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Fighting for families

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The Senate
Community Affairs Legislation Committee
Parliament House
CANBERRA

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Inquiry into the Australian Institute of Health and Welfare Amendment (Assisted Reproductive Treatment Statistics) Bill 2019

access is a consumer controlled, not-for-profit charity, providing whole of life support, information and advocacy for those who experience difficulties conceiving. A national voice for our community of more than 48,000, we build partnerships with medical professionals and policy makers to highlight their social, psychological and financial needs for equity of access to medical services to have a child.

access values the opportunity to participate on the Working Group, as it considers the complex variables in contributing to ART success to realise the Bill's intent. We welcome the Committee's commitment to providing information for people considering ART about the likelihood of success in their particular circumstances.

At the heart of a patient's question about a clinic's success rates is the need to know whether they can be assured of the best chance of taking home a healthy baby.

Choosing a clinic based solely on reported success rates on a national registry can create unrealistic expectations about the possibility of having a baby at a particular clinic.

While the Bill's proposals are well intentioned, they will not deliver the initial Bill's objective:

to provide(s) consumers with access to objective and consistent information about the performance of assisted reproductive technology (ART) centres, in order to help them make an informed choice about their prospective treatment facility.

access has published a fact sheet titled *How to Choose an IVF Clinic and Understand Success Rates* to help people who may be seeking fertility treatment to understand aspects of fertility treatment that may be relevant to them and to help them make decisions when choosing an IVF clinic.

Our submission summarises key issues for consumers from this fact sheet (Att. 1) and a chapter in *Assisted Reproductive Technology Surveillance* recently published, which I co-authored (Att. 2).

access counsels people through our website to [beware of clinics](#) that make false and misleading claims about their success rates, after reporting a few clinics to the ACCC, who acted quickly.

access looks forward to our continued collaboration to achieve shared objectives to build understanding for those considering the ART treatment they need to have a child.

Sincerely

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CEO and Managing Director



1. Introduction

Choosing Assisted Reproductive Technology (ART) is a major life decision. Patients have a fundamental right to patient-centered healthcare that respects their unique needs, preferences and values. Accurate, relevant and comprehensive information is essential to enable patients to make informed decisions about their treatment. (excerpts)¹

2. Expectations of ART treatment

The chance of an ART cycle being successful varies by prognostic factors including the age of patients, reasons for treatment, and for those who have already commenced treatment, how many failed attempts they have undertaken. These will inform a patient's decision-making, but their final choice will most likely be related to confidence in the treatment and quality of care provided by a particular clinic. They want to know which clinic will give them the best chance of taking home a healthy baby while respecting their particular circumstances and needs.

Choosing a clinic based solely on reported success rates either based on ART national registry data or published clinic data on their websites, can create unrealistic expectations about the possibility of having a baby at a particular clinic.

3. The problems with statistics

ART statistical data is complex to present and understand even by clinicians and scientists working in field.

A recent review of clinical trials evaluating ART treatment has identified over 800 reported outcomes measures [?].

The reason for the complexity relates to the many numerators and denominators that can be chosen to represent ART success. In addition, ART treatment involves multi-level exposures (e.g. multiple treatments within the one woman), multiple stages within an ART cycle (initiated, follicular aspiration, embryo transfer) and multiple endpoints (implantation, pregnancy, live birth/s). Therefore, where national ART surveillance data is published, it should be in patient friendly language and include comprehensive information about how to interpret the statistics. In particular, it should be emphasised that the results from national ART registries are population-based averages based on all patients who have undergone treatment and may not be applicable to an individual patient's circumstances and chance of success. Such guidance is important because it can help to inform expectations prior to deciding whether to embark on treatment.

At the heart of a patient's question about a clinic's success rates is the need to know whether they can be assured of the best chance of taking home a healthy baby.

Infertility is a major life crisis and for some, the treatment can be an "emotional roller-coaster". Emotional responses to infertility are complex and at times are so strong they can seem overwhelming. Having a professional counsellor available at the clinic can help patients understand that these feelings are normal.

The outcome of ART treatment is not only the possibility of getting pregnant. Emotional support during treatment by an infertility counsellor and spontaneous support such as a phone call when the treatment has not worked all help patients navigate the challenges of ART treatment.

For patients or potential patients reading ART surveillance reports, the stark numbers and percentages presented in multiple tables do not provide any indication of the complex emotions associated with falling on either side of the very binary outcome associated with ART treatment, that is achieving pregnancy or not.

¹ Use of ART Surveillance by People Experiencing Infertility. (2019). In D. Kissin, G. Adamson, G. Chambers, & C. De Geyter (Eds.), *Assisted Reproductive Technology Surveillance* (pp. 93-100). Cambridge: Cambridge University Press.

² Wilkinson J, Roberts SA, Showell M, Brison DR, A. V. No common denominator: a review of outcome measures in IVF RCTs. *Human Reproduction*. 2016;31:2714-22.

4. Measures that can be used to determine success rates

The following measures explain in patient-friendly language what each of these terms mean and give some indication of their respective limitations.

Live birth – this relates to the number of live births per treatment cycle, multiple births being classed as a single live birth. This measure is most close to the intention of the infertile couple, however collection of data is often slow – at least until all the live births have occurred and been followed up by the clinic and recorded. Live birth figures reflect a number of factors, including the following: age of the female, the number of eggs recovered, fertilisation rates, the quality of embryos and embryo transfer technique, not to mention the quality of the laboratory.

Clinical pregnancy – this relates to an ultrasound test usually at about 7 weeks into the pregnancy when a fetal heart is seen. This is a more rigorous test than that of biochemical pregnancy (the first blood test which shows a positive pregnancy test) and has the one advantage in that it provides more recent data from the clinic than live birth data. However, this data does not show how many of these clinical pregnancies result in a live birth.

Pregnancies/live births per treatment cycles commenced – this relates to the number of pregnancies/ babies born per cycles where hormonal stimulation of the ovaries has been initiated irrespective of whether any of the cycles were cancelled prior to egg pickup.

Pregnancies/live births per egg collection – this relates to the number of pregnancies/ babies born per cycles where the woman has proceeded as far as egg collection and would include also all those patients for whom eggs were retrieved but did not result in embryos for transfer.

Pregnancies/live births per embryo transfer – this relates to the number of pregnancies/ babies born per cycles where the woman has proceeded as far as embryo transfer and would not include those couples for whom the cycle was cancelled, who did not make it to egg pickup, who were overstimulated (ovarian hyperstimulation syndrome – OHSS) or who did not produce embryos. This data would also include frozen embryo transfers.

Pregnancies/live births per embryo – refers to the rate of pregnancies/ babies born per embryo transferred. There is now greater emphasis on transferring a single embryo and reducing the risk of multiple births.

Cumulative pregnancy rates – some clinics may have data on their cumulative pregnancy rate, which is either pregnancy or live birth per all transfers from one fresh egg collection and includes data from both fresh and frozen cycles.

It is important to realise that as we move down the above list, the apparent success rate increases. Armed with this information it becomes important to ask clinics about the specific per cent figure they are reporting.

5. Questions that may be useful for patients to ask include:

- What is the success rate for my particular age group?
- What is the success rate for my/our particular case of infertility?
- What is the risk of a multiple birth?
- How many cycles are conducted per year by the clinic?
- What is the success rate achieved for a so-called “gold standard” prognosis group?

6. Opportunities for ART clinics in using ART surveillance data.

Result presentation

There is an opportunity for clinics and ART registries to drive a new way of reporting their results. One that not only gives live birth rates but also presents the efficient running of the service, protocol personalisation, efficiency of stimulation, laboratory quality and utilisation of reproductive material, or the ability of the clinic to offer the largest number of good quality embryos from the oocytes and sperms made available to their laboratory.

While the performance of a clinic is best measured by comparing success rates in a “good prognosis” group, clinics could also offer information on their rate of complications during treatment, how efficient are they in creating an embryo from 100 eggs collected, what is the likelihood of a blastocyst forming from 100 fertilised eggs, percentage of patients that reach an egg collection and an embryo transfer, percentage of elective single embryo transfers and freeze rates, clinical pregnancy and delivery rates.

Service presentation

Reporting of results presents only part of the patient experience during treatment.

The idea that patients must only pay attention to the success rates should be challenged.

Clinics should describe how they offer a comprehensive treatment to include clinical and laboratory expertise, availability of counselling and support after the treatment, particularly if it has not worked. Presenting “results” creates the opportunity to misinform and mislead vulnerable patients.

In contrast, presenting the services provided can help patients to understand how the clinic will support them as they undergo treatment, with realistic expectations about reaching their desired destination. It is important for patients to be confident that the clinic will endeavour to meet their specific needs, where they can offer no guarantees of delivering their dream of a child, and in the majority of cases does not.

When reporting success rates should clinics be identified or anonymous?

An integral function of accrediting bodies and licensing authorities is to collect results in order to compare success rates at different units. The use of these data to measure performance for accreditation purposes is a useful means of identifying ways to improve practice, while maintaining confidentiality. A major strength of the data in surveillance reports where clinics are not identified, is its anonymity. There is no incentive to manipulate data, so stakeholders can be confident of its reliability [3].

Information that may be provided in national surveillance data identifying clinics, can be used to compare the results. But how meaningful is this comparison and do patients truly understand what it represents? It can weaken the quality of the information available for patients because they do not present an accurate picture of an individual's chance of success. This prevents them from making an informed decision about where they choose to undergo treatment.

The Fertility Society of Australia has recognised the need for more patient friendly information in developing a web based patient predictor tool that can be used by an individual to have a better idea of the possibility for them to conceive. It is important for this information to be discussed with an infertility specialist before considering appropriate treatment.

Factual, objective, and comprehensive information is essential to enable patients to make informed decisions about healthcare treatment [4].

³ Fitzgerald O, Harris K, Paul RC, Chambers GM 2017. Assisted reproductive technology in Australia and New Zealand 2015. Sydney: National Perinatal Epidemiology and Statistics Unit, the University of New South Wales Sydney.

⁴ Medical, Ethical and Social Aspects of Assisted Reproduction (2001: Geneva, Switzerland) Current practices and controversies in assisted reproduction: report of a WHO meeting / editors, Effy Vayena, Patrick J. Rowe and P. David Griffin. P8

What is important is not that one clinic's results are better than others, but how their services compare when plotted against all the other clinics in the country. Are the results in the top centiles or not after risk-adjusting for the prognostics characteristics of patients?

National ART surveillance data should be presented in such a way that identifies the best and worst performing clinics. This can be highly misleading. They create incentives for clinics to focus on pregnancy rates, at the expense providing a holistic approach to fertility treatment for patients suffering from infertility. For example, success rates can be optimised by limiting treatment to good prognosis patients and reporting their results, while refusing care to harder to treat patients.

7. The role of patients organisations

Patient involvement in health policy is supported by the World Health Organisation which states that patients organisations should engage in constructive dialogue with governments and health professionals and be represented on appropriate scientific and professional committees. The Australian example has led the world.

Federal and State governments have recognised the expertise of consumers with a personal experience of infertility, through representation on Ministerial, parliamentary committees and the National Health and Medical Research Council. The fertility sector has been open to the scrutiny of consumers, nominated by ACCESS, to the Board of the Fertility Society of Australia, the Reproductive Technology Accreditation Committee and the IVF Medical Directors Group.

8. Conclusion

Health services exist because of patients. ART patients read broadly, and often challenge practitioners with new data and new therapies, some which are of value, while others are without any proven benefit. The role of the practitioner and clinics is to assess patients for their suitability for ART, discuss the implications for them and the child to be and to ensure that all relevant information has been offered prior to their informed decision to proceed with treatment.

ACCESS recognises the Committee's commitment to working with patients as partners, not passive recipients, through constructive dialogue with consumer groups [5]. This ensures transparency and quality in the delivery of infertility services [6]. It is also appropriate, as it is patients who will live with the consequences of policy and treatment decisions.

We look forward to the Committee's findings with interest.

⁵ Fathalla, Medical, Ethical and Social Aspects of Assisted Reproduction (2001: Geneva, Switzerland) Current practices and controversies in assisted reproduction: report of a WHO meeting / editors, Effy Vayena, Patrick J. Rowe and P. David Griffin. P8

⁶ Dill S, Medical, Ethical and Social Aspects of Assisted Reproduction (2001: Geneva, Switzerland) Current practices and controversies in assisted reproduction: report of a WHO meeting / editors, Effy Vayena, Patrick J. Rowe and P. David Griffin. Ch. 4 p 258