

Chapter 8 **Gamete and Embryo Donation**

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Gamete and Embryo Donation

Gametes are sperm or ova (a woman's eggs).

The commission's terms of reference require us to consider the expansion of eligibility criteria in relation to any form of assisted reproduction. Gamete donation is essential to assisted reproductive technology (ART) treatments which use donated sperm, eggs or embryos to achieve a pregnancy. Donors of gametes are subject to counselling, medical screening and other eligibility criteria.

In this chapter, we consider whether changes should be made to provisions governing eligibility to donate gametes. We also ask whether people who donate gametes and embryos should be able to specify the characteristics of the person or couple who benefit from that donation.

DONOR ELIGIBILITY

The donation of gametes and embryos is regulated by the *Infertility Treatment Act 1995*, clinic licensing conditions and national guidelines on ART.

Section 41 of the Infertility Treatment Act prohibits the use of gametes, or embryos produced from the gametes, of a person younger than 18 years.¹ Upper age limits for donors are recommended in the Infertility Treatment Authority's (ITA) conditions of licence. Sperm donors should be under 55 years of age and egg donors should be under 35 years of age, unless there are exceptional reasons to depart from these limits.² Known donors may be older than the recommended age limits.³

The ITA's conditions of licence also stipulate that clinics 'must not knowingly allow the donated gametes of one person to be used to produce offspring in more than ten families'.⁴

In addition to these requirements, donors must undergo counselling, give consent to the use of their gametes, undergo medical screening and complete a tissue donation statement. Sperm must also be quarantined prior to use. These requirements are discussed below.

CONSENT AND COUNSELLING

The Infertility Treatment Act requires gamete and embryo donors, and any spouses or partners, to consent to use of their gametes in a treatment procedure.⁵ Donors of gametes and their spouses (if applicable) must receive counselling addressing their motivation for donating, the potential impact on their relationships with spouses and any children, and, if they are known to each other, the impact on relationships between donors and recipients.⁶

Donors must also provide information to be placed on the ITA's central register. They must receive advice about the rights of a person born using their gametes to obtain information recorded in the register.⁷

The commission supports these requirements because they assist donors to understand the implications of their decision to donate gametes. In accordance with Recommendation 27, the commission recommends that the definition of a donor's partner should be expanded to include a domestic partner.

HEALTH CHECKS AND TISSUE DONATION STATEMENT

Donors of gametes must undergo a number of tests which are intended to prevent recipients of donated gametes and any child born from being infected with diseases which could be transmitted during fertilisation. The health requirements include:

- Donors of gametes must complete a medical history declaration.⁸
- Donors of gametes must be tested for human immunodeficiency virus (HIV), hepatitis C virus, hepatitis B virus, human t-cell lymphotropic virus, syphilis and microbiological contamination.⁹
- In addition to these mandatory medical tests, donors may be tested for genetic conditions as well as other medical conditions.
- Sperm must be frozen for six months before use, after which time some medical tests will be repeated, for example for HIV and hepatitis C.¹⁰

Submissions to the commission were unanimous that some medical screening of donors is necessary and appropriate to protect the health and wellbeing of recipients of gametes and any children born. However, the current screening mechanisms for achieving this aim were criticised in many submissions.

Donors of gametes are screened for risk on the basis of a tissue donation statement or 'lifestyle declaration'.¹¹ Legislation does not prescribe that donors complete a tissue donation statement. However, this provides protection for doctors from liability if HIV or hepatitis C is transmitted through a gamete donation¹² and it is the practice of clinics for it to be completed. The Health (Infectious Diseases) Regulations 2001 prescribe the content of the tissue donation statement. Previously, the Reproductive Technology Accreditation Committee (RTAC) guidelines also contained a donor lifestyle declaration, but this was withdrawn from the most recent edition of the guidelines.¹³

The tissue donation statement requires the donor to answer questions about medical symptoms, sexual activity, drug use and exposure to infection, for example, through skin piercing. Some questions on the declaration are directed to certain activities; other questions seek to identify a perceived risk group. For example, Question 8 on the declaration asks:

Within the last 12 months have you:
8. Had male to male sex?¹⁴

The commission received a number of submissions which argued that the prescribed tissue donation statement discriminates against homosexual men. They argued that it excludes people based on their sexual orientation, rather than because they have been involved in activities which create a high risk of infection. Question 8 asks if a potential donor has engaged in homosexual sex, not whether sexual activities have been practised safely.

In submissions, the commission was informed that the effect of including this broad question in the screening process is that some people who wish to donate gametes are prevented from doing so, even where there is no risk they will transmit a communicable disease. Current practices for screening donors may also prevent women from using the sperm of known donors.¹⁵ One couple, who had approached a known donor, recounted their experience:

*We were outraged and upset when our donor Cameron, who was donating directly to us, was asked to sign a 'lifestyle declaration'. Even though there is a six-month quarantine period and extensive testing for blood born viruses and all STIs [sexually transmitted infections] he was still being asked about his lifestyle because he identifies as a gay man. The questions don't even ask about risk-taking or safe sex.*¹⁶

In submissions, the commission was also informed that the current form of the tissue donation statement exacerbates stigmatisation of particular groups in the community and seems to be based on the misconception that gay men are inherently diseased.¹⁷ Other people told the commission that the tissue donation statement offers no extra assurance for recipients of donations, which can only be provided through medical testing.

- 1 However, a gamete, zygote (cell formed from two gametes) or embryo formed from gametes produced by a person under the age of 18 may be used if the gamete was collected for use later in life due to the likelihood the person would become infertile due to treatment or illness: Infertility Treatment Regulations 1997, r 11.
- 2 Infertility Treatment Authority, *Conditions for Licence: Clinics, Hospitals and Day Procedure Centres* (7th ed, 2006), para 5.2.
- 3 The ITA's conditions for licence state that: 'Where a person or couple choose to use gametes from known donors who are over these recommended ages, they are to be offered additional counselling and clinical advice in relation to the possibility of adverse outcomes': *ibid*, para 5.2.
- 4 Infertility Treatment Authority, above n 2, para 5.11.
- 5 *Infertility Treatment Act 1995* ss 12, 13, 14.
- 6 *Infertility Treatment Act 1995* s 16, Infertility Treatment Regulations 1997 r 7.
- 7 *Infertility Treatment Act 1995* s 17.
- 8 Reproductive Technology Accreditation Committee, *Code of Practice for Assisted Reproductive Technology Units* (rev ed, 2005), para 9.1.
- 9 *Ibid*, para 9.9.
- 10 Reproductive Technology Accreditation Committee, above n 8, para 9.9. Mandatory tests are determined by the Therapeutic Goods Administration.
- 11 Health (Infectious Diseases) Regulations 2001 prescribe a 'tissue donation statement'. This is sometimes referred to as a 'lifestyle declaration'.
- 12 *Health Act 1958* s 133. The tissue donation statement can be found in the Health (Infectious Disease) Regulations 2001, Sch 8.
- 13 Reproductive Technology Accreditation Committee, above n 8.
- 14 Health (Infectious Disease) Regulations 2001, Sch 8.
- 15 Submissions CP 82 (Anonymous), CP 88 (Deborah Dempsey), CP 133 (Women's Health West), CP 149 (Prospective Lesbian Parents), CP 171 (Fertility Access Rights), CP 198 (Dr Elizabeth Short).
- 16 'Felicity and Sarah' in submission CP 149 (Prospective Lesbian Parents).
- 17 Submission CP 59 (Ian Seal).

RECOMMENDATIONS

48. The questions asked of donors in the tissue donation statement should relate directly to identifiable risk factors and should be no more intrusive of the donor's privacy than is necessary to be able to identify those factors. The form of the declaration should be reviewed periodically to ensure it is consistent with current medical knowledge.
49. Clinics should inform potential donors about the use of information given in answers to questions in the tissue donation statement.
50. The time period for which sperm should be quarantined before it can be used in a treatment procedure should be prescribed by the Infertility Treatment Authority, rather than by legislation. The period should reflect current medical knowledge about risk factors, and should be reviewed periodically.

Many submissions argued that the tissue donation statement should be redrafted to require doctors to focus on a donor's participation in activities which create a high risk of infection with a transmissible disease.¹⁸ The Equal Opportunity Commission of Victoria supported this approach:

*decisions about the use of donated gametes should be made on clinical grounds rather than grounds that are likely to be discriminatory or that reinforce erroneous assumptions or stereotypes.*¹⁹

There have already been some changes in clinic practices in response to these concerns. The ITA advised clinics on 20 September 2001 that the recruitment of homosexual men as donors is not automatically excluded under Victorian legislation. The ITA received advice from the Director of Public Health, Professor John Catford, that under the *Health Act 1958* a 'yes' answer to the question on the tissue donation statement does not require the person to refrain from donating until their health status is ascertained. Professor Catford advised the ITA that this 'is a matter for risk assessment by the medical practitioner or other person dealing with tissue donation'.²⁰ It is therefore at the discretion of the doctor to accept donors even if they say yes to some aspects of the tissue donation statement. The directive also leaves to the discretion of the doctor a decision about donation by a person who admits to having injected non-prescribed drugs.

The commission has been told that clinic doctors do exercise their discretion to accept donations from potential sperm donors who have answered 'yes' to having had sex with men, or any other question on the declaration. The potential recipients are advised that the donor has answered this way and are asked to sign a form to indicate they have been advised of this.²¹

However, the submissions the commission received suggest it has not been made clear to people wishing to access clinic services that a doctor may accept donors who answer 'yes' to some questions on a tissue donation statement. Women's Health West said that this uncertainty needs to be addressed:

*We also welcome any processes that would clarify clinics' obligations under the law, including their capacity to accept donations for anonymous use from gay men and from people who may have injected non-prescribed drugs.*²²

In light of the confusion regarding the criteria for eligibility to donate, particularly in relation to gay men but also to people who have ever injected non-prescribed drugs, the commission recommends the tissue donation statement be reviewed. We believe that the questions asked of donors should relate directly to identifiable risk factors and should be no more intrusive on a person's privacy than is necessary to be able to identify those factors. The commission also recommends that the format for tissue donation statements should be reviewed periodically to ensure they are consistent with current medical knowledge.

Clinics should inform people seeking to donate gametes about their use of information given in answers to questions. This will help to address current confusion about the use of the declaration.

QUARANTINE PERIOD

As noted above, the Health (Infectious Diseases) Regulations 2001 set out requirements that, if complied with, protect doctors from liability in the event that HIV or hepatitis C is transmitted through sperm used in an ART procedure. One of these requirements is that sperm is not used, or is quarantined, for six months prior to use.²³ The quarantine period is therefore framed to avoid liability for clinics and doctors, rather than being directed to the avoidance of risk of harm to women and children.

Most submissions received by the commission supported a quarantine period as part of the medical screening process. However, others said imposing a quarantine period on known sperm donations was unjustified:

Despite the fact that we have made the personal decision to use his sperm, the law requires that all sperm donations of donors be quarantined for six months, whereas for heterosexual women with male partners they can of course use his sperm (frozen or fresh) straight away as part of inter-uterine insemination for example. I understand that the six months wait is about the health of the woman and potential child, but this is more about the situation for heterosexual women using anonymous sperm. The law requiring six months quarantine doesn't allow for the fact that most lesbians by the time they have their donor leave a sperm deposit, have had him tested many months (sometimes years) before and have been using his sperm in home inseminations.²⁴

Some submissions pointed out that the quarantine period can add an extra six months to treatment when a known donor is used, as anonymous sperm has already been quarantined.

The commission has received advice that current research in the area of HIV and hepatitis C detection may support the reduction of the six-month quarantine period prescribed in the Health Regulations.²⁵

The commission believes the primary purpose of fixing a quarantine period should be to protect women and children from infection or disease. We therefore recommend that the ITA and the Department of Human Services seek advice on the quarantine period which should apply to donated gametes. The quarantine period should reflect current medical knowledge about risk factors and should be reviewed periodically.

In Chapter 3 we discussed the difficulty of fixing rules about ART in a climate of technological change. Gamete screening techniques and knowledge about the transmission of disease or infection will develop with time. The commission believes that the time period before gametes can be used in a treatment procedure should be prescribed by the ITA, rather than by legislation. This will ensure the quarantine period reflects current medical knowledge about risk factors.

- 18 Submissions CP 43 (Ian Coutts), CP 82 (Anonymous), CP 83 (Sexuality Law Reform Committee, Melbourne University Law Students Society), CP 89 (Ministerial Advisory Committee on Gay and Lesbian Health), CP 133 (Women's Health West), CP 149 (Prospective Lesbian Parents), CP 164 (Confidential), CP 171 (Fertility Access Rights). The commission also received 65 submissions in response to Position Paper One that made this point.
- 19 Submission PP1 313 (Equal Opportunity Commission of Victoria).
- 20 Correspondence from Professor John Catford to the Infertility Treatment Authority (ITA), 21 August 2001. Copy supplied to the commission by the ITA.
- 21 Information provided to the commission by Professor Gordon Baker, Melbourne IVF, 31 January 2007.
- 22 Submission PP1 319 (Women's Health West).
- 23 Health (Infectious Diseases) Regulations 2001, r 19.
- 24 Submission CP 110 (Lisa and Amanda).
- 25 Information provided by Professor Gordon Baker, Melbourne IVF, 31 January 2007.

DIRECTED DONATIONS

People who donate gametes and embryos to unknown recipients sometimes wish to specify the characteristics of the people who should, or should not, benefit from the donation. For example, they may wish to direct that the gametes or embryos are only made available to a person of a particular race or who is in a particular kind of family. This is referred to as directed donation. In this section we consider whether or not directed donations should be permitted.

CURRENT LAW

The conditions of licence for Victorian fertility clinics state that:

Except in the case of an identified donor (s 18.) a donor may not specify the type or class of person to whom the gametes or embryos are to be provided. Such a specification may result in a breach of federal or state discrimination laws.²⁶

The ITA obtained an opinion from the Victorian Government Solicitor on whether a clinic may or may not act on a donor's request to restrict the type of person who may be the recipient of his or her gametes.²⁷ The Government Solicitor's opinion was that a clinic may not pay regard to such a specification on the part of the donor. Treating potential recipients less favourably by decreasing the available pool of donor gametes on the basis of race, sexual preference, marital status and age would be likely to be in breach of the *Equal Opportunity Act 1995*, and on two of these bases it would also be in breach of Commonwealth Acts—the *Racial Discrimination Act 1975* (Cth) (if it was on the basis of race) and the *Sex Discrimination Act 1984* (Cth) (if on the basis of marital status).

The NHMRC ethical guidelines, however, recommend that clinics should not use gametes in a way which is contrary to the wishes of the donor,²⁸ unless state law indicates otherwise. The RTAC code of practice does not refer to directed donations and 'as such has chosen to comply with the NHMRC ethical guidelines'.²⁹

The ITA conditions of licence only apply where people donate to unknown recipients. If a donor wishes to donate to a particular person or couple (known donor donation), there is nothing to prevent this. Known donor donation is permitted under the Infertility Treatment Act.³⁰ However, people are only allowed to seek a donor by advertisement if authorised by the Minister for Health.³¹

GAMETE DONATION

Arguments for Directed Donations

Two main arguments are made in favour of allowing people to specify who should be able to use their gametes. The first argument is that permitting directed donations protects the wellbeing of the child to be born. It was noted in submissions that the legislative framework of ART supports disclosure of genetic origins,³² and the 'ethos is to foster knowledge of and contact between donors and children'.³³ Some submissions said that if the donor and the biological child later met and formed a relationship, the child might be psychologically harmed because the donor disapproved of the child's parents. For example,

if the donor is faced with a child whom has been brought up in a lesbian relationship and they do not agree with this, it may have implications for their potential ongoing relationship with the child.³⁴

Some argue that this risk justifies allowing donors to direct donations of gametes to a person or couple whose values they share.

The second main argument in favour of allowing directed donations is that donating gametes differs from other types of tissue donation because it results in the creation of a child. For this reason, it is suggested that both donors and recipients of gametes should have the right to express their wishes and to have those wishes respected.³⁵ Some infertility counsellors expressed the view that the discretion to direct donations benefits everyone involved and that it is 'crucial that all concerned ... can [express their views and] feel comfortable with the situation'.³⁶

A subsidiary argument in favour of allowing directed donations is that if people cannot make directed donations they may decide not to donate at all. This was of particular concern to doctors in Melbourne clinics, some of whom stated that:

*All should be done to promote donation from a range of people. It is very difficult to get donors from some racial groups and the inability to discriminate would make this even less frequent and promote more international reproductive tourism.*³⁷

Some people argue that without directed donations, the supply of gametes available for donation will be reduced and fewer people will be able to receive treatment.

Other submissions suggested that gametes may be seen as the property of donors, saying ‘the gametes we produce are our own to do what we want with, until such time as they are fertilised at which time we no longer have sole authority over them’.³⁸

Arguments Against Directed Donations

Most submissions which commented directly on the issue of directed donations argued against allowing this practice. The main argument against directed donations is that giving effect to a donor’s wishes may require clinics to discriminate against people of a particular racial origin or people in particular types of families. Fertility Access Rights and the Victorian Gay and Lesbian Rights Lobby said:

*it is discriminatory to allow people who are donating semen to an unknown recipient to stipulate qualities or characteristics of the recipient, and ... this practice should stop.*³⁹

Some submissions expressed the view that clinics which allow directed donations are in breach of federal anti-discrimination law⁴⁰ as well as international human rights instruments.⁴¹ Several submissions remarked on the important role of law in changing prejudicial community attitudes and argued that allowing discrimination in any form diminishes us as a community.⁴²

The Equal Opportunity Commission submitted that there should be further debate on the issue of directed donations, but commented that guidance should be given to service providers to enable them to avoid potentially discriminatory practices.⁴³ Another submission suggested that:

*Reproductive services should take no part in getting or allowing donors to stipulate which ‘types’ of women they will exclude from being the recipient of their donation ... they [should] make sure that potential donors know that the clinics give the donations to people who need them to help them have their family.*⁴⁴

In making recommendations on this issue, the commission has taken account of two guiding principles recommended in Chapter 5. The first is the principle that the law should protect the health and wellbeing of any child who may be born. The second is the principle that assisted reproductive processes should not discriminate against people on the basis of their sexual orientation, marital status, race or religion.

The commission’s view is that donors should not be able to direct that their gametes be used only for particular types of recipients, for example, those belonging to a particular race or religion, or having a particular sexual orientation or family type. A person who donates blood cannot specify that it should only be used to transfuse a white or a heterosexual person. A similar principle should apply to gamete donation. The commission acknowledges that gametes are not the same as other human cells, but believes it does not follow that the unique capacity of these cells to contribute to creating a child should enable a person who wishes to donate them to do so in a way that discriminates against others.

We are not convinced that the objective of protecting the welfare of children conceived through the use of donated gametes is served by permitting this form of discrimination. The possibility that a child who meets a donor may be adversely affected by a donor’s attitude to their parents is quite remote and does not justify breaching the guiding principle of non-discrimination which we have recommended.

The commission is also not aware of evidence supporting the view that preventing directed donations discourages people from donating to unknown recipients. In the absence of any evidence that allowing directed donations is necessary to protect the wellbeing of children, we recommend that clinics should only accept donors who are willing to donate to any patient approved by the clinic for a treatment procedure.

The commission’s recommendation that directed donations not be permitted is made in the context of a spectrum of decisions available to donors. Donors of gametes still have choices about whether they donate at all, and the law does not prevent people from donating to a known individual or family who they identify through their own contacts and networks.⁴⁵ These choices should be identified and discussed with donors in counselling.

- 26 *Infertility Treatment Authority (2006)*, above n 2, para 5.8.
- 27 Opinion by Victorian Government Solicitor, 8 August 2000, supplied to the Victorian Law Reform Commission by the Infertility Treatment Authority. The Victorian Government Solicitor noted that, in coming to this conclusion, his advice differed from the advice given to reproductive medicine units by the South Australian Council on Reproductive Technology. That advice was that, provided there were always donor gametes available for single people and treatment was not totally refused, donors could place conditions on donations and clinics could act on those conditions.
- 28 National Health and Medical Research Council, *Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research* (2004), para 6.9.
- 29 Submission PP1 338 (Fertility Society of Australia).
- 30 *Infertility Treatment Act 1995* s 18.
- 31 Section 40 of the *Human Tissue Act 1982* requires that when advertisements are placed for tissue donors, those advertisements must have the approval of the Minister for Health and must include a verification statement.
- 32 Submission PP1 313 (Equal Opportunity Commission of Victoria).
- 33 Submission PP1 226 (Professor HWG Baker and Dr JC McBain).
- 34 Submission CP 73 (Lauren Andrew).
- 35 Submission CP 52 (Helen Kane).
- 36 Submission CP 155 (Victorian Infertility Counsellors Group).
- 37 Submission PP1 226 (Professor HWG Baker and Dr JC McBain).
- 38 Submission PP1 148 (Barbara Roberts).
- 39 Submission PP1 251 (Fertility Access Rights). Many other submissions to Position Paper One supported this statement.
- 40 Submissions CP 177 (Australian Lawyers for Human Rights), CP 191 (Equal Opportunity Commission Victoria).
- 41 Submission CP 177 (Australian Lawyers for Human Rights).
- 42 Submissions CP 74 (Caitlin Coleman), CP 131 (Anonymous), CP 135 (Rebecca Olsen).
- 43 Submissions CP 191 (Equal Opportunity Commission Victoria), PP1 313 (Equal Opportunity Commission Victoria).
- 44 Submissions PP1 341 (Dr Elizabeth Short); see also CP 38 (Jacqueline Tomlins), CP 82 (Anonymous), CP 99 (Susan Koska), CP 133 (Women’s Health West), CP 137 (Melinda and Lisa), CP 143 (The Bouverie Centre), CP 149 (Prospective Lesbian Parents), CP 171 (Fertility Access Rights), CP 184 (Anonymous), CP 198 (Dr Elizabeth Short).
- 45 Note that advertisements are subject to restrictions under the *Human Tissue Act 1982* s 40.

RECOMMENDATIONS

51. Donors should not be permitted to specify the qualities or characteristics of the unknown recipients of their donated gametes and embryos.

EMBRYO DONATION

The commission also considered whether an exception to this principle of non-discrimination should apply in the case of embryo donations. People donating embryos to others have usually been successful in conceiving a child through the use of ART. They may then wish to donate the embryos, rather than disposing of them. The embryos may be genetic siblings of the donor's existing or future children.

Some submissions argued that directed donations should be possible in this case.⁴⁶ Although embryo donors are not permitted to direct their donations, in some cases clinics introduce embryo donors to potential recipients where both parties agree.⁴⁷

The commission does not agree with the practice of directed donation of embryos. The law already allows a person to donate embryos to a known recipient. Where the donation is made to an unknown recipient, the commission believes that the principle of non-discrimination should apply in the same way that it applies to gamete donation. We therefore recommend the law should not permit directed donations of embryos.

46 Submission CP 78 (Andrew McLean), PP1 226 (Professor HWG Baker and Dr JC McBain).

47 Information provided by Professor Gordon Baker, Melbourne IVF, 31 January 2007.