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Executive summary

The Australian Institute of Health and Welfare (AIHW) Amendment (Assisted Reproductive Treatment Statistics) Bill 2019 proposes to incorporate reporting of success rates of Assisted Reproductive Treatment (ART) in a highly prescriptive way to the AIHW for release to the public domain. The proposed changes have a number of unintended consequences which have not been articulated and which will be adverse for the health care budget and patient care. The goals of the proposed legislation, whilst laudable, will not be achieved by the proposed changes. Alternative ways of reassuring patients of standards of care provided and providing information on their chance of success should be developed and implemented. Mandated change in reporting of ART requires careful scenario analysis to reduce unintended consequences. International experience on the reporting of health outcomes shows significant challenges, inadequate validation of methods used, increased 'gaming' and reduced access of patients to care. The unintended consequences of the proposed legislation include attrition of patient choice, inevitable reduced use of less invasive and cheaper treatments in favour of ART, stifling of the development of innovative treatments and

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centres of excellence in complex disorders, increased cost of ART (a need to develop dual reporting systems and run two clinics (one for good prognosis patients and one for poor prognosis patients) for commercial viability) and failure to measure other parameters of success (for example patient satisfaction even if no live birth occurs). There may be additional unforeseen unintended consequences. It is recommended to extend the period of public and professional consultation, to set up an expert working party to review alternative proposals and possibilities and perform scenario analysis for all proposals generated by the working party.

Purposes of the proposed legislation

1, To provide couples/women with realistic information on their chance of achieving a live birth if they attend the nominated fertility clinic for treatment.

The proposed legislation has defined parameters of success which are summarised as a crude statistic which is not applicable to an individual couple. Many factors affect a couple's chance of achieving a live birth and some of these are listed in Table 1. Each of these factors influence a couple's chance of success. These have to be assessed within a consultative setting and rely on the experience, training and skill of the clinician.

Female factors	Male factors	Couple factors	Obstetric factors
Age	Age (particularly if greater than five years older than the female)	Duration of infertility particularly if no tubal block, normal semen analysis	Past pregnancies
Ovarian reserve/anti mullerian hormone (AMH)	Seminal analysis	Past treatment to optimise natural conception	Medical co-morbidities e.g. diabetes, hypertension, past thrombotic disease
Endometriosis	Genetic factors (karyotype, Y chromosome deletion)	Past IVF cycles and treatment	Past caesarean section
Adhesive tubal disease e.g. past infection, past surgery	Body mass index	Coital factors	Twinning
Adenomyosis	Exposure to endocrine disruptors	Opportunity for natural conception	Body mass index
Fibroids	Lifestyle factors e.g. cigarette smoking, marihuana use, alcohol use	Genetic composition of embryo	
Endometrial scarring	Aetiology of male infertility e.g. past vasectomy, past chemotherapy	Laboratory management of embryo	
Past caesarean section	Associated co-morbidities e..g	Social infertility	

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	prostatic disease, spinal cord injury		
Genetic factors	Medications e.g. sulphasalazine, finasteride	Use of preimplantation genetic testing	
Congenital defects of uterus	Cycling	Number of embryos transferred	
Ovulatory status		Timing of embryo transfer	
Body mass index		Cryopreservation of embryos	
Exposure to endocrine disruptors			
Lifestyle factors including exercise			
Embryo transfer			

2. To reassure couples that the nominated fertility clinic provides quality care at an acceptable standard

The heterogeneity of the population treated at a clinic will preclude reliable assessment of the standard of the clinic by the parameters proposed in the legislation. For example some clinics develop professed interest and expertise in social infertility and using donor gametes. Such treatments are associated with a higher chance of success. Specialists in reproductive endocrinology and infertility are more likely to treat complex conditions which are associated with reduced success rates.

To have reliable assessment of the function of the unit and particularly the laboratory the live birth rate from a clearly defined group of patients is required. A suitable statistic could possibly be developed. For example, couples with male factor infertility where the female is aged 29-34 years with an anti mullerian hormone (AMH) level within the age matched reference range and no other adverse factors (e.g. normal uterus) may be a suitable patient group to report in the public domain. The success rate for this predefined group of patients will be influenced by the number of patients in small clinics and potentially invalid.

It is a requirement of the Reproductive Technology Accreditation Committee (RTAC) that all units have in-house parameters which are continuously monitored and which measure the function of the laboratory. The use of RTAC accreditation in the development of a reportable statistic which measures the quality of treatment offered by a clinic is worthy of exploration. There are however potential flaws even in development of such measures and careful consultative consideration is required.

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Experience from overseas reporting of success rates

United Kingdom

Britain has had published reporting of success rates of IVF clinics under oversight of the Human Fertilisation and Embryology Authority (HFEA) for over ten years. Despite this standardised reporting in the public domains, information provided on clinic websites is not consistent (Wilkinson, 2017) and the overwhelming majority of the clinic use different numerators and denominators to express success rates. There is evidence that using the cumulative live birth (including results from all embryos transferred fresh and frozen from any oocyte collection is the best way of reporting success rates rather than using a single parameter such as live birth per cycle started (Wilkinson J, 2017). To report using cumulative live birth may take many years by which time the success rate is no longer contemporaneously representative of the clinic performance or the technologies available. The influence of patient characteristics on treatment outcomes, rather than the clinic's performance has been demonstrated and the validity of comparing clinics' success rates by the sparse data generated from IVF treatment registries questioned (Johnson, 2007). The effect of female age is well known but the effect of reduced ovarian reserve is less known and highly relevant (Kawwass JF & Group, 2017).

The HFEA prioritises "patient centred care" in its advice to patients on choosing a clinic. Accreditation reporting is also included in the metrics made available in the public domain. Neither patient centred care nor accreditation standard are proposed in the current legislation.

The HFEA acknowledges that unreliable ratios may results when small numbers of patients are treated and small clinics are not required to report their success rates. (HFEA, 2019)

United States of America

The United States of America has a voluntary system which reports clinic specific success rates in the public domain (Sparks, 2019), (Centers for Disease Control , 2019). However over time the number of cycles reported by some clinics has reduced and this underreporting is associated with higher pregnancy rates of the clinics. Changes in practice of management of poor prognosis patients to be freeze all may be a possible explanation of this change but it is uncertain "where all the cycles have gone" (Kulak D, 2016).

Other clinical domains

Reporting of health outcomes in the public domain in other areas such as cardiac surgery has been in place for many years and resulted in high risk patients being denied access to care (Burack JH, 1999). The process of reporting health outcomes in a meaningful way has been summarised by the American Heart Association and is reproduced here in Figure 1 (Krumholtz, 2005).

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Preferred Attributes of Models Used for Publicly Reported Outcomes
1. Clear and explicit definition of an appropriate patient sample
2. Clinical coherence of model variables
3. Sufficiently high-quality and timely data
4. Designation of an appropriate reference time before which covariates are derived and after which outcomes are measured
5. Use of an appropriate outcome and a standardized period of outcome assessment
6. Application of an analytical approach that takes into account the multilevel organization of data
7. Disclosure of the methods used to compare outcomes, including disclosure of performance of risk-adjustment methodology in derivation and validation samples

Figure 1

In particular the appropriate patient sample needs to be standardised to avoid differences in patient characteristics which determine health outcomes.

Conclusion

It would seem therefore prudent to learn from the experience gained in the past in international settings before mandating reporting of success rates from IVF clinics in Australia. This will take careful consideration and the goal should be to ensure that Australia leads the world rather than repeats the errors of Britain and USA.

Unintended consequences

Change always has unintended consequences and sometimes these are unforeseen consequences. Sometimes unintended consequences are significantly adverse. Anticipation of unintended consequences and scenario analysis before implementing change are necessary (and routinely performed in most organizations within the developed world). This is particularly important where the change is mandated (as it is here). Some of these unintended consequences and scenarios of the proposed legislation are discussed below.

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1.0 Attrition of patient choice

A major concern is that clinics will be under pressure to maintain a high pregnancy rate and this will become essential for the commercial viability of the organization. Clinics may have to decline to treat patients with a poor prognostic features in order to maintain a high pregnancy rate. This may include older couples, women with reduced ovarian reserve or severe endometriosis or those with a past history of unsuccessful cycles. Couples may have to attend several clinics to find one which is prepared to treat them (usually clinics with lower pregnancy rates – clinics which have lower pregnancy rates (and have borderline commercial viability) because they take poorer prognosis patients.)

2.0 Reduced use of less invasive and less expensive treatments (added expense)

Less invasive treatments such as ovulation induction (OI) for women who do not ovulate but have no other pathology are commonly used in Australia particularly by subspecialists holding a certificate in reproductive endocrinology and infertility [1](CREI). These treatments cost a fraction of the cost of ART, are many, are highly effective and are currently not captured in any of the ART MBS item numbers (13200, 13201, and 13203). As these women do not need ART and have a good reproductive prognosis, a potential scenario is that clinics may incentivise such women to proceed to have ART rather than OI. This might be achieved by increasing the out of pocket costs for OI to be greater than ART. Incentivising women with a good reproductive prognosis who do not need ART into ART programmes has the added benefit for the clinic of increasing success rates.

3.0 Increased use of more invasive and more expensive technologies

Clinics under pressure to increase success rates may require couples to undergo preimplantation genetic testing and to only transfer embryos which are euploid. A potential and very reasonable scenario is that the clinic requires all women undertaking ART who are over 38 to have PGT-A which is associated with 60% clinical pregnancy rate per embryo transferred rather than 40% clinical pregnancy rate per unscreened embryo transferred. PGT-A is an expensive and invasive treatment.

Another way to increase pregnancy rates is to transfer two blastocysts. Australia has led the world in commitment to single embryo transfer and reduction of higher order multiple pregnancies seen with multiple embryo transfer. Multiple pregnancies will place considerable burdens on the community in terms of increased rates of premature birth, NICU admissions, neonatal morbidity (including lifelong disability) and mortality, maternal complications of multiple gestation including increased risk of operative delivery

4.0 Requirement for each clinic to run parallel clinics

This method has been a commonly adopted way of managing publically advertised pregnancy rates in other countries. The parent ART unit only takes good prognosis patients but the related clinic which has a low pregnancy rate takes poor prognosis patients. Whilst this may be acceptable there are increased costs of accreditation, business management and branding which will result in reduced affordability for patients.

[1] CREI subspecialists are trained to offer comprehensive medical and surgical male and female infertility management as well as best practice ART. The training is an extra three years of full time supervised practice in infertility and reproductive endocrinology, two examinations and a research project after completing training requirements of a specialist in obstetrics and gynaecology. For further information see www.anzsrei.com

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5.0 Added expense of reporting

The current proposal of reporting to AIHW will duplicate current reporting to ANZARD and other state based reporting (such as in Western Australia and Victoria). This is unnecessary and will incur further administrative costs which will lead to increased costs for patients and for government. Any healthcare budget for clinical services will be diluted by these costs. Reduced affordability of ART is a consequence.

6.0 Dealing with complex patients and development of centres of excellence and new innovations

New innovations have been common in ART clinics in Australia and have significant risks in the early adoption phase. These cycles will be captured by the proposed statistic and may jeopardise a clinic's reported pregnancy rates. Similarly treating complex patients by new methods will be discouraged under pressure to maintain high pregnancy rates.

7.0 Reduced affordability of ART

Consequences of the change proposed detailed in items 2-5 above all increase costs of assisted reproduction and reduce affordability to patients. Currently 1 in 25 children born in Australia result from ART and one of the key drivers to use of ART is affordability. The long term economic benefit, largely from taxation, of live birth from ART offsets the cost of ART over time (Connolly, 2008) and is significant as birth rates per woman decline in the developed world.

8.0 Failure to measure parameters of success other than live birth

Live birth should not be the only measure of success of an ART unit. Having infertility is extraordinarily stressful for couples and many couples act in desperation at this vulnerable time. Inevitably some of these couples will be denied the option to try ART because of their poor prognosis with the proposed changes. The removal of hope and of access to care will remain with some of these couples for the rest of their lives. Denial of access to care often leads to anger and unresolved grief with far reaching and long term consequences for people. Managing and caring for couples at this stressful time of their life, particularly as they exit from treatment can be and often is performed well. Whilst these patients may not ever achieve a live birth they can exit positively and peacefully from fertility treatments administered by a clinic committed to quality holistic patient centred care. Patient satisfaction is not a parameter valued and measured by the proposed metrics. As cited above the HFEA uses a crude statistic of patient satisfaction as a parameter of clinic success.

Recommendations

1. Extend consultation time with professional bodies and consumer groups on the proposed legislation
2. Develop alternative proposals which will achieve the goals of the proposed legislation. This may include a national predictor tool though inevitably this will be a crude parameter given the complexity of factors which interplay and influence success of an IVF cycle.
3. Form a working group with representation from skilled clinicians working in the IVF industry, including those early and late in their careers, with female as well as male voices. This working party also should also include representation from ANZSREI (the society for reproductive endocrinology and infertility specialists as defined by APRHA (Medical Board of Australia, 2018)), representatives from small and large ART clinics, consumers and experts in

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health economics and health informatics. This working party would have the brief to develop strategies to assist couples accessing ART by methods other than the proposed mandated success rate reporting in the AIHW Amendment.

4. Fund and perform structured scenario analysis for all proposals developed by the working group.

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