

General Comments

The world and society that we live in today is very different to the one that framed the Human Reproductive Technology Act in 1991 and as a result is in need of significant change to bring it in line with both national legislation and community standards.

The 1991 Act established a Code of Practice at a time when one did not previously exist and help establish a framework of understanding for both patients seeking treatment and doctors working in the field. In that current ART clinic accreditation is based on adherence to national RTAC and NH&MRC standards, which are independently verified, the whole rationale for a State based Code of Practice has largely been lost and challenges the need for a distinct state based Code of Practice.

A change to the HRT Act is also an opportunity to bring the Act in line with both the Sex Discrimination Amendment Act (2013) and the Marriage Amendment Bill (2017). It also should allow for the recognition that Australia has moved to a more multicultural country. In this regard, it should be recognised that some of the proscriptions on the importation of donor gametes selectively disadvantage people in ethnic minority groups who are seeking ethically appropriate donor treatments and are therefore racist. Is it OK to deny ethnically appropriate donors to couples because of the ethical standards of the Australian white majority? Are we happy to tell them we know best or if they were a bit more culturally mature like us, they would see it our way?

Another important part of the 1991 HRT Act was the establishment of the Reproductive Technology Council to regulate, provide guidance in the use of reproductive technology and enforce the Act. Unfortunately, in recent years the Council has actually restricted good practice by acting in a contrary manner. It has recently demonstrated a lack of consistency in its judgements particularly where the Act explicitly provides scope for them to be act "compassionately". They are also failing to provide guidance by demanding clinics test what the Act means through the courts and as a result are abrogating their responsibility to provide guidance in the use of reproductive technology.

Specific Issues from the Terms of Reference

1) Research and experimentation on gametes-

I agree that a nationally consistent approach is most sensible. That said, it is difficult to see the justification for Western Australia specific legislation for any part of the Human Reproductive Technology Act or more specifically why research and experimentation should be treated differently to clinical matters.

2) Genetic testing of embryos, saviour sibling, mitochondrial donation and gene editing technology.

The genetic testing of embryos is becoming a mainstream therapy and improvement in gene sequencing technologies is only likely to make it more affordable and applicable in the future. Whilst it is right and reasonable to have control of these technologies this must be weighed against requiring onerous red tape. To force clinics to apply for treatments which are essentially rubber-stamped as approved when applied. There should be mechanisms in any future act to allow emerging technologies to enter in to accepted practice.

Similarly, any genetic problem that would regarded as a reasonable indication for termination of pregnancy in the 1st and second trimester should not require special permission to test embryos for. PGD for specific genes on the other hand I think should be more closely controlled to avoid any possibility of eugenics and the creation of saviour siblings through genetic testing I believe should be resisted in the interest of the child. It is too high a burden to place on them.

Mitochondrial donation and gene editing technologies: these need research and development before they can be regarded as a viable therapies. Any legislative change should be such that the research is encouraged rather than inhibited anything less would be a victimisation of people for whom those technologies hold promise of treatment or cure.

3) The posthumous collection, storage and use of gametes and embryos.

This should really be a matter of consent and practicality. If a man has consented to the posthumous collection of his sperm for use in the fertility treatment of his spouse and viable sperm can be collected then this should be permissible. To deny it because that child will not have a father is at odds with the ability of single women to access fertility treatments.

Similarly, men should, under the same circumstances, be able to collect oocytes from their female partners (if possible) for use in surrogacy treatments. Other Acts should be changed to allow this in the interest of fairness.

The death of donors should not affect the ability of the donor gametes or sperm to be utilised. Children born of donor gametes or embryos are entitled to know who their genetic parents were but are not necessarily entitled to a relationship with them so the question of them being alive or dead at the time of donation is moot.

4) The rights to store gametes and embryos in complicated relationships and mental incapacity.

These issues are again essentially a question of consent. If a couple has created embryos that are stored and the relationship ends and the one partner now finds they are sterile should they be able to use the embryos? In the interest of the child, it should be possible but only with the consent of the ex-partner. Mental incapacity should be treated the same as death and should not negate the use of the gametes or embryos as long as the use has been consented to before the incapacity of the person in question.

5) Rights to store gametes, eggs and sperm.

Increasingly women are taking advantage of this process to minimize the harmful effect that their aging has on their eggs. As this negative effect on gamete quality is most experienced by eggs the Act should be altered to, if not encourage this, then to not inhibit it.

With modern freezing techniques, both eggs and sperm can be safely cryopreserved and biologically gametes could be stored indefinitely with no harmful effects. As the legislation stands, the allowable duration of storage should be prolonged; 15 years is too short particularly for the many boys and girls who are treated for cancer in their teens. A limit though is definitely useful and therefore desirable, but it should be more like 30 years. For embryos, it can sometimes take couples a long time to finally decide to stop treatment and consider donation. Time limits are less of an issue for embryos as they are often used quickly but can be an issue for couples who have successful treatments and want to space their pregnancies out. At the very least, the time limit for donated embryos should start from when they have been donated rather than when they are created.

6) Storage of embryos.

Another change that needs to be made is concerning embryo banking. That is the creation of embryos with a view to their later use in treatment for the couple. Why should couples not be able to create embryos in their youth and store them for later use when they are financially more secure and more advanced in their work? With the move towards elective freeze all cycles for

safety and improved implantation rates this limit should be seen as the outdated and unfair restriction it clearly is.

- 7) The Chief Executive Officer's power. Regulations and guidelines.
The power to make a Code of Practice - Clinics throughout Australia should operate with the same Code of Practice enacted at a Federal level. This makes sense because technologies are funded federally through Medicare and failure of an Australia wide Code of Practice results in patients travelling interstate for treatments which they should be able access at home and therefore unnecessarily acts to disadvantage them.
- 8) Enforcement and disciplinary penalties. No comment.
- 9) Right of appeal of RTC decisions.
In the interest of fairness, I believe that some appeal process should be possible.
- 10) The impact of national legislation of the HRT.
I think the national legislation that already interacts with the HRT Act is providing the impetus for this current review of the Act and will only act to improve and modernize it. One of the most significant changes should be the incorporation of The Sex Discrimination Act (1984). For example while one might argue that human reproduction is inherently sexist in that men maintain their reproductive capacity in to old age and women lose theirs at menopause that doesn't seem a good reason to enshrine this bias in the Act. Men and women should, within the limits of their biology be treated the same within the Act.
Currently, it is hard to see the stipulation that the reason for infertility not be age (section 23 (d)) is anything other than a sexist one as age only effects female reproduction in this way. If the aim is to prevent older people having children in the interests of the child (a very debatable point) making an aggregate upper limit of both partners would be fairer i.e. the age of both parents added together should be less than, for example 80. This would enable a 52-year-old menopausal woman be treated with donor oocytes and have a child with her 28 year old partner where this would currently not be allowed. It would also stop 64-year-old men having children with 30 year old wives, which is currently not proscribed.
Another issue that I think needs to be addressed is the use of gametes in female same sex relationships. In many of these relationships, one partner rather than both intend to be birth mothers yet there is no simple means by which one partner can provide eggs for the other to carry. If they "donate" them they are not legally the parent and the non-carrying woman would have to demonstrate she is medically incapable to do so and that would, for many, necessitate a psychiatric opinion to that effect. Is that what we really want in 2018?
- 11) Current licensing requirement, fees, data reporting etc.
ART units currently require annual RTAC and NATA accreditation, and an annual and ever increasing ANZARD data submission. Any further impost on clinics would appear hard to justify and place unfair burden on the clinics. It is difficult to see why the clinics are charged any license fee at all. What do we get for the fee paid? It seems very little at all, while cost of data collection and submission alone adds as hidden further licensing fee for data we do not even retain the right of access to. It seems a very lopsided arrangement.

That said I believe giving the RTC the right to inspect clinics if a matter covered under the Act has been reported to them. They should be entitled to patient specific data without breaching the patient confidentiality Act.

12) Management of information.

Data collected by clinics and collated by the RTC should be the property of the IVF Clinics and the use of this data for research and to aid Government in the planning of services should be at the discretion of both the RTC and the IVF Clinics.

That data should include the Donor Register and Voluntary Register and access to these registers by donor conceived offspring should be consistent nationally so WA should change to 18 like other States or other states should conform to WA standards.

13) The need for the continuation of the functions conferred on the Council and the CEO by the HRT Act.

The need will remain as long as we continue to have a HRT Act. I think Australians should have a level playing field and all should have the same access to the same services independent of their state so would prefer to see a national HRT Act with a local RTC reporting to either the Federal Health Minister or a central body incorporating RTAC and NATA.

14) The Surrogacy Act 2008.

With increasing understanding of the effect of epigenetics on the final human genome it is increasingly recognised that the effect of carrying a foetus to term indelibly alters the child born. This is a fact that I often discuss with women who need donor oocytes or embryos to conceive. To then turn around and pretend that the surrogate is a passive vessel makes little sense. Legally separating birth mothers from the children they have carried I think says something profound about how we view that relationship which I think makes me uneasy. That said, the genie is out of the proverbial bottle and I suspect it will not be possible to return it. If we have to have it I think there are areas to be considered. The current Surrogacy Act fails to give commissioning parents certainty in that the surrogate is regarded as the child's mother. Its heavy reliance on lawyers to draw up the agreements makes it too expensive for many people.

All Australians should have the same access and rights to surrogacy arrangements which should not be dictated by the state they live in.

The Act should simplify the process which should not need a 2nd mortgage to pay the legal fees. Ideally, no lawyers should need to be necessary.

Surrogacy should be distinct from ovum donation and surrogates should not be able to carry embryos created with their own eggs.

Commercial surrogacy is necessary. The US experience supports this. Only in that way can surrogates can be compensated appropriately for their time, effort, inconvenience and risk and commissioners get contractual certainty. This way the need for international commercial arrangements will be negated and their prohibition should be maintained and can be reasonably applied. Something that is currently not happening.

15) International trade in gametes and embryos.

The local supply of gametes does not and will not meet local demand. The shortfall if anything will worsen in years to come with the changes in the Marriage Act, the Sex Discrimination Acts and changing community views on same sex couples and their families. There are a number of reasons for this but chief among them are the requirement for the donations to be altruistic and

the five family limit. To make matters worse different states apply the NH&MRC ethical guidelines differently and so we find that we in Perth cannot import World Egg Bank Oocytes yet clinics in New South Wales can, even though we are supposed to be operating under the same national ethical guidelines. Patients quite rightly do not understand how that can be because it makes no good sense. The five family limit on the other hand is not an internationally accepted standard and seems to have been plucked out of thin air. A 10 family limit, not including any number of families a donor may have would be fairer and would likely significantly increase the number of available donor. Another issue is the fair remuneration of donors for their time an effort in donating. No one would agree that donors should be incur a financial penalty to donate yet current legislation about what constitutes an altruistic donation sets the standard so high that it's virtually impossible to conform to. A reasonable fixed remuneration for donors needs to be set which is not so high as it would be regarded as an inducement.

Finally, the HRT Act currently allows for the importation of embryos created from donor sperm that would be exempt under the Act, and similarly the sperm used to create them, on compassionate grounds. This has always been interpreted to mean in situations where a child has already resulted from the treatment. The RTC and the CEO have recently, arbitrarily broken this understanding and prevented a couple continuing treatment in WA with an embryo stored in the ACT when they already had a child from an embryo created with the ones stored. They made this decision with the certain knowledge that this this would cause significant emotional and financial hardship to the family. Furthermore, to add insult to injury the process took over 6 months before it was settled definitively. The lack of justice in this decision still rankles and I think therefore ability to make these decisions should be taken away from them. The Act should instead clearly state that the provisions and restrictions that apply to the importation of sperm donated overseas or embryos created with it, do not apply to the family concerned if a child has been created from that donor. The Act should never be used to victimize the very people it should be serving.

The current RTC seems to have forgotten the promotion of the welfare of participants in favour of the strict enforcement of the Act.



Signed, Dr Vincent Chapple
13th March 2018

