fertilityspecialists of Western Australia
ABN 88 119 665 511

Consulting Suites
Bethesda Hospital
25 Queenslea Drive
Claremont WA 6010

Ph: 9284 2333
Fax: 9340 6383
Email: info@fertilitywa.com.au
Web: www.fertilitywa.com.au

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The Program Manager
Reproductive Technology Unit
Patient Safety & Clinical Quality
Clinical Excellence Division
Department of Health
189 Royal Street
PERTH WA 6004

By Email HRTSR@health.wa.gov.au

Dear Program Manager of The Reproductive Technology Unit,

Re: Review of the Human Reproductive Technology Act 1991 and the Surrogacy Act 2008

I am writing on behalf of Fertility Specialists of Western Australia and Fertility Specialists South, to the call for submissions for the Review of the Human Reproductive Technology Act 1991 and the Surrogacy Act 2008.

While we are supportive of the majority of the legislation within the Act, particularly with reference to supportive counselling for couples embarking on IVF treatment, we believe that as technology has advanced over the last decade, that it is very timely to consider a review, and we put forward the following suggestions to A/Professor Allen for her review:

IVF:

1. There should be no limit on the embryos that can be stored prior to embarking on a fresh IVF cycle. Currently 'exceptional circumstances' have to be fulfilled prior to gaining an exemption to proceed with a fresh IVF cycle. Exceptional means rare. We are now frequently freezing embryos for women prior to cancer treatment- if they have time for two IVF cycles before initiation of chemotherapy they would have to seek RTC approval. This current imposition is unnecessarily onerous on the couple, and potentially can lead to time delays. Embryo freezing for cancer is now becoming a frequent event- and hence with time the descriptor 'cancer' will not fit the definition of exceptional circumstances'. Furthermore, a woman embarking on IVF at 38-39 for her first child would be wise to consider to 'bank' some embryos for a potential second child before she proceeds to an embryo transfer. As her chances of IVF being successful with embryos generated when she is 38 is 4 times greater than if she were to embark on IVF at 42- which is the likely time-frame in this scenario, it is only fair that she be given this opportunity to bank some embryos for her future use, however the current legislation as it stands would preclude her from having this opportunity.

PGS:

1. We do not believe it appropriate to have a limit on the number of embryos that can be stored prior to seeking RTC approval to generate more embryos from an IVF – PGS cycle. This is unnecessarily onerous and requires the generation of an excuse of 'exceptional circumstances' to allow a waiver. When one considers that a woman over 40 years has a very high number of abnormal embryos in addition to having a poor ovarian reserve- the majority of women undergoing PGS will be required to seek approval of a waiver to this restriction to generate a 'batch' of embryos to test- rather than test them one at time. We feel the legislation was developed at a time when blastocyst freezing was not the norm, vitrification of embryos did not exist and genetic analysis of embryos was illegal. Hence, we propose an abolition on the limit of embryos that can be stored prior to the initiation of a further IVF cycle.

2. Further we believe it is a discriminatory distinction to only allow patients to have embryos screened for a genetic abnormality at age 35 years or above. This stipulation seems arbitrary and many women would potentially be able to benefit from this technology – particularly those women with unexplained infertility as this may well offer an insight into the cause of the couple's infertility. It is believed that 30% of a woman's eggs are chromosomally abnormal at 30 years of age and 50% at 35years. Hence, we advocate a removal on age restriction for women to able to undergo embryos screening

PGD:

1. We do not believe there is a need to seek approval from the Reproductive Technology Council prior to performing pre-implantation genetic diagnosis on an embryo. If the couple have had appropriate genetic counselling, a medical consultation and counselling, and the opportunity to discuss their situation with a trained counsellor- we believe that this obviates the need for a formal submission to the Reproductive Technology Council, as Commonwealth legislation provides adequate protections.

Surrogacy:

1. We do not believe that a couple should have to develop a surrogacy arrangement prior to the generation of embryos in the situation where she is at risk of imminently requiring a hysterectomy. Current legislation restricts the use of IVF to generate embryos for a woman who may require surrogacy until Council. However, a woman with a recent diagnosis of cancer of the cervix, uterus or ovaries may be forced to undergo a hysterectomy. If she were able to undergo a rapid IVF cycle to generate embryos- this would preserve her fertility and enable the development of a surrogacy arrangement when she has recovered from her cancer, as this would be impossible to do prior to her hysterectomy.

RTC Approvals – Impact on Patients:

We also note that in circumstances where RTC approval is required to progress diagnostic testing or treatment, this adds significant cost (which is ultimately passed onto the patient) and time to the treatment. This is a source of significant stress to the patients - and generally these patients have already been through a lengthy and costly fertility journey.

Whilst this is not in itself a reason to change any specific part of the Act or Regulations, we would suggest that at the time of the review, the impact on the patient should be considered when determining what procedure or test will require regulatory approval, and what will not. As noted previously, many of these items are already covered by Commonwealth Legislation.

Data Requirements – Duplication with ANZARD:

1. Currently, patient and cycle information relevant to various ART treatments is entered into a Fertility Specialists database at the conclusion of a treatment cycle. In Western Australia, we are required to submit such cycle specific information to a number of government and industry bodies (i) electronically submitted three monthly updates (spreadsheet format) of cycle data to the Data Collection Unit, Maternal and Child Health Department, WA Department of Health (DOH) (ii) electronically submitted annual data (spreadsheet format) to the Australian and New Zealand Assisted Reproduction Database administered by the National Perinatal Epidemiology and Statistics Unit (NPESU), University of New South Wales (iii) hardcopy and emailed annual summary report (report template format) to the Reproduction Technology Unit, WA Department of Health.

2. There is considerable overlap between the non-identifying data sets required by the DOH and ANZARD. Indeed, I believe the DOH data requirements were based on the original ANZARD requirements but are not as extensive as the current ANZARD V2.0 data fields.

3. This reporting structure involves a high level of duplication of data, not all of it as complete as it could be due to either out dated requirements or restrictive reporting time periods.

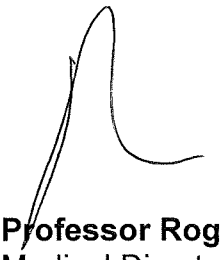
4. For example, the ANZARD data is a complete data set and includes birth outcome information. It is generally submitted at the end of each calendar year with data collected from treatment cycles commenced in the previous 12-month period. In comparison, the three-month DOH data submissions have fields for input but contains no pregnancy outcome information. The RTC annual report is based on a financial year time-period and requires submission by the end of July each year for data from the 12 months to the end of June. With respect to treatment cycle data, the report concentrates on numbers of cycles commenced rather than outcomes. The timing is such however, that pregnancy and birth outcome data would be incomplete.

5. We suggest an overhaul of the data submission requirements under WA legislation. A viable solution would be to adopt the same data set and reporting time requirements as required for ANZARD. In addition, patient identifying information can also be submitted to a single DOH department to allow linkage to the Midwives Notification of Births Data System as intended in the Human Reproductive Technology Act 1991 Directions (2004) (page 5450) to allow collection of birth information. This linkage is not currently being performed but would provide an enormous time saving measure for ART clinics whilst facilitating a more complete (at least for WA birth outcomes) and standardised birth outcome data set. Ideally, due to relatively constant change in the data desired to be collected for ART cycles, it would be preferable if the data collection process was not tied directly to the legislation.

In summary, we believe the key points to be addressed by the review with respect to data submission are:

- Prevent replication of data submission process, adopt ANZARD as standard for non-identifying information and timing of submissions
- Streamline process to allow ART clinics to liaise with a single department within the DOH
- Remove constraints of Legislation to allow data collection to change over time
- Facilitate linkage to birth outcome information as originally intended

Yours sincerely



Professor Roger Hart MD FRCOG FRANZCOG CREI
Medical Director of Fertility Specialists of Western Australia
& Fertility Specialists South

Fertility Specialists WA
Consulting Suites
Bethesda Hospital
25 Queenslea Drive
CLAREMONT WA 6010
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