SUBMISSION TO SENATE INQUIRY - AIHW AMENDMENT

This submission is made by Dr Richard Henshaw MD FRANZCOG FRCOG.

Assisted reproductive technology (ART) is a group of procedures that involve the in vitro (outside of body) handling of human oocytes (eggs) and sperm or embryos for the purposes of establishing a pregnancy. Each ART treatment involves a number of stages and is generally referred to as an ART treatment cycle.

There were 74,942 ART treatment cycles reported from 83 Australian fertility clinics in 2017. This equates to 14.8 cycles per 1,000 women of reproductive age (15–44 years) in Australia; nearly 5% of all women who gave birth in Australia in 2017 received some form of ART treatment (AIHW, 2019).

ANZARD (Australian and New Zealand Assisted Reproduction Database)

Pregnancy outcome data following IVF treatments has been collected since 1974.

The Reproductive Technology Accreditation Committee (RTAC - a sub-committee of the Fertility Society of Australia) is the "regulator" in Australia (see the RTAC Code of Practice on the FSA website).

Under the terms of the *"Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006"* it is a legal requirement for all IVF clinics in Australia (New Zealand has a different Act) to submit outcome data for every IVF treatment undertaken.

The database is analysed and the results published by the National Perinatal Epidemiology Statistics Unit at the University of New South Wales (the ANZARD report).

The report uses the agreed international standard of live birth as the primary outcome measure of effectiveness of IVF treatments.

Due to the length of time following ART treatment and birth, and then the time taken to collect and collate live birth data, there is usually around a two year delay in publishing results.

For example, the last ANZARD report, published in September 2019, reported on ART treatments that were performed in calendar year 2017.

Widely divergent outcomes following ART treatment in Australian IVF Clinics

In May 2015, in the ABC radio programme "The Health Report", hosted by Dr Norman Swan, we 'blew the whistle" and revealed that live delivery rate per treatment cycle (in 2012) varied significantly between fertility clinics.

This variation is measured using quartiles to rank a clinic's performance. In effect the clinics are ranked from the top 25% ("A graders") through to the bottom 25% ("D graders").

According to the report, Australian fertility clinics are spread evenly across the four quartiles:

Table 13: Live delivery rate of autologous fresh cycles by women's age group among fertility centres, Australia and New Zealand, 2012

	Live deliveries per initiated autologous fresh cycle (per cent)				
Age group (years)[(a)]	Overall	First quartile	Second quartile	Third quartile	Fourth quartile
< 35	25.2	29.1–38.6	24.3–29.0	19.9–24.2	5.4–19.8
35–39	17.0	18.6–30.2	15.8–18.5	14.6–15.7	2.5–14.5
≥ 40	5.7	8.1–20.7	5.6–8.0	4.3–5.5	0–4.2
All	**16.7**	**19.7–30.9**	**17.3–19.6**	**13.3–17.2**	**4.0–13.2**

(a) Age at start of a treatment cycle.

Of the 40,000 fresh IVF treatments *("autologous fresh cycles")* undertaken the live delivery rate varied from 4.0% to 30.9% *(Table 13 on page 16 of the report).*

So, data in the 2012 report, showed that the best clinic is likely to be 7 times more effective than the worst clinic in producing a live birth.

A patient attending the bottom clinic would have to undergo 7 IVF cycles to get the same result as one cycle performed by the top clinic.

In the 2019 reporting format has changed but the outcomes remain similar *(see Figure 1 on page 10)*. Each dot represents an individual clinic:

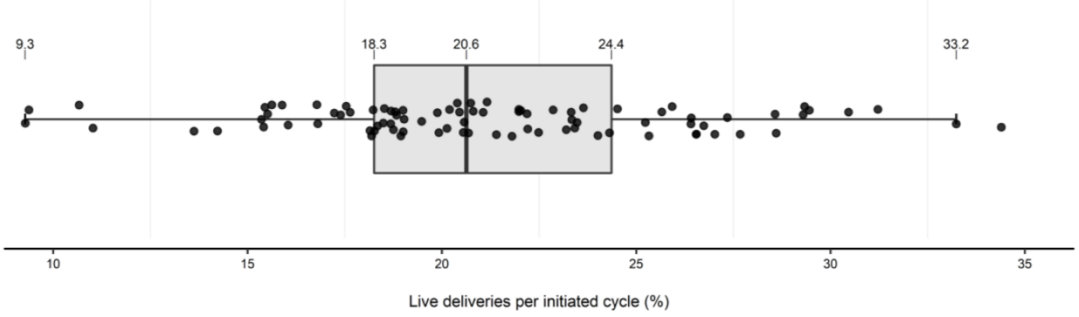

Figure 1: Live delivery rate per initiated fresh (excluding *freeze-all*) and thaw autologous and recipient cycle (%) among fertility clinics, Australia and New Zealand, 2017

The worst performing clinic showed a live birth rate of 9%, and the best performing 33% - nearly a fourfold difference.

So the patient who was unfortunate enough to unwittingly attend the worst performing clinic would have to undertake nearly four times the treatment of her peer who attended the best performing – this then has a significant multiplying effect on the grief and suffering experienced by patients, their partners and possibly close family members, not to mention costs incurred by the patient, Medicare and private health insurers.

It seems obvious to say that, if patients knew these outcomes, they would avoid the worst performing clinics.

How do patients find out which are the best and worst performing clinics nationally?

Sadly, and inexcusably, this is not possible (except in part in Victoria – see below)

Although this data is collected and analysed, it is closely guarded and presented in a non-identifiable way.

Data on "across the board" clinic performance is not made available to clinics, patients, Medicare or private health insurers.

Patents and their referrers have no independent verifiable advice on clinic outcomes (not unsurprisingly) every clinic website claims to be "one of the leading fertility clinics in Australia".

Historically the Fertility Society of Australia, which supervises collection of (and claims ownership of) information from clinics to compile the ANZARD database, has refused to contemplate producing identifiable national outcome data.

However, in Victoria, the Victorian Assisted Reproduction Authority (VARTA) produces an Annual Report in late October each year. Part of that report outlines clinical pregnancy and live births for each named Victorian ART clinic. An example of this, taken from the 2018 report is shown below:

Table 1.4a Fresh embryo transfer cycles and pregnancy outcomes, 2016-17 financial year
This data includes fresh embryos formed from thawed eggs.

Treatment site	No. of cycles with fresh embryo transferred	% of single embryo transfer	No. of clinical pregnancies	No. of live births	No. of liveborn babies	No. of cycles with fresh embryo transferred	% of single embryo transfer	No. of clinical pregnancies	No. of live births	No. of liveborn babies
	Women using embryos derived from their own, their partner's or donated eggs									
	< 35					35–39				
Ballarat IVF, Ballarat	59	100.0	21	18	19	34	94.1	9	7	7
City Fertility Centre, Bundoora	18	94.4	5	4	4	26	96.2	6	4	4
City Fertility Centre, Melbourne	138	87.0	38	23	24	154	82.5	36	31	34
Melbourne IVF, East Melbourne	425	93.6	174	141	146	601	86.7	175	124	132
Melbourne IVF, Mt Waverley	83	85.5	33	24	26	71	84.5	21	15	15
Melbourne IVF, Werribee	31	96.8	8	3	3	30	83.3	6	4	5
Monash IVF, Bendigo	29	93.1	5	3	4	20	90.0	4	4	5
Monash IVF, Clayton	314	90.4	123	107	109	289	86.2	88	68	73
Monash IVF, Geelong	53	92.5	18	15	16	36	94.4	10	8	8
Monash IVF, Mildura	19	94.7	8	7	7	16	100.0	5	4	4
Monash IVF, Richmond	337	87.2	124	109	115	495	79.2	125	98	100
Monash IVF, Sale	39	79.5	10	6	6	26	65.4	10	8	8
Monash IVF, Sunshine	77	88.3	26	23	24	51	82.4	14	9	10
Primary IVF, Preston	353	90.4	131	113	117	313	77.3	98	72	73
Reproductive Services, RWH (Melbourne IVF)	154	98.1	66	57	59	150	94.0	39	25	25
Aggregated total	**2,129**	**90.9**	**790**	**653**	**679**	**2,312**	**84.0**	**646**	**481**	**503**

Clearly, if you own a calculator, these data can be used to compare the performance of Victorian ART clinics – for example, in the 35-39 year age group, the live birth rate per embryo transfer at Melbourne IVF, East Melbourne and Monash IVF, Richmond are nearly identical, at 20.6% and 19.8% respectively.

International experience with success rate reporting

In the United Kingdom all IVF clinics report their success rates to a central agency, the UK Human Fertility and Embryology Authority (HFEA), which publishes national and individual IVF clinic pregnancy results on its website, allowing direct comparison of a clinics success with the national average. The results are reported as live birth per cycle started; egg collection; and embryo transfer.

In the USA, nearly 500 clinics voluntarily submit their success rates to The Society for Assisted Reproductive Technologies (SART)– whose mission statement is "Providing unbiased information and setting the standards for in vitro fertilization" which then publishes those clinic-specific rates on its website.

In recent years, SART has moved from reporting live birth per fresh embryo transfer to including births from both fresh and frozen cycles to enable assessment of live births per cycle started and egg collection. Success rates are given according to a woman's age, and the information can be filtered according to treatment type and diagnosis.

Both of these long standing and respected international organisations provide significantly superior information on per clinic IVF success rates than is available in Australia.

Potential risks around success rate reporting

All authorities (HFEA, SART, VARTA and ANZARD) warn of the potential hazards of success rate supporting. These include:

- There may be differences in the characteristics of patients being treated (for example age distribution, infertility diagnosis);
- Differences in ART treatment protocols (for example, transfer of one versus two embryos in a treatment cycle);
- Attempts by clinics to "game" the reporting system and inflate their success rates;
- Small numbers of patients who undergo treatment in some clinics (thereby invalidating statistical evaluation).

Whilst we acknowledge these potential hazards, we also need to accept that this is what they are – potential.

In large clinics, our experience is that patient case mix across clinics is remarkably similar We are unaware of any peer review academic publications that state the contrary, and totally reject the hypothesis (or excuse) that different clinics routinely treat different groups of patients.

Analyses can be made stratifying for patient age (which already happens)and major characteristics. Live birth per embryo transferred, not per treatment cycle, can be utilised to correct for the number of embryos transferred.

In the past, attempts have been made by less scrupulous overseas operators to "game" the system by excluding poor prognosis patients from treatment. This is fraud, and should be treated as such. However, let me be clear that there is no evidence that this has taken place in Victoria, where outcomes are reported by VARTA.

So, whilst acknowledging potential hazards, we also need to accept that we can mitigate these risks, and they should not be road blocks to progress.

In summary

The Australian Charter of Healthcare Rights (2019) states that patients have a right to clear information about their condition.

In denying patients access to outcome data that is known to the profession but kept deliberately hidden, we violate the ethical principles of autonomy, beneficence and justice.

In the USA and the UK patients are able to access information that enables them to make clear and informed choices about their fertility treatment.

The same outcome data exists in Australia; it has been collected for many years; we could attain the same quality of care and information as our international peers.

As the peak body and de facto regulator, the Fertility Society of Australia, has shown no inclination to act in the best interests of patients, it should be forced to do so by legislation.

For this reason, I support the principles of the proposed AIHW Amendment Act.

Dr Henshaw has been a Fertility Specialist for 25 years. He has served as Chair of the IVF Medical Directors Group of the Fertility Society of Australia, and on Council of the Royal Australian college of Obstetricians and Gynaecologists.

He currently serves on the Board of Directors of Monash IVF. He owns stock in, and is paid by, Monash IVF. The views expressed in this submission are entirely his own.