking, ovulation induction and timed intercourse or IVF.<sup>97</sup>*

Understandably, providers consistently made the point that each case of infertility is different and so the information and communication given to each case will vary. In their submission, Adora stated:

*Information regarding options, success rates, risks, outcomes and costs are provided through a variety of sources including Adora Fertility's website and patient collateral [...] an accurate position of each of the elements can only be, and is as such, provided via the medical consultation and informed consent process.<sup>98</sup>*

FS2 stated that, 'extensive written information and consents, web-based information and booklets' are provided and that the doctor, in an hour-long consultation, 'extensively discusses risks and complications, success rates, expectation management etc.'<sup>99</sup>

However, in submissions made to this inquiry, consumers' experiences do not always reflect these positive representations of communication by providers. Consumers' experiences of poor or inadequate communication are often reflected throughout the whole ART journey, not just at the start of treatment.

Some consumers felt they received information from providers on a need-to-know, piecemeal basis and that information given depended on the individual service. For example, C89 and her husband described their experience with three different providers: 'If their communication is great, their technical skills are not, and if their technical skills are great, then their communication is not.' She said she had 'yet to find a marriage of the two'.<sup>100</sup>

Other consumers commented on their experiences of poor provider communication regarding treatment decisions:

*We never felt like we had enough information, from both the Doctor and the clinic. We were constantly asking for more information.<sup>101</sup>*

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<sup>96</sup> Submission 2019/05740

<sup>97</sup> Submission 2019/05735

<sup>98</sup> Submission 2019/06631

<sup>99</sup> Submission 2019/05664

<sup>100</sup> Public consultation forum, Melbourne, 11 September 2019.

<sup>101</sup> Submission 2019/06834

*The most consistent feature of communication is how thoughtless it is – important details delivered as afterthoughts, or delivered after there is any time to do anything about them [...] On inspection, the best-seeming doctor turns out to use the same systems, facilities and nursing team as the very IVF service I am trying to get away from. So where do I go?<sup>102</sup>*

*There was no communication around clinical decision making, or changes to clinical plans, and no one could answer any questions when I asked them. I was repeatedly treated like a nuisance for asking questions. If I ever said I didn't understand an answer I was given, I was just given handouts even though I had previously told them that I was overwhelmed with the amount of written information that had been dumped on us rather than talked through.<sup>103</sup>*

But consumers were quick to point out where providers had been good communicators. Examples include:

*I felt very supported by [provider] and my specialist at the time. The specialist called out of hours a number of times, made medical certificates and pain medication easily accessible. [...] They always promptly returned phone calls. I never felt like I was pestering them. They ALWAYS called in the time frames they said they would. In all my treatments I never once remember not being called back or having to chase someone.<sup>104</sup>*

*My doctor has a fantastic team that have gotten to know me personally, which makes you feel known and cared for. The worst thing is when you feel like a number, not a person.<sup>105</sup>*

*Communication was strong [...] Lots of follow up calls and information. They were responsive to my needs as they unfolded. For example: the second time they changed from a frozen to fresh transfer. My doctor was even on holiday and he made sure to contact the clinic to inform me.<sup>106</sup>*

PS1, a former ART clinical nurse and patient services manager who practised in the 1980s stated in her submission that she felt communication practices in particular had deteriorated over time: 'During my employment, patients were told by both Nursing and Medical clinicians of outcomes re success rates, treatment options, costs, time involved, all explained in detail' and 'patients were encouraged and supported to make complaints and expect outcomes'. PS1 stated she 'would like to see the above transparency and practices implemented in the very beginnings of ART maintained and encouraged. The patient was always No 1 and considered and supported at every step of their journey.'<sup>107</sup>

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<sup>102</sup> Submission 2019/06630

<sup>103</sup> Ibid.

<sup>104</sup> Submission 2019/07371

<sup>105</sup> Submission 2019/07742

<sup>106</sup> Submission 2019/07760

<sup>107</sup> Submission 2019/05496

## Diagnosis and investigation

*[I]nformation 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.<sup>108</sup>*

*We naively, trusted that our fertility specialist was giving us the best advice, and we did not know that there are multiple causes for infertility, that possibly could have impeded our success.<sup>109</sup>*

Consumers discussed not being informed why they had fertility problems or the underlying causes. For example, from the beginning of the ART journey, C55 felt providers were inadequate at sharing information, particularly regarding idiopathic infertility.<sup>110</sup> C55 described the experience as poor communication on ‘a day to day level’, with no continuity of care. C1, who went through several IVF rounds with nine embryo transfers, felt ‘there was insufficient information available about [the] likelihood of success and no discussion by the doctors’.<sup>111</sup>

C55 stated that while undergoing treatment:

*I was given information that I have since learned was inaccurate, particularly with reference to my ovarian reserve. In addition, no assessment was made of my partner’s options, it was just assumed he was fine. Treatment decisions were made based on this inaccurate and missing info, and were essentially doomed to fail.<sup>112</sup>*

S10, a general practitioner with an interest in fertility treatment, stated before ART begins, several factors must be considered to find the cause of infertility, including untreated infections, autoimmune conditions and hormone imbalances – conditions she feels are poorly considered by ART providers or discussed with patients. Patients may undergo ‘invasive investigations and treatments that can be distressing’ that may be unnecessary if the origin of their infertility was fully investigated initially.<sup>113</sup>

C70 bore evidence to this. After being told by her fertility specialist that ‘we had a very low chance of conceiving given our age’, she consulted S10: ‘As in our case, a simple two weeks of blood tests [showed] low progesterone which is a symptom of endometriosis, and an underactive thyroid which can be treated with medication’. She concluded:

*We feel the clinic would have just continued allowing us to undergo costly cycles with the hope it would be eventually be successful [...] It felt like we were in a system at times and it was business generating money from ongoing IVF treatment with no real focus on investigation or emotional support.<sup>114</sup>*

C78 was distressed when an infertility diagnosis was not clearly explained to her or its future implications:

*[T]here was an issue with my fertility that was discovered during the pre-testing. This was brought up and dismissed with no explanation, causing me to feel very distressed [...] my*

<sup>108</sup> Gorton (n2) 16.

<sup>109</sup> Submission 2019/05188

<sup>110</sup> Public consultation forum, Ballarat, 13 September 2019.

<sup>111</sup> Submission 2019/05042

<sup>112</sup> Submission 2019/06630

<sup>113</sup> Public consultation forum, Melbourne, 11 September 2019.

<sup>114</sup> Submission 2019/07326

*provider took no time to explain what it meant and whether treatment would be impacted.*<sup>115</sup>

C56 had a Mirena (contraceptive device) removed, but her period had still not returned four months later. She was also underweight. Her fertility specialist told her and her husband they were 'young and healthy' and would fall pregnant quickly. C56 was eventually diagnosed with hypothalamic amenorrhea, but she said this diagnosis was never communicated to her. She only became aware of it when she requested her medical records because she was transferring her treatment to another specialist. 'My diagnosis was kept a secret,' she said.<sup>116</sup>

As a partner, C90 believes his potential part in ongoing infertility problems was poorly explored:

*There isn't a very holistic approach/much emphasis put on the causes of infertility especially for the male partner. I had one sperm test after the first consultation but no real interest in my health outside of that apart from the usual 'do you smoke', 'how much do you drink' kind of questions. There was no advice on what we should or shouldn't be eating/drinking, sports to avoid etc. In our case of 'unexplained infertility' as we had our daughter naturally it was put down to [partner's] age of eggs but there was no further investigation into my side. I know as a provider they are mainly interested in the treatments but surely all these things like lifestyle are intrinsically linked and can have profound effects on results. All of these things we researched but there are a lot of conflicting messages on the internet/from friends that it's hard to know which advice to take.*<sup>117</sup>

S11 agrees fertility-specific services for men are 'absent or sub-optimal. The workup [for men] is not as thorough as it should be before an invasive procedure like a testicular biopsy.'<sup>118</sup>

But other fertility specialists caution against over testing in preliminary investigations of infertility because it is often not pragmatic and attracts high costs. Clare Boothroyd, a specialist in infertility and reproductive endocrinology, explained it as 'a bit of a balancing act between inappropriate testing, delaying therapeutic attempt and potentially not having a clear diagnosis at the outset'.<sup>119</sup>

Consumers discussed the pain of being given 'false hope' about having a child. C40 stated her specialist told her she would be pregnant within six months: 'He had no idea I would be such a difficult case but it actually took five years. He shouldn't have said that if he didn't know.'<sup>120</sup>

Despite her low ovarian reserve, C55's specialist told her "No, no, you've still got years and years" ... basically lied to me'.<sup>121</sup> C72 was told: 'As I was young (30) with un-diagnosed infertility, excellent egg count, and no male issues they were overly positive about how quickly it would work. I was told in August 2014 I would be pregnant by Christmas, I was not pregnant until March 2016.'<sup>122</sup>

C77 found herself 'at the mercy of what your consultant chooses to tell you'.<sup>123</sup> Similarly, C89 felt providers' treatment information should be broader from the outset including:

<sup>115</sup> Submission 2019/07688

<sup>116</sup> Public consultation forum, Ballarat, 13 September 2019.

<sup>117</sup> Submission 2019/07766

<sup>118</sup> Public consultation forum, Melbourne, 11 September 2019.

<sup>119</sup> McCormack, A and Scott, S, 2019, 'IVF parents reveal "wasted time" and agony of missed infertility diagnoses', *ABC* <https://www.abc.net.au/news/2019-12-17/ivf-reproduction-parenting-babies-children/11794166> accessed 20 December 2019.

<sup>120</sup> Submission 2019/06122

<sup>121</sup> Public consultation forum, Ballarat, 13 September 2019.

<sup>122</sup> Submission 2019/07371

<sup>123</sup> Submission 2019/07648

- stress and anxiety management
  - dietician advice
  - natural therapy advice
  - data/ scientific information on treatments for mature age women/ couples
  - alternative options to IVF should treatment be successful/unsuccessful – adoption/ foster care options
- This information very well may exist but it is not actively promoted on an ongoing bases [sic] throughout treatments and processes.<sup>124</sup>*

<b>RECOMMENDATIONS 1–4</b>
It is recommended that ART providers, in consultation with ART stakeholders, develop an online 'consumer reference guide to ART', allowing consumers to access consistent and verified information to make better informed choices about their treatment.
In supporting the development of Individual Plans of Support, it is recommended that ART providers better understand the communication needs of their patients, including the frequency of contact, by whom and to whom.
It is recommended that ART providers deliver regular training to all staff employed within an ART clinic, including fertility specialists, nursing, counselling and administrative staff, both on the need for clear, timely communication with ART consumers, and the need for effective communication between clinic staff.
It is recommended that ART providers ensure timely and accurate coordination of information between fertility specialists, nurses and counsellors.

### **Treatment by a different fertility specialist**

Several consumers described their frustration that the specialist they chose to work with was only at the front end of the consultation and treatment planning stage. When it came to actual treatment, consumers recalled arriving for egg retrieval, for example, and were greeted by complete strangers who undertook the procedure. They were not informed this was normal protocol and felt they had been misled. Where many patients choose their provider based on working with a particular specialist, this was a jarring experience during a vulnerable time. Consumers described the experience in the following ways:

*I received a phone call from the nurse the day before the transfer confirming that my specialist was available and would be in attendance to carry out the transfer only to arrive on the day to a stranger advising me that my specialist was away on leave.<sup>125</sup>*

*[M]y chosen FS won't be the one who will do the procedures but more of giving instructions on the treatment plan. It wasn't personal. There was a rotation of qualified doctors who will do the procedures. This was barely mentioned.<sup>126</sup>*

*As I had first met with [the FS], I had expected that all my future consultations would be with him, however, it wasn't until I commenced my treatment that I noticed any further consultations scheduled were dependent on which specialist had completed the egg retrieval procedure in that cycle.<sup>127</sup>*

<sup>124</sup> Submission 2019/07764

<sup>125</sup> Submission 2019/07702

<sup>126</sup> Submission 2019/05377

<sup>127</sup> Submission 2019/06624

C62 noted that her daughter underwent an egg retrieval procedure ‘harvested by someone she had never met, not her specialist that she was paying over 15 thousand dollars to’.<sup>128</sup>

When C37’s partner went for her third round of IVF, she reported that the attending specialist, who was not her regular doctor, was ill-prepared, unfamiliar with her medical history and blamed scar tissue, her C-section and endometriosis for a difficult embryo transfer.<sup>129</sup>

#### RECOMMENDATION 5

It is recommended that where ART services are to be provided by more than one fertility specialist or by different fertility specialists at different stages, this must be disclosed to consumers at the time of developing an Individual Plan of Support.

Rapid changes to the ART industry and workforce have affected how consumers are treated. Regarding counselling, for example, S5 argues:

*Historically, within a small number of ART clinics in Victoria, staff stayed in their roles for many years and had a high level of knowledge and expertise. With an ageing workforce, industry expansion and increased competition, the workforce is changing, and counselling services have been impacted.*<sup>130</sup>

#### Care coordination and follow-up

The inquiry heard throughout submissions and in public consultations about the lack of coordination between ART specialists, nurses and counsellors in the delivery of care. Consumers described their frustration in having to ‘chase’ clinics for results and reports following procedures, or seeking explanations of might have gone wrong when treatments failed:

*[I]t was very difficult being able to contact reception and/or the nursing staff via phone; there were frequent long (5-15mins) wait times and the bulk of updates received during IVF cycles were received via text message.*<sup>131</sup>

*We always had to ask for more information and beg for appointments to see the specialist who never had time to really assist us when things weren’t working [...] The messaging phone system is stressful, the reception staff are often rude, or unaware of their clients. It’s hard to get appointments you desperately need.*<sup>132</sup>

*It can take 20-30 minutes to get through to the nurse during the day. Often times I give up and leave a message.*<sup>133</sup>

*[T]he issue was being able to get in contact with the nurses in a timely fashion, you often had to leave a message and they’d return it when suited them.*<sup>134</sup>

While suffering from severe ovarian hyperstimulation syndrome (OHSS), C25’s fertility specialist

<sup>128</sup> Submission 2019/07032

<sup>129</sup> Submission 2019/05930

<sup>130</sup> Submission 2019/06639

<sup>131</sup> Submission 2019/06624

<sup>132</sup> Submission 2019/07370

<sup>133</sup> Submission 2019/07757

<sup>134</sup> Submission 2019/07692

completed an embryo transfer, which she felt ‘had limited chances of working and a high chance of making me unwell further’.<sup>135</sup> She did not fall pregnant and recalled:

*After the failed embryo transfer no one phoned me to check how I was and no one requested I go in for an appointment to discuss what had happened and how to prevent it and where to go from there. It affected me to the point that I refused all treatment for 6 years.*<sup>136</sup>

When all C51’s stored embryos were destroyed by a freezer malfunction at her provider, she noted the lack of aftercare for such a devastating incident:

*There was no formal apology, there was no offer of counselling or psychological support. We met once with a counsellor as part of the process finishing IVF, but there was no mention of the accident. I still wonder what happened to those 14 embryos, why [provider] swept the accident under the carpet, why our grief wasn’t acknowledged or even cared for [...] there was no communication, other than a letter to offer us a replacement egg cycle.*<sup>137</sup>

C90 and C55 described their frustration in the poor coordination of information given by their clinics:

*[T]he confusion created by miscommunication, not from the information given on treatments but once treatment has commenced, between doctors, nurses, reception and the lab caused huge amounts of stress over the years. It would then be the fallout from a miscommunication between say a doctor and their receptionist that would then have the two of us going mad questioning whether we just didn’t understand something and why they have given us conflicting advice. It was the constant phone calls back and forth having to recheck the type of drugs/treatment needed, confirming whose advice to follow because a nurse has told you one thing and another something completely different.*<sup>138</sup>

*There was broken communication between the doctor and the nursing team, and I had to act as a conduit between them almost constantly.*<sup>139</sup>

C55 recalled the grief of receiving a positive pregnancy result via a phone call, but then a negative result via email from another provider staff member. She was not sure which was correct until a doctor confirmed it was negative. He could not tell her why it was originally positive or how the mix-up had occurred.<sup>140</sup> FS7 acknowledged that many of their patients’ complaints arose from ‘conflicting information being provided by different staff members and this is therefore an area of focus’.<sup>141</sup>

Similar responses were echoed across other consumer experiences when it came to provider care after different treatment stages:

*There needs to be more care whilst in a cycle as well as afterwards. That is where the emotional damage to individuals as well as couples is at its highest. It is a highly charged,*

<sup>135</sup> Submission 2019/05489

<sup>136</sup> Ibid.

<sup>137</sup> Submission 2019/06500

<sup>138</sup> Submission 2019/07766

<sup>139</sup> Submission 2019/06630

<sup>140</sup> Public consultation forum, Ballarat, 13 September 2019.

<sup>141</sup> Submission 2019/06547

*emotional time and these women are often full of artificial hormones from all of the medication and this needs to be taken into consideration. Often they only want to be heard, there isn't necessarily a solution that needs to be provided.*<sup>142</sup>

*Absolutely no support after any treatment. No follow up.*<sup>143</sup>

*I was totally ignored. No follow up. No visits from anyone whatsoever.*<sup>144</sup>

After an egg freezing procedure where C7 was left with permanent damage to her left ovary, she stated: 'NO one from [the provider] nor my specialist doctor who works for [the provider] ever followed up with me'.<sup>145</sup>

Accessing emergency care including after-hours assistance is listed in the *Code of Practice for Assisted Reproductive Technology Units*, which states:

*The ART Unit must ensure access to emergency care. It must provide evidence of implementation and review of policies and procedures on emergency physical and psychological care and ensure patients and their partners receive information on how to access emergency care including out of normal hours.*<sup>146</sup>

However, consumers expressed concerns about how to contact clinic staff for after-hours or emergency assistance. For example, when C59 suffered OHSS following an egg retrieval, she stated:

*I was unable to contact my provider outside of business hours and was not provided with an out of hours nurse contact. When I left a message with nurses the following morning I was not contacted for over three hours. Nurses take a significant period of time to reply to calls at this clinic.*<sup>147</sup>

Currently, only four of the 10 registered Victorian ART clinics provide clear online instructions regarding after-hours assistance.

#### **RECOMMENDATION 6**

It is recommended that ART providers give written information to consumers at the beginning of treatment regarding how and where to access emergency care out of hours, including telephone numbers and contact names.

Where and how ART patients receive news about the success or failure of tests and procedures was a consistent theme throughout the inquiry. For example, some consumers described an extremely painful part of the process of egg retrieval was the environment in which it was performed. They were not told their partners could not accompany them at any stage of the process until they got to the clinic.<sup>148</sup>

<sup>142</sup> Submission 2019/07586

<sup>143</sup> Submission 2019/05564

<sup>144</sup> Submission 2019/05895

<sup>145</sup> Submission 2019/05083

<sup>146</sup> Fertility Society of Australia (n84) 18.

<sup>147</sup> Submission 2019/06737

<sup>148</sup> Submission 2019/06642

After the procedure, they described being in a multi-bed recovery room with other women who had also undergone the procedure, with only curtains for privacy. Over time they would hear the results of other women's procedures and how many eggs were retrieved.<sup>149</sup> Conversely, when they received their test results, they knew other women could hear. If it was a disappointing personal result, it was doubly painful due to the lack of privacy and being able to hear about other women's successful results.

C54 described the lack of privacy and the effect of being in the recovery room after finding out her egg retrieval procedure was unsuccessful:

*With [ART provider], they informed me whilst in the recovery area at [day surgery centre], in front of the other women who had also undergone the procedure (likewise I would also hear the outcome of their procedures, which caused me further distress given the better egg retrieval results being received by other women compared to myself)[...] I got to overhear their results. I was numb ... I let myself out early, I couldn't stay there.*<sup>150</sup>

Several consumers raised the impact of another small but significant issue regarding communication. When phoned by a clinic and given bad news, such as that none of their embryos were viable, clinic staff did not consider the patient's current environment. C56 described being at work, in a meeting with clients and receiving a call from her provider clinic. She recalls being told casually, 'Sorry, looks like you've been unsuccessful'.<sup>151</sup> She burst into tears, creating an uncomfortable professional moment for a very private issue. C58 described the shock of receiving bad news while driving as a 'terrible experience'.<sup>152</sup>

As a teacher, C29 struggled when it came to communicating with clinic nurses, saying: 'The nurses were not flexible in making contact, I was a teacher at the time and answering calls during class time was not an option. It was not always easy to get on to them when I could.'<sup>153</sup>

As a partner, C90 discussed the toll of receiving calls at unpredictable times:

*At the end of a cycle if there is any communication it's a call to [partner] from the nurse to talk about the results and the next round to go on and an email reminding you about payment, I think the aftercare of these providers can be a lot better especially as this is one of the most emotional parts of the process. These calls are also normally in the middle of a work day and completely throw your world upside down.*<sup>154</sup>

Recalling ART in a different era, C68 reinforced the importance of having some control over your environment when receiving news:

*Our treatment was 20 years ago (pre mobiles and internet available to all). Maybe that was easier? I recall being called on a landline for outcomes of cycle results. I think I had more*

<sup>149</sup> Public consultation forum, Ballarat, 13 September 2019.

<sup>150</sup> Submission 2019/06624; Public consultation forum, Ballarat, 13 September 2019.

<sup>151</sup> Public consultation forum, Ballarat, 13 September 2019.

<sup>152</sup> Ibid.

<sup>153</sup> Submission 2019/05588

<sup>154</sup> Submission 2019/07766

*control over where I was when I received any end of cycle news (I could leave work early and be at home with my husband).<sup>155</sup>*

C79 suggested a more modern solution:

*[A]llow people to opt in if they'd prefer to get negative pregnancy results sent to them on the app, so they don't need to speak to someone, also provide optional counselling to anyone who has a negative pregnancy test and or miscarriage. I had to call to request counselling after my miscarriage.<sup>156</sup>*

## 5.2 Advertising

<b>SUMMARY OF FINDINGS 5-6</b>
Providers, while complying with the Reproductive Technology Accreditation Committee Code of Practice, advertise 'success rates' in a way that makes comparison between providers difficult for consumers.
ART provider advertising and promotional material can be difficult to interpret, potentially creating confusion and, in some cases, misleading consumers.

This inquiry asked consumers if they relied on advertising from ART providers before accessing services. When choosing a provider, 54 per cent of consumers stated they did not rely on advertising:

*It wasn't important as we were only looking into one goal which is to have a baby.<sup>157</sup>*

*...did not see any – was too distressed by [male infertility] diagnosis to look for advertising.<sup>158</sup>*

*Not important.<sup>159</sup>*

*Ads were '50%' important.<sup>160</sup>*

A total of 26 per cent of submitters did rely on advertising when choosing their provider/clinic, but half of those stated it was not an important element in their decision-making process.

While not stating advertising to be an important element of decision making, this inquiry found provider advertising and claims can be difficult to interpret, potentially creating confusion for consumers. C71 commented:

*I wasn't too sure why there were so many ads and the competitive nature alarmed me. This is a highly clinical and health related issue that should not be a competitive process, or such a lucrative business. It takes advantage of desperate infertile and same sex*

<sup>155</sup> Submission 2019/07321

<sup>156</sup> Submission 2019/07692

<sup>157</sup> Submission 2019/05377

<sup>158</sup> Submission 2019/06026

<sup>159</sup> Submission 2019/06284

<sup>160</sup> Submission 2019/06150

*couples.*<sup>161</sup>

Most clinics promote their accessibility and/or affordability, while others highlight innovative techniques, global standing and expertise in fertility. Some examples include:

*Let us change your world without costing the Earth.*<sup>162</sup>

*Recognised as an innovator, we are currently listed at number 18 on the Australian Financial Review's Top 50 Most Innovative Companies List (2018).*<sup>163</sup>

Ten per cent of consumers responding to this inquiry stated reputation was their primary influence when picking a provider/clinic:

*Monash created the first IVF baby so we felt as though that meant we would be in good, experienced hands.*<sup>164</sup>

*The reason for choosing the second clinic we attended (Ballarat IVF) was due to the strong reputation of its founder and director.*<sup>165</sup>

*I saw the wonderful results and thought we would get the same.*<sup>166</sup>

Most consumers chose providers by relying on referrals from their GP or specialist:

*We were 100% guided by our GP.*<sup>167</sup>

*Trusted my GP recommendation.*<sup>168</sup>

*Was always going to go with the specialist I was referred to.*<sup>169</sup>

## Success rates

In 2016 the Australian Competition and Consumer Commission (ACCC) completed an investigation into how the ART industry reported and advertised success rates. The ACCC's investigation of providers' website advertising practices showed 'some made success-rate comparisons without adequate disclosure about, or qualification of, the nature of the data or graphics used to make the claim'.<sup>170</sup> The ACCC found examples of websites using medically technical language that could confuse consumers, and some clinics used clinical pregnancy rate data to compare their success rates, reflecting the clinic's success in creating pregnancies rather than live births.<sup>171</sup>

The ACCC review resulted in some changes by ART providers in how they market their services, but advertising can still be confusing for consumers. As part of ART clinics' RTAC accreditation, providers must adhere to clause 2.2.2 of the RTAC Code, which states: 'Information presented in

<sup>161</sup> Submission 2019/07370

<sup>162</sup> Adora Fertility, <https://www.adorafertility.com.au/> accessed 29 November 2019.

<sup>163</sup> Genea, 'Our History', <https://www.genea.com.au/success-rates/history> accessed 29 November 2019.

<sup>164</sup> Submission 2019/05086

<sup>165</sup> Submission 2019/06624

<sup>166</sup> Submission 2019/05438

<sup>167</sup> Submission 2019/05588

<sup>168</sup> Submission 2019/05377

<sup>169</sup> Submission 2019/07198

<sup>170</sup> ACCC, 2016, 'Media Release: IVF "success rate" claims under the microscope' <https://www.accc.gov.au/media-release/ivf-success-rate-claims-under-the-microscope> accessed 7 October 2019.

<sup>171</sup> Ibid.

the public domain must be in language that can be understood by the public and ensure the overall conclusion is not misleading in any way.<sup>172</sup> The RTAC Code stipulates success rates must:

- i) be divided by age
- ii) specify live birth rates for fresh and frozen embryo transfers separately. Use of clinical pregnancy rates in advertised success rates may be permissible provided that the live birth rates are also available for comparison in the same communication
- iii) be accompanied with the following clarifying information: the time period during which the advertised data was collected and unambiguous details of the population group from which they are derived
- iv) be accompanied by a qualifying statement of broad factors that affect success rates e.g. age, weight, and cause of infertility, and that individual results will vary with individual circumstances
- v) be accompanied by a statement that not every treatment cycle will result in an egg collection, an embryo transfer or embryo cryopreservation
- vi) be accompanied by a reference and/or hyperlink to the FSA statement on “Interpreting Pregnancy Rates: a consumer guide”
- vii) ensure that any clarification, qualifying statement or reference be clear and prominent and not hidden in a disclaimer.<sup>173</sup>

All ART providers have a reporting criterion under the RTAC Code to provide ANZARD with required data regarding cycles, treatments and live birth rates. While this is an annual reporting requirement, the ANZARD report is currently two years behind, with its September 2019 report presenting 2017 findings.

In general, the inquiry found ART providers’ promotional information could be misleading. An analysis of provider websites indicates that not all providers publish their success rates online, but those that do, present this information in very different ways; so much so, that it renders meaningful comparison almost impossible.

Both ANZARD and VARTA acknowledge the difficulty of comparing success rates across providers. ANZARD cautions comparing clinical pregnancy and live delivery rates following cleavage state embryo and blastocyst transfer, stating: ‘Patient characteristics, prognosis and treatment strategies (e.g. PGT) may be different between these groups.’<sup>174</sup> VARTA warns that data presented in its annual reports cannot be used to compare success rates:

*ART clinics in Victoria practise differently in terms of patient selection and use of laboratory techniques. When considering clinic success rates, personal circumstances and medical history must be considered in estimating an individual’s chance of having a baby. The age of the woman treated, the stage of the embryo transferred (day 2-3 stage embryo or day 5-6 blastocyst), the use of fresh and/or thawed embryos, the type of infertility problem, lifestyle of the women treated, population of women receiving treatment at a particular clinic and other factors will have an impact on success rates. The information on intention to treat is not available in the VARTA data. It is not correct to compare the efficacy between ART procedures since cancelled cycles and other factors are not taken into consideration. Therefore, the data reported here only presents number of cycles, type of*

<sup>172</sup> Fertility Society of Australia (n84) 16.

<sup>173</sup> Ibid.

<sup>174</sup> Newman et al (n11) 16.

*ART procedures, number of pregnancies and number of births, not the success rates.*<sup>175</sup>

In practice, how RTAC stipulates that success rates should be published still gives ART clinics the choice to determine from which treatment population groups they derive their data, alongside inconsistent details about the kinds of treatments included and the periods those data represent.

Consumers who made submissions to this inquiry expressed confusion when attempting to compare various providers' success rates and interpreting them in a meaningful way:

*Clearer information about chance of success would have been beneficial. I still don't truly know our chances of falling pregnant and I do wonder if we have a false sense of hope.*<sup>176</sup>

*We understand that IVF is not an exact science so 'live birth' rates based on our exact demographics may be difficult. However, there is a large degree of reticence on behalf of providers to outline probabilities at each step. We are tertiary educated in mathematics and understand statistics to a high degree and have found the lack of disclosure frustrating – we have sought external publications (VARTA) to assist us in calculating our own statistics.*<sup>177</sup>

*[I]t was impossible to get info on individual consultant success rates etc... We looked closely at the carefully put together graphs on pregnancy rates. [W]e didn't realise it meant pregnancy rates, not live birth rates [...] the info I found ultimately to be quite misleading.*<sup>178</sup>

*I think the data presented on success rates and number of cycles could have been presented in a more personalized way to be relevant for someone with my history. For example after my first stimulated cycle which was unsuccessful (most the eggs released prior to retrieval) I was told the first cycle is always a test run. Yet I felt like I had been given an expectation that I would only require one cycle. No one mentioned it was only a 'test run' prior.*<sup>179</sup>

Other consumers commented on the need for more transparent success rates. C45 felt that providers should advertise success rates by 'age and medical factors'.<sup>180</sup> C39 recommended even providing 'failure rates' rather than success rates.<sup>181</sup> C67 stated she wanted to see an independent body do a comparison of success rates, a review of additional services and their usefulness and cost.<sup>182</sup>

Today VARTA monitors ART providers' websites for manipulative or fraudulent testimonials or claims. A national Parliamentary Committee is currently deliberating whether to give the Australian Institute of Health and Welfare the authority to collect data and report on the success rates of each ART clinic.<sup>183</sup> The Australian and New Zealand Society of Reproductive Endocrinology and Infertility has opposed this proposal.

As a recent ABC analysis of the 2017 ANZARD report noted:

<sup>175</sup> VARTA, 2019, 'Annual Report 2019', Melbourne, 25.

<sup>176</sup> Submission 2019/07697

<sup>177</sup> Submission 2019/07757

<sup>178</sup> Submission 2019/07648

<sup>179</sup> Submission 2019/07371

<sup>180</sup> Submission 2019/06284

<sup>181</sup> Submission 2019/06026

<sup>182</sup> Submission 2019/07260

<sup>183</sup> Griff, S, 2019, 'People seeking IVF are flying blind. Success rates should be public', *The Guardian* <https://www.theguardian.com/commentisfree/2019/apr/01/people-seeking-ivf-are-flying-blind-success-rates-should-be-public> accessed 3 December 2019.

*There have been growing calls, particularly in recent years, that IVF clinics should publish their data [...] The fertility industry says the solution isn't really as straightforward as just publishing the data, there's a few reasons why clinics might have varying rates of success. So that might depend on the demographics of the women they see, they might be older and therefore their success will be lower, or they might only accept second referrals and so on. And so they are kind of concerned that just publishing that data would in some ways create a bit of a league table that could come with its own problems.<sup>184</sup>*

The ACCC review, the Gorton Review and VARTA have all raised concerns with the ART industry's use of advertising and 'success rates'. The Gorton Review reported 'significant variations in clinical practice and outcomes between clinics'<sup>185</sup> and has 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'.<sup>186</sup>

#### **RECOMMENDATION 7**

The findings of this inquiry support Recommendations 26 and 27 of the Gorton Review regarding compliance standards for published public information forming part of ART providers' registration.

## 5.3 Counselling

#### **SUMMARY OF FINDINGS 7-9**

Mandatory counselling for potential ART consumers does not provide a therapeutic and supportive role and is often seen as a 'tick box' exercise.

Currently, supportive counselling is not always offered or proactively encouraged by ART providers throughout treatment. If consumers do not seek out additional counselling beyond what is mandated in legislation, they are often without the support needed.

The timing of counselling currently does not provide the emotional and psychological support consumers need. Consumers want supportive counselling provided throughout their treatment, particularly following a failed cycle or procedure, and at the end of treatment.

*[O]ur medical needs have been well cared for. Our emotional needs have not been addressed at all.<sup>187</sup>*

*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.<sup>188</sup>*

The Gorton Review states 'the health and wellbeing, including emotional and mental health, of

<sup>184</sup> ABC, On Health Report with Dr Norman Swan, 2019, 'IVF improving, but comparing clinics a challenge' <https://www.abc.net.au/radionational/programs/healthreport/ivf-improving-but-comparing-clinics-a-challenge/11515798> accessed 14 October 2019.

<sup>185</sup> Gorton (n2) 15.

<sup>186</sup> Ibid, 43.

<sup>187</sup> Submission 2019/07697

<sup>188</sup> Gorton (n2) 16.

persons undergoing treatment, donors and surrogates must be protected'.<sup>189</sup> The NHMRC guidelines also state:

*Clinics must provide accessible counselling services from professionals with appropriate training, skills, experience and competency to support individuals and couples in making decisions about their treatment, before, during and after the procedures. Clinics should actively encourage participation and keep a record of participation. The counselling services should:*

- *provide an opportunity to discuss and explore issues [and]*
- *provide personal and emotional support for the individual or couple, including help in dealing with adverse or undesired results.*<sup>190</sup>

Consumer submissions to this inquiry made it clear that many ART patients do not feel supported by providers throughout their treatment journey. Table 7 shows most consumers described their counselling experience as unhelpful or a 'tick-box' process.

**Table 7: Responses to counselling by ART consumers**

Response to counselling/support	Number of consumers	Percentage
Unhelpful / a 'tick box' process	39	42%
Unstated	21	23%
Very helpful	13	14%
Somewhat helpful	10	10.5%
Should be ongoing through treatment	6	6.5%
Should be independent	2	2%
Never received any	1	1%
Cannot remember	1	1%
<b>Total</b>	<b>93</b>	<b>100%</b>

### Mandatory counselling

*When undergoing IVF, counselling appears to be a hurdle to pass, not a support for the patient.*<sup>191</sup>

*I feel that it should be a requirement for all IVF clinics to offer counselling as part of their services. It is extremely expensive and difficult to get external counsellors and many of them do not have an adequate understanding of the IVF process and treating patients who are undergoing IVF. This has been the most challenging experience of my life and has had a huge impact on my mental and physical well-being, my career, my relationships and future planning.*<sup>192</sup>

Victorian legislation currently mandates that an individual or couple seeking ART must undergo at least one session of mandatory counselling, with a specialised counsellor who provides services on behalf of a registered ART provider.

<sup>189</sup> Ibid, 28.

<sup>190</sup> National Health and Medical Research Council (n87) 34.

<sup>191</sup> Submission 2019/06737

<sup>192</sup> Submission 2019/07697

The NHMRC guidelines state 'ART plays an important role in assisting people to grow their families and reduce the burden of psychological distress associated with infertility'.<sup>193</sup> But most consumers reported that their overall experience of the mandatory counselling session was largely unhelpful, commenting:

*I got the impression that this session was used as a means of ensuring that our intention to use IVF services was legitimate; that both of us consented to the treatment. In terms of counselling of a more wellbeing/psychological/emotional focus, none was provided. This was something I had to source for myself; even after the surgery I underwent. What has been difficult is seeking out the support of a counsellor with knowledge of IVF and prior experience of working with IVF patients and their partners; yet who is not aligned to a particular clinic.*<sup>194</sup>

*I would describe this more as a legal implications and consequences session however. It was explained we could have counselling whenever we wanted going forward but at an additional cost.*<sup>195</sup>

*Wasn't helpful or unhelpful. Just one more thing to tick off.*<sup>196</sup>

For C58, seeking ART to screen out a genetic disease in her partner's family, felt counselling for genetic selection was 'sucking eggs for us'.<sup>197</sup> C23 and C66 called it 'useless'.<sup>198</sup>

Despite the criticisms of the mandatory counselling session, that did not equate to consumers wanting to remove counselling from the ART protocol. Rather, a clear message from consumers is that most want more counselling and better support throughout their treatment journey. The content of this needs to be changed away from a forced, prescriptive, inflexible, short session undertaken before treatment when patients have little idea what they may go through in their wish to have a baby. For example, C56 commented that her mandatory counselling session was 'bullshit'. She said that her marriage started to break down during ART and that 'no-one prepares you for this'.<sup>199</sup>

ART providers' comments to the inquiry equally showed their frustrations with the current system. FS20 argued that mandatory counselling is wrong;<sup>200</sup> FS21 described it as '[p]ure discrimination, making patients jump through hoops'.<sup>201</sup> FS21 explained the current arrangement as ultimately damaging:

*We are our own worst enemy, we don't counsel patients between cycles. Patients go through cycle after cycle without seeing their clinician. Counselling was introduced in the 80s to stop doctors pushing patients into IVF treatment. Now it's a block in accessing treatment.*<sup>202</sup>

<sup>193</sup> National Health and Medical Research Council (n87) 13.

<sup>194</sup> Submission 2019/06624

<sup>195</sup> Submission 2019/07326

<sup>196</sup> Submission 2019/05438

<sup>197</sup> Submission 2019/06646

<sup>198</sup> Submissions 2019/05439 and 2019/07259.

<sup>199</sup> Public consultation forum, Ballarat, 13 September 2019.

<sup>200</sup> Provider consultation forum, Melbourne, 12 September 2019.

<sup>201</sup> Ibid.

<sup>202</sup> Ibid.

FS3 described his understanding of mandatory counselling:

*As mandated by Government all patients undertake extensive counselling not only with a medical practitioner but also a dedicated counsellor to discuss all the implications associated with IVF and so that patients have a realistic expectation of the chance of success.*<sup>203</sup>

The NHMRC guidelines state:

*To support their decision-making, individuals and couples seeking ART are entitled to the provision of 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.*<sup>204</sup>

The ART Act requires counsellors to speak to prospective ART patients ‘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’,<sup>205</sup> meaning the session can seem more a legal process than a supportive one. The Gorton Review concluded ‘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’.<sup>206</sup>

Over one mandatory counselling session, ART counsellors are expected to begin a relationship with patients, giving them information that is ‘prescriptive and inflexible’,<sup>207</sup> and consider every possible treatment scenario and potential risk. This does not encourage the establishment of a therapeutic relationship.

This inquiry heard of the need for counselling at different stages of the ART journey. The HCC supports the Gorton Review’s recommendations to reconsider the current mandatory counselling requirement in Victoria and remove:

*... 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.*<sup>208</sup>

There is also considerable difference between clinics’ approaches to counselling, which can confuse consumers. After describing her mandatory counselling experience with one provider as a ‘cookie cutter tick the box’ exercise, C32 described her subsequent experience with another provider as ‘an integral part of my journey and managing the bumps as they came along and then

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<sup>203</sup> Submission 2019/05709

<sup>204</sup> National Health and Medical Research Council (n87) 25.

<sup>205</sup> Gorton (n2) 46.

<sup>206</sup> Ibid, xiv.

<sup>207</sup> Ibid, xiii.

<sup>208</sup> Ibid, xv.

also sorting out counseling [*sic*] for my known donor and myself to explore the implications of that arrangement. It's been amazing and really helpful to my journey.<sup>209</sup>

Some clinics use group counselling sessions, which arguably devalues individual consumers' experience and concerns. Although she found the mandatory session 'informative', C38 described the session as including her and 'at least 30 people'.<sup>210</sup> C55 described a similar depersonalised counselling experience: 'We were in a room with 30 other couples, and nothing about this session could have been said to amount to counselling. It was a chalk and talk session.'<sup>211</sup> This demonstrates individual circumstances being ignored, where mandatory group counselling largely comprises a didactic, one-way information session.

An LGBTQ consumer noted that she felt '[i]nitial counselling for a gay couple is intrusive, however we understand it's the law'.<sup>212</sup> A transgender consumer commented on the lack of ART counsellors' experience in dealing with queer identities:

*The counselors [*sic*] I was required to see invariably did not have the (legal/policy) information to be able to accurately assess my ability to give consent, or to answer my questions. I went through as a single transgender person, assigned female at birth... The first counselor [*sic*] I saw interrogated me about whether or not I was legally in a relationship for forty minutes (not an exaggeration) when the answer can be found by asking four questions: do you live together, do you share finances, are you in a relationship, do others consider you to be in a codependent relationship?; and couldn't answer my questions about the rights of the child on the consent form they were asking me to sign.<sup>213</sup>*

## Supportive counselling

*I never expected my going through IVF would result in a lengthy hospitalisation, surgery and the removal of one of my ovaries, as well as the workplace difficulties I experienced following my return to work. The shock, pain and grief of having experienced these events I have struggled with every day since and has hugely impacted my psychological, emotional and financial wellbeing.<sup>214</sup>*

*[C]ounselling should be a weekly/ fortnightly compulsory activity for couples both during and after the IVF process [...] Counselling is needed much more throughout the process, after a process and for 6-12 months after completing your final treatment.<sup>215</sup>*

Internationally, ART is acknowledged as an unusually stressful medical experience for patients and partners and, without the right support, it can leave a traumatic legacy. In the UK, the HFEA states, 'how patients are treated as individuals counts more than anything else for how they view their experiences during and after fertility treatment'.<sup>216</sup>

The NHMRC guidelines state:

<sup>209</sup> Submission 2019/05717

<sup>210</sup> Submission 2019/05961

<sup>211</sup> Submission 2019/06630

<sup>212</sup> Submission 2019/07370

<sup>213</sup> Submission 2019/07222

<sup>214</sup> Submission 2019/06624

<sup>215</sup> Submission 2019/07764

<sup>216</sup> Human Fertilisation and Embryology Authority (n51) 3.

*ART involves complex decision-making and individuals and couples may find it an emotional and stressful experience. Clinics have an ongoing responsibility to provide access to counselling services to support the individuals involved and their decision-making. The types of counselling required may change throughout the treatment process or between procedures.<sup>217</sup>*

However from consumer submissions it is apparent that the counselling and support involved in ART does not meet consumers' needs.

Providers indicated they provide supportive counselling as needed:

*Mandatory counselling is provided as per the legal requirements. Our counsellors are very experienced and thorough. Patients can make supportive counselling appointments if they need which they are made aware of.<sup>218</sup>*

*We offer mandatory and supportive counselling for all our patients. Our clinic has been a leader with many presentations and publications in this area.<sup>219</sup>*

*Supportive counselling and genetic counselling are provided as required by the individual patient's needs. This can be initiated by the patient/partner or family member/support person, by a staff member or by their treating specialist.<sup>220</sup>*

*[O]ngoing counselling support provided for patients who need or request additional support (and dr/nurse, admin request referrals for patients if they feel extra care needed) at no cost specialised sessions [including] single mums, same sex couples, surrogacy, donor egg and sperm and embryo groups, bereavement, relationship sessions, resilience sessions, additional programs.<sup>221</sup>*

*Patients are also able to request supportive counselling during treatment or following treatment. Adora Fertility values this opportunity to discuss with the clients the social and emotional aspects of treatment.<sup>222</sup>*

The Victorian Infertility Counsellors Group (VICG) comprises counsellors employed by ART clinics in Victoria and fertility counsellors in private practice contracted by ART providers. In their submission to this inquiry, VICG recommended much broader counselling services be offered to ART patients and proposed reforms to the current system, including:

- consistency of practice between clinics to ensure the highest standard of counselling services
- counselling support should be provided at every stage of ART including before treatment, during, in between treatment cycles and post treatment
- counselling should not be restricted to in-cycle only or limited to certain numbers of sessions if IVF/fertility relevant.<sup>223</sup>

<sup>217</sup> National Health and Medical Research Council (n87) 34.

<sup>218</sup> Submission 2019/05735

<sup>219</sup> Submission 2019/05736

<sup>220</sup> Submission 2019/06547

<sup>221</sup> Submission 2019/05664

<sup>222</sup> Submission 2019/06631

<sup>223</sup> Submission 2019/06573

Current access to ongoing, supportive counselling by ART providers varies depending on the provider. S5 noted, 'Following treatment, patients may believe that the ART clinic will follow up with them personally as opposed to them needing to take the initiative to ask for support from counsellors. Proactive follow-up of patients after treatment varies.'<sup>224</sup> C75 commented the counselling she and her partner received was generic, it stopped as soon as the treatment did and 'during treatment no one checked-in, to see how we were going now, how we were going at the time; no-one'.<sup>225</sup>

Consumers who did access additional supportive counselling felt it was valuable, adding weight to its potential value:

*My husband and I did access the counselling service which was very helpful. This was very separate to the specialist. He never recommended this service or brought up the topic. I don't know if he even knew. It was excellent. They were highly skilled it really helped us in a difficult time.*<sup>226</sup>

C50 noted she was made aware of the option of counselling at any time along the way, saying: 'I took them up on this several times and was always very happy with the quality of the session.'<sup>227</sup>

There is always the option of patients accessing non-provider counselling, but this attracts further costs for consumers. While rebates are available for Non-Directive Pregnancy Support Counselling Services for up to three sessions per patient, this is predicated on the patient being pregnant or having been pregnant in the preceding 12 months. It does not support individuals or couples who may be going through ART cycles without falling pregnant. Access may also be available through a Medicare-funded mental health treatment plan via a GP, entitling Victorians to 10 subsidised sessions with a counsellor or psychologist. But this still attracts some cost, and it might be challenging to find counsellors with infertility expertise.

It is clear how difficult and complex the tasks undertaken by ART counsellors have become. S5 commented:

*Fertility specialists may not always understand or value the speciality knowledge that infertility counsellors have regarding grief and loss, managing mood and relationship issues, and assisting patients to explore local donor options. Some patients exploring donor treatment report that their fertility specialist recommended an overseas donor program and advised against speaking with an infertility counsellor, as this was 'a waste of time'.*<sup>228</sup>

The importance of ongoing, specialised psychological support for ART patients and partners is essential.

## Timing of counselling

Several consumers made the point that counselling would be more useful after a failed ART cycle or procedure or when deciding to discontinue treatment after it was ultimately unsuccessful: '[I]

<sup>224</sup> Submission 2019/06639

<sup>225</sup> Public consultation forum, Melbourne, 11 September 2019.

<sup>226</sup> Submission 2019/07371

<sup>227</sup> Submission 2019/06454

<sup>228</sup> Submission 2019/06639

would have preferred to have paid for this service when we need it or after a failed cycle. And with a counsellor of my choice.<sup>229</sup> Others noted that a counselling session before undertaking ART was largely ineffectual because they did not know what treatment would be like and, for some, how distressing and time consuming it could be.

The unpredictability of ART means it is difficult for consumers to estimate what their support needs may be. When during treatment, her embryos were accidentally thawed and all were lost, C51 noted: 'We should have been provided grief counselling for the loss of our embryos.'<sup>230</sup>

C80 described the psychological toll of ART and the need for better support during, not before, treatment:

*We had to seek counselling external to our IVF clinic and we have had to discontinue this due to the additional financial pressure and time away from work [...] I had already been seeing this counsellor prior to the commencement of IVF due to the emotional stress caused by our infertility. We have one brief, joint appointment as part of the IVF process. This was in no way adequate to prepare ourselves for the IVF process.'*<sup>231</sup>

### Other forms of provider support

Apart from counselling, C73 summarised a common sentiment from consumers to this inquiry about feeling generally supported by their provider: 'Medically, extremely well. Socially/emotionally, extremely poorly.' He added, 'We were told about the IVF procedure, and felt well-informed (about the medical aspects) when beginning treatment. We were not told, however, about the social/emotional aspects of treatment, for either the birthing partner or the non-birthing partner.'<sup>232</sup>

With her provider, C55 felt 'there was a strong sense that all the doctors hated their jobs' and said she did not feel she 'treated as a person'.<sup>233</sup> Echoing the feeling of her ART experience being impersonal, C92 noted:

*... more options would have been appreciated and more emotional support from the clinic. It definitely felt like I was just another patient on the books and my concerns and fears – particularly around needles, internal examinations and the embryo transfers weren't heard or taken seriously. It was only after my 8 week postnatal check up with my doctor that he said I could be sedated during a transfer. I wish I knew this prior as I found this process terrifying and extremely painful.'*<sup>234</sup>

While C72 generally praised the communication and support she experienced, she felt specialists had different priorities:

*I think the specialists in general probably wanted to avoid people crying in their office. I never once got asked about my mental health or how I was coping by any specialists. Sure,*

<sup>229</sup> Submission 2019/05582

<sup>230</sup> Submission 2019/06500

<sup>231</sup> Submission 2019/07697

<sup>232</sup> Submission 2019/07581

<sup>233</sup> Public consultation forum, Ballarat, 13 September 2019.

<sup>234</sup> Submission 2019/07816

*they were sympathetic when a treatment didn't work but they didn't really want to talk about anything other than next steps.*<sup>235</sup>

Clinic nurses generally have the most patient contact and provide emotional support during treatment cycles. Nurses also work in close contact with the fertility specialist, whereas counsellors are usually not involved in this aspect of the treatment journey, unless the patient decides to independently seek out counselling as an adjunct to their treatment: 'The siloed framework from which counselling staff operate in some clinics may leave patients feeling that the support services provided are inadequate.'<sup>236</sup>

C54 felt she received most emotional support from clinic nurses:

*Something I have reflected on a lot lately has been the dominance of male medical staff in making the decisions [regarding] my IVF treatment, hospitalisation and surgery, despite the majority of on-the-ground support being provided by female nursing staff. In retrospect, I would've appreciated had one of the nursing staff been present during my specialist consultations. I think this would have helped ensure better communication and sense of support for IVF patients.*<sup>237</sup>

C69 agreed:

*The nurses employed by the ART provider are usually the first point of contact and I have found most of them to be great at providing information, likely courses of action/treatment/medication options, how to administer medications and their common side effects and the details on 'what to expect next'. They also provide support, and I have found at times I prefer to discuss options with them before discussing with my doctor.*<sup>238</sup>

Others related their experience of feeling completely unsupported by provider staff, especially following receiving bad news. In one example, C22 remembered:

*I was in the waiting room, waiting for a very unwanted blood test to confirm that I wasn't pregnant and was hysterically crying, not one member of staff looked at me or even offered me a tissue. Even months later the doctor hasn't tried to make contact, unless you're willing to pay the \$400 fee to make an appointment so he can tell you the obvious, the round failed [...] I felt very alone, and just like another number in their book.*<sup>239</sup>

## Access to counselling

Despite ART clinics saying they provide mandatory and ongoing counselling as needed to patients, infertility and miscarriage support group Pink Elephants describe a different situation:

*ART clinics tend to only provide counselling while women/couples are in cycle, and even then it is hard to get in to see someone. Many of the women we support cite inadequate*

<sup>235</sup> Submission 2019/07371

<sup>236</sup> Submission 2019/06639

<sup>237</sup> Submission 2019/06624

<sup>238</sup> Submission 2019/07326

<sup>239</sup> Submission 2019/05438

*counselling services offered through their clinics, particularly in terms of failed cycles and miscarriages. Hence, so many of them seek out alternative support such as ours.*<sup>240</sup>

Echoed by several consumers, access to timely counselling is unpredictable in many clinics. S5 noted an 'increase in the waiting time for patients to receive counselling in some ART clinics. Having counsellors available on call for urgent appointments is optimal.'<sup>241</sup>

C40 commented that access for support when needed was crucial: 'I had access to counselling during and after failed cycles but it was very hard to get into as I often needed it in an emergency situation when I just wasn't coping.'<sup>242</sup> She commented that counsellors were stretched too thin, suggesting providers could establish a voucher system for patients to see external counsellors.<sup>243</sup>

As noted above, workforce changes in the ART industry have had a particularly negative impact on counselling services, through:

- decreased levels of expertise within teams as new and inexperienced staff begin working as counsellors
- cutbacks in counselling staff and hours to reduce clinics' operating expenses among larger clinics in Victoria and interstate
- an increase in group counselling sessions at certain clinics, which may not suit everyone.<sup>244</sup>

S5 argues that changes in the ART industry as it has expanded means:

*There is a distinction between the counselling currently mandated by the ART Act and supportive counselling for emotional difficulties that may arise before, during and after ART treatment. While counselling is not defined in the ART Act and matters to be covered are prescribed in the Regulations, the methodology rests with clinics. Where cuts to clinics' counselling budgets have occurred, there may be diminished patient access to supportive counselling, which can be just as, or more important than, the mandated counselling in preparation for treatment.*<sup>245</sup>

Expansion of the ART industry has also created inconsistencies between what the legislation defines as an 'appropriately qualified counsellor'. S5 highlighted there are 'no minimum work experience requirements, specific training requirements or professional development requirements for counsellors who work in this specialised area' except that membership of the Australian and New Zealand Infertility Counsellors Association (ANZICA) is required for counsellors employed within clinics. S5 notes, 'support for counsellors to attend professional development opportunities through ANZICA is variable and numbers of counsellors attending professional development events has dwindled'.<sup>246</sup>

Some other problems identified in the counselling arm of the ART industry include:

<sup>240</sup> Submission 2019/07125

<sup>241</sup> Submission 2019/06639; see also Submission 2019/07125

<sup>242</sup> Submission 2019/06122

<sup>243</sup> Ibid.

<sup>244</sup> Submission 2019/06639

<sup>245</sup> Ibid.

<sup>246</sup> Ibid.

- The quality of on-the-job training for infertility counsellors can vary enormously between clinics.
- Patient care, and the reputation of the counselling team, can be compromised when patients are required to see more than one counsellor due to the mandatory components of donor or surrogacy counselling.
- In many clinics, the counselling department operates independently of other teams/departments (e.g. nursing, fertility specialist). Some clinics outsource their counselling services to individual counsellors who work in private practice. This limitation and reduction in information sharing across departments/specialities restricts the counsellors' ability to advocate and support their patients in a multidisciplinary setting.<sup>247</sup>

## Conflicts of interest

*Take counselling away from the clinics ... Clinics need to recognise how vulnerable you are.*<sup>248</sup>

A clear barrier articulated by consumers is the mistrust engendered by ART counsellors being attached to their treatment provider. Counsellors employed by ART clinics represent a potential conflict of interest, especially in the context of a patient deciding whether to continue with more costly treatment. It may undermine the benefit of engaging with a counsellor or discourage a consumer from seeking future support that may benefit them.

C59 commented on what she saw as a conflict of interest on the part of her ART counsellor:

*The interview with the counsellor is very clearly about deciding whether or not we will be taken on as clients and whether we would be able to obtain IVF services, not to assist us with the process. It was very clearly a judgement of our relationship. Consequently, as a patient you feel that you cannot ask questions or be difficult because then you will be denied treatment. Also, the initial consultation is generally positive to entice the patient, then a treatment plan is formed over which you are not given options and options and choices are not explained – the treatment plan is decided within the first hour and then you are asked to sign that you understand the costs and treatment.*<sup>249</sup>

She said the experience 'actually had a negative impact'.<sup>250</sup>

Some consumers felt anything they said to a provider-funded ART counsellor may have a detrimental effect on their treatment or the counsellor's assessment of their psychological readiness to undergo ART. Barriers to consumers taking up further in-house counselling is the fear they may be seen by the counsellor (and by extension the provider) as 'not coping' and denied further treatment. This is another area where consumers, by being honest, fear retribution from providers. Tellingly, C58 told the Commissioner that her husband, a psychologist, advised her to say as little as possible during her mandated counselling session so nothing she said could be 'used against her'.<sup>251</sup>

<sup>247</sup> Ibid.

<sup>248</sup> Public consultation forum, Melbourne, 11 September 2019.

<sup>249</sup> Submission 2019/06737

<sup>250</sup> Ibid.

<sup>251</sup> Public consultation forum, Ballarat, 13 September 2019.

VICG noted:

*Better expectation management about purpose/ benefit of counselling should be promoted not only by clinics but could also be promoted by VARTA. This would be helpful with demystifying the role of counselling and promote how it could assist people with managing grief, anxiety, and stress associated with infertility and infertility treatment and cessation of treatment.<sup>252</sup>*

Culture within clinics can also have an impact:

*... if ART clinics do not adequately value their counselling staff and mandatory counselling is perceived as a 'tick-box' session by clinicians, this may set up a negative bias for the patient. From a medical and business perspective, the counselling process may be viewed as being obstructive and holding up the treatment process.<sup>253</sup>*

If this fundamental mistrust exists, improving services may have little effect. For example, as Monash IVF stated in its submission: 'A further example of continuous improvement activities is the implementation of a supportive counselling contact for patients who have a negative pregnancy test. This has been implemented to ensure that patients do not feel abandoned and alone at this difficult time.'<sup>254</sup> This may be a sound initiative. but if there already exists an underlying lack of trust between a patient and ART counsellor, it is unlikely ongoing counselling would be utilised.

Independent counselling may prove more beneficial than the current system, better fostering a sense of trust between the counsellor and the consumer.<sup>255</sup> For example, C10 feels an independent counsellor is needed to help make decisions, not counsellors affiliated with 'money-making businesses'.<sup>256</sup>

While counselling must be an integral part of ART, its current delivery needs to better reflect the needs of consumers by:

- being more flexible and tailored to the particular needs of each consumer or couple
- ensuring that counselling providers have specific qualifications and training in dealing with infertility and grief
- making counselling more uniform across Victorian providers
- investigating providing counselling services that are independent of providers.

#### **RECOMMENDATION 8**

The findings of this inquiry support Recommendations 33–35 of the Gorton Review relating to:

- qualifications and eligibility of counsellors; and
- freedom of choice of counsellor by consumers.

<sup>252</sup> Submission 2019/06573

<sup>253</sup> Submission 2019/06639

<sup>254</sup> Submission 2019/06547

<sup>255</sup> Gorton (n2) 59.

<sup>256</sup> Public consultation forum, Melbourne, 11 September 2019.

## 5.4 Adjuvant ('add-on') treatments

SUMMARY OF FINDINGS 10-12
There is widespread use of adjuvant or 'add-on' treatments as part of ART. These treatments are without a clear evidence base and consumers have a poor understanding of their efficacy or benefit.
There is little agreement among fertility specialists as to the efficacy of many adjuvant treatments or what is classified as an adjuvant treatment.
Many ART providers claim not to use adjuvant treatments or employ them only at the insistence of patients, despite their widespread use by ART providers and poor understanding by consumers.

*Fertility treatments are complex, and each assisted reproduction cycle consists of several steps. If one of the steps is incorrectly applied, the stakes are high as conception may not occur. With this in mind, it is important that each step involved in assisted fertility treatment is supported by good evidence from well-designed studies.<sup>257</sup>*

*[W]hen you've had a series of failures it's very easy to just try the next thing, not knowing if it will really help. It's a bit of a stab in the dark.<sup>258</sup>*

Over time, IVF and related evidence-based medical interventions for fertility have been joined by a collection of additional treatments that vary from over-the-counter medications to surgical procedures. 'Add-on' or adjuvant treatments are one of the most contentious areas within ART and remain poorly understood by consumers and disagreed upon between providers. As Monash IVF states, adjuvant treatments 'are the subject of significant professional disagreement'.<sup>259</sup> Submissions from providers and from consumers reflect the challenges that exist in this area of ART, despite their use by many providers.

The FSA defines an adjuvant treatment as a therapy 'undertaken in addition to recognised standard ART treatment regimens', comprising:

- treatments which are purported to improve outcomes, but for which there may be little or no supportive evidence
- treatments for which extra cost is charged
- treatments from which there may be known or unknown side effects and other harms.<sup>260</sup>

The first challenge is in assessing the efficacy of adjuvant treatments because there is no clearly defined, agreed-upon list of adjuvant treatments in Australia. For example, VARTA's website lists endometrial scratching, time lapse imaging of embryos, the prescription of steroids, testosterone and growth hormones as examples of adjuvant treatments but does not provide an exhaustive list. HFEA's website expands the list to assisted hatching, artificial egg activation, calcium ionophore, elective freeze all cycles, embryo glue, intrauterine culture, preimplantation genetic screening

<sup>257</sup> Farquhar, C and Marjoribanks, J, 2018, 'Assisted reproductive technology: an overview of Cochrane Reviews', *Cochrane Database of Systematic Reviews* <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6513476/> accessed 28 August 2019.

<sup>258</sup> Submission 2019/07742

<sup>259</sup> Submission 2019/06547

<sup>260</sup> The Fertility Society of Australia, 2019, 'Use of Adjuvants in ART' [https://www.fertilitysociety.com.au/wp-content/uploads/Technical-Bulletin\\_Adjuvants-11-FINAL.pdf](https://www.fertilitysociety.com.au/wp-content/uploads/Technical-Bulletin_Adjuvants-11-FINAL.pdf) accessed 28 August 2019.

(PGS), reproductive immunology tests/treatment, intracytoplasmic morphologically selected sperm injection (IMSI) and physiological intracytoplasmic sperm injection (PICSI).<sup>261</sup>

The HFEA recently called for UK-based ART clinics to provide better information to consumers regarding adjuvant treatments:

*[HFEA] and 10 leading professional and patient fertility groups agreed a consensus statement after growing concern that patients are being frequently offered, and charged for, optional extras to their treatment which claim to improve their chances of having a healthy baby [...] Offered responsibly, they can be a sign of healthy innovation in the fertility sector. However, there is currently no conclusive evidence that any of the add-ons increase the chance of a pregnancy or live birth.*<sup>262</sup>

The second challenge is that while ART clinics may claim in their advertising that they do not use adjuvant treatments in their protocols, individual fertility specialists can use adjuvant treatments separate to the clinics to which they are contracted. Monash IVF explained: ‘Certain treatments, especially those that are generally referred to as add-ons or adjuvants [...] may be ordered by the Fertility Specialist as part of any patient’s treatment cycle.’<sup>263</sup> FS3 agreed that this is standard practice:

*Each patient/doctor interaction is independent of the ART provider. Just like any medical procedure the doctor will discuss the risks and benefits of any additional treatment. There is an understanding that some treatments have not had validation scientifically but that in a certain population of patients and in small studies adjuvants have worked.*<sup>264</sup>

Healthy Male similarly recognises that adjuvant protocols ‘are often directed by private clinicians, not ART programmes’.<sup>265</sup>

## **Uptake of adjuvants**

*This combination of patient expectation, market forces and a recasting of the professional patient relationship in an online information age appears to be driving the supply of, and demand for, treatment add-ons.*<sup>266</sup>

Despite several providers’ advertised claims that they do not or rarely employ them in treatment, 70 per cent of individual ART providers who made a submission confirmed they utilise adjuvant treatments. Of those consumers who made submissions to the inquiry, 29 per cent revealed they had received 45 adjuvant treatments between them as part of their ART journey.

While there is significant debate about the medical merits of adjuvant treatments, it is clear they are widely employed at additional cost and potential risk to consumers. In the UK, the HFEA report revealed three-quarters (74 per cent) of ART patients in the past two years experienced at least one type of adjuvant treatment, with the top three being endometrial scratching (27 per cent),

<sup>261</sup> Human Fertilisation and Embryology Authority, ‘Treatment add-ons’, <https://www.hfea.gov.uk/treatments/explore-all-treatments/treatment-add-ons/> accessed 22 December 2019.

<sup>262</sup> Human Fertilisation and Embryology Authority, ‘The responsible use of treatment add-ons in fertility services: a consensus statement’, <https://www.hfea.gov.uk/media/2792/treatment-add-ons-consensus-statement-final.pdf> accessed 22 December 2019, 2.

<sup>263</sup> Submission 2019/06547

<sup>264</sup> Submission 2019/05709

<sup>265</sup> Submission 2019/06410

<sup>266</sup> Human Fertilisation and Embryology Authority (n267) 2.

embryo glue (23 per cent) and use of an embryoscope (22 per cent).<sup>267</sup>

From those submissions to this inquiry where Victorian consumers underwent adjuvant treatments, Table 8 shows the type and prevalence.

**Table 8: Types and instances of adjuvant treatments experienced by consumers**

Treatment	Number of consumers
PGS/preimplantation genetic testing (PGT)	11
Endometrial scratching	7
Steroids	6
Embryoscope	5
Natural Killer Cell testing	3
Acupuncture/Chinese medicine	3
Dehydroepiandrosterone (DHEA)	1
T-cell assessment	1
Intralipid infusion	1
Intravenous Immunoglobulin	1
Lymphocyte immunisation therapy	1
Endometrial receptivity assay test	1
Ovarian rejuvenation	1
Ovarian diathermy	1
Embryo glue	1
Melatonin	1
<b>Total</b>	<b>45</b>

The two most reported adjuvant treatments were PGS or PGT and endometrial scratching.

When Table 8 above was shown to ART providers during their consultation session, some remarked that not all the treatments listed are considered adjuvants. There was also disagreement between providers over the efficacy of various treatments. This highlights how difficult it is for consumers in differentiating adjuvant treatments from standard treatment protocols.

C50 explained her rationale for additional treatments, including endometrial scratching, a stem cell procedure aimed at ovarian rejuvenation and steroid therapy:

*I tried all of the 'extra' treatments and procedures that were ever offered to me. As a patient of IVF we are so limited in what we know so I trusted that my Doctor always had my best interests at heart and if they suggested it, it must be worthwhile. They are the expert with the firsthand experience of the effectiveness and relevance of these treatments [...] As a woman in her mid 40s who can see her chances of having a baby slipping away from you, you become willing to try any new process or procedure. You don't want to leave any stone unturned.<sup>268</sup>*

Submissions to this inquiry highlighted that ART providers do not always educate consumers about the lack of evidence for the efficacy of adjuvant treatments. The Gorton Review also noted the poor information given to consumers by providers about adjuvants:

<sup>267</sup> Human Fertilisation and Embryology Authority, 'Fertility regulator calls for clinics to be more open about treatment add-ons', <https://www.hfea.gov.uk/about-us/news-and-press-releases/2019-news-and-press-releases/fertility-regulator-calls-for-clinics-to-be-more-open-about-treatment-add-ons/> accessed 20 December 2019.

<sup>268</sup> Submission 2019/06454

*[T]he 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.<sup>269</sup>*

Many consumers stated they were not informed what treatments were adjuvants versus standard protocols. C72 underwent endometrial scratching:

*I was not told it was experimental. It was not offered it as an extra (sic). Each IVF cycle they like to try something different [and] this was what the specialist wanted to do differently this particular cycle. I was horrified when I later changed specialists to find out that there is no evidence supporting this. I didn't know there was no evidence or that it was an adjuvant treatment. It was not explained in this way. The third specialist [I saw] was far more transparent and always made it clear where the evidence sat with treatments and options. He would refuse to do endometrial scratching for this reason.<sup>270</sup>*

Others said they were also unaware parts of their individual treatment plans were adjuvants, believing they were a standard part of their treatment protocol:

*We had no option other than to do the genetic testing on our embryos [and] sperm glue or something similar for both our ICSI cycles. Both weren't options but additional treatments at the specialist preference and our cost.<sup>271</sup>*

*I was angry about the add-ons because it was presented as essential to the treatment without explanation of why I was taking the supplements I was given. They were also provided in a format that wasn't suitable for me so I had to pay for them twice to have them made again at a compound pharmacy [...] I assumed that the doctor was offering the best treatment and my own private medical research provided assurance for what I was being offered – vitamin supplements.<sup>272</sup>*

*I also had endometrial scratch [...] but this was later found to have no associated improvements in implantation results leading to pregnancy or live both rates.<sup>273</sup>*

*I was offered an embryoscope which was at first an add on, and then I was told this is not negotiable and was charged for it anyway, despite asking if it was optional. There are no abilities to discuss the services (and their necessity) related to the costs, as the cost providing admin staff do not understand the treatment, and the doctors who understand the treatment do not know or understand the costs. This seems like a massive oversight which leaves the patient in the dark and less able to make an informed decision.<sup>274</sup>*

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<sup>269</sup> Gorton (n2) 16-17.

<sup>270</sup> Submission 2019/07371

<sup>271</sup> Submission 2019/06452

<sup>272</sup> Submission 2019/06737

<sup>273</sup> Submission 2019/07764

<sup>274</sup> Submission 2019/05961

Several consumers noted that since they had already spent so much time, money and effort on ART, agreeing to additional unproven treatments was more appealing than deciding to cease treatment:

*Because you try everything you can to achieve your goal.<sup>275</sup>*

*Why not, when you've spent so much already a few hundred more seems worthwhile if they recommend it.<sup>276</sup>*

*We felt like If we didn't then the money we had spent already would be for nothing!<sup>277</sup>*

Patients can be trapped in a cycle of 'if we do it enough, it must eventually work', not acknowledging that their chance of a successful pregnancy is largely the same each time, except the passage of time might mean it progressively becomes more difficult. After several failed cycles, C54's attitude was 'we've got through this far, let's keep going ... You become a good soldier. You continue on.'<sup>278</sup>

In 2018 new conditions were imposed on registered ART providers in relation to adjuvant use, including a requirement 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, as part of a program of treatment, by the doctors who carry out treatment procedures on behalf of the ART provider, including accurate information about the evidence which demonstrates those risks and benefit.<sup>279</sup>*

A designated person from each registered ART provider must attest that the provider is fulfilling this requirement each year. Ballarat IVF stated a common response – that patients are given all available information about treatments:

*Appropriate and relevant risks of all treatments, whether pre-ART treatments, or ART, are discussed during medical consultations, written information is provided prior to obtaining consent, and patients are encouraged to allow time to consider choices prior to requesting treatment.<sup>280</sup>*

VARTA is 'currently examining published systematic reviews, meta analyses, and Cochrane reviews to help determine the strength of the evidence for benefits of commonly offered add ons'. It continues to be important for the Victorian ART industry to build a reliable knowledge base for providers and consumers alike to draw from when making collaborative decisions about individual treatment plans. As FS20 commented to the Commissioner: 'Some patients want it, and some patients don't. If they aren't given lots of information to make an informed choice, then that's on us.'<sup>281</sup>

S5 points out that a lack of evidence base for adjuvant treatments does not mean there will not be one in the future:

<sup>275</sup> Submission 2019/07764

<sup>276</sup> Submission 2019/05439

<sup>277</sup> Submission 2019/05489

<sup>278</sup> Public consultation forum, Ballarat, 13 September 2019.

<sup>279</sup> Submission 2019/06639

<sup>280</sup> Submission 2019/06693

<sup>281</sup> Provider consultation forum, Melbourne, 12 September 2019.

*Future research findings may support use of certain adjuvants for selected patient groups. However, in the meantime, it is important that clinicians and staff provide appropriate information about adjuvants to inform patient decision-making, including that their effectiveness in terms of improving chance of success is unproven and that some adjuvants may potentially be harmful.<sup>282</sup>*

For example, a recent randomised controlled trial suggested endometrial scratching may actually reduce the chance of a successful pregnancy.<sup>283</sup> However, all the women in this study were having their first or second IVF cycle; the researchers concluded while endometrial scratching was not helpful for them, more research is needed to find out if it might help women who have had several unsuccessful IVF cycles.<sup>284</sup>

Some providers referenced adopting the traffic light system employed in the UK, which rates adjuvant treatments according to their proven efficacy through all available clinical evidence.<sup>285</sup> This followed a finding by the HFEA that common add-on treatments had little or no evidence backing their claims.<sup>286</sup> None achieved a 'green' light,<sup>287</sup> but those rated either 'amber' (approach with caution and/or requires more research) or 'red' (no evidence that a treatment aids in ART) are still used in the Australian ART industry. These include PGT, which is a procedure so common in Victorian ART clinics that many providers no longer deem it an 'add-on' procedure. It is expensive and current research shows it does not improve the chance of IVF success. However according to the HFEA, it does 'reduce the number of embryo transfers a woman needed before having a baby and also reduced the risk of miscarriage'.<sup>288</sup>

C82 also mentioned the potential efficacy of the UK traffic light system as a guide to adjuvant treatments:

*A similar system would be beneficial here as doctors tend to recommend treatments but there's not a lot of clarity on whether it's appropriate to your particular care, and why, and the research behind it. I'm comfortable reading scientific papers to find out more – but not everyone has the access or understanding to do that.<sup>289</sup>*

While Healthy Male supports the use of the traffic light system as a guide for providers to communicate with consumers, the organisation also noted a cultural change first needs to occur around the inconsistent use of adjuvants between providers:

*Any strategies to address adjuvant use/misuse must recognise regulation of clinician behaviours falls under AHPRA, while 'cultural change' and the practice of ART units can be best influenced through RTAC/FSA, professional societies and government agencies. Indeed, a role for ACCC in clinic promotional behaviours is also evident.<sup>290</sup>*

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<sup>282</sup> Submission 2019/06639

<sup>283</sup> Ibid.

<sup>284</sup> Ibid.

<sup>285</sup> Human Fertilisation and Embryology Authority (n266).

<sup>286</sup> Ibid.

<sup>287</sup> Ibid.

<sup>288</sup> Submission 2019/06639; see also Verpoest, W, Staessen, C et al. 2018, 'Preimplantation genetic testing for aneuploidy by microarray analysis of polar bodies in advanced maternal age: a randomized clinical trial', *Human Reproduction* <https://academic.oup.com/humrep/article/33/9/1767/5063306> accessed 20 December 2019.

<sup>289</sup> Submission 2019/07742

<sup>290</sup> Submission 2019/06410

FS2 acknowledged: 'We all agree there is an issue on how we represent adjuvant add-ons.'<sup>291</sup>

<b>RECOMMENDATIONS 9-10</b>
It is recommended that ART providers obtain written consent from consumers before each use of any adjuvant treatment.
It is recommended that regulatory bodies, in consultation with ART providers, develop comprehensive written materials on current commonly used 'add-ons' or adjuvant treatments including: <ul style="list-style-type: none"> <li>• identifying the treatment as an adjuvant treatment</li> <li>• informing consumers of the current evidence base for the efficacy of adjuvant treatments and where there is no evidence base or the efficacy is not established, clearly stating this</li> <li>• informing consumers of the possible risks or side effects of adjuvant treatments.</li> </ul> This should be provided to consumers before beginning ART.

## Consumer demand

ART providers highlighted the influence of consumer-driven demand for adjuvant treatments. Fertility specialist Professor Rob Norman stated 'patients often come into the clinic with their add-on treatments already decided', adding: 'They are involved in chat groups and they usually are quite demanding as to why you're not offering a particular treatment.'<sup>292</sup> FS11 showed frustration with patients 'demanding treatment even when they have been advised it's futile [such as] if advanced maternal age, poor response in the past and this is still Medicare funded!'<sup>293</sup>

Similarly, S5 noted:

*It has been reported that a significant proportion of patients put pressure on treating doctors to have treatment using adjuvants following participation in online discussions, use of the internet or discussion with friends. The power of hearing advice about medical treatments from 'someone like me' is evident. Treating clinicians have reported to VARTA that these types of conversations with patients are challenging and that there is pressure to provide adjuvant treatment.'*<sup>294</sup>

Adjuvant use is more prolific among some clinicians than others.<sup>295</sup> This may encourage consumers who are willing to try adjuvants to target those clinicians who are known for using particular adjuvant treatments, leading to their ongoing use.

Pink Elephants discussed the influence of the internet on today's ART consumers' choices of treatments that are not evidence-based but touted on forums and in social media:

*[T]he biggest issue, particularly in Australia, is that many women who are desperate for a positive outcome and who have been struggling to conceive for a long time, seek answers elsewhere, often from international forums or clinics. Other countries tend to be more advanced or at least more willing to try other avenues to produce a pregnancy, therefore*

<sup>291</sup> Provider consultation forum, Melbourne, 12 September 2019.

<sup>292</sup> Scott, S, Knight, B and Gartry, L, 2019, 'Calls for overhaul as desperate parents spend thousand on unproven IVF treatments', ABC <https://www.abc.net.au/news/2019-05-05/fertility-adds-ons-a-waste-a-money-according-to-some-experts/11004434> accessed 15 October 2019.

<sup>293</sup> Submission 2019/06399

<sup>294</sup> Submission 2019/06639

<sup>295</sup> Ibid.

*arming Australian women with information about treatments that our doctors are perhaps unwilling or unable to support.*<sup>296</sup>

Consumers acknowledge they can be the driving force behind the decision to use adjuvants, even when aware there is little evidence of efficacy. When asked to explain the decision process behind seeking adjuvant treatments, C40 wrote:

*I had endometrial scratches and my doctor advised it was unclear whether they worked but by that time I was prepared to try anything and could afford it so agreed. It was the most awful painful part of the whole process. I had to take a Valium and painkillers beforehand. I also had ovarian drilling, the doctor gave me the information about that. I also did testing for NKC's and PGD ... After so much loss and disappointment I became desperate and basically wanted to throw everything at it.*<sup>297</sup>

It is clear there is a delicate relationship between fertility specialists and consumers regarding managing expectations and balancing this with retaining a patient, maintaining a clinical reputation, practising ethically and achieving positive outcomes. As FS19 noted during the ART provider consultation forum, ART providers are in an unenviable state: 'You're criticised if you do give an adjuvant and criticised if you don't.'<sup>298</sup>

Proven or not, adjuvant treatments have become a regular part of ART that many providers use, and many consumers are willing to try. Given the cost and potential health risks, it is imperative that ART providers give consumers accurate information about the costs and evidence base, or lack thereof, for adjuvant treatments. Ensuring they have obtained fully informed written consent before a procedure should also include information about the current evidence base for its efficacy.

## 5.5 Adverse events

<b>SUMMARY OF FINDINGS 13-14</b>
ART patients may experience higher numbers of adverse events during their treatment than is reported, particularly ovarian hyperstimulation syndrome.
There is a lack of transparency by ART providers in the reporting of adverse events to patients.

<sup>296</sup> Submission 2019/07125

<sup>297</sup> Submission 2019/06122

<sup>298</sup> Provider consultation forum, Melbourne, 12 September 2019.

## Adverse events<sup>299</sup>

Of the consumers making a submission to the inquiry, 31 per cent reported suffering an adverse event, with many requiring hospitalisation. Table 9 lists all the adverse events experienced by consumers who submitted to the inquiry. Over half of all adverse events among consumers was OHSS.

**Table 9: Adverse events following ART reported by consumers**

Adverse event experienced	Number of consumers	Percentage of adverse events
Ovarian hyperstimulation syndrome	16	55%
Removal of ovary	3	10%
Adverse drug reaction	2	7%
Complications from multiple pregnancies	2	7%
Damage to ovary requiring surgery	1	3.5%
Ovarian cysts following cycle	1	3.5%
Cancer (Lynch syndrome)	1	3.5%
Hospitalisation – unknown diagnosis	1	3.5%
Ectopic pregnancy	1	3.5%
Pelvic infection	1	3.5%
<b>Total</b>	<b>29</b>	<b>100%</b>

ART providers must report any adverse events to RTAC and VARTA. In 2018–19 VARTA received 80 reports of adverse events from Victorian providers, 58 of which were clinical adverse events, with almost half of those relating to moderate to severe OHSS.<sup>300</sup> The Gorton Review reported, ‘performance across clinics can be highly varied and that adverse events, in particular ovarian hyperstimulation syndrome, are underreported’.<sup>301</sup>

VARTA conducts investigations into adverse events resulting from reported incidents by ART providers. It reports: ‘The number of adverse incidents is only associated with 0.3% of ART treatment cycles.’ VARTA also acknowledges all adverse events data wholly depends on self-reporting by providers.

Several providers mentioned using the program RiskMan to log and track adverse events. While not related to ART providers, a study of the use of RiskMan in two Melbourne hospitals found:

<sup>299</sup> An adverse event is any event associated with ART treatment that:

- causes harm, loss or damage to patients or their reproductive tissues
- causes a significant medical or surgical condition to arise directly from ART treatment
- results in hospitalisation following, and as a result of, the ART treatment.

A serious notifiable adverse event is an abnormal unintended outcome associated with ART operations that:

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

Source: Fertility Society of Australia 2017, *RTAC Code of Conduct for Assisted Reproductive Technology Units*.

<sup>300</sup> VARTA (n180) 6.

<sup>301</sup> Gorton (n2) 26–27.

*Senior staff at both hospitals suspected error-reporting rates did not reflect real error rates. At both hospitals, this was felt to result primarily from concern about blame, the effort involved in reporting, and the lack of feedback on reports.<sup>302</sup>*

This study noted that ‘blame culture’ in some hospitals creates an atmosphere where staff are less likely to report adverse events and errors due to a range of factors including: fear of disciplinary action or appearing incompetent; a belief that reporting will not translate into better outcomes; lack of management support for reporting negative outcomes; and concerns about subsequent litigation.

The study also found a lack of general understanding about what constituted an adverse event and a lack of training in how to use RiskMan.<sup>303</sup> The authors concluded software systems such as RiskMan ‘are only as useful as the data input. This study shows that without proper engagement, data entered will be incomplete and dirty.’<sup>304</sup>

#### **RECOMMENDATION 11**

The findings of this inquiry support Recommendation 77 of the Gorton Review relating to the development of compliance standards in relation to ART providers’ reporting requirements.

Pink Elephants stated in its submission to this inquiry: ‘In our personal experience and also what has been cited by the women we support, ART providers/clinics do not adequately manage adverse events.’<sup>305</sup> The Gorton Review also suggested ‘significant variations in clinical practice and outcomes between clinics’ as well the increasing corporatisation of the industry ‘may be contributing to a reluctance to report or disclose adverse outcomes or support a culture of learning and improvement’.<sup>306</sup>

### **Ovarian hyperstimulation syndrome**

OHSS was the number one adverse event experienced among ART consumers and is a condition almost completely unique to ART. Following hormone stimulation, most patients hope between eight and 15 eggs can be retrieved for fertilisation. OHSS results from an over-production of eggs and can cause severe pelvic pain, swollen ovaries, excessive fluid retention, rapid weight gain, nausea, vomiting and diarrhea.<sup>307</sup> It is also possible for ART patients to experience OHSS when pregnant.

In severe cases, OHSS requires hospitalisation and additional treatment.<sup>308</sup> While it is often described by providers as being ‘rare’,<sup>309</sup> other research presents it as a relatively common complication that can be life threatening.<sup>310</sup> The 2017 ANZARD report states cases of OHSS that

<sup>302</sup> Lederman, R and Dreyfus, S et al. 2013 ‘Electronic error-reporting systems: A case study into the impact on nurse reporting on medical errors’, *Nursing Outlook*, 420.

<sup>303</sup> Ibid.

<sup>304</sup> Ibid.

<sup>305</sup> Submission 2019/07125

<sup>306</sup> Gorton (n2) 15.

<sup>307</sup> Mayo Clinic, 2019, ‘In vitro fertilization (IVF)’ <https://www.mayoclinic.org/tests-procedures/in-vitro-fertilization/about/pac-20384716> accessed 2 December 2019.

<sup>308</sup> Mayo Clinic, 2019, ‘Ovarian hyperstimulation syndrome’, <https://www.mayoclinic.org/diseases-conditions/ovarian-hyperstimulation-syndrome-ohss/symptoms-causes/syc-20354697> accessed 2 December 2019.

<sup>309</sup> Lucidi, RS, 2016, ‘Ovarian Hyperstimulation Syndrome’, *Medscape*, <https://emedicine.medscape.com/article/1343572-overview> accessed 2 December 2019.

<sup>310</sup> Chen, C, Wu, M et al. 2011 ‘Update on management of ovarian hyperstimulation syndrome’, *Taiwanese Journal of Obstetrics and Gynaecology* <https://www.sciencedirect.com/science/article/pii/S1028455911000155> accessed 2 December 2019.

require hospitalisation are reported by clinicians and validated against hospital records by fertility clinic staff.<sup>311</sup> In 2017 there were reported 175 OHSS cases admitted to hospital in Australia and New Zealand,<sup>312</sup> but OHSS is inconsistently reported.<sup>313</sup>

## RECOMMENDATION 12

It is recommended that regulatory bodies work with ART providers in improving reporting of adverse events, particularly cases of ovarian hyperstimulation syndrome, regardless of the severity of the diagnosis.

The inquiry heard those consumers who experienced OHSS were not aware that they might develop it or were told it was extremely rare. Several women who developed it said they were never told that the hormone stimulation process could cause OHSS. Some reported not even understanding what was happening to them as symptoms developed or having their symptoms diminished or attributed to other, less serious origins.

When it did develop, many described feeling dismissed when they reported their symptoms to providers, faced difficulties receiving the right care or were not told they had developed OHSS:

*The doctor did not inform me of the risks of developing ovarian hyper stimulation syndrome and I had 43 eggs collected. I ended up very unwell and hospitalised with plural effusions and required an albumin infusion. The doctor did not take the serious nature of my condition seriously and proceeded to complete an embryo transfer. This embryo transfer resulted in a chemical pregnancy.*<sup>314</sup>

*I found out from my new fertility specialist that after looking at my results I had OHSS, which explained why I felt to terrible after my second round. I didn't receive a call from [ART provider] checking up on me or letting me know that my estrogen levels were super high and would be more at risk.*<sup>315</sup>

*Ended up in intensive care for about a week. Treating doctors and [the fertility specialist] had no idea of what was going on. [FS] provided no support or showed any compassion to my situation. No follow up once I was discharged from hospital. I was so sick blood could not be taken from my body. Intensive care staff believed I could have died. I felt like I could have died ... No information provided to me about potential risks of overstimulation prior to treatment.*<sup>316</sup>

*I was never told that it was OHSS, I had no idea that I could have gotten very sick. It was only when I went back to him for something else that I told him what happened and he said 'sorry about that' and I confirmed with him that it actually was OHSS.*<sup>317</sup>

C47 similarly developed OHSS without knowing anything about it. She stated that when symptoms

<sup>311</sup> Newman et al (n11) 44.

<sup>312</sup> Ibid.

<sup>313</sup> Ibid.

<sup>314</sup> Submission 2019/05489

<sup>315</sup> Submission 2019/05438

<sup>316</sup> Submission 2019/05371

<sup>317</sup> Submission 2019/07198

presented, her fertility specialist said he would see her the next day. Her GP advised her to go directly to emergency. 'I met the criteria for sepsis on admission,' she said in her submission to the inquiry.<sup>318</sup> Hospitalised for 10 days, she had six litres of fluid drained from her abdomen and went through two selective reductions because she was pregnant with octuplets.<sup>319</sup>

Alarming, three consumers reported losing an ovary due to severe OHSS. During her fourth IVF treatment cycle treatment, C54 lost her right ovary due to a ruptured ovarian abscess. Ovarian cysts had developed during her three previous cycles but she was told it was normal and not to be concerned.<sup>320</sup> She described the process, her difficulty getting the right care and the attitude of her fertility specialist:

*After being discharged from hospital and during my follow-up appointment with fertility specialist the following Monday 4 March, 2019, I was then informed I would have to undergo surgery and there was a possibility my right ovary would have to be removed. I then had to complete the paperwork for the surgery in the clinic's reception area, quite upset and in shock at what I had just been informed. Later that night I underwent surgery and my right ovary was removed. Whilst I had been informed that there was a risk that my ovary may be removed, given surgery was scheduled for later that night, there wasn't a lot of time for me to process this information. It wasn't until I met with [the fertility specialist] on 9 April, 2019 that I received the opportunity to ask questions about what exactly happened to me [...] I do believe that what happened to me could have been and should have been handled much better.<sup>321</sup>*

Considering its rarity in the non-ART patient population, it is not surprising that some consumers discovered a general lack of knowledge about OHSS among emergency hospital staff. While pregnant following IVF, C64 developed severe OHSS. She presented to emergency at a private hospital, where the staff contacted her fertility specialist. He advised the team that C64 was no longer his patient and to refer the matter to her obstetrician.<sup>322</sup> She was transferred to another private hospital where a covering obstetrician suspected she had ovarian torsion. After one of her ovaries was removed, she recalled: 'He told me that the ovary was completely dead [...] I was never told it was OHSS.'<sup>323</sup>

When C54 was hospitalised as described above, she commented:

*When I first presented to the hospital, I felt that the medical staff were very unsure how best to deal with my case; their knowledge of IVF seemed very limited and initially they seemed reliant on receiving further advice from staff at [ART provider].<sup>324</sup>*

Similarly, when C62's daughter was diagnosed with OHSS after producing 48 eggs, she stated she was met with disbelief by hospital staff. Her daughter also had a reaction to an anti-nausea drug

<sup>318</sup> Submission 2019/06397

<sup>319</sup> Ibid.

<sup>320</sup> Public consultation forum, Ballarat, 13 September 2019.

<sup>321</sup> Submission 2019/06624

<sup>322</sup> Submission 2019/07198

<sup>323</sup> Submission 2019/07198

<sup>324</sup> Submission 2019/06624

during treatment, developing tremors and lockjaw but was told by a nurse she was just being 'anxious' and was sent home. She experienced severe pain, and three days later her daughter presented to emergency to find 'she had ovaries the size of grapefruits and they were twisted'.<sup>325</sup>

C84, who experienced OHSS in 2019 felt she was given good information about it, but not of other risks in an overall IVF cycle:

*Everything I read about egg freezing brushed over the risks of serious internal bleeding, which I suffered [...] I am not sure whether I was simply an unlucky person, or whether the risk was not adequately mitigated. Certainly I don't think there was sufficient information about what to do about pain that I suffered post egg collection. I also suffered OHSS. There was a lot of information about OHSS provided, not so much about other risks.*<sup>326</sup>

But she praised the response by her ART provider:

*In the aftermath of my adverse incident, there has been a lot of communication. I feel they are concerned about what happened. I've had calls from nursing staff and the general manager of [ART provider]. I've been able to call and contact staff as necessary, including psychological support. Prior to the incident there was also a good level of communication, especially from my nurse.*<sup>327</sup>

## Other adverse events

*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.*<sup>328</sup>

The inquiry heard of other adverse events, including implantation of the wrong embryo, dropping of collected eggs and thawing of the wrong embryos. Among 93 consumer submissions, 11 individuals reported experiencing serious clinical errors during their ART. Table 10 shows the types of incidents reported.

**Table 10: Types of reported other adverse events by inquiry consumers**

Other adverse events	Number of consumers	%
Harvested eggs dropped	2	18.5%
Wrong numbers of embryos thawed	2	18.5%
Wrong sperm used to fertilise egg	1	9%
Missed test result	1	9%
Wrong embryo transfer	1	9%
Embryos mistakenly destroyed	1	9%
Wrong medication dose	1	9%
Wrong quality sperm implanted	1	9%
Clinical fraud	1	9%
<b>Total</b>	<b>11</b>	<b>100%</b>

<sup>325</sup> Submission 2019/07032

<sup>326</sup> Submission 2019/07750

<sup>327</sup> Ibid.

<sup>328</sup> Gorton (n2)19.

Two consumers lost their retrieved eggs when they were dropped by lab technicians. The mother of C45 submitted that ‘their lab dropped her eggs, and she had to fight to have some sort of compensation for this – not what she needed after the psychological stress she was under after another failed procedure’.<sup>329</sup>

When her specialist called to tell C51 that all her embryos had been lost due to a freezer malfunction, she said: ‘We were grief struck; I remember collapsing to the floor.’<sup>330</sup>

When C14 found out the wrong embryo had been thawed (untested by PGS), she said:

*I have never been treated so poorly. They pretended that it wasn’t a big deal and refused to deal with the issue [...] They also treated me in an incredibly belittling way. To this day I cannot understand how [provider] can justify thawing and transferring the incorrect embryo.*<sup>331</sup>

C66 told the inquiry of being inseminated by sperm that had been assessed as low quality. While she fell pregnant, she subsequently miscarried. She only found out about the sperm quality when she sought a second opinion and accessed a clinic report that ‘clearly stated that sperm used on my eggs was “very poor quality”’.<sup>332</sup>

A former clinical embryologist who worked in three Victorian ART clinics detailed several concerning adverse events she witnessed and expressed concern that an increase in patients accessing ART also translated to more clinical errors made. (These incidents were also reported to the Gorton Review.) PS10 noted in her experience there was not a concurrent increase in transparency surrounding these errors:

*While errors did occur in the clinics I worked for, in the early years of my career they were rare and usually reported to patients. However, as the clinics became much busier and were taken over by corporate interests, the number of incidents increased. Of great concern, many of these incidents were not disclosed to the patients involved.*<sup>333</sup>

These incidents included: a mislabelling of sperm, discovered after an ICSI procedure had already occurred; the transfer of a dead embryo; and a faulty incubator that meant some embryos did not survive but the patient was told their embryos had ‘succumbed naturally’.<sup>334</sup> In another incident where embryos were lost through clinical error and the patient was not informed, PS10 claims she was ‘threatened with “consequences”’ if she did not do as instructed.<sup>335</sup>

PS10 wants to see stronger protections around whistleblowing in Victoria that ‘allow for the reporting of potential misconduct and patient incidents’.<sup>336</sup> PS10 stated, ‘if IVF is to remain regulated by the State, there needs to be a better mechanism for these incidents to be recorded and monitored to ensure the patient has been informed and action taken to prevent a reoccurrence’.<sup>337</sup>

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<sup>329</sup> Submission 2019/06286

<sup>330</sup> Submission 2019/06500

<sup>331</sup> Submission 2019/05297

<sup>332</sup> Submission 2019/07259

<sup>333</sup> Submission 2019/05897

<sup>334</sup> Ibid.

<sup>335</sup> Ibid.

<sup>336</sup> Ibid.

<sup>337</sup> Ibid.

A current ART embryologist who requested anonymity expressed her concern over the technology behind embryo freezing. PS17 stated:

*A big concern that I see in multiple clinics is within the embryo freezing process. Rarely, embryos are not on the vitrification device when they are warmed – meaning they've been lost in the freezing process. Patients are often told that the embryo just didn't survive the freeze and no adversity process is followed afterwards.*<sup>338</sup>

Two consumers reported embryos were thawed without their authorisation. C81 recalled during her last IVF cycle:

*[A]ll of our stored embryos (there were 6 remaining) were thawed without our authorisation. In meetings prior to this cycle, we had made it clear that we never wanted to thaw more than the 1 embryo we were to transfer.*<sup>339</sup>

C83 had her eggs mistakenly fertilised by the sperm of another patient, not her partner. As a result, all her eggs from that collection were destroyed. She commented: 'They then provided cycles at no out of pocket costs, but I wonder why the government (Medicare) should have to cover any expenses given it was their mistake.'<sup>340</sup>

The consequences of adverse events are severe, particularly in a field where the emotional toll is already high. What is concerning is the potential lack of transparency regarding such adverse events, particularly with respect to notifying patients.

A common theme expressed by women who discussed their adverse events is that they did not feel believed or listened to by their specialists or treating doctors at hospitals. One of the reasons contributing to this may be the high rate of male fertility specialists. A recent study has stated, 'For much of documented history, women have been excluded from medical and science knowledge production, so essentially we've ended up with a healthcare system, among other things in society, that has been made by men for men'.<sup>341</sup>

C1 described feeling dismissed and ignored by her fertility specialist. Following her ninth egg collection procedure, she said she developed terrible pain. She said her fertility specialist dismissed her symptoms three times after ruling out an ectopic pregnancy. Following a chemical pregnancy, she eventually collapsed and spent 10 days in hospital with an acute pelvic infection that took six months' recovery. She said: 'Due to this infection I missed whatever small window I had remaining to conceive a child.'<sup>342</sup>

Even through her pre-existing condition of factor V Leiden (making her prone to blood clotting and deep vein thrombosis) was known to her specialist, C50 was prescribed a high dose of Progynova. After taking it, she woke up in pain and vomiting blood. She rushed to emergency where she

<sup>338</sup> Submission 2019/07589

<sup>339</sup> Submission 2019/07702

<sup>340</sup> Submission 2019/07746

<sup>341</sup> Jackson, G, 2019, 'The female problem: how male bias in medical trials ruined women's health', *The Guardian* <https://www.theguardian.com/lifeandstyle/2019/nov/13/the-female-problem-male-bias-in-medical-trials> accessed 20 December 2019.

<sup>342</sup> Submission 2019/05042

discovered it was a reaction to the Progynova, dose which is contraindicated in patients with factor V Leiden. When C50 called the ART provider to make them aware of her hospitalisation, she was unhappy with the response. After leaving several messages with her IVF nurse and waiting weeks for a reply she recounts her experience when she finally saw the doctor:

*[S]he looked at me and said ‘so where are we with you at the moment?’ I was a bit taken aback as I thought she would discuss what had happened – when I started to recount the whole story to her, she indicated that she didn’t realise that had been my experience [...] at the end of my story she simply said ‘well if I can’t give you Progynova, I am not sure what I can do for you’ – she then asked me if I had a sister or knew somebody who could carry a baby for me instead. I was so upset. She didn’t apologise or admit any responsibility for the issue which I believe she caused.<sup>343</sup>*

### Provider perspectives

FS3’s thoughts on adverse events echoed a position common among providers:

*The recent articles surrounding OHSS and media articles that scare patients about IVF are at odds with what is current medical practice in our state. Victoria was one of the first IVF providers in the world and the quality of care we provide is the envy of the world. As a medical practitioner whose focus is on women’s health there appears to be more focus on my fertility practice than on any other part. Despite the adverse events that could potentially occur during my laparoscopic surgeries or during pregnancy being far greater. Fortunately given my dedication to patient care and safety, my commitment to continual medical education, and due to the support structure inherent in [ART provider] – the incidents [sic] of adverse events is well below what would be expected of any practitioner.<sup>344</sup>*

But as noted above, current clinical protocols rely on clinics self-reporting adverse events. In addition, hospital data about ART-related adverse events is often difficult to capture and disseminate to the relevant authorities. S5 also reports that the onus for dealing with patient adverse events and complaints falls on ART counsellors, who:

*may not be briefed on complaint handling pathways and the reporting of adverse events. On occasion, patients are referred to counselling after an adverse event has transpired [...] counsellors need to be familiar with complaint handling pathways and the reporting of adverse events and empowered to support patients that have undergone sub-standard experiences and/or adverse events to navigate the complaint handling pathway and make a complaint.<sup>345</sup>*

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<sup>343</sup> Submission 2019/06454

<sup>344</sup> Submission 2019/05709

<sup>345</sup> Submission 2019/06639

## 5.6 Complaint handling

SUMMARY OF FINDINGS 15-17
ART providers who made submissions consider their complaint handling processes to be robust and patients' grievances are dealt with promptly and comprehensively.
Consumers making submissions were largely unaware of their ART providers' complaint handling procedures.
Some consumers expressed fear of repercussions if they made a complaint while undergoing ART.

All health service providers, as defined under the *Health Complaints Act 2016*, must comply with the complaint handling standards set out in the Act. These standards aim to strengthen and improve complaint handling systems across the Victorian health sector. They provide a common benchmark for all health service providers to meet, offering consistency for consumers, complainants, health service providers and other stakeholders.

ART providers are health service providers under the *Health Complaints Act*, so the complaint handling standards apply to all ART providers. The complaint handling standards complement other existing standards, reinforcing the importance of consumer feedback and person-centred care in all health services. The *Health Complaints Act* complaint handling standards also deal with how complaint handling information should be communicated to consumers and provides that consumers can make a complaint to the HCC about the way a health service provider handles a complaint.

In addition to the *Health Complaints Act*, the ART Act, the RTAC Code and the NHMRC guidelines, contain clear provisions for complaint handling by ART providers.

Of the ART providers that made submissions, most detailed their commitment to promptly and comprehensively resolve patients' grievances:

*all RTAC accredited/VARTA licensed ART Units have a complaints handling system.*<sup>346</sup>

*Our Patient Feedback and Complaints policy maintains alignment to the Commonwealth Ombudsman's Better Practice Guide to Complaint Handling.*<sup>347</sup>

*[ART provider] communicate the complaints handling process to all patients in the Patient Handbook, provided at the start of their treatment journey.*<sup>348</sup>

*Patient is made aware that they have the right to complain and given the pathway to do so.*<sup>349</sup>

*We inform patients through our patient collateral how they can make a complaint and receive feedback. All sites have on display the Australian Charter of Healthcare Rights which informs patients of their right to comment on their care and have their concerns addressed.*<sup>350</sup>

Several providers mentioned using RiskMan to log and track complaints.<sup>351</sup>

<sup>346</sup> Submission 2019/06693

<sup>347</sup> Submission 2019/06631

<sup>348</sup> Submission 2019/06547

<sup>349</sup> Submission 2019/05735

<sup>350</sup> Submission 2019/06631

<sup>351</sup> Submissions 2019/05709, 2019/05664 and 2019/06547

FS2 wrote in her submission that her workplace offered an extensive complaint handling process:

*We have patient advocates and quality managers and accessibility well-documented. We have [the] RISKMAN system for incidents and complaints [and] we have [a] committee which reviews all complaints. If a patient makes a complaint, she/he is referred to our contact details for patient advocate. Then patient details their complaint and RISKMAN process for investigation generated. Team remains in contact with patient. Patient then meets with senior specialist and exec manager. Whole exec and medical specialist group then discuss complaints and incidents once investigated. And then senior team member follows up to completion with patient. If further steps required, patient referred to HCC.<sup>352</sup>*

Monash IVF also stated they use RiskMan to improve the complaint handling process:

*Monash IVF have a relatively low threshold for recording feedback in Riskman (61 complaints from 1 July 2018 to 30 June 2019) to ensure that all process issues can be addressed. This represents an overall incidence of <1% of cycles completed. While we do not individually 'risk rate' complaints, only 15 of the 61 (0.24%) have been flagged as higher risk (meaning that they have required further medical treatment or experienced an infection or have threatened legal action).*

*The Riskman system further allows us to identify trends and areas of focus for improvement activities.*

### RECOMMENDATION 13

It is recommended that ART providers adhere to the minimum complaint handling standards set out in the *Health Complaints Act 2016*.

While providers may have established complaint handling procedures, it is clear from the submissions made to this inquiry that most consumers are unaware of them. Many consumers who commented on complaint handling stated that their ART provider failed to give them any information in this area:

*I do not recall being given any information whatsoever regarding the ability to make a complaint [...] I have kept all the information we have ever been provided, across all 5 attempts and there is nothing.<sup>353</sup>*

*I never knew there was an option to make complaints. If I had known I would have done so.<sup>354</sup>*

*We were given no information about lodging a complaint.<sup>355</sup>*

*No information was given about a complaint process.<sup>356</sup>*

*As far as we recall we were given no information about how to make a complaint.<sup>357</sup>*

<sup>352</sup> Submission 2019/05664

<sup>353</sup> Submission 2019/07815

<sup>354</sup> Submission 2019/05374

<sup>355</sup> Submission 2019/07702

<sup>356</sup> Submission 2019/07754

<sup>357</sup> Submission 2019/06500

**RECOMMENDATION 14**

It is recommended that ART providers ensure that consumers are made aware of the provider's own complaint handling standards and that a consumer has the right to make a complaint to the Health Complaints Commissioner.

Of the consumers who responded to the survey question about complaint handling, 69 per cent stated they were not provided with information to make a complaint. Of these, on their own initiative, 13 per cent were successful in sourcing complaint handling information. Several consumers told the inquiry they never heard back from their provider after lodging a complaint or knew if it had been investigated.

It is noted that some ART providers' submissions had information relating to the HCC that was out of date. [ART provider], a recent provider in the Victorian ART industry, lists the 'Office of Health Services Commissioner' on its website (under 'Privacy Policy') with the incorrect address, contact number and website. [ART provider] provides consumers with similarly erroneous information about the HCC in its *Patient Handbook*, appended to its submission. The HCC replaced the Health Services Commissioner on 1 February 2017, meaning these service providers are giving consumers information nearly three years out of date.

There are numerous ways complaint handling information can be provided to ART consumers – verbally, patient guides, posters and/or pamphlets.<sup>358</sup> Complaint handling information needs to be readily accessible, and by providing this information online, providers would be taking steps to remove barriers – real or imagined – to making a complaint.<sup>359</sup>

Only two of the 10 registered Victorian ART clinics provide complaint handling information on their websites. Of those, only one explains how to make a formal complaint and their complaint handling process. Similarly, only two service providers currently refer to the HCC on their websites as an avenue patients can explore if they are dissatisfied with the providers' complaint handling procedures.

Being provided with accessible and accurate complaint handling information is a vital component in quality of care. ART providers must comply with the complaint handling standards set out in the *Health Complaints Act* and must give patients clear and accessible complaint handling information as well as descriptions of the roles of the HCC and VARTA.

**Fear of repercussions**

At the end of her submission, C69 wrote:

*Please ensure I remain anonymous in this review, especially as I am receiving ongoing treatment with my ART provider. It is very important that I retain a comfortable and open relationship with my doctor and the nurses going forward and for these reasons I haven't complained directly to the ART provider or my doctor about any of the issues raised in this submission.*<sup>360</sup>

<sup>358</sup> Commonwealth Ombudsman, 2009, *Better Practice Guide to Complaint Handling*, Commonwealth of Australia, Canberra, 11.

<sup>359</sup> Ibid.

<sup>360</sup> Submission 2019/07326

Throughout the inquiry, consumers stated they did not want to make or escalate their complaints, particularly if their treatment was still ongoing, for fear a complaint would adversely affect their care and treatment. Comments included:

*We did not want to make a complaint against the clinic, for fear it would negatively impact our treatment in some way, we feared that the treating Dr would no longer have our best interest in mind.*<sup>361</sup>

*We were afraid to be labelled as ‘troubled patients’ if we transferred.*<sup>362</sup>

*I thought I’d be penalised, made to feel like a troublesome patient.*<sup>363</sup>

#### **RECOMMENDATION 15**

It is recommended that ART providers ensure that no ART patient shall experience reprisals because of providing feedback or making a complaint to a health service provider.

When this fear was communicated to ART providers during their consultation session, FS2 commented that it was the ‘most worrying thing’ reported to them.<sup>364</sup>

FS16 acknowledged how the complexity and low success rates of ART inevitably produce unhappy patients: ‘Given the volume of these contacts, and the fact that Assisted reproduction does not always lead to a positive outcome, it is understandable that some patients are unhappy with services provided.’<sup>365</sup>

Some clinics ‘try to pre-empt legal and other complaints by negotiating with affected patients. This often includes offers of free treatment cycles to compensate for errors.’<sup>366</sup>

FS19 commented that some ART patients use ‘the threat to go to the HCC as blackmail to get you to say: “I’ll give you a free cycle, to shut you up.” They like holding the complaint to the HCC over our head.’<sup>367</sup>

#### **RECOMMENDATION 16**

It is recommended that ART providers access the training and events offered by the Health Complaints Commissioner in how to manage complaints, and information on implementing the complaint handling standards to create a culture where feedback and complaints are seen as leading to continuous improvement of the quality of their service.

## **5.7 Costs**

#### **SUMMARY OF FINDING 18**

Costs are a significant issue for consumers accessing ART, and the information relating to the costs of treatment and the rebates available is poorly communicated by ART providers.

<sup>361</sup> Submission 2019/05086

<sup>362</sup> Public consultation forum, Ballarat, 13 September 2019.

<sup>363</sup> Ibid.

<sup>364</sup> Submission 2019/05664

<sup>365</sup> Submission 2019/06693

<sup>366</sup> Krispin, R, 2019, ‘Dodgy and unethical IVF practices under the microscope’, *MOJO News* <https://www.mojonews.com.au/features/dodgy-and-unethical-ivf-practices> accessed 20 December 2019.

<sup>367</sup> Provider consultation forum, Melbourne, 12 September 2019.

*Fertility treatments are costly and the stakes are high.*<sup>368</sup>

While Victorians are fortunate to have a range of ART providers from which to choose, the high cost of ART services remains a significant barrier to access. There has been a recent emergence of some low-cost private providers, which has improved affordability for some patients, but these services are narrowly focused and not available to all who want them.<sup>369</sup>

The Gorton Review noted: ‘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.’<sup>370</sup> Such reforms include establishing a public gametes bank and allowing fertility nurses to perform artificial insemination procedures.<sup>371</sup>

In general, ART represents an expensive journey for consumers – and most are aware of this – but this inquiry found that consumers still felt that the communication of costs was inadequate. While consumers may understand that ART can be expensive, few enter ART with a clear picture of the actual costs of multiple cycles, adjuvant treatments, medications and time off work to attend appointments and recover from procedures.

Some consumers commented on what they felt was the mercenary nature of the ART industry. While noting that she loved her specialist, C14 stated, ‘I have spent close to \$40,000 [...] I didn’t pay attention because I was so desperate to have a baby [...] they treat you like a cash cow not a person.’<sup>372</sup> C59 expressed her mistrust of the industry: ‘For fertility specialists, financial gain comes from repeated failed service provision. In no other industry does remuneration increase with failure.’<sup>373</sup>

The NHMRC guidelines specify clinics must provide individuals or couples with ‘sufficient information regarding the likely fees and the associated out-of-pocket expenses so that they are able to make an informed financial decision’.<sup>374</sup> A common grievance expressed by consumers as part of the inquiry was that the costs of an IVF cycle, for example, was well communicated when beginning treatment, but not the possibility that success may take multiple cycles, involving cumulative and initially undisclosed costs. Each new cycle might attract different medications, investigative procedures and tests, and every cycle holds the possibility of failure. Consumers commented:

*I feel that the individual costs of a procedure are well disclosed. But what is not discussed is the long potential cost of a journey. What is not discussed is options. Looking back I feel that [the fertility specialist] did not have my best interests when making recommendations. I feel exploited financially.*<sup>375</sup>

<sup>368</sup> Farquhar and Marjoribanks (n262).

<sup>369</sup> Gorton (n2) xx.

<sup>370</sup> Ibid, 13.

<sup>371</sup> Ibid, vi.

<sup>372</sup> Submission 2019/05297

<sup>373</sup> Submission 2019/06737

<sup>374</sup> National Health and Medical Research Council (n87) 30.

<sup>375</sup> Submission 2019/05749

*I thought the cycle included all costs including medications and theatre costs, and transfer costs too. Which wasn't the case. It wasn't until we saw the finance office [that] we received all of this information. I feel like it should have been told to us prior.<sup>376</sup>*

*I felt costs directly to be paid to [ART provider] were clear, but the extensive nature of additional (necessary) costs (imaging, pharmacy, hospital, anaesthetist etc) which were charged separately, where very unclear. I needed to ask specific information about cost of medications. Costs escalated dramatically as I had a complication with my procedure, that required emergency surgery. My one egg freezing cycle is likely to cost at least double the anticipated cost, despite having top hospital private health cover.<sup>377</sup>*

Other consumers told similar stories to the inquiry, across providers:

*It felt like at each step we were being asked to pay for something else we didn't know needed to be paid for and once you are in the process, you can not exactly say no. Also, there was no mention of storage fees around fertilised embryos and again, once they are there, you do not really have a choice.<sup>378</sup>*

*We got the outline of the costs of the procedure but that didn't include a hospital fee that we were only alerted to on the day, nor did include preliminary appointments and testing fees. We were surprised by many of our fees.<sup>379</sup>*

*Only some procedures were explained. Extra costs were not advertised (FET, clinic transfer fees, fees for admin, police checks, counselling, medications etc).<sup>380</sup>*

*The information was unclear, particularly regarding the 'administration' costs. Additionally, we asked the clinic to provide a breakdown of the costs as the out of pocket seemed excessive and they were apprehensive to do so, in fact we never got a complete breakdown. Each different treatment cycle had differing costs and the treating Doctor never provided detail on these costs, we were always referred to a staff member from [provider] to discuss and they always referred back to the doctor's treatment protocols.<sup>381</sup>*

*I was not aware of all of the additional costs that continued to rack up as we went through the process. Obviously it helps when you reach the Medicare Cap but almost every week there was something else that you had to pay for that was not clearly outlined from the onset.<sup>382</sup>*

*Communication around fees was poor as I mentioned all of the extras that were not even broached before they needed to be paid.<sup>383</sup>*

The cost of medications was an area where consumers felt especially aggrieved:

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<sup>376</sup> Submission 2019/05438

<sup>377</sup> Submission 2019/07750

<sup>378</sup> Submission 2019/07586

<sup>379</sup> Submission 2019/07688

<sup>380</sup> Submission 2019/05582

<sup>381</sup> Submission 2019/06834

<sup>382</sup> Submission 2019/07815

<sup>383</sup> Submission 2019/07586

*I wasn't really encouraged to ask questions nor given any information about the risks, effectiveness or costs of these treatments. I didn't realise how expensive the DHEA medication was until the first script I had filled – \$90 for a month's supply of 100 tablets (I was instructed to take this medication three times daily).<sup>384</sup>*

*We weren't advised as to the costs of the many IVF medications however (which can be very expensive).<sup>385</sup>*

*Pharmaceutical costs were not discussed.<sup>386</sup>*

*They also don't detail the costs of medications, which can be a significant amount. A medication cost sheet would be useful. I found out later that many medications were cheaper elsewhere rather than from the clinic's pharmacy. They should be transparent about process, and they shouldn't be able to mark up more than a certain amount.<sup>387</sup>*

*We had an overview of costs, however we found that throughout the treatment the costs kept increasing as additional things were added. We had no idea about medication costs which was a huge consideration once pregnancy was achieved [...] I felt like we were treated like a walking credit card and had to go looking for information rather than it being explained to us [...] I felt that once they achieved the goal of pregnancy that they no longer cared.<sup>388</sup>*

C89 made the point that not only are ART costs cumulative as patients go through cycle after cycle, but costs are not static: 'Each year treatment costs and fees e.g. bed fees increased.'<sup>389</sup> C89 went through over a dozen cycles with a base rate of \$9,000 each time but was ultimately unsuccessful.

Even when not receiving treatment, consumers spoke of being charged for procedures. For example, when C21 developed OHSS, she said, 'they still charge cancellation fees. I mean there wasn't a chance to be pregnant that cycle but you're still charged.'<sup>390</sup>

The inquiry heard from consumers whose inability to pay costs directly impacted their scheduled treatment cycles:

*For our most current cycle we had no idea how much it would cost, and we're told to ring on day 1 of my period. When I called to commence the cycle we were informed of the upfront cost and that it would need to be paid that day for us to commence the cycle. As the cost was significantly higher than we anticipated, we had to postpone until a future cycle.<sup>391</sup>*

*On our first cycle [...] I attended the clinic to collect the prescribed medication only to be advised I couldn't collect it unless I could pay right there and then and provide proof of*

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<sup>384</sup> Submission 2019/06624

<sup>385</sup> Submission 2019/07326

<sup>386</sup> Submission 2019/07648

<sup>387</sup> Submission 2019/07742

<sup>388</sup> Submission 2019/05489

<sup>389</sup> Submission 2019/07764

<sup>390</sup> Submission 2019/05377

<sup>391</sup> Submission 2019/05605

*payment. Quite frustrating when this hadn't been explained previously and timing of commencing medication during IVF is such an important aspect.*<sup>392</sup>

From ART providers' points of view, most claimed that costs are always communicated ahead of treatment:

*Our clinic clearly outlines the cost of IVF treatments once the protocol for treatment has been determined by the treating medical specialist.*<sup>393</sup>

*The full range of appropriate treatment options for patients is provided during medical consultations. The appropriateness of treatment options depends heavily on the clinical context of the person's circumstances and requires careful and considered discussion with them [...] Written quotes, specific to the treatment chosen are provided to each patient, and out of pocket costs are never increased during or after treatment, even if additional costs are incurred by [the ART provider].*<sup>394</sup>

FS9 stated that she felt that competition over costs between providers created a situation where, she said, 'Scientifically driven and caring clinics are being tarred by money making clinics and those with poorly trained [doctors] and staff'.<sup>395</sup>

A few consumers mentioned the relatively new development of drawing down superannuation funds to pay for ART cycles, with brokers specifically engaged by ART providers to facilitate this:

*My specialist knew that we were not financially rich yet did not tell me that bulk billing was available in other clinics. I was given information however that you can access superannuation to pay for IVF – and there were businesses that you could pay to help access these funds. I find that deplorable.*<sup>396</sup>

C89 and her husband accessed their superannuation to fund their recent treatment at the suggestion of their clinic's Patient Liaison Officer. C89 said it was an extensive process, including requiring a separate psychological assessment at an additional cost.<sup>397</sup>

## Rebates

Medicare will only provide rebates for ART if individuals or couples are deemed medically infertile by a specialist. C59 felt that the high costs of ART were discriminatory: 'infertility is a medical condition. Why does it not have full coverage under PBS?'<sup>398</sup>

Consumers clearly felt information about what Medicare and private health rebates are available during ART were poorly communicated by providers:

*We received an outline of costing, but the finance staff were unable to articulate the breakdown of costing in regards to what is a complete cycle. For example we were initially under the impression that implantation was covered in our ICSI cycle cost and not an*

<sup>392</sup> Submission 2019/07702

<sup>393</sup> Submission 2019/05736

<sup>394</sup> Submission 2019/06693

<sup>395</sup> Submission 2019/05742

<sup>396</sup> Submission 2019/05096

<sup>397</sup> Public consultation forum, Melbourne, 11 September 2019.

<sup>398</sup> Submission 2019/06737

*additional cost. We were then told it was 100% Medicare rebated, which it isn't. It's an additional cycle with only 1/3 rebated by Medicare.*<sup>399</sup>

*It would be useful to have a breakdown showing what elements are covered by Medicare [...] You can see the upfront costs but it's hard to get a sense of what rebates you might get, and what can be claimed.*<sup>400</sup>

*I wasn't advised about being able to claim some prescribed medications with my private health insurance. I think it would have been so helpful if the clinic gave me that type of heads up because I would have been in the position to alter my cover so I could claim back some of the money I spent on the more expensive drugs.*<sup>401</sup>

In another viewpoint, S2 felt no part of ART should be subsidised:

*No taxpayer's money should be spent encouraging people to get pregnant. If anyone wants to use professional services to do this they should use their own money. It should not be claimable on Medicare. I would wonder at the ability of people who are too poor to pay for their own treatment to be able to afford to raise any child arising from the treatment.*

*As I consider there are already too many people in the world we need to discourage excess births. Anyone who wants to use ART/IVF should instead be encouraged to foster or adopt a child or children [...] The ART/IVF success rate seems to be very low for the amount of money spent on it.*<sup>402</sup>

The NSW Health Ministry is currently hearing a suite of proposals from a group of providers to make ART more affordable. These include:

- two free rounds of IVF for women under 40
- embryos be frozen free of charge for people diagnosed with cancer who are about to have chemotherapy.

NSW Health Deputy Secretary, Nigel Lyons, stated:

*In the private sector, IVF can cost up to \$9000 or \$10,000 in out-of-pocket costs, even after Medicare rebates. We want to bring that down substantially but we don't know how far we can go. It is a trade-off between how many women we can treat and how heavily we reduce the costs.*<sup>403</sup>

## International costs of ART

In Europe, the average cost of an IVF cycle is €4000–€5000 (approximately \$6400–\$8000).<sup>404</sup> The

<sup>399</sup> Submission 2019/06452

<sup>400</sup> Submission 2019/07742

<sup>401</sup> Submission 2019/07816

<sup>402</sup> Submission 2019/05840

<sup>403</sup> Morphet, J, 2019, 'Free rounds of IVF a proposal to make procedure more affordable', *The West Australian* <https://thewest.com.au/news/nsw/free-rounds-of-ivf-a-proposal-to-make-procedure-more-affordable-ng-01c7e216453394c32bfc65ac8384a66d> accessed 7 August 2019.

<sup>404</sup> ESHRE, 2017, 'The funding of IVF treatment' <https://www.eshre.eu/Press-Room/Resources> accessed 4 December 2019.

European Society of Human Reproduction and Embryology (ESHRE) reports almost all European Union member states (except Ireland and Lithuania) provide some government funding or subsidies for ART. The extent of state support varies from around 90 per cent in Belgium, France, Greece, Netherlands and Slovenia, to 20–30 per cent in Bulgaria, Romania and Spain.

Belgium, Denmark, Netherlands and Slovenia are reputed to have the most generous reimbursement policies in Europe, with almost full coverage for up to six IVF cycles. Germany reimburses 50 per cent of IVF/ICSI costs for up to three cycles.<sup>405</sup>

Eligibility for state-funded treatment is determined mainly by patient age, previous ART attempts and relationship status. For example, in France, treatment is reimbursed for up to four cycles in women up to the age of 45. Currently eligibility is limited to heterosexual couples with a diagnosis of infertility.<sup>406</sup> But, in October 2019, France's lower house of parliament overwhelmingly passed a bill that aims to give single women and lesbian couples up to the age of 43 legal access to IVF, egg freezing and fertility medication. This bill will be debated in January 2020.<sup>407</sup>

In the UK, the National Institute for Health and Care Excellence (NICE) fertility guidelines recommends women under 40 be offered three cycles of ART covered by the National Health Service (NHS) if they have been trying to get pregnant for two years or have undertaken 12 cycles of artificial insemination without success. The NICE guidelines also state women aged 40–42 should be offered one cycle of IVF subsidised by the NHS.

Individual NHS clinical commissioning groups decide who can have NHS-funded IVF in their local area, and their criteria may be stricter than those recommended by NICE.<sup>408</sup> Although NICE recommends that three cycles of ART should be offered on the NHS, some clinical commissioning groups only offer one cycle, or only offer NHS-funded ART in exceptional circumstances.

Access to ART in the United States is still largely for those who can afford it privately.<sup>409</sup> With no federal law regulating ART, only a small number of states mandate insurance companies and employers to cover or subsidise the costs of fertility treatment.<sup>410</sup> Otherwise, treatment is performed within a private market system, which in 2014 was estimated to cost an average of US\$12,000 per cycle. With the average ART patient undertaking two IVF cycles, the cumulative costs can be much higher.<sup>411</sup>

## 5.8 Inclusivity and access

The ART Act intentionally removed many restrictions that prevented LGBTIQ+ individuals and couples and single people from accessing ART. Today many providers proudly advertise catering to LGBTIQ+ Victorians, and some specialists are recognised as particularly prominent in working with this community. For example, the newly opened Rainbow Fertility (part of City Fertility) has clinics nationwide, specifically supporting the LGBTIQ+ community.<sup>412</sup> Its website states: 'Rainbow Fertility has always advocated that Assisted Reproductive Treatment (ART) laws in Australia

<sup>405</sup> Ibid.

<sup>406</sup> Ibid.

<sup>407</sup> Corbet, S and Gaschka C, 2019, 'France Oks bill legalizing IVF for lesbians, single women', ABC, <https://abcnews.go.com/Health/wireStory/french-lawmakers-vote-giving-ivf-lesbians-singles-66283314> accessed 4 December 2019.

<sup>408</sup> NHS, 2018, 'Availability', <https://www.nhs.uk/conditions/ivf/availability/> accessed 4 December 2019.

<sup>409</sup> ESHRE, (n415).

<sup>410</sup> Fertility IQ, 'Does Insurance Cover IVF?' <https://www.fertilityiq.com/ivf-in-vitro-fertilization/costs-of-ivf#does-insurance-cover-ivf> accessed 4 December 2019.

<sup>411</sup> Ibid.

<sup>412</sup> Rainbow Fertility, <https://www.rainbowfertility.com.au/> accessed 3 December 2019.

should reflect the world we now live in and the advances in medical technologies and services that exist, while always adhering to the highest standards to ensure the safety and security of all.<sup>413</sup>

This inquiry only heard from a handful of same-sex couples, who mostly felt that they were not treated differently from any other couple. C16 stated: ‘As a same sex couple, respect was very important to us (as it is for everyone!) but we didn’t once feel like we were made to feel “less than” because of our sexuality.’<sup>414</sup> Overall, this inquiry found that as Victorian and national legislation continues to remove legal barriers for same-sex couples and for those who identify as queer, transgender and non-binary, the ART industry has largely kept pace.

As noted earlier, C65 made the point that while clinics may be up to date in dealing with LGBTIQ+ patients, ART counsellors need better training:

*Being a queer person, I think counsellors need training in how to support queers / LGBTIQA+ folks. We often have fear (based on experience) that any system is not there to support us and may actively seek to inhibit our choices and actions. So I went to counselling at first with trepidation and by the end anger and fear. I have heard similar from other queer folks.*<sup>415</sup>

Some LGBTIQ+ community members cannot access Medicare subsidies unless their specialist deems them medically infertile, so they may pay more for ART.<sup>416</sup> The Gorton Review also noted ART clinics still have work to do in responding appropriately to the needs of single people, men with infertility, sole parents, culturally diverse people, Aboriginal people and people with disability.<sup>417</sup> For people undergoing cancer treatment whose fertility may be affected, fertility preservation is currently inadequately covered by Medicare.<sup>418</sup>

There should be no different treatment for any groups and all should have equal access to ART.

## Accessibility

Accessibility and clinic location were the third highest choice when submitters were asked why they chose their particular provider/clinic, but rural and regional Victorians have few options when accessing ART. Only 28 per cent of registered Victorian ART clinics are situated in regional Victoria and only nine per cent of submitters to the inquiry accessed ART services in a regional location.

Of the 10 registered ART providers in Victoria, only five are exclusively state-based,<sup>419</sup> with other providers also offering services in other Australian jurisdictions. There are currently 25 registered Victorian ART clinic locations across Victoria. New clinics continue to open, but only one of these is located in a Victorian regional area (Albury).<sup>420</sup>

Most Victorian ART providers are based in Melbourne, meaning patients from other areas must

<sup>413</sup> Rainbow Fertility, ‘Victorian Art Amendments Make It Fairer’, <https://www.rainbowfertility.com.au/victorian-art-amendments-make-it-fairer/> accessed 3 December 2019.

<sup>414</sup> Submission 2019/05349

<sup>415</sup> Submission 2019/07222

<sup>416</sup> Gorton (n2) 79.

<sup>417</sup> Ibid, 61.

<sup>418</sup> Ibid, 74.

<sup>419</sup> New Life, Ballarat IVF, City Babies, Number One Fertility and the Women’s Hospital Reproductive Services Unit.

<sup>420</sup> VARTA (n176).

take significant time off work to attend appointments and have procedures, and may have to travel long distances each time. C80 commented that she felt she did not have a choice in providers: 'This is the only IVF provider in our regional town. It will be too disruptive to our working lives to travel to Melbourne for treatment.'<sup>421</sup>

Many regional satellite ART clinics operate on a part-time basis or only as day procedure clinics. One consumer who underwent ART at a regional ART provider stated: 'I only dealt with the clinics nurses/co-ordinators and didn't see my Obstetrician or any doctor at all during the process – only before I was referred to do IVF and once I was pregnant.'<sup>422</sup>

Both the interim and the final reports of the Gorton Review made extensive recommendations relating to inclusivity and access, particularly in relation to removing unnecessary or discriminatory barriers to access. This inquiry supports the recommendations of the Gorton Review with respect to inclusive practice and access and affordability.

#### RECOMMENDATION 17

The findings of this inquiry note and support the recommendations of the Gorton Review relating to inclusivity and access.

## 5.9 Criminal record and child protection order checks

#### SUMMARY OF FINDING 19

There is strong opposition from both ART providers and consumers to the required criminal record and child protection order checks for potential ART patients.

***It is noted this issue is currently being considered by the Victorian Government.***

*I was very upset when I discovered that we were required to get a police check prior to being able to commence IVF. This is yet another burden on those struggling with IVF and made me feel like a second class citizen.'*<sup>423</sup>

Provisions unique to Victoria in the world, currently, the ART Act requires both a woman and her partner (if any) to undergo criminal record and child protection order checks before beginning ART.<sup>424</sup> Potential ART patients can be denied treatment if a woman or her partner have proven charges of sexual or violent crimes, or a child protection order removing a child.

There was universal agreement across consumers and providers who made submissions to the inquiry regarding abolishing these mandatory checks for prospective Victorian ART consumers. Consumers described the process as 'offensive', 'humiliating', 'discriminatory', 'demeaning', 'invasive', 'unnecessary', 'disrespectful' and 'degrading'. Several questioned the fairness, considering individuals and couples without fertility problems are not required to undergo such a process. For consumers, the process of obtaining these checks adds an additional and unnecessary layer of stress to an already difficult ART journey:

<sup>421</sup> Submission 2019/07697

<sup>422</sup> Submission 2019/07816

<sup>423</sup> Submission 2019/07697

<sup>424</sup> Sections 3 and 14, *Assisted Reproductive Treatment Act 2008 (Vic)*.

*Despite endless years of medical certification, attempts at pregnancy and a medical diagnosis of infertility, the patient and her partner will also need to prove that they are not paedophiles and have acceptable police records. This is humiliating and demeaning and hurtful. This is a discriminatory process that only applies to infertile women – no other mother to be or expectant mother is required to prove she is in a State-sanctioned relationship, and that she is not a paedophile.<sup>425</sup>*

*You already feel low and potentially a bit faulty when you go into this process, and having to process you're not a criminal is just another blow.<sup>426</sup>*

*I was made to feel like I had to prove that I am worthy to be a parent. An already emotionally difficult situation was made so much worse [...] You shouldn't be made to feel like a criminal because you struggle to have a family.<sup>427</sup>*

*If the counselling session was initially an offensive suggestion, the requirement to undertake a police check was downright hurtful. We tried in vain to conceive for almost two years before we started IVF. For this two year period, everywhere we looked, we saw people with children. Friends and colleagues all around us seemed to be falling pregnant by simply looking at the opposite sex, and particularly for my wife, we saw ourselves as complete failures [...] Honestly; unnecessary, hurtful and downright offensive. If there were a group of people who should require a police check before having a child, it is not the people who have tried and tried and tried and tried, who will then go and be poked and prodded, and belittled with the need to ejaculate into a cup and then let a lab technician do what we can't do naturally. It is not those people. So please get rid of this ridiculous requirement.<sup>428</sup>*

Criminal record and child protection order checks can also add weeks to a process where the clock is usually already ticking. C24, who was undergoing ART to preserve her fertility as she entered treatment for cancer, mentioned her anxiety in waiting for her approvals: 'I went into surgery not knowing if my police check had arrived in time for them to make embryos. For our situation, it was time critical and they received the police check only as I was admitted.'<sup>429</sup> C79 noted the process of securing a counselling appointment and then going through the checks added two months to her ART.<sup>430</sup>

C61 stated:

*I also took great distaste to a criminal record check – especially given I am practicing [sic] Paediatric doctor in training and had a completed national check only a few weeks prior but was forced to repeat it as it didn't state 'ivf applicant' – what exactly the state wants so know beyond what they want for a paediatric professional is beyond me ... It also takes weeks. We don't have weeks.<sup>431</sup>*

<sup>425</sup> Submission 2019/07692, see also 2019/06737

<sup>426</sup> Submission 2019/07742

<sup>427</sup> Submission 2019/06408

<sup>428</sup> Submission 2019/05575

<sup>429</sup> Submission 2019/05487

<sup>430</sup> Submission 2019/07692

<sup>431</sup> Submission 2019/06834

Currently under the ART Act, ART counsellors are responsible for the paperwork involved in the checks. ART providers commented that removing the checks would benefit the working relationship between counsellors and patients, with one specialist stating that police checks were 'inappropriate'.<sup>432</sup>

The Gorton Review elaborated on this point:

*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.*<sup>433</sup>

In February 2020, the Victorian Government announced it will be removing the requirement that Victorians must undergo criminal record and child protection order checks to access ART.<sup>434</sup>

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<sup>432</sup> Submission 2019/05736

<sup>433</sup> Gorton (n2) 59.

<sup>434</sup> Tuohy, W, 2020, 'Police checks for IVF patients to be scrapped', *The Age*  
<https://www.theage.com.au/politics/victoria/police-checks-for-ivf-patients-to-be-scrapped-20200218-p541y2.html>

## CONCLUSION

*ART was not an enjoyable experience, it is always going to be hard. We were one of the very lucky ones to now have a healthy family. I believe ART providers need to work hard on caring for the person/couple, not just being clinical and money driven in their approach. It's a bloody expensive process to go through and an absolute emotional roller coaster.<sup>435</sup>*

When this inquiry began, there were concerns that there were unscrupulous providers of ART services preying on Victorians desperate to have children. The Commissioner is satisfied that ART providers and fertility specialists who made submissions to this inquiry and who attended the provider consultation forum are committed to achieving successful outcomes for their patients. What is clear however, despite the best intentions of providers, is that there is significant room for improvement and consumers want a more patient-centred approach.

The treatment journey for every individual or couple going through ART is unique. All want the same outcome, but each path can comprise varying levels of information, different treatment protocols offered by different providers and confusion over clinical decision making.

Most consumers who made submissions to the inquiry described their ART journey as a negative experience, primarily due to poor communication from providers and suffering unexpected adverse events. Many expressed feeling unheard and unsupported through their treatment. Apart from the toll on patients' bodies, the inquiry heard the negative psychological impact of ART can extend years beyond receiving treatment.

Technology and medical advancements in ART continue to develop rapidly, adding to the complexity of what providers can offer consumers. However, this has not been met with a corresponding increase in patients feeling they are being given comprehensive information regarding the risks and likelihood of success in undergoing treatment. ART remains a confusing and impersonal experience for many consumers. As well, access to ART in Victoria remains in the purview of those that can afford it – or who can undertake extreme financial hardship in the process.

In conclusion, this inquiry found an industry that can lack transparency and erects barriers to good service provision, including unclear communication about procedures, likelihood of success and costs, or how to complain when consumers are unhappy with their treatment. The use of non-evidence-based 'add-on' or adjuvant treatments among providers continues to be inconsistent, and consumers lack the requisite information about such treatments' efficacy.

This inquiry has not considered the regulatory environment of the sector beyond putting ART into context. The Gorton Review made recommendations regarding the legislative and regulatory framework, which this inquiry had the benefit of reading before finalising this report. Where this inquiry heard messages consistent with those of the Gorton Review, it has not sought to make recommendations on those matters but supports the proposals of the Gorton Review. What this inquiry has identified are other areas for improvement and in those cases the inquiry has made recommendations that may assist ART providers in Victoria to improve certain areas of their practices that consumers have stated need improvement, including relating to ART providers' communication, counselling, adjuvant treatments and complaint handling.

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<sup>435</sup> Submission 2019/05588

The HCC will continue to monitor the complaints it receives and to work with ART providers to ensure their industry is the best it can be for all Victorians. Where the HCC learns of unscrupulous or predatory behaviour, the Commissioner will act.

## **APPENDIX 1: HCC ART discussion paper**

The *Inquiry into Assisted Reproductive Treatment Practices Discussion paper June 2019* is available on the [Health Complaints Commissioner website](https://hcc.vic.gov.au/public/inquiry-assisted-reproductive-treatment-art-practices/discussion-paper) <<https://hcc.vic.gov.au/public/inquiry-assisted-reproductive-treatment-art-practices/discussion-paper>>.

## APPENDIX 2: HCC survey questions to consumers, providers and stakeholders

# PART A: SUBMISSIONS TO INQUIRY - FOR CONSUMERS

Please answer some or all of the following questions if you have previously accessed or are currently accessing ART services in Victoria. If you have accessed ART outside of Victoria, we are unable to consider your experiences as part of this Inquiry.

If you are providing a submission on behalf of someone who has accessed ART services then we recommend that you ask their permission to tell their story.

DO YOU WISH TO REMAIN ANONYMOUS?

Yes

No

Even if you ticked the box to show you want to remain anonymous, if we have any follow-up questions it would assist us to be able to contact you. For that reason, please provide us with as much information as possible, including your personal details, but clearly noting that you want your submission to be anonymous.

Q1. Please provide your personal details including:

Name

Email

Phone

Address

Are you making a submission as someone who has undergone ART services?

Yes

No

Are you making a submission as a friend or family member of someone who has undergone ART services?

Yes

No

Q.2 Please briefly describe your experience of ART services, including when and where the ART services were received and the name of the ART provider/clinic.

Q.3 Why did you choose your particular ART provider/clinic?

Q.4 (a) Did you research your ART provider/clinic before you accessed ART?

- Yes
- No

Q.4 (b) If yes to (a), what research did you do? Please describe the methods you used, including whether you approached the provider directly or contacted agencies, such as Victorian Assisted Reproductive Treatment Authority, ART support groups, peak bodies etc.

Q.5 Before accessing ART services, did you rely on any advertising by the ART provider/clinic in choosing that particular provider/clinic?

- Yes
- No

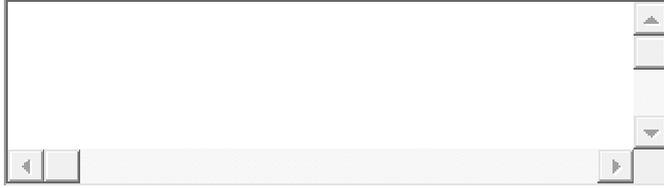
Please describe how important the ART provider/clinic's advertising was on your decision-making about that provider/clinic.

Q.6 What information, if any, did you get about costs before commencing ART? If you received costs information after commencing ART please also comment on that.

Thinking about your experience, do you feel the information you received was sufficient?

- Yes
- No

Is there information you were not given that you think would have been useful?



Q.7 Before commencing ART, were you given information about the treatment options, risks and possible outcomes?

- Yes
- No

Would you say that the information was easily accessible and accurate?

- Yes
- No

Q.8 (a) Were you offered any 'add-ons' or adjuvant treatments as part of your ART? Please see Discussion Paper Appendix 2 for more details about adjuvant treatments.

- Yes
- No

Q.8 (b) What information were you provided about those services and when was that provided to you?



Q. 8 (c) Were you given an opportunity to ask questions about the risks, the effectiveness or necessity of those treatments or their costs?

- Yes
- No

Q.8 (d) Did you decide to try an add-on or adjuvant treatment?

- Yes
- No

Q.9 (a) Did you experience any adverse events during your ART?

- Yes
- No

An adverse event is defined as -

**A serious adverse event is any event associated with ART treatment which:**

- Causes harm, loss or damage to patients or their reproductive tissues.
- Causes a significant medical or surgical condition to arise directly from ART treatment.
- Results in hospitalisation following, and a result of, the ART treatment.

**A notifiable adverse event is an abnormal unintended outcome associated with ART operations which:**

- Might result in the transmission of a communicable disease.
- Might result in death or a life-threatening, disabling or incapacitating condition.
- Might impact safety of people, gametes, embryos, equipment or facilities as a result of a disease.
- Results in a potential or actual breach of legislation.

*RTAC Code of Conduct for Assisted Productive Technology Units, Fertility Society of Australia, Oct 2017*

Q.9 (b) If you did experience an adverse event how well do you think the ART provider/clinic handled that event? Were you informed promptly? Who informed you about the event?

Q.10 (a) What information were you given about your ability to make a complaint about your ART provider/clinic or the treatment you received?

Q.10 (b) Do you feel the information you were given was sufficiently clear, in plain English and easy to understand?

- Yes
- No

Q.10 (c) Is there any additional information you think should have been provided?

- Yes
- No

An adverse event is defined as -

**A serious adverse event is any event associated with ART treatment which:**

- Causes harm, loss or damage to patients or their reproductive tissues.
- Causes a significant medical or surgical condition to arise directly from ART treatment.
- Results in hospitalisation following, and a result of, the ART treatment.

**A notifiable adverse event is an abnormal unintended outcome associated with ART operations which:**

- Might result in the transmission of a communicable disease.
- Might result in death or a life-threatening, disabling or incapacitating condition.
- Might impact safety of people, gametes, embryos, equipment or facilities as a result of a disease.
- Results in a potential or actual breach of legislation.

*RTAC Code of Conduct for Assisted Productive Technology Units, Fertility Society of Australia, Oct 2017*

Q.9 (b) If you did experience an adverse event how well do you think the ART provider/clinic handled that event? Were you informed promptly? Who informed you about the event?

Q.10 (a) What information were you given about your ability to make a complaint about your ART provider/clinic or the treatment you received?

Q.10 (b) Do you feel the information you were given was sufficiently clear, in plain English and easy to understand?

- Yes
- No

Q.10 (c) Is there any additional information you think should have been provided?

# PART B: SUBMISSIONS TO INQUIRY - FOR PROVIDERS AND CURRENT/FORMER EMPLOYEES

Please answer some or all of the following questions if:

- you have previously worked at or are currently working at, an ART provider/clinic in Victoria;
- you represent an ART provider or ART clinic;
- you represent other fertility service providers;

Where a question refers to “your ART provider/clinic” it is intended to apply to representatives of the organisation and employees and former employees.

DO YOU WISH TO REMAIN ANONYMOUS?

Yes

No

Even if you ticked the box to show you want to remain anonymous, if we have any follow-up questions it would assist us to be able to contact you. For that reason, please provide us with as much information as possible, including your personal details, but clearly noting that you want your submission to be anonymous.

Q.1 Please provide your personal details, including:

Name

Email

Phone

Address

Are you making a submission on behalf of an ART provider/clinic or other fertility service?

Yes

No

Are you making a submission as a current/former employee of an ART provider/clinic or other fertility service?

Yes

No

Q.2 (a) Does your ART provider/clinic advertise its services?

Yes

No

Q.2 (b) Does your ART provider/clinic use patient testimonials to promote its services?

Yes

No

Q.3 How does your ART provider/clinic provide patients with information regarding treatment options, success rates, risks, possible outcomes and costs?



Q.4 Counselling is an important part of ART and a legal requirement. Please set out details of the counselling your ART provider/clinic provides to patients who wish to undergo ART.



Q.5 (a) Does your ART provider/clinic offer 'add ons' or adjuvant treatments?

Yes

No

Q. 5 (b) Is the efficacy of such 'add ons' and adjuvant treatments discussed with patients?

Yes

No

Q.6 (a) Does your ART provider/clinic have a complaints handling system or processes?

Yes

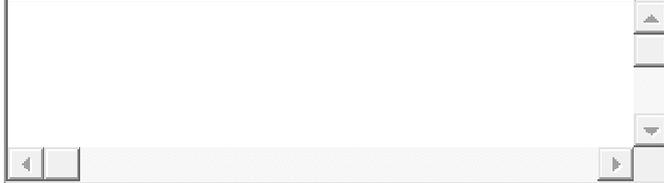
No

Q.6 (b) Is your ART provider/clinic aware of the role of the Health Complaints Commissioner?

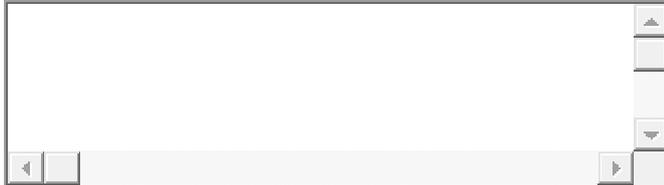
Yes

No

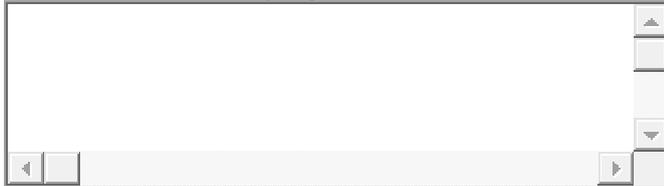
Q.7 If a patient makes a complaint to your ART provider/clinic, what information is the patient given about their rights in relation to the complaint?

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Q.8 How does your clinic manage adverse events? Please briefly describe the process that follows an adverse event.

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Q.9 Please provide any further information you would like the Commissioner to consider in this Inquiry.

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# PART C: SUBMISSION TO INQUIRY - FOR OTHER STAKEHOLDERS

Please answer some or all of the following questions if you are a stakeholder or other interested party that is not included in Parts A or B, based on your understanding of the provision of ART in Victoria. We welcome any other information or insights you can provide to the Inquiry.

DO YOU WISH TO REMAIN ANONYMOUS?

Yes

No

Even if you ticked the box to show you want to remain anonymous, if we have any follow-up questions it would assist us to be able to contact you. For that reason, please provide us with as much information as possible, including your personal details, but clearly noting that you want your submission to be anonymous.

Q.1 Please provide your personal details, including:

Name

Email

Phone

Address

If you are making a submission on behalf of an organisation, please name the organisation and briefly describe your role and the relationship your organisation has with ART.

Q.2 (a) Are you aware of ART provider/clinics' advertising practices?

Yes

No

Q.2 (b) Are you aware of ART providers/clinics using patient testimonials to promote their services?

Yes

No

Q.3 Do ART providers/clinics provide adequate counselling?

Yes

No

Why do you hold that view?



Q.4 (a) Are you aware of ART providers/clinics offering 'add ons' or adjuvant treatments?

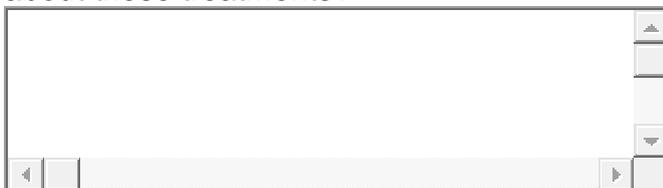
Yes

No

Q.4 (c) What do you understand about the efficacy of 'add ons' or adjuvant treatments?



Q.4 (d) What is your understanding of the information (if any) patients are given about these treatments?



Q.5 Do ART providers/clinics adequately manage adverse events?

Yes

No

Please explain why you hold that view.

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Q.6 Do ART providers/clinics comply with the Australian 'Open Disclosure' framework?

- Yes
- No

Please explain why you hold that view.

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Q.7 Please provide any further information you would like the Commissioner to consider in this Inquiry.

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## APPENDIX 3: De-identified inquiry submissions and consultation forum participants

### Consumers

Category of submitter	HCC case number	Report reference	Anonymity requested
A	2019/05042	C1	Unstated
A	2019/05060	C2	Unstated
A	2019/05065	C3	Unstated
A	2019/05066	C4	Unstated
A	2019/05073	C5	Yes
A	2019/05075	C6	Unstated
A	2019/05083	C7	No
A	2019/05086	C8	No
A	2019/05090	C9	No
A	2019/05096	C10	Yes
A	2019/05188	C11	Yes
A	2019/05235	C12	No
A	2019/05237	C13	Yes
A	2019/05297	C14	Yes
A	2019/05348	C15	Yes
A	2019/05349	C16	No
A	2019/05365	C17	No
A	2019/05368	C18	Unstated
A	2019/05371	C19	No
A	2019/05374	C20	Yes
A	2019/05377	C21	Yes
A	2019/05438	C22	No
A	2019/05439	C23	Yes
A	2019/05487	C24	Yes
A	2019/05489	C25	No
A	2019/05564	C26	Yes
A	2019/05575	C27	No
A	2019/05582	C28	Yes
A	2019/05588	C29	No
A	2019/05605	C30	Yes
A	2019/05648	C31	Yes
A	2019/05717	C32	Yes
A	2019/05749	C33	No
A	2019/05821	C34	Yes
A	2019/05894	C35	No

Category of submitter	HCC case number	Report reference	Anonymity requested
A	2019/05895	C36	Yes
A	2019/05930	C37	No
A	2019/05961	C38	No
A	2019/06026	C39	Yes
A	2019/06122	C40	No
A	2019/06123	C41	Yes
A	2019/06135	C42	No
A	2019/06150	C43	Yes
A	2019/06177	C44	Yes
A	2019/06284	C45	Yes
A	2019/06286	C46	Yes
A	2019/06397	C47	Yes
A	2019/06408	C48	No
A	2019/06452	C49	Yes
A	2019/06454	C50	Yes
A	2019/06500	C51	No
A	2019/06589	C52	No
A	2019/06590	C53	Yes
A	2019/06624	C54	No
A	2019/06630	C55	Yes
A	2019/06642	C56	No
A	2019/06644	C57	No
A	2019/06646	C58	No
A	2019/06737	C59	Yes
A	2019/06739	C60	Yes
A	2019/06834	C61	Unstated
A	2019/07032	C62	Yes
A	2019/07035	C63	Yes
A	2019/07198	C64	No
A	2019/07222	C65	Yes
A	2019/07259	C66	Yes
A	2019/07260	C67	No
A	2019/07321	C68	No
A	2019/07326	C69	Yes
A	2019/07326	C70	Yes
A	2019/07370	C71	Yes
A	2019/07371	C72	No
A	2019/07581	C73	No
A	2019/07582	C74	Yes
A	2019/07586	C75	No

Category of submitter	HCC case number	Report reference	Anonymity requested
A	2019/07590	C76	No
A	2019/07648	C77	Yes
A	2019/07688	C78	No
A	2019/07692	C79	No
A	2019/07697	C80	No
A	2019/07702	C81	Yes
A	2019/07742	C82	No
A	2019/07746	C83	Yes
A	2019/07750	C84	Yes
A	2019/07752	C85	Yes
A	2019/07754	C86	Yes
A	2019/07757	C87	Yes
A	2019/07760	C88	Yes
A	2019/07764	C89	No
A	2019/07766	C90	No
A	2019/07815	C91	No
A	2019/07816	C92	Yes
A	2019/07818	C93	Yes
A	Public forum participant	C94	Unstated
A	Public forum participant	C95	Unstated

## ART providers/staff

Category of submitter	HCC case number	Report reference	Anonymity requested
B	2019/05496	PS1	No
B	2019/05664	FS2	No
B	2019/05709	FS3	No
B	2019/05710	FS4	Yes
B	2019/05716	FS5	Yes
B	2019/05735	FS6	No
B	2019/05736	FS7	Yes
B	2019/05740	FS8	Yes
B	2019/05742	FS9	Yes
B	2019/05897	PS10	Yes
B	2019/06399	PS11	Yes
B	2019/06409	PS12	Yes
B	2019/06547	Monash IVF	No
B	2019/06573	Victorian Infertility Counsellors Group	No
B	2019/06631	Adora Fertility	No
B	2019/06693	Ballarat IVF	No

Category of submitter	HCC case number	Report reference	Anonymity requested
B	2019/07589	PS17	Yes
B	2019/08067	FS18	No
B	Provider forum participant	FS19	Unstated
B	Provider forum participant	FS20	Unstated
B	Provider forum participant	FS21	Unstated

## Other stakeholders

Category of submitter	HCC case number	Report reference	Anonymity requested
C	2019/05649	S1	No
C	2019/05840	S2	Yes
C	2019/06410	Healthy Male	No
C	2019/06638	ARMS (Vic)	No
C	2019/06639	S5	Yes
C	2019/06982	S6	Unstated
C	2019/07037	S7	Yes
C	2019/07125	Pink Elephants	No
C	2019/07690	AHPRA	Unstated
C	2019/07821	S10	Unstated
C	Public forum participant	S11	Unstated

## ABBREVIATIONS

<b>AHPRA</b>	Australian Health Practitioner Regulation Agency
<b>ANZARD</b>	Australian and New Zealand Assisted Reproduction Database
<b>ART</b>	assisted reproductive treatment
<b>FSA</b>	Fertility Society of Australia
<b>Gorton Review</b>	Michael Gorton AM's <i>Helping Victorians create families with assisted reproductive treatment: Final Report of the Independent Review of Assisted Reproductive Treatment (2019)</i>
<b>HCC</b>	Health Complaints Commissioner
<b>HFEA</b>	Human Fertilisation and Embryology Authority (UK)
<b>ICSI</b>	intracytoplasmic sperm injection
<b>IVF</b>	in-vitro fertilisation
<b>NHMRC</b>	National Health and Medical Research Council
<b>NHMRC guidelines</b>	NHMRC's <i>Ethical guidelines on the use of assisted reproductive technology in clinical practice and research</i>
<b>NHS</b>	National Health Service (UK)
<b>NICE</b>	National Institute for Health and Care Excellence (UK)
<b>OHSS</b>	ovarian hyperstimulation syndrome
<b>PGS</b>	preimplantation genetic screening
<b>RTAC</b>	The Reproductive Technology Accreditation Committee of the Fertility Society of Australia
<b>VARTA</b>	Victorian Assisted Reproductive Treatment Authority

## GLOSSARY

**Assisted reproductive treatment** – a group of procedures that involve the in vitro (outside of the body) handling of human eggs and sperm or embryos for the purpose of establishing a pregnancy.

**Autologous** – an ART cycle in which a woman uses her own eggs or fertilised embryos.

**Blastocyst** – the stage when an embryo is transferred to the womb. The embryo is cultured to this stage of development (five days after fertilisation) when it would normally move out of the fallopian tube into the uterus.

**Chemical pregnancy** – an early pregnancy loss that occurs shortly after implantation.

**CRISPR-Cas9** – a recent technology that enables geneticists and medical researchers to edit parts of the genome by removing, adding or altering sections of the DNA sequence.

**Egg retrieval** – a procedure to collect egg(s) from a woman.

**Embryoscope** – allows embryologists to monitor developing embryos through their growth to a blastocyst.

**Endometrial scratching** – a technique that purports to improve the ability of an embryo to implant in the uterus after IVF by artificially injuring the endometrium with a plastic pipette.

**Endometriosis** – a condition that occurs when cells similar to those that line the uterus are found in other parts of the body, causing inflammation and often severe pain.

**Embryo** – an unborn or unhatched offspring in the process of development, in particular during the period from approximately the second to the eighth week after fertilisation.

**Frozen embryo transfer** – where a frozen embryo from a previous IVF cycle is thawed and transferred back into a woman's uterus.

**Gamete** – an egg or sperm.

**Hypothalamic amenorrhea** – a condition in which menstruation stops for several months due to a problem involving the hypothalamus.

**Intracytoplasmic morphologically selected sperm injection (IMSI)** – a technique to examine and select sperm using a high-magnification digital microscope for microinjection into the egg.

**Intracytoplasmic sperm injection (ICSI)** – usually only used in male factor infertility, an additional part of an IVF treatment cycle where a single sperm is injected into each egg to assist fertilisation using fine micro-manipulation equipment.

**In-vitro fertilisation (IVF)** – a process of fertilisation where an egg is combined with sperm outside the body. In a standard IVF process, a woman is given hormone injections to stimulate her ovaries' egg production, sometimes in tandem with other medications. When eggs are detected via ultrasound, a procedure follows to retrieve them. They are then mixed with the partner/donor's sperm. After waiting up to five days to see if any successful embryos develop,

one will be implanted in the woman's uterus and any other viable embryos frozen. Patients can also elect to freeze all embryos for later implantation. Around two weeks later, the women will take a pregnancy test to see if the procedure was successful. An IVF cycle takes about three weeks but may take longer.

**Intrauterine insemination (IUI)** – also known as artificial insemination, a procedure where sperm is injected into the vagina, cervical canal or uterus of a woman. Sperm can come from her partner or a donor.

**Live birth** – a birth event in which a live born baby is delivered. Live births are counted as birth events, e.g. a twin or triplet live birth is counted as one birth event.

**Liveborn baby** – a foetus delivered with signs of life after complete expulsion or extraction from its mother, beyond 20 completed weeks of gestational age.

**Oocyte** – a woman's unfertilised egg.

**Ovarian hyperstimulation syndrome** – occurs when too much injectable hormone medication leads to ovaries producing too many eggs and becoming swollen and/or painful.

**Ovulation induction** – fertility treatment that involves taking oral or injectable medication to stimulate regular ovulation.

**Physiological intracytoplasmic sperm injection (PICSI)** – a procedure that employs sperm binding to hyaluronic acid to help choose which sperm to use for intracytoplasmic sperm injection.

**Polycystic ovarian syndrome** – a hormonal disorder causing enlarged ovaries with small cysts on the outer edges.

**Preimplantation genetic diagnosis** – a procedure used prior to embryo transfer to detect serious genetic conditions, diseases or abnormalities, where the gamete provider(s) are known to be at risk, to carry or to be predisposed.

**Preimplantation genetic screening (PGS)** – a procedure used to test embryos for unspecified and multiple genetic or chromosomal abnormalities where the gamete providers are not known to have any genetic condition, disease or abnormality, or who do not carry a known causative abnormality. PGS may be undertaken to improve live birth rates (by improving pregnancy rates from embryo transfer and reducing incidence of miscarriage) and may be suitable in cases of advanced maternal age and repeated implantation failure.

**Preimplantation genetic testing** – a sophisticated scientific technique that can be used to test embryos for either a specific known genetic condition or chromosome abnormality.

**Progesterone** – a steroid hormone involved in the menstrual cycle, pregnancy and embryogenesis of humans and other species.

**Registered ART provider** – an ART provider registered under Part 8 of the *Assisted Reproductive Treatment Act 2008*.

**Surrogacy** – an arrangement whereby a woman carries an implanted embryo to

pregnancy with the intention or agreement that the offspring will be parented by the commissioning parent(s).

**Thaw cycle** – a cycle where frozen eggs, sperm or embryos are thawed prior to transfer.

**Transfer** – the procedure of placing embryos into a woman's uterus.



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