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The Senate
Community Affairs Legislation Committee
Department of the Senate
PO Box 6100
Parliament House
CANBERRA ACT 2600

Dear Committee members,

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

Thank you for the opportunity to make a submission to the inquiry into the AIHW Assisted Reproductive Treatment Statistics Bill 2019. I present this submission on behalf of the National Perinatal Epidemiology and Statistics Unit (NPESU), UNSW Sydney.

I hope that you find this information useful to your inquiry. Should the Committee have any questions or require any additional information, please do not hesitate to contact me.

Kind regards,

A/Prof Georgina Chambers

Inquiry into the Australian Institute of Health and Welfare Amendment (Assisted Reproductive Treatment Statistics) Bill 2019 – Submission by the National Perinatal Epidemiology and Statistics Unit (NPESU), UNSW Sydney.

Introduction

Australian and New Zealand Assisted Reproduction Database (ANZARD)

ANZARD, which is the Australia's assisted reproductive technology (ART) clinical quality registry was established as a collaboration between the Fertility Society of Australia (FSA) and the National Perinatal Epidemiology and Statistics Unit (NPESU) in 1983, making it the oldest ART registry in the world. As the Director of the NPESU at UNSW Sydney, I am the Data Custodian of ANZARD and responsible for the security, quality and privacy of, and access to, the information it collects.

ANZARD's initial purpose was to monitor possible congenital anomalies resulting from ART treatment, but its role quickly expanded to include; i) monitoring treatment practices, success rates and perinatal outcomes, ii) informing standards for accreditation and monitoring of fertility clinics, iii) international benchmarking, and iv) providing a database for research purposes.

ANZARD is considered one of the best ART registries in the world with 100% ascertainment from the 95 fertility clinics operating across the two countries. The NPESU collects over 100 data variables on each of the 85,000 ART cycles performed in Australian and New Zealand clinics and the resulting 14,000 babies born year. ANZARD achieves 100% compliance because under the Reproductive Technology Accreditation Committee (RTAC) audited Code of Practice clinics must report their treatment and outcome data to ANZARD as a licencing requirement to practice ART in Australia. This level of compliance is not achieved by most other countries, including the US where reporting is covered by the *US Fertility Clinic Success Rate and Certification Act* (e.g. 463 of the 502 clinics operating in the US submitted data in the last reporting period) [1].

Furthermore, ANZARD is one of the very few ART registries in the world that can report longitudinal success rates based on women undergoing treatment, rather than simply cross-sectional data based on a single cycle. This is important because most women will undergo more than one ART cycle and knowing their chance of success after previous failed attempts and over of course of treatment is important to them.

The *Annual ANZARD Report* produced by the NPESU is also arguably the most comprehensive in the world with 87 data tables and 9 figures published each year [2].

The FSA partially funds the NPESU to manage ANZARD and prepare the *Annual ART Report*, however, and as stated in the annual reports, the NPESU produces the report independently with no influence from the FSA.

National Perinatal Epidemiology and Statistics Unit (NPESU)

The NPESU is a joint academic unit of the School of Women's and Children's Health and Centre for Big Data Research in Health at UNSW Sydney. It has approximately 15 academic and professional staff, mainly epidemiologists and statisticians, and a number of higher degree and medical students.

It was formed in 1979 and is a leading source of statistical and epidemiological information on pregnancy, birth and the neonatal period to inform policy, community discussion and decision-making on the health and wellbeing of mothers and babies. The NPESU also has extensive experience in managing perinatal data collections and was the former Data Custodian of the National Perinatal Data Collection (NPDC) before it was taken in-house by the Australian Institute of Health and Welfare (AIHW) in 2010. In addition to ANZARD, the NPESU manages the Australian and New Zealand Neonatal Network (ANZNN) which is a clinical quality registry of babies cared for in Neonatal Intensive Care Units (NICU) across Australia, New Zealand and an increasing number of Asian countries.

Associate Professor Georgina Chambers

As Director of the NPESU I bring a wealth of expertise in the analysis ART data and reporting of ART success rates. In addition to being the ANZARD Data Custodian for the last 5 years, I am a recognised international leader in the epidemiology, surveillance and policy analysis of ARTs. I am a member of the International Committee for Monitoring ARTs and recently co-edited an international book on ART surveillance, personally authoring the Chapter on 'Reporting ART Success Rates' [3,4]. I also hold a PhD on the health economics of ARTs and continue to publish and present widely on this topic.

I have also advised a number of governments on surveillance of ARTs, most recently as a member of the Australian Government's 2017/8 MBS Review Taskforce on assisted reproductive technologies.

Response to the proposed Bill to Amend the AIHW Act

The NPESU supports the public reporting of fertility clinic success rates. It does, however, strongly recommend that the principles of clinical quality registry benchmarking and reporting be followed to ensure that the process of measurement itself does not create perverse incentives in terms of altering clinic and clinician behaviour. The NPESU also recommends that individuals and couples are provided with unbiased user-friendly information about their individual chances of having a baby in a single ART cycle and over a course of treatment.

There are a number of ART-specific issues that must be considered to ensure the best possible public reporting of clinic-specific success rates. These are detailed below.

Reporting requires a high level of expertise

ART data is inherently complex and difficult to analyse, largely due to the multi-stage nature of an ART treatment cycle, and the hierarchical nature of the data (e.g. a women will usually have many ART cycles, an ART cycle can involve many eggs and embryos, within a cycle there may be multiple embryo transfer procedures, and more than one baby may be born from a single cycle). Indeed, there is no single agreed upon measure of ART success, nor definition of what an ART cycle is. A recent appraisal of ART trials reported in excess of 800 different possible computations [5]. As is the case in other countries around the world, it is important that those with the expertise in ART registry data and analysis undertake the reporting of clinic-specific success rates, to minimise the risk of providing misleading information to women and couples.

Reporting should not incentivise unsafe practices

The greatest risk of ART treatment for both mothers and babies is multiple gestation pregnancy (twins and triplets) due to the transfer of more than one embryo during ART treatment. For example, being born as an ART twin carries a 50% risk of prematurity and low birth weight compared to 10% for ART singleton babies, putting twins at much greater risk of early and long-term health, social and educational problems throughout their lives. The cost to the health system of caring for ART twins has been shown to be a significant proportion of the total cost of ART treatment in a number of settings [6].

The best way to reduce the multiple birth risk is to perform single embryo transfer (SET) during treatment. However, transferring more than one embryo during a single ART cycle increases the pregnancy and live birth rates in that cycle. Therefore, all things being equal, the success rates for clinics that transfer more embryos will be higher. As a consequence, if not done carefully, public reporting of clinic success rates encourages aggressive embryo transfer practices at the expense of the safety of women and their babies. Indeed, the US and UK, who have had public reporting of clinic success rates for many decades, still have multiple birth rates are over 15% and 10% respectively, despite concerted efforts over the last decade to reduce these [1,7]. By contrast, Australia's ART multiple birth rate has been 5.5% or lower since 2013 and continues to fall each year without any legislative or funding incentives [2].

There are a number of reporting strategies for clinic success rates that minimise unsafe embryo transfer practices while still achieving comparable success rates for patients. This is best performed using longitudinal ART registry data that provide women/couples with their overall chance of success from a course of ART treatment as well as from a specific cycle.

Reporting should not penalise clinics that treat poorer prognosis patients

The chance of ART success is highly dependent on patient characteristics, with the strongest predictors of success being female age, period of infertility and number of previous failed ART attempts. For example, the chance of a live birth in women aged 30-34 in their first fresh embryo ART cycle is 32.9% compared to 8.5% in women aged 40-44[2]. Therefore, an individual clinic's success rate is partially dependent on the characteristics of the patients that they treat. As in other medical fields where 'report cards' are used to compare provider performance, care needs to be taken during analysis and reporting to take account for differences in patient profiles and to not penalise clinics and clinicians who treat poorer prognosis patients. In fact, it is often the best clinicians that treat the most difficult patients and thus will have relatively lower performance. Unless reporting takes account of such differences, clinics will be incentivised to refuse treatment to poorer prognosis patients, 'hide' such cycles from public reporting, or undertake aggressive treatment practices (aggressive ovarian stimulation or multiple embryo transfer).

Reporting should be understandable and unbiased

Related to the complexity of ART data and the potential to provide misleading information, it is important that success rates are easily understood and as relevant to individuals as possible. A review undertaken by NPESU of clinic websites in 2016 found that of the 94 clinics reporting to ANZARD, 80% reported success rates on their website, but that there was huge variation in the statistics used and the presentation of data. The majority (80%) of clinics chose embryo transfer cycles to define an ART cycle ignoring the almost one in two fresh cycles that don't reach this stage

in a cycle, and 43% reported a pregnancy as 'success' rather than the birth of a live born baby which is ultimately what a patient wants. Few websites included warnings about the limitations of clinic-specific success rates.

Clinics and clinicians also need to be confident that when their data is used for public reporting it is done in such a way that is unbiased and respects their autonomy to practice medicine for the benefit of their patients.

It is therefore critical that consumers and clinicians inform the ways that the data are publicly reported, together with scientists and epidemiologists.

Reporting should be independent

ART is almost exclusively provided by private fertility clinics in Australia, many of which are part of large publicly listed fertility networks. Furthermore, approximately 50-70% of each ART cycle performed in Australia is funded through Medicare, making it of considerable fiscal interest to the Australian government. It is therefore important that public reporting be performed by an independent group that has the expertise and knowledge to do so and where financial interests play no role in influencing the reporting.

Reporting does not require a change in the AIHW Act

While amending *The Act* will ensure that clinics provide an annual tranche of data for clinic-specific reporting, this can be more easily achieved by adding a similar clause to the Reproductive Technology and Accreditation Committee (RTAC) audited Code of Practice, stating that their data will be used for public reporting. Clinics must demonstrate they abide by the Code to be granted a licence to practice ART within Australia. The advantage of this is that clinics already supply all the data required (plus much more) to ANZARD under the current requirements of the Code. The NPESU uses this data for its Annual ART Report and internal clinic performance benchmarking for RTAC. Another advantage of amending the Code (rather than changing *The Act*) is there would no additional effort by the clinics to make multiple submissions, or resources required to manage a parallel ART data registry. The costs of running a second registry would be significant. The Human Fertility Embryology and Authority (HFEA), which reports clinic success rates in the UK has 64 staff and a total annual operating cost of $10.7 million [8], yet the UK performs less ART cycles than Australia. The Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR), funded by the Commonwealth costs ~$3.2 million annually to collect and report data in data for ~1.4 million joint replacements [9].

Furthermore, creation of parallel registry presents potential for creating confusion for women and couples if different approaches are taken to analysis and reporting.

Reporting should include individual patient predictions of success

While clinic success rates are important to prospective patients, a recurring question asked by individuals contemplating whether to start ART is; 'What is my chance of success from treatment with one or more cycles?', and those contemplating continuing treatment after one or more failed attempts is; 'What is my chance of success if I continue?'.

The NPESU, with the support of the Australian Government and the FSA is currently developing a web-based tool, the *IVF Patient Predictor*, to facilitate patient counselling and clinical decision-making. The online calculator will allow patients to enter information such as their age, female and male infertility diagnosis, number of previous ART attempts, whether the women has previously achieved a live birth (with or without ART treatment), type of ART cycle, use of donated eggs and sperm, number of oocytes collected, and number of embryos transferred. Their chance of a live birth and a multiple birth in a particular ART cycle and future cycles will be then calculated based on ANZARD.

The *IVF Patient Predictor* will complement clinic-specific success rates by providing much more individualised estimates of ART success based on all cycles undertaken in Australia. It is envisaged that prospective and existing patients would use the *IVF Patient Predictor* to estimate their chance of individual success and then choose a clinic based on a number of factors, including that clinic's success rates.

Conclusion and Recommendations

Greater use of health data by patients, clinicians, regulators and policy makers is a hallmark of the digital age, making the ART registry a central player in modern health care delivery. The NPESU supports public reporting of clinic-specific success rates and has a long history of successfully managing and reporting ART outcomes. It is well placed to take on the role of public clinic-specific reporting. On behalf of the NPESU I make the following recommendations:

1. The NPESU should be responsible for undertaking the reporting of clinic-specific success rates using the ANZARD registry. It is an independent academic unit, and the only group in Australia with the extensive expertise required to undertake this function. The clinic-success rates should also be prepared from the same dataset (ANZARD) that the *IVF Patient Predictor* will be developed from so that the information generated is complimentary.

2. Rather than change the AIHW Act, the RTAC Code of Practice should be amended to state that the data provided to ANZARD will be used for public reporting of clinic success rates, thereby avoiding multiple data submissions and registries.

3. Reporting should be designed to minimise unsafe clinical practice and 'gaming' and should not disadvantage particular patient groups.

4. Reporting should be centralised on one website so that patients can compare clinics. Information should also be included for each clinic on whether they are currently accredited, their fees, and the services they offer.

5. A Steering Committee should be established to oversee the content, design and acceptability of the clinic-specific reporting. Members should include the NPESU Director and epidemiologists, clinicians, scientists, patients, regulators and government.

References

1.   Centers for Disease Control and Prevention, American Society for Reproductive Medicine, Society for Assisted Reproductive Technology. 2016 Assisted Reproductive Technology Fertility Clinic Success Rates Report. Atlanta (GA): US Dept of Health and Human Services. Available at: https://www.cdc.gov/art/reports/2016/national-summary.html. 2018.

2.   Fitzgerald O, Paul RC, Harris K, Chambers GM. Assisted reproductive technology in Australia and New Zealand 2016. Sydney: National Perinatal Epidemiology and Statistics Unit, the University of New South Wales Sydney. Available at: https://npesu.unsw.edu.au/data-collection/australian-new-zealand-assisted-reproduction-database-anzard. 2018.

3.   Kissin DM, Adamson GD, Chambers GM, De Geyter C. Assisted reproductive technology surveillance Cambridge, United Kingdom: Cambridge University Press (2019). ISBN 978-1-108-49858-6 Hardback and online. www.cambridge.org/9781108498586. DOI: 10.1017/9781108653763; 2019.

4.   Chambers GM, Doody K, Crawford S. 'Reporting ART Success Rates' in in 'Assisted reproductive technology surveillance'. Ed. Kissin DM, Adamson GD, Chambers GM, De Geyter C. Cambridge, United Kingdom: Cambridge University Press (2019). ISBN 978-1-108-49858-6 Hardback and online.; 2019.

5.   Wilkinson J, Roberts SA, Showell M, Brison DR, Vail A. No common denominator: a review of outcome measures in IVF RCTs. *Human Reproduction* 2016; **31**(12): 2714-22.

6.   Chambers GM, Ledger W. The economic implications of multiple pregancy following ART. *Seminars in Foetal and Neonatal Medicine* 2014; **19**(4): 254-61.

7.   Human Fertilisation and Embryology Authority (2018). Fertility Treatment 2014-2016 Trends and Figures. Human Fertilisation and Embryology Authority. Available at: https://www.hfea.gov.uk.

8.   Human Fertilisation and Embryology Authority. Annual report and accounts 2017/18. Available at: www.gov.uk/government/publications. 2018.

9.   Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR). Available at: https://aoanjrr.sahmri.com/home.