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Does the Human Assisted Reproductive Technology Act 2004 need a review?

Abstract

The use of assisted reproductive technologies (ART) in New Zealand is governed by the Human Assisted Reproductive Technology Act 2004 (the HART Act), which provides for all procedures currently undertaken by fertility clinics and other centres involved with ART. Although the Act has provided good coverage for the use of ART over the last 16 years, it did not have a revision clause. Here, we explore whether the HART Act should be reviewed, and outline the important considerations that need to be taken into account to ensure that the legislation is up to date with current issues and technologies.

Keywords HART Act, review, cryopreservation, surrogacy, research, new technologies

The Human Assisted Reproductive Technology Act 2004 (HART Act) has a long history prior to being passed into law. Initially introduced into Parliament as a private member's bill by Dianne Yates in 1996, it went through many iterations before being passed as a government bill in 2004. The original concept of the bill was based on the Human Fertilisation and Embryology Act passed in the United Kingdom in 1990, which itself had a long gestation and was based on the Warnock Committee report to the UK Parliament in 1984. The Human Fertilisation and Embryology Act was reviewed in 2008 and some significant revisions were made, as well as additional supplementary legislation passed, to provide for new technologies. By the time the final version of the HART Act was passed into law, assisted reproductive technologies (ART) were established in New Zealand and the first baby conceived by in vitro fertilisation (IVF) in New Zealand was 20 years old. At the time it was passed the HART Act was certainly fit for purpose, having had the benefit of the UK legislation plus the experiences in the UK under that legislation. This experience was not referred to very often in the HART bill debates, but did influence the drafting of the bill (Legge, Fitzgerald and Frank, 2007; McLauchlan, MacCormick and Park, 2010).

While the HART Act has provided adequate legislative cover in New Zealand, there have been small changes, such as the revision of cryopreservation of gamete and embryo storage time (Human Assisted Reproductive Technology (Storage) Amendment Act 2010). In addition, many of the regulations have undergone subtle changes or revision by the Advisory Committee on Assisted Reproductive

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Technology (ACART), the advisory committee established under the legislation. Given that, with all modern medical technologies, there are changes in procedures and technologies, as well as in public perception of the use of technologies, the question that must be asked is whether it is time to review the HART Act, especially as there was no review requirement built in. While the everyday business end of the HART Act is to provide a safe regulatory environment for fertility clinics, ART, patients and children born as a result of IVF, how fit for purpose is the Act 16 years on, in the rapidly changing clinical and scientific world? There are many aspects of ART that have changed and were not considered in the lead up to the passing of the Act in 2004, due to either scientific and technology changes or changing societal outcomes and expectations.

While several considerations presented here could possibly be addressed by modifications to the relevant sections of the HART Act, two issues arise from a piecemeal approach. The first relates to issues of consequential impacts of changes in various parts of the HART Act, as well as, potentially, other Acts of Parliament. Second, as the Act is 16 years old, and while Parliament at the time may have been 'farsighted', a review of the Act, as has happened in the UK with the Human Fertilisation and Embryology Act, should be considered as good legislative practice. Here, we consider some of the aspects that should be considered in a review of the HART Act.

Rethinking aspects of the Hart Act

Cryopreservation of gametes, embryos and reproductive tissues

Currently, these procedures are subject to a ten-year time limit (HART Act, s10), with extensions over that limit being subject to approval by the Ethics Committee for Assisted Reproductive Technologies (ECART). Given that there have been no reports in either the international clinical or scientific literature of any unfavourable outcomes for children born from cryopreserved human gametes and embryos in over 30 years of cryopreservation, is it necessary to legislate a time frame for gamete and embryo storage, and to require ethical approval for any extensions? Should this section be removed from the HART Act for routine ART, and the matter left for a decision between the patient(s) and the fertility clinic?

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Associated with cryopreservation is the removal and storage of gametes or reproductive tissue from children. Under the current legislation it is an offence to remove gametes from a person under the age of 16 years, or to use those gametes (s12). This lacks clarity in relation to treatment for cancer or other potentially life-threatening diseases where treatment may affect the ability to conceive children later in life. Gametes from under-16-year-olds could be cryopreserved prior to any treatment for future use. A secondary consideration would be the issues relating to the storage and potential posthumous use of the gametes in the event of death. ACART currently has this issue under review as part of its wider work programme, but the public consultation process cannot lead to a law change.

Surrogacy

Surrogacy was still controversial in 2004, and although the HART Act allows surrogacy, payment (or 'valuable consideration' as it is framed in the Act (s13)) is illegal. This has led to significant confusion over whether payment of 'reasonable expenses' constitutes commercial surrogacy, and whether the surrogate should be 'compensated' for the pregnancy expenses and the inherent risks associated with the pregnancy. Section 14 of the HART Act allows payment to the 'provider' of the reproductive services (i.e. the clinic), and for legal advice to the woman intending to be the surrogate, but not to the surrogate during the pregnancy. Surrogacy is often the only option for couples wishing to have a child using their own gametes, and the confusion surrounding payments to the surrogate risks such couples opting for a private arrangement with a prospective surrogate, with no safeguards for either the surrogate, the intending parents or the future child. Clarity about the role of 'valuable consideration' is required.

In addition, the current law requires the surrogate to retain the child for ten days before handing the child over to the intending parents for adoption, as the surrogate is recognised as the child's birth mother. Should there be a process to transfer parentage of the child to the intending parents during the surrogate's pregnancy? An opportunity should be taken to review this aspect of the law (see further discussion below).

Mitochondrial transfer

The approval by the UK Parliament of mitochondrial transfer in oocytes and zygotes to prevent inherited mitochondrial disorders merits consideration in any review. As mitochondria are present in all cells, this does constitute a modification (albeit small: less than 1% of total DNA) of all cells, including those of the germ cell lines, and thus may currently be illegal under the HART Act. When considering the potential use of mitochondrial transfer it will be necessary to define 'nuclear DNA' as distinct from mitochondrial DNA. Additionally, should the transfer of mitochondria to oocytes unaffected by mitochondrial disorders, which may improve their success in a pregnancy, be allowed, a technique generally known as mitochondrial transfer therapy? This technique has been used overseas.

Research using human embryos

The HART Act is permissive as regards the use of human embryos in research (ss16, 19). However, no minister of health since 2004 has given permission for ACART to issue guidelines for research using 'viable'

human embryos (Goodman et al., 2018). The guidelines currently being used by both ACART and ECART were issued in 2005 by the now defunct National Ethics Committee on Assisted Human Reproduction. However, the terms 'viable' and 'non-viable' embryos used in these guidelines cannot be found in their stated reference source, the guidelines produced by Australia's National Health and Medical Research Council (NHMRC) in 2004, or in any subsequent NHMRC documents. The Australian documents consistently, from 2004 onwards, used the term 'excess ART embryo(s)' (NHMRC, 2017). Until appropriate guidelines are issued by ACART, no research using viable human embryos is permissible.

While it is possible to conduct research using non-viable embryos, internationally the definition of 'non-viable' has been subject to considerable discussion (Choudhary et al., 2004; Poulin et al., 2014; Rosenwaks, 2017; Borman et al., 2020). The restriction of research using viable human embryos has limited New Zealand's contribution to international research to improve ART and to better understand embryo development in vitro and assessment of embryo viability. The inability to use viable embryos has also limited New Zealand scientists' ability to create human embryonic stem cells to improve understanding of developmental genes and the potential for regenerative medicine.

Research also raises the question as to whether gametes and embryos no longer required for treatment could be 'banked' for research following appropriate consent. International evidence indicates that embryo donation for research is the preferred option rather than disposal, and is considered as facilitating further knowledge in treating infertility (Samorinha et al., 2016). The law requires greater clarity in relation to the term 'human reproductive research', and this should be linked to appropriate regulations governing this part of the legislation. Here it is worth noting that an ACART report to the minister of health in 2007, following public consultation on embryo research, provided evidence of strong public support for human embryo research; however, no action was taken by the then minister or subsequent ministers on any of the recommendations made by ACART (ACART, 2007). The term 'hybrid embryos' in the HART Act (ss5, 9) is no longer appropriate and these should be more correctly indicated as 'admixed embryos', with a more detailed interpretation of the term. This would be consistent with international trends.

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Embryo culture beyond 14 days

The current legislation restricts the culture of human embryos beyond 14 days of development (s9(4)). While this was a recommendation of the UK Warnock Committee prior to the implementation of the Human Fertilisation and Embryology Act, the committee also considered up to 28 days; however, 14 days was embedded into the UK legislation as a compromise (Williams and Johnson, 2020), and subsequently the 14 days was incorporated into the New Zealand legislation. Notwithstanding the moral and ethical debates relating to culture, embryo culture up to 12–13 days of development has been achieved (Deglincerti et al., 2016; Shahbazi et al., 2016), primarily due to significant advances in embryo culture technologies. Embryo culture beyond 14 days is likely to provide valuable information in areas such as the cellular mechanisms for twinning, early pregnancy loss, birth defects, understanding the function of developmental genes and gene switching in the development of cancer. It could not be used for ectogenesis. While extended embryo culture technology is still technically difficult, culture technologies move at a very rapid pace; therefore, consideration should be provided for it in any revised legislation.

Furthermore, progress in the development of endometrial organoid cultures may provide significant opportunities for extended embryo culture to resolve issues relating to early implantation and other unresolved issues in early development (Bui et al., 2020). If embryo culture was extended, defined markers would be required for the embryo staging as with the current 14-day rule, i.e. the appearance of the primitive streak (HART Act, s9). Again, it is the authors' opinion that any change to embryo culture conditions cannot be considered piecemeal and must be considered in the global context of rapidly changing technologies and legislation review.

Emerging technologies

Gene editing

Gene editing has moved centre stage with the prospect of correcting genetic defects in pre-implantation embryos. While there is current uncertainty relating to the success of this technology for human embryos, there should be room in the legislation to accommodate the development and possible control of advanced technologies such as gene editing.

Whole genome sequencing

Whole genome sequencing is rapidly becoming accessible as a technology, and as the cost of undertaking the technique progressively declines, this technology is beginning to be used for human embryos (Wells et al., 2014; Weizman et al., 2019). There may well be a need to consider what, if any, limitations should be placed on the use of this technology for social rather than diagnostic purposes.

Trait prediction

Trait prediction from whole genome DNA sequencing data is rapidly becoming possible (Kayser, 2015; Lippert et al., 2017),

with current predictive models testing for facial structure, voice, eye and skin colour, height and weight, but not yet in use for embryo DNA (although some American gene analysis companies are beginning to promote this type of analysis). With the decreasing cost of whole genome sequencing, it may become possible for early embryo biopsies to be used to predict (or select) embryos on the basis of phenotype-based genomic selection. This is not covered in the current legislation, where only 'social' sex determination of embryos is not permitted (s11).

Redefining gametes and embryos

While gamete and embryo are correctly defined in the HART Act (s5), gametes and embryos may now be created by other means, such as stem cell modification using induced pluripotent stem cells, and this would require a separate section in any revised legislation. In addition, gametes should now include immature gametogenetic cells, such as primary oocytes and spermatocytes, which have the potential to be matured into eggs and sperm.

Organoids

Organoids are small, self-organised three-dimensional tissues grown in culture that are derived from stem cells and can be programmed to replicate the function of a body organ or certain cell types. In the not too distant future the development of human tissue organoids will almost certainly have a role in clinical medicine – for example, pancreatic organoids for diabetes treatment – as well as in research investigating tissue formation, development of cancers and drug testing. While the current technology for using organoids is centred on the use of induced pluripotent stem (iPS) cells, there are distinct advantages in using embryonic stem cells with their early gene activation and induction. However, should organoids from either stem cell source develop into embryos or embryo-like features, should they be regarded as embryos, and how would they be regarded under the current legislation, as they will not be formed from gametes? Similarly, the development of testicular and ovarian organoids could result in sperm and eggs being created from non-reproductive tissues and may result in their use in infertility treatment, possibly as a source of hormones. A second question would be whether they can be programmed to produce functional gametes and the subsequent outcome of any children from this manipulation.

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Other likely impacts of a review of the HART Act

While there are a number of clinical, scientific and technical issues for consideration in a review of the HART Act, there are also social and procedural aspects that should be considered.

Adoption Act 1955 and Status of Children Act 1969 (amended 1987, 2004)

These are outdated and not 'in step' with society in the context of defining 'parents'. Surrogacy, for example, did not form part of the 1950s reproductive culture. There need to be credible linkages with modern reproductive procedures and the significant changes in society, and revision of the Adoption Act 1955, particularly in relation to a distinction between payment for adoption and for surrogacy (s25), should be considered. The Status of Children Act 1969 initially identified the gamete donor as the legal parent, forming a genetic link to parenthood (s17). However, the 1987 amendment changed this to a social link instead of a genetic link, which at the time, with the uncertainty of the response to surrogacy, was considered a safer option (Van Zyl and Walker, 2015). Therefore both Acts require review whereby the intending parents become the legal parents at birth and requirement for adoption is removed. Similarly, the definition of 'family member' is very broad and requires ECART approval for gamete and embryo donations for individuals who are remotely related, for example through marriage.

Welfare of women

Although one of the principles of the HART Act is, 'the health and well-being of women must be protected in the use of these procedures' (s4c), the statement is broad and lacks clarity, especially for egg donors, women undertaking a surrogate pregnancy, and any potential issues arising from uterine transplants.

Defining 'procedures'

There is uncertainty relating to 'established procedures' and 'assisted reproductive procedures', which leads to degrees of confusion in assessing ACART guidelines for ECART to use when considering applications by the public for ART procedures outside the procedural guidelines. The creation of new 'established procedures' is a long and often convoluted process, with final ministerial approval of a recommendation sometimes taking years. This process needs to be streamlined to ensure that up-to-date procedures and technologies are delivered for patient care in a timely manner. In addition, under the current legislation there is no 'ownership' or 'right' of donors to donated gametes and embryos. This creates uncertainty for both the clinics and the recipients.

Conclusion

The HART Act 2004 has proved to be effective legislation, providing a 'fit for purpose' law for assisted reproductive technologies in New Zealand which was relevant at the time. However, since 2004 there have been significant scientific developments, as well as changes in society's perception and understanding of ART. The use of ART is not only providing fertility treatment for heterosexual couples, but also provides the opportunity for same sex couples to achieve parenthood. Within this broad use of ART there have been significant changes in both the technologies and alternative options for achieving a pregnancy – for example,

surrogacy. Cryopreservation in particular has made significant advances in both safety and successful pregnancies since 2004, and the question now is whether it should be included in any legislation, given the absence of any complications internationally relating to its use. Research promotes new developments and improvement of existing ART technologies, and it is time that New Zealand scientists had the opportunity to contribute to this rapidly developing area by using donated excess embryos for IVF procedures.

Similarly, there should be discussion of the 14-day rule. It seems incongruous that both the use of pre-implantation embryos for research and in vitro embryo culture times are thus limited when the Abortion Act 2020 permits the termination of an in vivo foetus up to 20 weeks' gestation. The HART Act does not accommodate any of the new or rapidly developing technologies which could be used in the ART arena, some of which have significant social as well as scientific implications – for example, whole genome sequencing, gene editing and trait prediction.

Along with the significant scientific considerations, there are issues with existing parallel legislation, such as the Adoption Act 1955 and the Status of Children Act 1969, which need to be reconsidered to be made consistent with societal changes in the acceptance and use of ART. Similarly, there are many procedural matters relating to ACART and ECART that may make the decision-making processes more efficient and effective.

In summary, it is recognised that some of the changes proposed here will have moral and ethical issues associated with them that are beyond the scope of this article. However, we consider that it is essential that the current ART legislation is reviewed, and that the debate on social change and new or rapidly changing technologies forms a core of this review.

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