HEALTH COMPLAINTS COMMISSIONER

Addendum to Inquiry into Assisted Reproductive Treatment Practices Discussion Paper June 2019

Extension of submission closure date

In June 2019 I released a Discussion Paper and announced my Inquiry into the provision of Assisted Reproductive Treatment (ART) services, inviting submissions from: past and current ART patients (including family members and friends); ART providers and their staff (former and current); and other interested stakeholders. I requested that submissions be made by 16 August 2019.

To ensure interested parties have enough time to make a submission, and to hold a series of consultation sessions throughout September, the closing date for submissions to the Inquiry into ART Practices has been extended to **20 September 2019.**

More information about the Inquiry can be obtained at: www.hcc.vic.gov.au/public/inquiry-art-and-ivf-practices.

Karen Cusack
Health Complaints Commissioner
16 August 2019

HEALTH COMPLAINTS COMMISSIONER

Inquiry into Assisted Reproductive Treatment Practices

Discussion paper

June 2019

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FOREWORD BY THE HEALTH COMPLAINTS COMMISSIONER

In March 2019, the Minister for Health, the Hon Jenny Mikakos MP, referred to me for Inquiry under section 103 of the *Health Complaints Act 2016* (Act), the matter of the provision of Assisted Reproductive Treatment (ART) services.

To carry out the Inquiry, it is vital that I have available to me as much information as possible relating to ART services. With this in mind, this discussion paper has been developed which asks a series of questions that will be open to everyone. Responses to these questions will form submissions to the Inquiry to provide the important information I need to understand the breadth of concerns relating to the provision of ART services in Victoria and to consider the next steps in the Inquiry.

I am inviting submissions from: past and current ART patients (including submissions from family members and friends); ART providers and their staff (former and current); and other interested stakeholders. I urge members of the public, including those working in the sector to respond to this discussion paper. I want to hear from a wide range of people to ensure that the findings of the Inquiry are as informed as possible. I want to hear from people of all backgrounds, including those residing in rural and regional Victoria and people from diverse communities including people who identify as Aboriginal and Torres Strait Islander, people living with physical or intellectual disabilities, people from culturally diverse backgrounds and members of the LGBTQI+ community.

Importantly, anyone wishing to remain anonymous may do so. I understand that it may be distressing for people who have used ART services to discuss their experiences. I can assure anyone who contacts my office that they will be treated with respect, sensitivity and confidentiality.

The purpose of the Inquiry is broad ranging and may include recommendations to positively influence the sector. If, as part of the Inquiry, individual cases identify that there are dangerous and unethical practices occurring and I believe those matters should be investigated, then a separate investigation may be conducted. All Victorians have the right to receive safe and ethical health care. That applies across all health care settings and is equally true in the context of ART services which can be an emotional and challenging time for many patients.

I look forward to and welcome feedback and input into the Inquiry. More information can be obtained at: www.hcc.vic.gov.au/public/inquiry-art-and-ivf-practices.

Karen Cusack
Health Complaints Commissioner

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1 – INTRODUCTION

On 13 November 2018, the Victorian Government committed to task the Health Complaints Commissioner (Commissioner) to lead an Inquiry into ART providers.

The commitment was made following the release of the interim report of the review of ART, *Helping Victorians Create Families and Assisted Reproductive Treatment*, prepared by Mr Michael Gorton AM (Gorton Review) which highlighted some concerns including:

- potentially dangerous and unethical practices of ART providers
- use of "add-ons" or "adjuvant therapies" not medically proven to be effective
- potential misleading and deceptive conduct in relation to advertisement of costs and success rates

In March 2019, the Minister for Health, the Hon Jenny Mikakos MP, referred to the Commissioner for Inquiry under section 103 of the *Health Complaints Act 2016* (Act), the matter of the provision of Assisted Reproductive Treatment (ART) services. The Minister's terms of reference were finalised (Terms of Reference) and are included in **Appendix 1.**

To conduct the Inquiry, the Commissioner is seeking submissions responding to a series of questions in this discussion paper. The submissions will provide important information about the breadth of concerns relating to the provision of ART services in Victoria and will guide the next steps in the Inquiry.

Complaints to the Health Complaints Commissioner

Between 1 February 2017 and 31 March 2019, the Commissioner received 56 complaints about ART relating to 83 separate issues. A single complaint may relate to multiple issues. Inadequate or inappropriate treatment was the single most common issue cited, followed by access to services and communication.

If a complaint has previously been made and dealt with, the issues that gave rise to the complaint will be looked at and separately considered as part of the Inquiry, but it won't be treated as a submission to the Inquiry. The Inquiry is interested to hear submissions from any person in relation to their experiences, whether they have previously lodged a complaint or not.

In accordance with section 152 of the Act, where a complaint was, or is currently being dealt with in the formal conciliation process under the Act, any information provided as part of the conciliation cannot be considered due to the confidential nature of the process.

Any person who has previously lodged a complaint with the Commissioner's office or as part of the Gorton Review may also wish to make a submission to this Inquiry and are encouraged to do so.

People working on the Inquiry

The Inquiry is being led by Ms Karen Cusack, Health Complaints Commissioner, and she will be assisted by Counsel Assisting the Commissioner, Ms Estelle Frawley, a member of the Victorian Bar. Ms Cusack will also be assisted by staff from her office.

The Commissioner is an independent and impartial statutory officer and will undertake the Inquiry in accordance with the Act with the aim of supporting safe and ethical healthcare in Victoria.

Purpose of the Inquiry

The Minister for Health has referred a health service matter (provision of ART) to the Commissioner under section 103 of the Act.

The purpose of the Inquiry is broad. The Inquiry invites submissions from all members of the public about their experiences of ART, ART providers and staff and other key stakeholders. One element of the Inquiry will be to consider whether there are unsafe and/or unethical practices being carried out in the provision of ART in Victoria. It is important to note that there are no pre-conceived assumptions being made leading into the Inquiry, which is why the Commissioner needs to hear from as many people as possible.

Outcomes of the Inquiry could include the Commissioner working together with the ART sector to improve education, making recommendations to the Minister for Health to promote continuous improvement in the sector or referral to another appropriate body (or a combination of these potential outcomes).

If consumer law matters are identified during the Inquiry, including matters of false, misleading and deceptive conduct relating to advertisement of success rates and costs, the Commissioner will work with Consumer Affairs Victoria (CAV) to address any matters which fall under CAV's jurisdiction.

Where matters are identified as part of the Inquiry that are outside the jurisdiction of the Commissioner or CAV, those matters may be referred to other regulators as appropriate such as the Australian Health Practitioner Regulation Agency (AHPRA), in accordance with both regulator's usual practice.

Scope of the Inquiry

The Inquiry will not re-open complaints that have previously been dealt with under the Act or its predecessor, the *Health Services (Conciliation and Review) Act 1987*. Any complaint currently being dealt with by the Commissioner's office will continue to be managed through the complaint resolution process. However, the Inquiry is interested to hear submissions from any person in relation to their experiences, whether they have previously lodged a complaint or not. If someone wishes to make a complaint, they can do so by completing the online complaint form at www.hcc.vic.gov.au/make-complaint or by calling the Health Complaints Commissioner on 1300 582 113.

Further, the Inquiry is not looking at the operation or scope of the *Assisted Reproductive Treatment Act 2008* or the regulation of ART generally.

Interstate and overseas practices and those procedures that are illegal in Victoria are outside the scope of the Inquiry. This Inquiry will only examine ART services within Victoria.

Finally, the Inquiry is focusing on health service provision and ART providers, whether registered Reproductive Technology Accreditation Committee (RTAC) ART providers or others offering fertility treatment. For this reason, the conduct of other statutory bodies and departments relevant to ART (but not involved in the delivery of ART services) are not in the scope of the Inquiry.

Approach and purpose

The findings and recommendations of the Inquiry will be informed by:

- relevant matters identified throughout the public consultation process
- previous complaints about ART providers received by the Commissioner
- relevant incidents identified by respondents in the Gorton Review

The Commissioner seeks the views of anyone with knowledge, experience or information relevant to the Inquiry. The Commissioner wants to hear from people of all backgrounds, including those residing in rural and regional Victoria and people from diverse communities including people who identify as Aboriginal and Torres Strait Islander, people living with physical or intellectual disabilities,

people from culturally diverse backgrounds and members of the LGBTQI+ community. The Commissioner also wants to hear from people who have experienced ART or know someone who has; people who have worked in the ART sector (both former and current); ART clinics; peak bodies and regulators; and other health service providers.

Public Hearing

In conducting an Inquiry under section 103 of the Act, the Commissioner may (but does not have to) hold public hearings. In conducting a public hearing, the Commissioner:

- may take oral or written submissions from the public
- may send for persons, documents or other things
- is bound by the rules of natural justice
- is not bound by the rules of evidence
- must keep a record of all submissions and evidence given before the Commissioner and decisions made by the Commissioner.

A public hearing held by the Commissioner would be open to members of the public, ART providers and the media.

The Commissioner would prefer to voluntarily obtain information rather than compel the provision of information through a public hearing. Depending on the submissions received and the nature of the issues arising, the Commissioner may decide to hold a public hearing and if so, determine how such a hearing should be conducted.

The ways you can contribute

To inform the Inquiry, the Commissioner will conduct a wide-reaching consultation and public engagement process to identify experiences of the public (including patients and staff working in ART clinics) through a range of engagement forums and strategies that may include:

- direct and indirect engagement with stakeholders
- formal and informal mechanisms for providing feedback
- using existing networks and forums such as online and industry forums
- promotion of the consultation and engagement process including protections for people making a complaint.

The Commissioner encourages submissions from as many people as possible to ensure that the Inquiry reflects the Victorian community's experiences and expectations.

To make a submission, the Commissioner asks that you:

Provide a written response by **16 August 2019** -

- **by completing the online submission form at:**
  hcc.vic.gov.au/public/inquiry-art-and-ivf-practices

- **by email to:**
  hcc@hcc.vic.gov.au

- **by post to:**
  Health Complaints Commissioner
  ATTENTION ART INQUIRY
  Level 26, 570 Bourke Street
  Melbourne Vic 3000

Email and postal responses should be clearly marked ***'ATTENTION: ART INQUIRY'.*** Submissions should address some or all of the consultation questions.

Anonymous responses will be considered but we encourage respondents to provide their name, relevant organisation/s (if applicable) and contact details so that we can clarify any aspect of the matters raised. We will respect your anonymity and any matters raised will not form part of the report if an individual can be identified from the submission.

If you make a submission, please indicate if your submission is confidential and whether you are prepared to have your submission quoted within a report to the Minister for Health. Please note that the report may, at the discretion of the Minister for Health, be publicly released and may be subject to disclosure through freedom of information processes.

All formal submission responses must be received by **16 August 2019**. This will ensure that the responses can be considered in the final report to the Minister for Health. It will also ensure that if secondary consultation is required, such as a public hearing, this can occur prior to reporting to the Minister for Health by December 2019.

The Discussion Paper is separated into three parts:

- The first part is directed at individuals who want to make a submission either as someone who has received ART services or as a family member or friend of a person who has received such services. This part is headed: **Part A – Consumers of ART Services**.
- The second part is directed at staff members (former or current employees) of an ART clinic or service provider and operators of an ART clinic or service provider. This part is headed: **Part B - Providers of ART Services**
- The third part is directed at other interested stakeholders, such as peak bodies and other health service providers. The part is headed: **Part C – Other stakeholders.**

We look forward to your response.

The closing date for all submissions is 16 August 2019.

Further information is available at: https://hcc.vic.gov.au/public/inquiry-art-and-ivf-practices

2 – SUBMISSION QUESTIONS

Part A – Consumers of ART Services

Please answer some or all 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, we recommend that you ask their permission to tell their story.

DO YOU WISH TO REMAIN ANONYMOUS? YES ☐

Q.1* Please provide your personal details, including:

- ***whether you are making a submission as someone who has undergone ART services or whether you are making a submission as a friend or family member of someone who has undergone ART services***

***even if you ticked the box to show you want to remain anonymous, if we had 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.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?

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?

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?

Thinking about your experience, do you feel the information you received was sufficient? If not, why not?

Is there information you were not given that you think would have been useful?

If you received costs information after commencing ART please also comment on that.

Q.7 Before commencing ART, were you given information about the treatment options, risks and possible outcomes?

Please describe that information. Would you say that the information was easily accessible and accurate?

Q.8 (a) Were you offered any 'add-ons' or adjuvant treatments as part of your ART? (Please see Appendix 2 for more details about adjuvant treatments)

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?

Q.8 (d) Did you decide to try an add-on or adjuvant treatment? If so, why?

Q.9 (a) Did you experience any adverse events* during your ART?

Please briefly describe the adverse event and what occurred next.

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?

'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 as a result of, the ART treatment.

A **Serious 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
- 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.

RTAC Code of Conduct for Assisted Reproductive Technology Units, Fertility Society of Australia, Oct 2017

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?

Q.10 (c) Is there any additional information you think should have been provided?

Q.11 (a) In your view, how well do you think your ART provider/clinic communicated with you?

Q.11 (b) Why do you have that view?

In answering this question, it may be useful to consider issues such as: if you feel you were given enough information, was that information easy to understand, were you given enough time to consider the information and ask questions, were your questions answered, were you given updates?

Q.12 (a) Throughout your ART treatment did the ART provider/clinic support you, for example, by addressing your questions, explaining what to expect, treating you with respect or providing emotional support etc?

Q.12 (b) How well do you think your ART provider/clinic did in providing you with the support you expected?

Q.13 Did you receive counselling prior to commencing ART?

Please provide details about your experience of the counselling provided, including whether you found it helpful.

Q.14 Please provide any further information you would like the Commissioner to consider in this Inquiry.

Part B – Providers of ART Services

Please answer some or all the following questions if:

- you previously worked or currently work 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 ☐

Q.1* Please provide your personal details, including:

- ***if you are making a submission as an employee or former employee, briefly describing your role, name of the ART provider/clinic and when you worked at the clinic***
- ***if you are making a submission on behalf of an ART provider/clinic or other fertility service, the name of the ART provider/clinic or fertility service and your role within the organisation.***

***even if you ticked the box to show you want to remain anonymous, if we had 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.2 (a) Does your ART provider/clinic advertise its services?

Q.2 (b) Does your ART provider/clinic use patient testimonials to promote its services?

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? If so, how are these discussed with patients?

Q. 5 (b) Is the efficacy of such 'add ons' and adjuvant treatments discussed with patients? If so, please describe the process for discussing the efficacy and information given in relation to 'add ons' and adjuvant treatments.

Q.6 (a) Does your ART provider/clinic have a complaints handling system or processes?

If so, please explain how complaints are handled within your service.

Q.6 (b) Is your ART provider/clinic aware of the role of the Health Complaints Commissioner?

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?

Q.8 How does your clinic manage adverse events?

Please briefly describe the process that follows an adverse event.

Q.9 Please provide any further information you would like the Commissioner to consider in this Inquiry.

Part C – Other Stakeholders

Please answer some or all 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.

Q.1 Please provide your personal details, including a brief description of your role, the name of your organisation and the relationship your organisation has with ART.

Q.2 (a) Are you aware of ART providers/clinics' advertising practices?

Q.2 (b) Are you aware of ART providers/clinics using patient testimonials to promote their services?

Please provide examples of such practices.

Q.3 Do ART providers/clinics provide adequate counselling?

Why do you hold that view?

Q.4 (a) Are you aware of ART providers/clinics offering 'add ons' or adjuvant treatments?

Q.4 (b) If so, do you know if patients are encouraged to utilise 'add ons' or adjuvant treatments?

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?

Please explain why you hold that view.

Q.6 Do ART providers/clinics comply with the Australian 'Open Disclosure' framework?

Please explain why you hold that view.

Q.7 Please provide any further information you would like the Commissioner to consider in this Inquiry.

3 - NEXT STEPS IN THE INQUIRY

Following receipt of submissions, the Inquiry will consider the issues raised. Depending on those issues, the Commissioner may conduct a public hearing(s).

The Commissioner's website – hcc.vic.gov.au – will be regularly updated as the Inquiry progresses.

4 - PRIVACY COLLECTION NOTICE

The Commissioner is committed to protecting your privacy.

Any person working on the Inquiry has agreed to comply with the provisions of the Code of Conduct for Victorian Public Sector Employees of Special Bodies, the Act, the *Health Records Act 2001* and *Privacy and Data Protection Act 2014.* They have also agreed to confidentiality obligations relating to all personal information and to only disclose information in accordance with legal obligations.

The information collected will be used for the Inquiry into ART practices and to provide a report to the Minister for Health in December 2019. The information may also be used to identify if we should engage in further consultation with other organisations or stakeholders.

To complete the Inquiry, we may draw on your submission response and the report relating to the Inquiry may be publicly available. However, if you request that your information is not published, no identifying information will be included, and your submission will not be directly quoted. If you request that your submission is treated as anonymous, it may be referenced and quoted but no identifying material will be included.

We may also wish to publish submissions (in whole or part) online. Submissions will only be published with the consent of the person(s) making the submission. All submissions where consent has been given, will be published at the discretion of the Commissioner and may be redacted or published only in part.

5 - ASSISTANCE

We understand that it may be distressing for people who have used ART services to discuss their experiences.

If providing a submission or making a complaint in relation to these services has caused you any distress, you may wish to contact the following:

- Beyond Blue on 1300 22 4636
- Lifeline on 13 11 14

Appendix 1 – Terms of Reference

See attached

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Appendix 2 – Background/context

Add-ons and Adjuvant Treatments

The Victorian Assisted Reproductive Treatment Authority (VARTA) is a statutory authority established under the *Assisted Reproductive Treatment Act 2008*. VARTA is responsible for registering ART providers and has power to include conditions on the registration of ART providers.

According to the VARTA website, examples of "add-ons" or "adjuvant therapies" include *"endometrial scratching, time lapse imaging of embryos, and the prescription of steroids, testosterone and growth hormones."*

VARTA states *"many of these add-ons are experimental or have not been properly tested, so it's not known if they actually make a difference to your chance of having a baby. They may also cause negative side effects and cost you more money with no Medicare refund available."*

VARTA has included within the conditions for registration that "an ART provider must provide its patients and the public with accessible and easily understood information about the risks and benefits of adjuvant therapies and new treatment procedures that are offered…including accurate information about the evidence base which demonstrates those risks and benefits."

Success rates and costs of ART and information provided to patients

In 2016, the Australian Competition and Consumer Commission (ACCC) investigated potentially misleading advertising by Australian ART providers. The ACCC and Consumer Affairs Victoria (CAV) are responsible for enforcing compliance with the Australian Consumer Law including the obligation to not engage in misleading and deceptive conduct, false or misleading representations or unconscionable conduct. The ACCC found some providers made success rate comparisons without adequate disclosure about, or qualification of, the nature of the data or graphics used to make the claim. The ACCC issued a public statement about its findings and advised it would continue to monitor complaints received and *"won't hesitate to take further action if IVF providers are making false or misleading claims".* The ACCC for example cited the term "clinical pregnancy rate" as a term used to advertise success rates when that term does not necessarily translate to a live birth.

The revised RTAC Code of Practice, issued 2017, responded to the ACCC concerns by setting out additional requirements for ART providers in relation to public information (item 2.2.2). The RTAC Code of Practice requires that information presented in the public domain be in a language that is understandable by the lay public and not be in anyway misleading.

ART providers are not permitted to use patient testimonials in advertising materials or social media accounts. For example, section 133 of the Health Practitioner Regulation National Law (Victoria) Act 2009 (the National Law) and the Medical Board's *Guidelines for advertising regulated health services* prohibit the use of testimonials. Further, the RTAC Code of Practice specifically states that *"ART Units must not incorporate patient comments on social media that promote their practice or service".* Finally, the VARTA conditions of registration require that public claims, comparisons and advertising by an ART provider must comply with section 133 of the National Law and have due regard to the AHPRA *Guidelines for Advertising Regulated Health Services*. Despite this, the ACCC found it was not difficult to locate patient testimonials in advertising material for ART providers.

Complaint handling

The Act sets out several requirements relating to health service providers, including ART providers.

Schedule 1 of the Act sets out interim standards for complaint handling by health service providers. Those standards have recently been the subject of broad consultation to develop new minimum

standards in the handling of complaints which set the benchmark for all health service providers in Victoria, including ART providers. ART providers and other health service providers must:

- promptly acknowledge and attempt to resolve the complaint in a manner that is appropriate to the circumstances
- provide information (in an accessible and understandable form) about how a complaint may be made and the procedures for making a complaint to all persons provided or offered a service by ART providers
- ensure that a person who has made a complaint is informed of the progress of the complaint and outcome of the complaint
- ensure personal information collected in respect of a complaint is kept in a confidential manner
- ensure that a record of complaints is kept including action taken about a complaint.

Breach of these minimum standards is grounds for a complaint to the Commissioner.

ART providers are also required, pursuant to the RTAC Code of Practice (good practice criterion 2), to acknowledge and investigate complaints, including systematic recording, review and corrective action of complaints.

Counselling services, communication and support

Prior to receiving ART in Victoria, people who are planning to undergo treatment procedures must receive counselling from the clinic/ART provider. This is a mandatory legal requirement and treatment cannot commence or consent to the treatment be given until counselling has occurred.

In any health service provision, effective communication and support of patients and their families are vital, and ART is no different. While not required by legislation, effective communication and support should be a central part of the provision of ART services.

Incidents identified by the Independent Review into Victoria's Regulatory Framework for ART

In 2018 the Gorton Review, *Helping Victorians Create Families and Assisted Reproductive Treatment*, reviewed Victoria's regulatory framework for ART to assess if it creates or enables unnecessary barriers to access, if consumers have access to adequate information to facilitate informed choices and if the regulatory framework remains appropriate given the changing nature of the ART market.

During the conduct of the Gorton Review three incidents and one case study were identified as follows:

- **Incident 1** – An incident occurred during which an error in a freezing schedule resulted in the loss of embryos. It is understood senior management elected not to advise the affected patients and chose not to keep records of the incident.
- **Incident 2** – An incident occurred where faulty incubators within the laboratory of an ART provider resulted in the loss of several embryos. The affected patients were not advised of the equipment failure, but rather were led to believe the embryos succumbed naturally.
- **Incident 3** – A scientist was ordered, by a doctor, to load a degenerate embryo into a transfer catheter. Despite this, the doctor told the patient she had a viable embryo and a good chance of success. The doctor then transferred the embryo into the patient. The doctor later explained to the scientist that the doctor did not explain to the patient that her embryo had not survived because they did not believe the patient would understand. The scientist is

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

- **Case Study** – A patient found communication with an ART provider frustrating and there were repeated failures of communication about recognising the potentially serious nature of
- her condition. Consequently, the patient spent over two weeks in hospital with fully developed ovarian hyperstimulation syndrome in much pain and with difficulty breathing.

It is hoped that those who informed the Gorton Review about the incidents and case study above will also make a submission to the Inquiry or, alternatively, contact the authors of the Gorton Review and consent to the sharing of information between the Review and Inquiry.

Australian Open Disclosure Framework

VARTA's 2017/2018 annual report notes that it includes a condition on the registration of all Victorian ART providers that providers should be guided by the *Australian Open Disclosure Framework* in communicating with patients about any adverse incident.

According to Department of Health and Human Services website, the *Australian Open Disclosure Framework* developed by the Australian Commission on Safety and Quality in Health Care means that the open disclosure process should occur whenever a patient has suffered an adverse event. Open disclosure includes an apology and explanation of an incident without apportioning blame. Patients are to be provided with information about what happened in a timely, open and honest manner. Health services should ensure staff members are supported through the open disclosure process.

Appendix 3 – Resources

Gorton, Michael, Helping Victorians create families with assisted reproductive treatment, Interim Report of the Independent Review of Assisted Reproductive Treatment, October 2018.

National Health and Medical Research Counsel 2017, *Ethical Guidelines on the use of assisted reproductive treatment technology in clinical practice and research,* NHMRC, Canberra.

Reproductive Technology Accreditation Committee 2017, *Code of Practice for assisted reproductive technology units, Fertility Society of Australia, Melbourne.*

https://www.fertilitysociety.com.au/wp-content/uploads/2017-RTAC-ANZ-COP-FINAL-1.pdf

Information from the website of the Australian Competition and Consumer Commission (accessed 9 April 2019)

https://www.accc.gov.au/media-release/ivf-success-rate-claims-under-the-microscope

Information from the website of the Department of Health and Human Services (accessed 9 April 2019)

https://www2.health.vic.gov.au/hospitals-and-health-services/quality-safety-service/clinical-risk-management/open-disclosure/open-disclosure-framework (accessed 9 April 2019)

Information from the website of the Victorian Assisted Reproductive Treatment Authority:

https://www.varta.org.au/resources/blogs/what-you-need-know-about-ivf-add-ons (accessed 9 April 2019)
https://www.varta.org.au/regulation/list-registered-victorian-art-clinics (accessed 9 April 2019)
https://www.varta.org.au/sites/default/files/public/2018-09-04%20Annual%20Report%202018%20-%20Final%20-%20Web.pdf (accessed 9 April 2019)
https://www.varta.org.au/resources/publications/assisted-reproductive-terminology (accessed 9 April 2019)
https://www.varta.org.au/regulation/clinic-information (accessed 9 April 2019)

Information from the website of the Human Fertilisation and Embryology Authority:

https://www.hfea.gov.uk/treatments/explore-all-treatments/treatment-add-ons/ (accessed 9 April 2019)

Information from the website of the Conversation:

http://theconversation.com/baby-gammy-case-reveals-murky-side-of-commercial-surrogacy-30081 (accessed 9 April 2019)

Information from the website msn:

https://www.msn.com/en-au/kids/other/this-is-what-the-nazis-wanted-to-do-aussie-couples-are-spending-dollar20000-to-choose-the-eye-colour-and-sex-of-their-children-as-the-overseas-clinic-is-slammed-as-promoting-eugenics/ar-BBVrHCD?li=AA4RE4 (accessed 9 April 2019)

HEALTH COMPLAINTS COMMISSIONER

Supporting safe and ethical healthcare.

Level 26, 570 Bourke Street
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Review of practices by assisted reproductive treatment providers

Terms of reference

Background

On 13 November 2018, the Victorian Government committed to crack down on unscrupulous IVF providers, and to task the Health Complaints Commissioner (the Commissioner) to lead an investigation into dodgy, dangerous and unethical practices by IVF providers including where providers fail to be up front about success rates or costs – with hefty penalties for those who don't comply.

The commitment was made following the release of the interim report of the review of assisted reproductive treatment (the Review), *Helping Victorians Create Families with Assisted Reproductive Treatment,* prepared by Mr Michael Gorton AM.

The interim report notes that between 1 February 2017 and 20 July 2018, the Commissioner received 28 complaints relating to 58 separate issues[1]. Inadequate or misleading information was the single most common issue cited, followed by inappropriate fees or billing, and inadequate or inappropriate treatment.

In 2016 the Australian Competition and Consumer Commission (ACCC) conducted an investigation into potentially misleading advertising by Australian assisted reproductive treatment providers. The ACCC and Consumer Affairs Victoria (CAV) are responsible for enforcing compliance with the Australian Consumer Law including misleading and deceptive conduct, false or misleading representations, or unconscionable conduct. The ACCC found that some providers made success rate comparisons without adequate disclosure about, or qualification of, the nature of the data or graphics used to make the claim. The ACCC issued a public statement about its findings and advised it would continue to monitor complaints received.

The interim report notes the Review found some isolated instances of clinics and individual fertility specialists publishing information that may mislead. The Victorian Assisted Reproductive Treatment Authority (VARTA) notes the difficulty in assessing success rates of different fertility clinics as clinics measure their success rates in various ways. The interim report also notes that it heard evidence about a number of serious incidents related to a clinical error, inadequate communication with a patient, unethical practice, and sub-optimal care of a patient.

Purpose

To refer a health service matter under section 103 of the *Health Complaints Act 2016* in relation to practices of assisted reproductive treatment providers including potential dangerous and unethical practices.

To request the Commissioner conduct an inquiry into this matter, noting any consumer law matters arising out of the inquiry including matters of false, misleading and deceptive conduct of assisted reproductive treatment providers including success rates and costs will be referred to CAV for investigation.

It is expected that appropriate action is taken against providers, consistent with the legal remit of the Commissioner and CAV.

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[1] Twenty-four complaints related to health services and four related to health records. A single complaint may relate to multiple issues.

Where matters are identified as part of the inquiry which are outside the jurisdiction of the Commissioner or CAV, those matters may be referred to other regulators as appropriate such as the Australian Health Practitioner Regulation Agency, in accordance with both regulator's usual practice.

Scope

To inform the inquiry, it is anticipated a wide reaching consultation and public engagement process would be undertaken to identify experiences of the public (including patients and people working in clinics), of potentially dangerous, unethical, false, misleading or deceptive practices by assisted reproductive treatment providers, through a range of engagement forums and strategies that may include:

- direct and indirect engagement with stakeholders
- formal and informal mechanisms for providing feedback
- using existing networks and forums, such as online patient and industry forums
- promotion of the consultation and engagement process including protections for people making a complaint.

In conducting the inquiry, the Commissioner would have regard to:

- relevant incidents identified by respondents in the interim report of the Review
- previous complaints of assisted reproductive treatment providers received by the Commissioner
- relevant matters identified through the public consultation process.

Where a health service matter arises as part of the inquiry that warrants an investigation and meets the relevant legal thresholds, the Commissioner may consider conducting an investigation under Part 4 of the Health Complaints Act into the matter and taking any appropriate action through that process.

Where a consumer law matter arises as part of the inquiry the Commissioner is expected to forward the matter to CAV to investigate and if appropriate, take enforcement action.

Reporting

A final report should be delivered approximately nine months after referral to the Commissioner and address the matters outlined in Scope above and any residual issues. On completing the inquiry, the Commissioner may make recommendations about the matter to the Minister for Health.

Consultation with CAV should be undertaken as necessary to complete the final report and reflect any outcomes, residual issues, recommendations or options in relation to consumer law matters.

Individual matters should be reported in a manner that protects the privacy of individuals.