



Dear Associate Professor Sonia Allan,

The Telethon Kids Institute welcomes the opportunity to make a submission to the review of the Western Australian *Human Reproductive Technology Act 1991* (HRT Act). I have been asked to respond on behalf of the Institute, given my extensive involvement and experience as a researcher in the field. I am an epidemiologist at the Telethon Kids Institute and am also a Deputy Member of the Reproductive Technology Council (RTC) and a member of its Scientific Advisory Committee. Given the Telethon Kids Institute is a research organisation concerned with improving the health and wellbeing of children, this submission will focus on the Terms of Reference (TOR) relating to **management of the Reproductive Technology Register** and the implications for **research**. These TOR were stated as follows:

"Management of information / the Reproductive Technology Registers, including;

- *Confidentiality of information*
- *Use of data for research*
- *Use of data for purposes of national data collection*
- *Access to information about donation, genetic parentage and donor conception*
- *The Voluntary Register (donor -assisted conception)"*

The statutory Reproductive Technology Register (RTR) was established in 1993/94 to collate information on every treatment cycle undertaken in WA IVF clinics to enable monitoring of clinics' compliance with legislative requirements and the safety of treatments provided for the women treated and children born following these procedures. While the TOR relating to management of the RTR (above) include consideration of the use of data for research and for the purposes of national data collection, **they are silent as to the use of RTR data for the purposes of monitoring and evaluating ART treatment at the State level**. This important omission will be addressed as part of this submission.

Telethon Kids Institute researchers have used data from the RTR linked with other population-based health registers to examine many safety aspects of ART treatment for the children born, including comparisons of perinatal outcomes, birth defects, hospital admission, cerebral palsy and intellectual disability in children born following ART compared with naturally conceived children (1994-2002). Our current research has sought access to RTR data for a more recent birth cohort (2003-2014) and we have found that these more recent data contain numerous errors and have not kept up with important shifts in IVF clinical practice. The RTR was originally set up as a relational database but was subsequently collapsed into an Excel flat file format. Many data errors stem from this retrograde step; previous automated data checking queries were lost and the ability of staff to perform data validation severely compromised. Excel does not handle one-to-many relationships well – precisely the sort that need to be mapped in ART treatment e.g. one egg retrieval mapping to several different embryo transfers. Excel files also become unstable as they increase in size, raising concerns for security of the data.



We submit that inadequacies in management of the Register are leading to poor data quality with two major negative consequences:

1. **The clear intent of the legislation in the establishment of the RTR for safety monitoring purposes is being seriously undermined.** Basic tabulated treatment cycle and birth outcome data have not been published in the Appendix of the Reproductive Technology Council annual report since 2004. We therefore have no information about how many children are born following IVF treatment in this State, or whether there are any problems with specific techniques based on the treatment cycle data collected. The health impacts of important shifts in clinical practice, such as the introduction of an ultra-rapid embryo freezing technique to WA clinics in 2008, cannot be evaluated because information on such techniques has not been added to the Register.
2. **The ability of researchers in this area to conduct valid, timely research is in jeopardy. If our research findings are to inform policy and improve clinical practice, they must be based on valid data.** Our current research into child health outcomes following ART has experienced lengthy delays due to the identification of numerous errors in RTR data. We are currently waiting for our third re-extraction of these data in a 12-month period, rendering progress with this research impossible.

Providing RTR data to the national data collection (ANZARD) is listed as part of these TOR (as above). However, the RTR was *not* established for this purpose. While Telethon Kids fully supports the alignment of variables common to both data collections in order to minimise the reporting burden for WA IVF clinics, the main role of the RTR in facilitating safety monitoring of treatments at the State level should be clearly acknowledged. The reviewed Act should make very clear the rationale for data collection and the importance of these data for a range of purposes including public health research and **monitoring of ART practice within this State**.

In our view and in order to realise the true intent of the legislation, the Act and/or Directions should:

1. Make explicit the requirement for this complex dataset to be restored to a **relational database**, managed by staff with expertise in data management practices *and* a clear understanding of IVF clinical practice.
2. Make explicit the requirement for **adequate resourcing** to allow appropriate management (cleaning/validation) and use of Register data.
3. Describe a mechanism to **enable more rapid changes in reporting requirements** to better reflect *current ART practice* and allow for appropriate safety monitoring of new treatments. This may involve removal of the data dictionary from the Directions so that it can be updated more easily; however, this must be balanced against the ability to enforce reporting requirements. Provision should be made for the retrospective collection of information about important changes to clinical practice (such as ultra-rapid embryo freezing) that have not been recorded on the register.
4. Make explicit the requirement to undertake **annual internal linkage of RT treatment cycle data with the Midwives' Notification of Birth System** to obtain basic birth outcome information. This information would also facilitate accurate birth outcome reporting by WA clinics to the national register. Current processes see clinics contacting patients individually to ask about pregnancy outcomes which is likely to be particularly distressing for couples that have experienced a pregnancy loss or complicated birth.
5. Make explicit the requirement for **register data to be used by the RT Unit (DoH) for monitoring and evaluation of the treatments undertaken in WA** and for summary information based on register data to be included in annual reports of the Reproductive Technology Council. At a minimum, this should include information about the total number of births occurring each year, the live birth rate per treatment cycle commenced for different types of ART treatment (e.g. fresh vs. frozen-thawed embryo transfer; ICSI vs. standard IVF); the occurrence of single and multiple pregnancies, and the proportion of live vs stillbirths. In addition, annual reporting would provide an important impetus for data checking and correction.

6. Make explicit the requirement for **validation studies** of a random sample of treatment cycle data against clinic records to be undertaken periodically to help identify any problem areas in data reporting and accuracy.

In addition to the points mentioned above, the reviewed Act should clearly recognise the importance of safety data for the parents of ART-conceived children. In 2016, Telethon Kids held a Community Forum at which parents who had used ART were invited to share their experiences and concerns, and outline what they thought should be research priorities in this area. Parents were extremely positive about the existence of the RTR, and were keen for research to be undertaken to investigate outcomes for their children, but also for their own health in the future – specifically women who had received high dose hormone treatment as part of their ART treatment. They wanted all aspects of treatment to be documented so that the data could be used to identify methods for improving treatment safety and any conditions they should particularly consider when monitoring the health and development of their children. These safety concerns could be addressed with an up to date, high quality data collection and analysis of these data both by the Department and through external research projects.

In its early days, the WA RT Register was the envy of researchers and health professionals in the ART field internationally –a statutory collection sitting in the midst of a whole network of other population-based health registers which could be linked together with the assistance of a dedicated data linkage branch. The first research study to use linked data from the RT Register examined birth defect prevalence following IVF conception. The findings showed that births conceived using ART in WA from 1993-1997 had a two-fold increased risk of major birth defects compared with naturally conceived births, and the paper was published in the *New England Journal of Medicine* (2002). The study raised awareness of the importance of long term follow-up of ART children, stimulated many other research groups to assess the prevalence of birth defects in ART cohorts, and led to changes in the information provided to patients at pre-treatment counselling; it has since been cited over 1000 times. Fifteen years later, WA remains the only state in Australia where such research can be undertaken, but the RTR has languished and the current poor data quality means that we are unable to adequately address the many unanswered questions in this field that an up-to-date register would allow us to address.

Telethon Kids strongly supports that this statutory data collection be upgraded and maintained in accordance with its main purpose and its statutory obligations.

Yours sincerely,



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15 March 2018