ASSISTED REPRODUCTIVE TECHNOLOGY ACT 2007

STATUTORY REVIEW

DISCUSSION PAPER

Contents

1 Introduction

1.1 Outline of the Act

The Assisted Reproductive Technology Act 2007 (the Act) was passed by the NSW Parliament in November 2007 and commenced in 2010. The ART Act regulates many of the ethical and social issues aspects of assisted reproductive technology, with the objects of the ART Act being[1]:

(a) to prevent the commercialisation of human reproduction, and

(b) to protect the interests of the following persons:

(i) a person born as a result of ART treatment,

(ii) a person providing a gamete for use in ART treatment or for research in connection with ART treatment,

(iii) a woman undergoing ART treatment.

The Act aims to achieve these objectives by requiring ART providers to be registered with the NSW Ministry of Health and by setting certain core standards for the provisions of ART treatment.

For example, the terms of the Act:

- make it clear that gametes can only be used in a manner consistent with a gamete providers consent, so individuals retain control over the use of their own genetic material;
- essentially prohibits anonymous donation of gametes;
- requires ART providers to place information about donors on a central register which children born as a result of ART treatment can access once they turn 18; and
- establishes the register to operate prospectively, from the commencement of the Act in January 2010, and providing a voluntary register for offspring born prior to the starting point of the Register

1.2 The Review

Section 74 of the ART Act requires a review of the ART Act to take place to determine whether the policy objectives of the ART Act remain valid and whether the provisions of the ART Act remain appropriate for securing those objectives.

[1] Section 3 of the Assisted Reproductive Technology Act 2007

As part of the review, the Ministry of Health has prepared this Paper to canvass issues associated with the Act. This includes matters that have arisen through the operation of the Act over the last few years as well as matters canvassed at recent and current Parliamentary Inquiries[2].

Many of the issues raised by the Discussion Paper are socially and ethically complex with key stakeholders and members of the community likely to have highly divergent views. The object and focus of the Review in seeking comment and submissions on these issues to try and find a position that best balances and protects the interests of all parties involved in ART procedures. The Ministry would also welcome submissions on any other issue relevant to the Act which are note specifically highlighted in this Paper.

Once submissions have been received a report on the issues raised will be prepared and tabled in the NSW Parliament, in accordance with the terms of section 74 of the Act.

1.3 Submissions

Comment is invited on the Review of the ART Act. There is no special form for submissions. Submissions should be in writing and directed to:

> Legal & Regulatory Services – Legal Branch
> NSW Ministry of Health
> Locked Bag No. 961
> North Sydney NSW 2059
> Fax: 9391 9604
> Email: legal@doh.health.nsw.gov.au

This Paper can be found at http://www.health.nsw.gov.au/aboutus/legal/actsreview.asp. The closing date for comment is **16 August 2013**. Inquiries can be made to Legal Branch on (02) 9391 9606.

Individuals and organisations should be aware that generally submissions made to a Review can be made available under the *Government Information (Public Access) Act 2009*. The Ministry of Health, in formulating its Report may also wish to circulate submissions for further comment to other interested parties or to publish parts of submissions. If you wish your submission (or any part of it) to remain confidential, this should be stated clearly and marked.

[2] The NSW Legislative Assembly Law and Safety Committee has initiated 2 inquiries. First, the 2011 *Inquiry into the Inclusion of donor details on the register of births*; second, the 2012 *Inquiry concerning Managing information related to donor conception* (yet to report at the time of writing this Paper)

2 An Overview of the Assisted Reproductive Technology Act 2007

2.1 History

The ART Act was introduced into the NSW Parliament in 2007. It followed a lengthy consultation process that commenced in 1997 with the release of a Discussion Paper, the "*Review of the Human Tissue Act 1983 - Assisted Reproductive Technologies*", which was followed by the release of an Exposure Draft Bill in 2003.

Submissions on the Exposure Draft Bill then guided the development of the ART Act which was also guided by three important principles:

1) *recognising the obligations already imposed on assisted reproductive technology providers by the existing laws;*
2) *a recognition of the rights of individuals to have control over the use of their genetic material; and*
3) *a recognition that the legislation should be guided by the best interests of the child.*

These factors influenced not only the objects, but also the substantive provisions of the Act, details of which are set out below.

2.2 Key Features of the ART Act

2.2.1 Central ART Donor Register

A core objective of the Act is to give people born as a result of donor conception access identifying information about their genetic parentage. The Act also aims at giving donors and parents access to a range of more limited and generally de-identified information.

To that end, the ART Act establishes a Central Register[3] to hold this information. The information on the register is sourced directly from ART providers, who are required to collect certain information specified in the ART Act and Assisted Reproductive Regulation 2009 (Regulation) on participants in ART treatment and provide it to the Register following a birth using donated gametes. The information is then placed on the Register and adult offspring, donors and parents have rights to access to certain information on the Register.

The ART Act and the Regulation sets out the information providers are required to collect and provide to the Register. The legislation also specifies the information children, donors and parents are entitled to access.

[3] Section 32A of the *Assisted Reproductive Technologies Act 2007*.

The Central Register does not operate retrospectively and only holds information relevant to children conceived after 1 January 2010.[4] However, recognising that many adult donor offspring seek information about their donor and genetic background, the Act also establishes a voluntary register where both donors and persons born through ART treatment can voluntarily place information, with access via consent.

The Register is administered by the Ministry of Health.

(i) Accessing information on the Central Register by Children

On reaching the age of 18, a child born of donor gametes is entitled to access the following information[5]:

- certain identifying information about the donor (including name, date of birth);
- certain non-identifying information of the donor (such as ethnicity and physical characteristics, some medical information);
- non-identifying information regarding other offspring of that donor (being the sex and year of birth of each other offspring of the donor); and
- identifying information about other offspring of that donor, but only where those offspring have given consent to the disclosure.

A person born from donor gametes can also place on the register the terms of any consent they have given to enable their own information to be disclosed to their donor or their donor siblings.

(ii) Accessing information on the Central Register by Parents or Guardians

Parents or guardians of children conceived using donor gametes or embryos are entitled to ascertain:

- non-identifying information of the donor (such as ethnicity and physical characteristics, medical information);
- non-identifying information regarding other offspring of the donor (being the sex and year of birth of each other offspring of the donor).

A parent or guardian of the child may also make an application to obtain the identity of the donor of a child prior to the child turning 18 years old. This option is only available if the information is necessary to save the life of the child or prevent serious damage to the child's health and the information cannot reasonably be obtained in any other way[6].

[4] Some births that occur after 1 January 2010 may not be registered if these come under the transitional provisions of the *Assisted Reproductive Technologies Act 2007*.
[5] Section 37(2) of the Assisted Reproductive Technology Act 2007
[6] Section 38 of the Assisted Reproductive Technology Act 2007

(iii) Access of information on the Central Register by Donors

The donor of a gamete is entitled to ascertain the following information held on the Register:

- non-identifying information relating to a person born as a result of ART treatment using their donated gametes;
- other information about the person, where that that adult donor offspring has consented to the release of such information[7].

2.2.2 Regulation of ART Providers and use of gametes

The ART Act does not seek to create a full licensing system for ART providers as there is already significant regulation applying to ART providers at both State and Federal level. For example:

- The requirement for ART clinics using embryos to be licensed by the Reproductive Technology Accreditation Committee of the Fertility Society of Australia under the Commonwealth Research Involving Human Embryos Act 2002 and Prohibition Of Human Cloning For Reproduction Act 2002.

- Ethical guidelines, developed by the National Health and Medical Research Council, on the use of assisted reproductive technology in clinical practice and research.[8]

- The clinical competence and conduct of medical practitioners who undertake ART clinical services is regulated under the Health Practitioner Regulation National Law (NSW)

Given this, the Act requires ART providers to register with the Director-General of the Ministry of Health. A person who is not registered under the ART Act cannot provide ART services. The Act sets minimum standards more specifically relevant to ART type services, including infection control standards, the provision of counselling services and a requirement to disclose certain information to participants in ART treatment.

The ART Act also imposes limits on the use of gametes, including:

- that consent to the collection and use of gametes must be obtained from the gamete provider;
- gametes cannot be used in research except with the consent of the gamete provider;
- gametes cannot be used in ART treatment if the gamete provider is deceased unless the gamete provider had given his or her consent to the use of gametes after death;

[7] Section 39 of the Assisted Reproductive Technology Act 2007
[8] http://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/e78.pdf

- gametes can only be used and stored for 10 years after being obtained from a gamete provider (unless the Director-General otherwise allows);
- ART treatment using a donated gamete cannot be provided if the treatment is likely to result in offspring of the donor being born, whether or not as a result of ART treatment, to more than 5 women;
- prohibiting the use of a gamete to create an embryo if gamete provider is a close family member of the other person whose gamete will be used to create the embryo; and
- prohibiting ART treatment being provided to a child (ie a person under the age of 18)[9].

The Act also contains some very limited provisions relevant to surrogacy. These are confined to the information that should be collected and stored on the Register. Broader issues relating to surrogacy are dealt with by the Surrogacy Act 2010 and are therefore not covered by this Paper.

3 Areas for Review

3.1 Objectives

The Act's objectives, as outlined above at para 1.1 are:

(a) to prevent the commercialisation of human reproduction, and
(b) to protect the interests of the following persons:
  (i) a person born as a result of ART treatment,
  (ii) a person providing a gamete for use in ART treatment or for research in connection with ART treatment,
  (iii) a woman undergoing ART treatment.

These objectives appear comprehensive and, by focussing on protecting the interests of the various parties – people most affected by issues addressed in the Act – the Ministry's preliminary view is they remain relevant. However, the Ministry is keen to hear any submissions on whether the current objectives remain valid or indeed whether any additional objectives should be included in the Act.

[9] ART treatment can be provided to a child only if there is a reasonable risk the child might become infertile before becoming an adult and the ART provider obtains a gamete for the purpose of storing the gamete for the child's future benefit: s29 ART Act

Questions for Submissions – objectives of the Act

1. Are the objectives of the ART Act still valid?
2. Should any further objectives be included in the ART Act?

The rest of paper progresses on the basis that the objects and need for regulation remain valid, so focuses more on the effectiveness of the Act in achieving these objects.

3.2 Effectiveness of the Act in achieving objectives

Since the Act was passed and commenced operation a number of issues have arisen, suggesting the Act could more effectively meet its objectives in a number of areas.

This includes issues arising from correspondence from individuals and families affected by the Act and, more recently, a number of public inquiries including the NSW Legislative Assembly Committee on Law and Safety[10] inquiries into ART and access to information about genetic parentage and legislative reviews in Victoria[11] and the Commonwealth.[12]

In NSW, the NSW Legislative Assembly Committee on Law and Safety Inquiry into the *Inclusion of donor details on the register of births* reported in October 2012. The Report looked primarily at the question of whether donor's details should be included in some manner on a child's birth certificate.

However, during the course of that Inquiry, the Committee identified a number of other issues that it considered required further inquiry. As such, the Committee has commenced a second Inquiry regarding *Managing Information Related to Donor Conception*. The second Inquiry is considering issues such as whether the Register should operate retrospectively and be required to include (and enable access to) information about donors of children conceived before January 2010. Some of the issues that have been raised in these two inquiries are also considered further in this Discussion Paper.

[10] The Committee on Law and Safety recently completed its Inquiry into the *Inclusion of donor details on the register of births* in late 2012 and is currently conducting an Inquiry to *Managing Information Related to Donor Conception*. Information on these inquiries can be found at http://www.parliament.nsw.gov.au/lawandsafety?open&refnavid=CO3_1.

[11] The Victorian Parliament's Law Reform Committee's Report on the *Inquiry into Access by Donor-Conceived People to Information about Donors* was tabled March 2012. The report is available for download as a PDF file. 2.09 Mb; http://www.parliament.vic.gov.au/lawreform/article/1468.

[12] The Senate's Legal and Constitutional Committee completed its report into Donor conception in Australia in February 2011: http://www.aph.gov.au/Parliamentary_Business/Committees/Senate_Committees?url=legcon_ctte/completed_inquiries/2010-13/donor_conception/report/index.htm

4 Information and the Register

4.1 Information held on the Register

As outlined in Part 2.2, one of the main purposes of the ART Act is to ensure that offspring born through ART treatment using donated gametes have access to information on their genetic parents.

The Act currently achieves this through the Central Register.

The Act and Regulation requires the information set out below to be collected and placed on the Register. This information can then be provided to adults conceived from donor gametes[13]:

(a) the full name of the donor,

(b) the residential address of the donor,

(c) the date and place of birth of the donor,

(d) the ethnicity and physical characteristics of the donor,

(e) any medical history or genetic test results of the donor or the donor's family that are relevant to the future health of:
(i) a person undergoing ART treatment involving the use of the donated gamete, or
(ii) any offspring born as a result of that treatment, or
(iii) any descendent of any such offspring.

Adults conceived from donor gametes can also access identifying information about their "donor siblings", but only with consent of the other individual[14].

Parents of donor conceived children can access the following non-identifying information[15]:

(a) the ethnicity and physical characteristics of the donor,
(b) any medical history or genetic test results of the donor or the donor's family that are relevant to the future health of:
(i) a person undergoing ART treatment involving the use of the donated gamete, or
(ii) any offspring born as a result of that treatment, or
(iii) any descendent of any such offspring,
(c) the sex and year of birth of each other offspring of the donor

Donors can access only limited non-identifying information about children conceived using their gametes, with the Act limiting this to *"the sex and year of birth of each*

[13] Clauses 12 and 16 of the ART Regulation and s37 of the ART Act
[14] Section 37 of the ART Act
[15] Ibid

offspring born using a donated gamete of the donor"[16]. Donors can also access identifying information, but only with the consent of the offspring[17].

Adults born from donor gametes can also access the sex and year of birth of each other offspring of the donor[18], but again, any identifying information about "donor siblings" can only be provided where the sibling consents to access.

Issues for discussion

The range and type of information held on the Register was subject to consultation when the Draft Assisted Reproductive Technology Regulation was released for consultation in 2009. The Ministry is seeking comment as to whether this information remains relevant and appropriate, whether additional information should be prescribed (or indeed, a more limited range of information collected).

A second issue is whether the information to be collected should continue to be set out in the Regulation, or whether it should be moved to the Act itself. Currently, most of the information that ART providers are required to collect is set out in the Regulation.

On the one hand, inclusion of the information in the ART Regulation allows for a greater degree of flexibility in that Regulations are more readily and more quickly able to be amended than legislation, enabling a ready and quick response if change is needed. Regulations however are also subject to staged review and repeal and must be re-made generally every 5 years. This means that there is a lesser degree of certainty, as years go by, as to what information may, consequentially, be available to offspring, donors and parents as the Regulation changes from year to year. There are also arguments that given the very personal nature of the information and need to access the information, it would be better to have the key elements set out in the Act itself.

The Ministry's preliminary view is that there are strong grounds to consider moving the list of information to be held on the Central Register to the Act. Such a move would give a greater degree of on-going certainty about what information on donors will be collected and stored. Views on this proposal are therefore sought.

Questions for Submissions – Content of Register

3. Is the current information required to be collected on donors and held on the Register appropriate?
4. Should the provisions in the ART Regulation setting out the information that is collected and held on the Register be moved to the Act?

[16] Clause 16 of the ART Regulation
[17] Section 39 of the ART Act
[18] Ibid

4.2 Private arrangements- sourcing information outside ART providers

The Register only holds information about offspring conceived via ART treatment using donated gametes and provided by an ART provider. It does not collect or hold information about donor conception arising from private arrangements, not reliant on ART procedures.

The 2012 NSW Parliamentary Inquiry recommended that donors and women who use their gametes involved in private arrangements (i.e. those entered into privately outside ART processes in Fertility Clinics) should be able to add their information to the Register on a voluntary basis. [19]

While many women in private arrangements use donors known to them, this recommendation was based on the idea that is would be beneficial to include information about such private arrangements so that if parents and donors in private arrangements lose contact, offspring would still be able to find out basic information about their genetic parentage, as recorded on the Register.

This would clearly provide a benefit to people born through these private arrangements, with a potential extra source of information if they are seeking information on their genetic heritage. At the same time however, it raises a number of policy and practical issues, including how to ensure the accuracy of the information in these circumstances.

The Act currently relies exclusively on information collected from ART providers, with sanctions for non-compliance. The reliance on ART providers helps ensure that contained on the Register is accurate. The inclusion of private information would have no similar objective point of reference, raising potential issues as to the accuracy and reliability of data. One method to address this might be to require all parties to the arrangement to agree to provision of the information and to sign a statutory declaration as to its accuracy. Giving false information in a statutory declaration attracts penalties.

A further matter arising is the potential public health implications which may be associated with private arrangements.

An important objective of the ART Act is to protect the interests of women undergoing ART treatment. One of the ways this protection occurs is by setting minimum infection control standards with which ART providers must comply. Appropriate infection control standards help ensure that donors are appropriately screened for sexually transmitted infections (STIs) and that women are not infected with a STI from the donated material. Infection control standards not only help

[19] *Inclusion of donor details on the register of births: Final Report*, Legislative Assembly, Committee on Law and Safety, recommendation 6

protect the individual woman but the greater public by minimising the spread of STIs within the community.

While it is clear that nothing in the current Act can or will prevent individuals, couples or families entering into private arrangements, there is a concern that expanding the Register to cover them, without (potentially) also expanding the regulatory requirements on these types of issues sends a poor public health message to the community.

Private arrangements necessarily will not be subject to such stringent protections. The Ministry holds public health concerns in extending the Register to private arrangements which offer no protection towards women and may present public health implications for the community. Accordingly, the Ministry would like to hear submissions regarding whether information from private arrangements should be able to be included on the Register.

Questions for Submissions – Expand Register to include private arrangements

5. Should the ART Act be amended to allow information about private arrangements to be held by the Register?

4.3 Retrospectivity – mandating information prior to 2010

The ART Act and Regulation only applies to ART treatment that is provided after 1 January 2010 and does not apply retrospectively. This means mandatory access to information on the Register only applies to offspring conceived after 1 January 2010[20]. However, as outlined earlier in the paper, the Act allows pre 2010 donors and donor conceived offspring to include information on the Register and consent to its disclosure to other parties.

The voluntary Register has received registrations from 14 donors and 11 donor offspring from the commencement of the ART Act in 2010 to 2013, which would not seem to reflect a high uptake from either donors or donor conceived offspring. By way of contrast Victoria has regulated ART treatment since 1988 at the commencement of the Infertility Treatment Act (Vic) 1984, with a voluntary register operated in Victoria since March 2001. Victorian legislation provides for 2 voluntary registers, one for births resulting from donor treatment procedures before July 1988, and the other for similar births since July 1988.

[20] It also does not apply to a small group of children born after 1 January 2010, who fall within the "transitional provisions". The issue of the transitional arrangements is looked at in para 4.4 of the Paper

The equivalent voluntary registers in Victoria administered by the then Infertility Treatment Authority reported that in its first three years of operation to 31 December 2003 received voluntary registrations by 48 donorss and 9 offspring (Infertility Treatment Authority Annual Report 2004:13). The higher number of donors voluntarily registered by December 2003 in Victoria may be attributed to the publicity associated with the prior 13 year regulation of ART treatment in that State.

Over the last three years the NSW Ministry of Health distributed pamphlets though InfoMed to NSW GPs and ART providers publicizing the voluntary register. The Ministry developed an accessible and informative website for ART interested people in 2011.

The fact that the Act does not mandate collection of and access to information prior to January 2010 was, and remains, controversial among some sections of the community, particularly donor conceived offspring.

There are strong arguments put on behalf of the right for adults born as a result of ART procedures to access information about their donors, and their genetic parentage. Knowledge about genetic parentage is important not just in respect of self-identity but also so people conceived from donor gametes can access their medical history.

The contrary argument is that donors who donated in the past did so under strong assurances and promises of anonymity, confidentiality and privacy and that it would, consequentially, be unfair for the Government to retrospectively override donors' rights and expectations. It has also been argued that retrospectively taking away a donor's right to privacy and anonymity may potentially impact the donor's family, if they were previously unaware that the donor donated gametes which led to the birth of children.

These competing views appear difficult to reconcile. One option, if the information was included in the Register, might be to consider access to de-identified medical information separately from identifiable details, or to consider separate procedures, along similar lines to that of adoption information, to be followed before access to identifying information is granted, such as contact vetos.

The NSW's Legislative Assembly's Committee of Law and Safety is currently conducting an inquiry into the question of retrospectively. The inquiry, *Managing information related to donor conception*, has released a Discussion Paper which canvass more fully the issues arising[21]. Given this, the Government will consider the issue of retrospectivity more fully following the completion of the Committee's Inquiry but the Ministry is still keen to receive any comments or submissions on the issue as part of this review.

[21] A copy of the Inquiry's Discussion Paper can be accessed at http://www.parliament.nsw.gov.au/Prod/parlment/committee.nsf/0/EE71C90F0F8B8713CA257ABC001A28AA?open&refnavid=CO3_1

4.4 Transitional Arrangements and "anonymous" donors

One impact of the introduction of the Central Register was that it effectively prevents the use of "anonymous" donors in ART procedures after January 2010, as it requires providers to collect identifying and non-identifying details about the donors.

When transiting to the new Act, it was recognised this prohibition would significantly affect women and families who had already started their family with an unknown donor, unless transitional arrangements were made to support them completing their family. For example, if a woman had embryos created prior to 1 January 2010 in storage, the prohibition on the use of gametes from anonymous donors may have prevented the woman from using these embryos unless she was able to obtain the donor's consent to include his or her information on the Register. In many cases, obtaining consent from a previous donor would be impracticable if not impossible, particularly if the donor was no longer contactable.

To allow women in this situation to complete their families, transitional provisions were included in the ART Regulation. These transitional provisions provide that ART providers are not required to collect or provide information on a donor if the donated gamete was obtained from a donor before 1 January 2010 and:

(a) an embryo was created using the donated gamete before 1 January 2010 and the embryo is used to provide ART treatment to a woman prior to 1 January 2015, or
(b) the gamete is used to provide ART treatment to a woman before 1 January 2015 and the woman has, before 1 January 2010, already conceived an offspring as a result of ART treatment using a donated gamete from the donor[22].

The transitional provisions aimed to ensure women falling within the transitional arrangements had 5 years to complete their families using anonymous gametes from the same donor or embryos created using an anonymous donor without the donor's details being included on the Register.[23]

Experience with the operation of the Act to date suggests that the time frame limit set by the Act may not be appropriate. Having accepted that women who commenced ART treatment prior to 1 January 2010 should be given a chance to complete their families using the same gametes or embryos created using the same gametes, a question arises as to whether the ART Regulation should create an additional, artificial time frame in which to allow women to do so. In this regard, the Act does not set any legislative timeframe for women starting treatment after 2010 to complete their families. ART treatment is already self limiting in that there is period of time in

[22] Clauses 12 and 13 of the ART Regulation
[23] Originally, the time provided to women who had already conceived a child using the donated gametes before 1 January 2010 was 3 years, but this was extended to 5 in the Assisted Reproductive Technology Amendment (Transitional Provisions Relating to Donated Gametes) Regulation 2012

which treatment can be given and in which a women will continue to try and conceive using ART treatment.

It is questionable what purpose a 5 year limit, as opposed to a longer or no time limit, achieves anything other than forcing women to complete their families within a time period set by the Regulation rather than a time frame which is medically appropriate and of their own choosing.

The Ministry's preliminary view is that the current transitional period of 5 years should be amended so the ART Regulation imposes no limit on how long women, who fall within the transitional provisions have to complete their families, using the same anonymous donor's gametes or embryos created with anonymous donor's gametes.

The Ministry is keen to hear submissions on this issue.

Questions for Submissions – Removing timeframe on transitional arrangements

6. Is the 5 year limit on the transitional arrangements appropriate?
7. If not, what time limit, if any, should be set for women falling within the transitional arrangements?

5 Storage and use of donated gametes

5.1 Section 27 and the "5 women limit"

Section 27 of the Act effectively prevents[24] an ART provider from using donated gametes if it is likely that this would result in offspring of a single donor being born to more than 5 different women[25]. The terms of the section require the number of women to include the donor (if a woman), and any current or former spouse, and makes no distinctions between children conceived naturally or through ART. This is known as the "5 women limit".

The 5 women limit was included in the Act as part of a balancing exercise in relation to the use of gametes from a single donor. Imposing a limit of allowing five different women to use gametes of one donor was considered sufficient to enable a woman to have and complete a family. At the same time, an upper limit of five was also seen as a means of reducing the risk of multiple or unlimited use of a single donor, with the consequent risk of offspring unknowingly entering into a relationship with a close genetic relative when they become an adult.

[24] Section 27 and the 5 women limit does not apply to women falling with the transitional provisions.
[25] The donor can also impose a limit of less than 5 when donating, but cannot consent to a higher number.

Since the commencement of the ART Act, however, it has become apparent that the limit has also had unintended consequences.

This initially arose in relation to same sex female couples where both members of the couple wish to carry a child using gametes from the same donor, to complete their family. If one woman has already conceived a child, there is no statutory limit on how many more children she can conceive using gametes from the same donor. However, if her partner wishes to also use gametes from the same donor, then this can only occur if the 5 women limit has not been reached.

There is also potential for the limits to cause issues in other situations. For example, if an infertile man had used donated sperm with his first wife but latter sought to use donated sperm from the same donor with a second wife, then if the 5 women limit had been reached, the man and his second wife would be prevented from using the same donor's sperm. Similar difficulties may also arise if a couple sought to use two different surrogates to carry a foetus created using the same donor's gametes if the 5 women limit had been reached.

There are questions as to whether, in these family situations, the 5 women limit necessarily meets its objective. As noted above, this was to limit the number of children born to different women with the same donor so as to prevent offspring unknowingly entering into a consanguineous relationship with a blood relative in the future. However the risk of the children brought up in the same family, entering into an unknown consanguineous relationship is eliminated as the children are brought up together as siblings.

One option suggested is to replace the "5 women limit" with a "5 family limit" as it will be the familial relationships, or lack thereof, that will influence the risk of unknown consanguineous relationships.

However, this approach, in turn, raises its own issues, due to the difficulties in defining the meaning of a family. In particular, if a couple has a child using donor gametes, but the relationship later breaks down, if partners re-couple and one partner (or both) want to continue using the same donated gametes, are there now two families to count towards the 5 family limit? If so, what happens if the 5 family limit has been reached with respect to the donor: would or should either or both parties to the initial relationship be prevented from using the same donor gametes?

Further, a family based limit is likely to be more difficult to regulate at the operational level. The purpose of a limit, to prevent a large number of donor conceived children from one donor, is dependent on being able to accurately track when the limit is reached. Accurately identifying and "tracking" the number of families is more difficult than identifying and recording individual women who attend ART providers and have conceived a child using donated gametes.

In looking to the regulatory systems in other jurisdictions for guidance, while a limit on the number of women or families that can use the same donor's gametes is common across Australia, there is no consistency in how the limit is applied or defined. Victoria's Assisted Reproductive Treatment Act 2008 limits donated gametes being used by more than 10 women[26]. Western Australia has a 5 family limit.[27]

The National Health and Medical Research Council's *Ethical guidelines on the use of assisted reproductive technology in clinical practice and research* on the other hand does not place a specific limit on the number of either families or women but rather requires ART providers to limit the number of families who use a single donor with the number of families determined by a range of factors, including:

- the number of genetic relatives that the persons conceived using the donation will have;
- the risk of a person conceived with donor gametes inadvertently having a sexual relationship with a close genetic relative (with particular reference to the population and ethnic group in which the donation will be used);
- the consent of the donor for the number of families to be created. [28].

The consensus supports retention of a limit on the number children born from a single donor. However the experience in NSW to date suggests that the current 5 women limit may require reform. As concerns arise in adequately defining and applying a "family" based limit, the better option may be to simply increase to current limit to 10, in line with the Victorian approach. Although an increase to a 10 women limit will not automatically remove all difficulties associated with a limit based on the number of women, it may ameliorate some of the effects by increasing the number of women who can use gametes from the same donor.

Questions for Submissions – the 5 women limit

8. Is the 5 women limit still appropriate?
9. Should the 5 women limit be changed to a 5 family limit?
10. Should the 5 women limit be changed to a 10 women limit?

[26] Section 29, Assisted Reproductive Technology Act 2008 (Vic)
[27] Part 8.1 of the *Human Reproductive Technology Act Directions 2004 (WA)*, which can be accessed at http://www.rtc.org.au/legislation/index.html.
[28] Part 6.3, *Ethical guidelines on the use of assisted reproductive technology in clinical practice*, National Health and Medical Research Council, 2004 (revised 2007): http://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/e78.pdf

5.2 Sections 25 and 26: 10 year limit on storage and use

Sections 25 and 26 of the ART Act effectively create a maximum 10 year limit on the storage and use of donated gametes or embryos created using donated gametes. [29] However, that 10 year limit can be extended with the approval of the Director-General[30]. Since 2010, the Director General (or delegate) has approved 19 requests from ART providers in relation to donated gametes and embryos created from donated gametes. Generally applications for extensions of time to use or store gametes or embryos have been by ART providers on behalf of clients who wished to extend their family using the same donor's gametes, so children of their family would have the same biological father and mother. No applications have, to date, been refused.

A storage limit, which also effectively acts as a usage limit is common among other jurisdictions. Victoria's Assisted Reproductive Technology Act 2008 places a 10 year limit on the storage of gametes and embryos, with an extension allowed on approval by a Patient Review Panel.[31] In Western Australia the limit is 10 years for embryos and 15 years for gametes.[32] The National Health and Medical Research Council's Ethical Guidelines recommend clinics limit the duration of the storage of embryos to a maximum of 10 years. This is expressed as an initial five year period with the possibility of re-consenting to storage for an additional five year period[33].

The rational for placing a limit is closely tied to the recent changes which prevents anonymous donation and focus on allowing offspring of donors to access information about their donor, and have the option of making contact. The Act provides that a child born using donated gametes can only access identifying information after they turn 18. If donated gametes are not used until an extended period of time after donation, the potential for contact, or for the person to develop a meaningful relationship with their donor is substantially compromised, due to the increasing age of the donor. The Act therefore imposes time limits on the storage and use of the donated gametes and embryos created using donated gametes.

Experience in the operation of the limit to date however, also highlight other competing concerns which need to be considered in applying such a limit. This includes balancing the time limits for use and storage against giving women an adequate period of time in which to complete their families. There is some concern that the 10 year period unduly restricts women from completing their families in a time of their own choosing.

[29] The 10 year limit is the outer possible limit. Donors are free to consent to any lesser period of storage which will affect the period of time in which gametes may be used.
[30] Sections 25 and 26 of the ART Act
[31] Sections 31 and 33 of the Victorian Assisted Reproductive Technology Act 2008
[32] *Human Reproductive Technology Act Directions 2004 (WA)*
[33] Part 8.8, *Ethical guidelines on the use of assisted reproductive technology in clinical practice*, National Health and Medical Research Council, 2004 (revised 2007):

Where ART treatment using donated gametes is started by a woman in her early twenties, the 10 year limit may force the woman to complete her family in a timing that does not meet her, or her family's, needs. As fertility treatment is ultimately self limiting due to a woman's capacity to conceive and deliver a child, a question arises as to whether it is appropriate to create time barriers for women to complete their families.

Further, in the case of donated embryos, the 10 year limit starts from the date in which the gametes were donated, not the date the embryos were created[34]. Where embryos are donated, this often occurs after a woman has completed her own family and has excess embryos in storage she wishes to pass on to another woman. This may already be many years after the gametes were donated. The 10 year limit may therefore severely limit the use that can be made of the donation of those embryos.

As with many aspects of the ART Act, the 10 year limit on the storage and use of donated gametes seeks to set a balance between the rights of women and their partners to have a family in a manner and timing of their own choosing and the right of adult donor conceived offspring to be able to have a meaningful relationship with the donor if both so chose. The Discussion Paper asks whether the current provision provides an appropriate balance.

Questions for Submissions – time limits on storage and use

11. Should there be a limit on the use and storage of donated gametes and embryos created using donated gametes?

12. If so, what limit should apply? The current 10 year limit or another time period?

13. If a limit is applied, should there continue to be a process for exemption? How should this occur?

6 Collection and use of gametes from deceased persons

There have been a number of cases since the ART Act commenced which have highlighted an anomaly between the way the ART Act and the Human Tissue Act deals with the use of tissue of a deceased person.

[34] Section 25(3)(c) of the ART Act

Human Tissue Act

The Human Tissue Act broadly regulates the donation of tissue by living persons as well as the removal of tissue from deceased persons.

The definition of tissue used under the Act includes ova and sperm. Under the Human Tissue Act, a designated officer can consent to the removal of tissue from a deceased person where:

- the deceased had, during their lifetime, given their written consent to the removal; or
- the deceased had not, during their lifetime, objected to the removal of his/her tissue and the deceased's senior next of kin consents or, if the person had expressed such an objection, based on the most recent views expressed by the deceased person, the person no longer had an objection to the removal of tissue from the person's body and the deceased's senior next of kin consents.

In situations where the Coroner has jurisdiction to hold an inquest into a death, the designated officer cannot authorise the use of any tissue removed without the consent of the Coroner[35].

The Human Tissue Act is primarily concerned with the removal of tissue for transplantation and research purposes. In 2011 however the Supreme Court determined that the Human Tissue Act would also allow a designated officer to authorise the removal of sperm from a deceased man so as to allow the deceased's widow to use the sperm for ART treatment[36].

ART Act

While the ART Act does not regulate the removal of gametes or tissue[37], as outlined earlier in the Paper, it establishes a comprehensive system for regulation of ART treatment, including IVF and donor insemination and the use of gametes, including, in this context:

- only a registered ART provider can carry out ART services (which includes obtaining a gamete, storing gametes and providing ART treatment); and
- an ART provider must not use, supply or export a gamete except with the written consent of the donor and in a manner consistent with the donor's consent; and
- an ART provider must not provide ART treatment to a woman using a gamete if the donor is deceased, unless the donor has consented to the use of the gamete after his or her death.

[35] Section 31B of the Human Tissue Act 1983
[36] *Jocelyn Edwards; Re the estate of the late Mark Edwards* [2011] NSWSC 478 (23 May 2011)
[37] Except with the situation relating to obtaining a gamete from a child where s29 of the ART Act generally prohibits providing ART treatment to a child unless the child is at risk of becoming infertile and gametes are obtained from the child for the purpose of storing the gametes for the child's future benefits.

The combined impact of the two Acts is to establish two different and potentially conflicting regimes, whereby a designated officer under the Human Tissue Act may authorise the collection of sperm or ova, but the wife or partner may be unable to use the tissue for ART in NSW, as the ART Act expressly prohibits an ART provider from storing or using the sperm in NSW unless the deceased had given his written consent[38] prior to death. Given cases, such as that in 2011, often arise from the sudden death of a partner, this is not always likely to have occurred.

The legal situation is further complicated by the fact that the NSW consent requirements do not prevent the donated tissue being transferred out of the jurisdiction, to allow a widow or de facto partner to use ART services in another state. In the 2011 case, the Court agreed to the deceased's widow to take possession of the sperm and take it out of NSW to be used[39]. This is because the ART Act only regulates ART providers, not individual members of the community, and therefore an individual citizen may export gametes without the donor's consent.

This leads to a situation in NSW where sperm can be obtained from a deceased person, cannot be stored or used in NSW by an ART provider but can be taken out of the State by a deceased person's partner for use in another State or Territory.

The prohibition on the use of gametes after the gamete provider has died unless there is express consent is not limited to NSW. Victoria also requires written consent to the posthumous use of gametes[40] and the NHMRC Guidelines also require specific consent to the use of gametes after death[41]. Western Australia on the other hand has an outright ban on the posthumous use of gametes[42].

In looking at these issues, it is worth considering further why legislation in this area imposes such strong consent requirements on the use of this particular type of tissue.

One of the principles underlying the ART Act is that *"individuals involved in assisted reproductive technology treatment either directly or as donors to have control over the use of their genetic material".*[43] This principle finds expression in the ART Act in the prohibition on ART providers using gametes except with consent of the gamete provider and in accordance with that consent.

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[38] Section 17 of the ART Act
[39] *Jocelyn Edwards; Re the estate of the late Mark Edwards* [2011] NSWSC 478 (23 May 2011)
[40] Section 46 of the Assisted Reproductive Technology Act 2008 (Vic)
[41] Part 17.22, *Ethical guidelines on the use of assisted reproductive technology in clinical practice*, National Health and Medical Research Council, 2004 (revised 2007):
[42] Part 8.9, *Human Reproductive Technology Act Directions 2004 (WA)*
[43] Agreement in Principle speech on the Assisted Reproductive Technology Bill 2007, Legislative Assembly, 7 November 2007: http://www.parliament.nsw.gov.au/prod/parlment/nswbills.nsf/d2117e6bba4ab3ebca256e68000a0ae2/640ce471e940f9b2ca25738b0014b984?OpenDocument

The requirement for consent to be given by the individual to the use of their gametes is important in that donated gametes are used to create a life and most would agree that an individual should consent before their gametes are used to create a child. This can be contrasted with tissue donated under the Human Tissue Act which is used to save a person's life or improve health.

The different purposes of donation arguably call for different rules in relation to the circumstances in which the different tissue may be used. However, while the ART Act regulates the use of gametes in ART treatment, the Human Tissue Act allows tissue to be removed from a deceased person for a therapeutic purposes, medical purposes or scientific purposes[44]. While "therapeutic or medical purposes" would encompass ART treatment, where people consent to be organ donors after death, few, if any, people would contemplate that consenting to organ donation could potentially involve the collection and use of their gametes after death. The general understanding of organ donation does not encompass gamete donation. In can therefore be argued that allowing the removal of the gametes and their use by the deceased's partner in another State or Territory is unethical as the deceased had no control over the removal or use of his gametes and had not provided consent to the removal.

On the other hand, if a death occurs suddenly, although an individual may not have had the chance to expressly consent to the removal of his sperm or to their use after death, there may be surrounding circumstances in which consent could be implied.

Some case studies of possible scenarios that either have, or could arise, demonstrate the variety of circumstances which may need to be covered by the law and some of the difficult ethical issues that may arise in these situations, irrespective of where the law ultimately lands:

- a couple are already in an ART program and have signed general consent forms for the treatment, but there is no indication as to whether the deceased partner had considered or taken a view on the treatment progressing in the event he or she died;
- a couple with fertility problems have been discussing ART treatment. After the sudden death of the husband, the woman requests her partner's sperm be obtained from the deceased, advising hospital staff that while there was nothing formally in writing, they had verbally agreed to proceed with ART treatment if one of them died;
- the parents of the deceased (rather than the partner), seeks to have sperm removed and stored to enable a grandchild using a surrogate, to be born;
- a young man commits suicide and his partner requests his sperm be removed so she can obtain ART treatment. The woman advises that they had

[44] Section 23 Human Tissue Act 1983

discussed having children at some future point, but they had not discussed ART treatment or what would happen if he or she died.

It should also be noted that all of the situations in Australia that the Ministry is aware of involve a request to remove sperm for a deceased male. Should the law be amended to allow gametes to be removed from a deceased person and used where there is no written consent, the law would also apply to females and the removal of ova after death. While no cases in Australia involving a request to remove ova have come to the Ministry's attention, in 2011 an Israeli Court authorised the removal and storage of ova from a 17 year old girl who died in a car accident following a request from the girl's parents[45]. Though it should also be noted that the removal of ova from a deceased woman is likely to be clinically more complex than the removal of sperm and therefore less likely to occur.

These above scenarios, some elements of which have been drawn from real incidents, demonstrate how complex the factual situations which clinicians may be faced with are, and the difficulty in applying a strict consent/non consent rule. Due to the complex individual situations that are likely to arise, it may be useful to have an external arbitrator, such as the Director-General, a court or a tribunal, to assess different scenarios. Such an external arbitrator could consider a range of factors in order to assess the views of the deceased to the use of his or her gametes after death. In addition, as such a proposal involves the creation of life with the express consent of the donor, consideration could also be given to limiting the persons who could use the gametes after the death, in particular limiting use to a spouse or de-factor (including same sex partner) of the deceased.

In essence, should the Act be amended to allow the use of gametes after death where there is no express consent, there could be a two pronged test that the external arbitrator, would have to be satisfied of before allowing the posthumous use of gametes:

- although no written consent had been given, the external arbitrator was satisfied that the deceased would have given his or her consent to the posthumous removal and use of gametes; and
- the gametes would only be used to create a child with the spouse of the deceased.

In considering the issue of posthumous use of gametes by a spouse without express consent of the deceased, other issues also arise, such as who are the legal parents of the child are and issues relating to inheritance. In this regard it is noted that under

[45] Harriet Sherwood, "Israeli family can freeze eggs of daughter killed in road accident", published in the Guardian on 8 August 2011, http://www.guardian.co.uk/world/2011/aug/08/israeli-family-can-freeze-eggs-daughter.

the Status of Children Act 1996, where a woman undergoes ART treatment, her spouse is only considered the legal parent if the spouse consents to the treatment[46].

While the issue of posthumous use of gametes only arises rarely, the question of whether gametes should be able to be removed and used after death without written is a complex ethical and moral issue and views and comments on matters arising in respect of this issue are sought so that the Ministry can find a position that best reflects the needs and views of the community.

14. Should the ban on the use of gametes after death except with the written consent of the gamete provider remain in the ART Act?

15. If not, in what circumstances should the use of gametes after death occur where there is no written consent?

7 Conclusion

The ART Act deals with the socially and ethical complex are of donor conception and seeking to protect the interests of donor offspring, donors and women undergoing ART treatment. However, on occasion the interests of these three groups are not in harmony and may in fact be in direct conflict. The ART Act seeks to set an appropriate balance between the sometimes competing rights of donor offspring, donors and parents. The review of the Act presents a timely chance to consider whether an appropriate balance has been achieved. While this Paper seeks submissions on specific issues, the Ministry is also keen to receive submissions on any other issue relating to the ART Act.

[46] Section 14, Status of Children Act 1996 (NSW).

Appendix A: List of organisations to be consulted

AccessAustralia
Andrology Unit, Concord Reparation Hospital
Australian Medical Association (NSW)
Central Coast Local Health District
Demeter Laboratories
Donor Conception Support Group of Australia
Far West Local Health District
Fertility East
Fertility First
Fertility Society of Australia
Genea Limited
Illawarra Shoalhaven Local Health District
IVF Australia
Hunter IVF
Hunter New England Local Health District
Information and Privacy Commissioner
Law Society of New South Wales
Legislative Assembly Committee on Law and Safety
Medical Services Committee
Mid North Coast Local Health District
Murrumbidgee Local Health District
Nepean Blue Mountains Local Health District
NSW Attorney General's Department
Northern NSW Local Health District
Northern Sydney Local Health District
NSW Commission for Children and Young People
NSW Gay and Lesbian Rights Lobby
Palantrou Pty Ltd
Plunkett Centre for Ethics
Public Interest Advocacy Centre
Reproductive Medicine Albury
South Eastern Sydney Local Health District
South Western Sydney Local Health District
Southern NSW Local Health District
St James Ethics Centre
St Vincent's Health Network
Sydney Local Health District
University of Technology of Sydney, Faculty of Law
VANISH
Western NSW Local Health District
Western Sydney Local Health District
Westmead IVF