EXECUTIVE SUMMARY

CHAPTER 1: INTRODUCTION TO THE STUDY

The aim of this research project is to help improve the laws, policies and practices concerning assisted reproductive treatment (ART) around Australia, directly informed by the perspectives of those most affected. This research focused on the views of in vitro fertilisation (IVF) patients who had embryos in storage, either past or present, as those who were most intimately concerned with the subject matter of our inquiry. We did not seek the views of the general public or those contemplating treatment.

ART regulation in Australia is piecemeal, complicated and overlapping. There are federal ethical guidelines issued by the National Health and Medical Research Council which are tied to accreditation requirements for fertility clinics ('NHMRC Ethical Guidelines').[1] In addition four states also have specific legislation on ART: New South Wales, South Australia, Victoria and Western Australia.[2]

We set out to explore how laws and policies in all states and territories impacted upon the decisions people had made, or wanted to make, with respect to their frozen embryos. We drew on the experiences of past and present IVF patients across over 20 different clinical sites, spanning over two decades, covering all jurisdictions in Australia except the Northern Territory.

The study utilised both qualitative and quantitative methods. In all, 349 eligible surveys and 51 interviews were completed. Interviews were conducted with 54 participants in total. In common with most empirical research on fertility, participants in the study were overwhelmingly female (>90%). They tended to be in married or de facto relationships and were generally aged between 31 and 40 years old. Participants had typically commenced treatment in the last 2-10 years, conceived children through IVF, and most still had embryos in storage at the time of their participation. Nearly half of those with embryos in storage indicated that they had completed their IVF treatment. While the majority of participants had used their own gametes in their IVF treatment, around one third were recipients of donated gametes or embryos.

A key theme, highlighted throughout this report, is that for many participants, their remaining stored embryos, even if no longer intended for their own use, remain significant

[1] National Health and Medical Research Council, *Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research* (2007). Under the *Research Involving Human Embryos Act 2002* (Cth), embryos can only be used or developed in the course of a woman's reproductive treatment by ART units accredited by the Fertility Society of Australia's Reproductive Technology Accreditation Committee ('RTAC'). The RTAC Code in turn requires evidence of compliance with the NHMRC Ethical Guidelines.

[2] *Assisted Reproductive Technology Act 2007* (NSW); *Assisted Reproductive Treatment Act 1988* (SA); *Assisted Reproductive Treatment Act 2008* (Vic); *Human Reproductive Technology Act 1991* (WA).

to them. Disposition of unused embryos was something that many had not contemplated at the outset of treatment.

Our feminist-oriented approach was particularly mindful of the greater physical risks and emotional toll experienced by women involved in IVF, as well as women's more limited reproductive years in contrast to men. We do not discount the views of partners in this report, but we do recognise and validate the centrality of the experience of the woman who underwent the IVF treatment – something that was repeatedly emphasised by both male and female participants in this study.

Each chapter of the Report addresses a particular focus of our inquiry: consent and information giving (**Chapter 2**); issues for recipients of donated gametes (**Chapter 3**); using the embryo beyond the relationship (after separation or death) (**Chapter 4**); embryo storage (**Chapter 5**); embryo destruction (**Chapter 6**) and finally embryo donation for the reproductive use of others (**Chapter 7**). In each chapter we make recommendations for change. Below is a **summary** of the key findings and recommendations of each chapter. For more detail on any point please refer to the Report.

CHAPTER 2: CONSENT, INFORMATION GIVING AND COUNSELLING

At the commencement of IVF treatment, women and their partners are asked to sign consent forms which may provide for outcomes for additional stored embryos in the event that either or both partners die, their relationship ends or they are otherwise unable to give further instructions at the expiration of storage limitation periods. The need for clearer initial consent, ongoing provision of information and the desirability for consent to be revisited and altered as people's circumstances change were universal themes.

One of the troubling findings of this study was that many participants were unsure of what they had originally signed in their consent forms. A number of participants reported that the process of being informed of their options and signing consent forms was rushed and did not allow sufficient time for reflection. Some reported that they were not able to read and review consent documentation in advance of treatment and/or were not provided with copies of the signed documents afterwards.

A number of interviewees reported that only later in their treatment, or after they had completed their family, did they realise that their preferred embryo disposition option (for example, donation for research or donation for reproductive use by others) was not available to them. The *absence* of these options on consent forms was not sufficient to alert them to this issue. It was apparent that clinics do not routinely volunteer this information or make it publicly available on websites or in other public materials such as brochures.

We found a strong theme concerning a lack of communication and support once treatment ended. Clinics, having assisted patients to achieve the goal of pregnancy, tend to communicate subsequently through billing reminders in the mail (which also operate as a

truncated form of re-consent as patients agree to continue storage, or elect to discard or donate) rather than through telephone contact. A number of study participants reported that they had not undertaken, nor been offered, counselling. Many did not know that they were able to ask for it. Nearly two thirds of survey respondents desired more information or counselling on rights and options on embryo disposition.

We conclude that it would be helpful to address the issue of consent to IVF treatment and decisions about embryo storage and future disposition separately. We also propose multiple points of consent before, during, and after treatment, to properly reflect the stages of decision-making and need for embodied consent. To ensure informed consent, we believe embryo directive forms should be accompanied by plain language explanations of their effect: what elements are binding, the source of authority (eg state legislation or clinic policy), and directions to independent sources of information and dispute resolution avenues. Having consent forms available on websites would allow greater opportunity for reflection as well as enabling patients to compare the options available at each clinic.

RECOMMENDATIONS:

2.1 Simple, standardised, and transparent documents concerning consent and embryo directives are highly desirable.

2.2 The consent form for treatment should address the IVF treatment cycle only.

2.3 Decisions regarding stored embryos should be addressed in a separate 'embryo directive' form (addressing storage, separation and death). The embryo directive form must make it clear that it can later be altered and that a further directive will be obtained at the end of treatment.

2.4 Embryo directive forms should be accompanied by plain language explanations of their legal effect: what elements are binding, the source of authority (state legislation, NHMRC Ethical Guidelines, contract with clinic) and available information and dispute resolution avenues.

2.5 Development of protocols to ensure that patients are aware they can revisit the directive or make a new decision about stored embryos periodically: eg at the end of treatment, and every 1-2 years subsequently.

2.6 Provision of an in-person information giving session with designated clinic personnel in addition to the treating doctor, prior to signing of consent forms and embryo directives.

2.7 Provision of consent and embryo directive documents in advance of the initial medical treatment meeting. Copies of signed consent forms provided subsequently.

2.8 Consent forms and embryo directive forms to be available via websites to allow greater opportunity for reflection and informed consent, as well as enabling patients to compare the options available at each clinic.

2.9 The requirement of Victorian ART law that patients seeking treatment must undertake criminal records and child protection order checks and the presumption against treatment should be immediately repealed.

2.10 Development of practice protocols for a standard form of 'exit counselling' at the time of treatment/family completion.

2.11 Each jurisdiction to develop an external information giving and support agency, whether a state body or under state license. This agency would work in conjunction with, but be distinct from, a dispute resolution body.

2.12 Development of a clear 'ready reckoner' or flow chart which outlines options in relation to the storage and disposition of embryos. This should be made available as a hard copy information sheet and via clinic and external information giving websites.

2.13 Advance provision of information by clinics concerning which embryo disposition options they facilitate and which they do not, with clear differentiation provided between legal requirements and clinic policy.

CHAPTER 3: ISSUES FOR RECIPIENTS OF DONATED GAMETES (SEE CHAPTER 7 FOR EMBRYO DONATION)

We set out to examine how recipients experienced the rules that govern gamete donation in Australia, including exploring decision-making processes concerning the choice of donors, views about family limits from each donor, the practice of 'reciprocal donation' and views on 'early contact' with the donor as well as with other families from the same donor.

The study did not directly seek information about the availability of donor sperm. Yet a number of experiences that were spontaneously reported by interviewees indicate a shortage of donor sperm in Australia. This had a major impact upon recipient participants' family formation decisions and options, including: their choice of donor, duration of waiting times for treatment, their ability to reserve sperm for subsequent children and the kind of treatment they were offered. Several women we interviewed had utilised sperm imported from the USA because their Australian clinic was unable to supply local sperm at the time of their treatment.

We suggest the establishment of a non-profit body to facilitate reproductive donation.

Reciprocal Donation

Reciprocal donation refers to schemes practiced in some jurisdictions outside Australia such as the 'egg sharing' and 'benefits in kind' schemes operating in the UK. The intention of such schemes is to encourage donation through the provision of certain reciprocal benefits for

those already undertaking treatment, such as discounted treatment and storage. It is likely that such practices would be unlawful in Australia at present. We canvassed recipient views to see if current laws are in sync with patient values.

Views were very divided. Those in favour of such a scheme often expressed the principle of solidarity: that it would provide an opportunity to give back, as well as potentially make IVF treatment more affordable. Those against reciprocal donation were concerned about the potential for inducement or undue pressure. Given the complexities of the issue and strong division of views, we recommend further exploration of ethical models of reciprocal donation to determine whether it could be contemplated within the Australian system.

Numerical limits

Of the states with statutory limits on the number of offspring from a single donor, Victoria has a limit of 10 *women*; Western Australia has five *families*; and NSW has five *women*. Legislative changes in NSW and Victoria, which became operative in 2010, replaced the previously used category of 'families' with wording specifying 'women' in setting the numerical limit. This change in wording had a major adverse impact on the reproductive options available to lesbian couples (who were suddenly counted as two women and not one family).

Participants were broadly in favour of having an upper limit to the number of offspring who can be born from a single donor. However, many were not sure of the relevant upper limits in their jurisdiction and were confused about which body set that limit (law or clinic). A number of interviewees did not know how many other families had been formed at the time of their treatment, how many families had been formed since, or that they were able to request this information from their clinic.

Our analysis of recipients' views and experiences of numerical limits leads us to conclude that policy makers need to think more carefully about what numbers mean in different contexts and centre the issue on informed consent to any limit rather than, as is presently the case, simply focusing upon the number itself. At present, state law in NSW and Victoria and the NHMRC Ethical Guidelines offer donors (but not recipients) the option of specifying only a *lower* (not higher) family limit. We conclude that because the number itself has very different meanings for different people, *both* donors and recipients should have the option of giving informed consent to lower limits. Equally, they should have the option of giving informed consent to slightly higher family limits. We argue that moderate and carefully monitored numerical limits will actually serve the interests of donor conceived people far better than an unrealistically low limit. If a limit is set so low that it drives evasion, important protections available in current regimes will be lost.

Identity Disclosure Regimes

There is no overarching federal regime of donor identity records in Australia. Although all clinics must only use donors who consent to being identifiable once offspring reach 18, the

source and content of the disclosure requirements, and the location of identity records, vary considerably across the states and territories. Most interviewees reflected that information about the donor's identity was an important resource for their child, regardless of their own views or feelings.

Interviewees' concerns about communication and identification were focused on 'early contact' with both the donor and other recipient families: an area largely unaddressed by government registers. The option of early contact with donors was noted as a preference by over a third of the survey respondents who were gamete recipients and several interviewees. Participants consistently reported that this was not because they wished to build a close or on-going relationship with the donor, but was rather because they wanted to be certain of access to information or contact in the future should their child seek it. A number of interviewees had joined formal and informal voluntary registers to enable earlier contact with donors and other recipient families.

Not all parents will want to make contact with other recipient families, nor with donors. For those that do, we support consideration of the ways in which such contact can be made, while still respecting the privacy of all participants.

The passive operation of both voluntary government registers and clinic matching programs was the source of frustration for some participants. Regulators will only make contact if both parties have already joined; they will not actually invite someone who is not already on the register to join in order to make a match. Overall, clinics were more responsive to a wider range of requests for mediated communication than were voluntary government registers, which were limited by the terms of their governing statutes as well as their more impersonalised mode of operation (for example their lack of counselling and support facilities). On the negative side however, clinic practices were also more diverse, non-transparent and unpredictable.

We conclude that the current regimes in place around Australia are failing for a number of reasons. Clear and transparent information about what disclosure options are available, the mandatory or voluntary nature of the system, as well as the organising body behind it, was notably lacking. Moreover the inflexible and non-responsive nature of government held registers means that they may not ultimately serve their intended purpose. We support information disclosure regimes that are intended and understood to be something more than a public records office. They must be flexible and responsive, with integrated support services.

RECOMMENDATIONS

3.1 Development of practice models to enable the ability to reserve supplies of local sperm from a selected donor per family for set periods.

3.2 Development of non-market based responses to donor shortages including a body to undertake research into donor needs and to undertake donor recruitment.

3.3 Further exploration of ethical models of reciprocal donation to determine whether it could be contemplated within the Australian system.

3.4 New South Wales and Victorian law should be amended so that donor limits are based on the number of *families* created.

3.5 Family limits under state law should be nationally applied.

3.6 The standard or default family limit should be 10 families per donor. We recommend that NSW and Western Australia amend their legislation accordingly.

3.7 Both donors and recipients should have the option of giving informed consent to lower *or* higher family limits up to a maximum of 20 families.

3.8 Where imported sperm is utilised, patients should be made aware of the prospect of additional families in other jurisdictions, including, if available, information on the maximum family limit set by the overseas supplier.

3.9 Development of protocols concerning clinic approaches to voluntary communication and contact between donors and recipients.

3.10 Provision of accessible information in advance about clinic practices concerning early contact.

3.11 In each jurisdiction, the establishment of an independent organisation, state run or licensed (such as the Victorian Assisted Reproductive Treatment Authority) to manage a voluntary register and facilitate donor-recipient-offspring contact, including provision of associated counselling and support services.

CHAPTER 4: USING THE EMBRYO BEYOND THE RELATIONSHIP

Although by no means routine occurrences, death and separation are triggers for difficult decisions about embryos in which there is likely to be disagreement or an inability to secure consent for one outcome from all parties. Overall, we found there was moderate support for own use of embryos after **separation**, coloured by widespread acknowledgement of the complexity of raising a child in these circumstances. Use by a partner after separation was generally opposed, although it was more supported by women in lesbian relationships compared to heterosexual ones.

The response to the situation of **death** was markedly different, with an overwhelming desire for own use and majority support for a partner's use across all participants.

Separation

Less than half of the survey respondents in relationships at the time of commencing treatment recalled signing a consent form which dealt with what should happen to their embryos in the event of separation. Confusion was also prevalent among interviewees: several contradicted themselves in the course of the interview about what it was they had signed, and many did not have a copy of the forms in their possession.

There is widespread misunderstanding of rights in the context of relationship break down. The NHMRC Ethical Guidelines and state legislation require that partners mutually consent to the use of embryos *at the time of use.* Only a small number of survey respondents indicated they signed something to this effect. There appeared to be confusion among some clinics about the role of mutual consent after separation, with destruction treated as a default requirement.

In interviews, we explored in more detail why and in what circumstances women would want to use embryos following separation. A number of themes emerged: reluctance to use embryos and raise children without mutual consent; original consent to use as not necessarily dependent on remaining in a relationship; and the balancing of competing interests and needs of both parents and children on a case-by-case basis. Some of these themes were common to the scenarios of both separation and death, in particular the weighing of the welfare of a future child and one's own ability to solo parent. There were also considerations of opportunity and investment if these embryos represented the only, or most likely, chance of having children. Greater investment in the embryos by the woman who had undertaken IVF treatment was expressed variously as a more intense physical burden, a more acute emotional attachment, and as a simple practical ability to make use of stored embryos.

We found that interviewees in lesbian relationships approached the question of using stored embryos following separation differently. Generally, the view was that a partner should not 'stand in the way' of use post-separation.

Eleven study participants had separated from their partners while they had embryos still in storage (of whom only one was a man). Among the ten women, all had contemplated or pursued own use. Interviewees who had experienced separation expressed that their reproductive opportunities were more limited compared to those of former male partners and that their sense of loss at the destruction of embryos was greater. There was also a view that the former male partner should be able to opt in or out of parental status.

In addressing the issues of own use and partner use after separation, many participants were reluctant to support a 'black and white' rule, acknowledging that their own situations and others' may differ. This led a number of interviewees to suggest that, for separation in particular, there should be some flexibility to make case-by-case decisions. A forum for dispute resolution, such as mediation, was supported by a number of participants.

Death

Only half of the survey respondents in relationships at the time they commenced treatment recalled signing a consent form which dealt with what should happen to their embryos in the event of death. Few understood that the lack of advance written consent could actually prevent them or their partner from using their embryos posthumously. Of all the issues we address in the study, it was on the issue of own use after death of a partner that we found the most dramatic mismatch between law, consent forms and people's express wishes.

The situations of separation and death were seen as distinctly different by most participants. While separation was seen as involving conflicting positions and the need for agreement was stressed, death was viewed as an unexpected intervention in family formation, in which a conception attempt by the woman was simply seen as continuing on the agreed path. It was notable that there was no gender differential in responses about death – both female interviewees contemplating their own use and male interviewees contemplating their partner's use largely believed in *the woman's* right to use the embryos in the event of a partner's death.

These findings strongly indicate that IVF participants did not regard posthumous reproduction with stored embryos as 'highly controversial', but rather as a continuation of their family formation decision-making, in which the survivor was best placed to make the decision.

RECOMMENDATIONS

4.1 Every state and territory should provide an accessible external dispute resolution body and appeals process to address issues arising in use of gametes and embryos in ART.

4.2 Each external dispute resolution body should be empowered to adjudicate on interpretative issues with the relevant state legislation and also have power to adjudicate on discretionary aspects of each regime, such as exceptional circumstance claims.

4.3 In cases of use after separation, the former partner of the woman undertaking treatment should have the option of opting into legal parenthood.

4.4 While mutual consent to use should remain the guiding principle in assisted reproduction, external dispute resolution bodies should have the power to grant approval of use after separation in exceptional circumstances.

4.5 For women who are undertaking fertility preservation treatment, such as in the situation of IVF treatment in advance of cancer treatment, counselling and consent protocols should be developed to ensure that they are given the fullest range of options available. This should include being counselled

and given information separately from their partners and discussion of options such as use of donor sperm or undertaking egg freezing.

4.6 Although the death of a partner while embryos are still in storage is an unlikely event, posthumous use should not be regarded as an unusual or uncommon wish. Our finding that it is widely supported means that the current legal and ethical framework should be reconsidered.

4.7 The current position of state legislation and the NHMRC Ethical Guidelines (requiring express written consent to posthumous use by the deceased) should be reversed. That is, in the absence of express provision to the contrary in the *embryo directive form*, any decision on embryo disposition, including posthumous use, should rest with the surviving partner.

CHAPTER 5: EMBRYO STORAGE

Just over three quarters of survey respondents and interviewees had embryos in storage at the time of their participation in our study. Of these, just under half had completed their IVF treatment, one third described their treatment as ongoing, and the remainder were unsure of whether they would continue their treatment. Thus, up to half of the study participants were storing their embryos in anticipation of making a disposition decision rather than for their own future use.

Storage Limits

There are various limits across Australia concerning how long an embryo may be kept in storage. Generally this is 10 years, comprised of an initial five year period and a five year extension. This was misunderstood by many participants to be a five year limit. It was apparent that there was a high degree of confusion amongst survey respondents over not only the length of storage that was permitted but also the source of the limits. Only 41% of survey participants reported that they were aware of a time limit on how long they could store their embryos.

All survey respondents were asked what, if any, time limit on embryo storage they would prefer. Only a minority elected a time limit of less than 10 years, with most preferring no limit or one based on a patient's need or ability to use.

A number of interviewees remarked that their own and others' decisions about the timing and spacing of children may be at odds with statutory storage limits. For some, storage limits directly impacted upon their ability to use their embryos in their own reproductive treatment. Overwhelmingly, participants expressed the view that the decision to end storage was one that they needed to make for themselves, without external pressure or compulsion.

A number of interviewees expressed concern at the degree of control that clinics had over embryo use or disposition. Some interviewees thought of clinics as 'owning' or controlling

their embryos, with little understanding that there was the possibility of transferring them elsewhere. This issue was exacerbated by the fact that clinics were also the main source of patients' information about their options, including transferring embryos elsewhere.

Storage limits should be dramatically reconsidered, both in terms of the time periods set and in terms of their rationale. It is our strong view that there should be no coerced destruction. However, many people will want to discard embryos, even if this is emotionally painful. Having some time periods may help to set expectations about storage and can be useful to assist in making decisions and re-visiting consents. We therefore propose that storage rules be directed towards a different purpose: to assist in making decisions rather than as mandating destruction once a set time is reached. Storage *limits* should be reframed as storage *periods*; that is, as periods of time in which decisions can be made and revisited in a manner that respects individual family formation and completion decisions, and accommodates the fact that views about stored embryos are intensely personal and infinitely variable. The prospect of extension should always be available.

RECOMMENDATIONS

5.1 Standardisation of time period for warning that the storage period is approaching so that requests for extension or decisions about disposition are not rushed.

5.2 Standardisation and clarification of the costs of storage.

5.3 Provision of information to patients about options and processes to transfer embryos elsewhere.

5.4 Establishment of an external storage facility independent of IVF clinics, whether state held or licensed.

5.5 New South Wales law should be amended so that embryos created with donor gametes and own gametes are subject to the same storage rules: all storage periods should run from the date of embryo storage.

5.6 Victorian law should be amended to remove any requirement for consent of gamete donors to subsequent disposition decisions (including the decision to end or continue storage).

5.7 Storage periods should be set at an initial 10 years with an option to extend for another 10 years through simple request.

5.8 The ability to extend storage beyond 20 years should be available on request based on reasonable circumstances.

5.9 There should not be compelled destruction of embryos, including as a result of storage limits.

CHAPTER 6: EMBRYO DESTRUCTION

For many participants, embryo destruction was experienced or anticipated as a difficult and emotional event. This was greatly exacerbated when the destruction was not a result of their own choice or at a time of their own readiness. Compulsory destruction sometimes occurs when mandatory storage limits have been reached, but may also be triggered if a couple has separated and one partner no longer consents to any form of use or storage. Compelled destruction when participants were not sure they had completed their own family was experienced as a severe curtailing of their reproductive options. Equally, some reported that embryo destruction felt acceptable for them at the point of family completion because the embryos *had* completed their purpose. Others reflected that destruction is a natural and inevitable outcome for many embryos.

Just under one third of survey respondents indicated that they would like the option of participating in some way in the disposal of their embryos in the event that this occurred. Many participants expressed the view that giving people greater choices over, and a sense of involvement in, embryo disposal would make the process easier. Another prevalent theme was the desire for greater availability of counselling to offer options for disposal and support people through the process. We support the destruction of embryos where this is desired by patients. We recommend the provision of information to patients about disposal options in addition to information regarding the act itself. Patients should be given the widest range of choice about the process.

Removing Embryos from Clinic for Own Process

The most common destruction option preferred by both survey respondents and interviewees was a form of private ceremony or burial, often in their own garden. Self-disposal was seen to mitigate the distress of destruction. We found that there was confusion about whether self-disposal was permitted.

While counsellors in some clinics offer the option of removing embryos for self-disposal if patients make contact and appear distressed about embryo destruction, this option is not one that is routinely offered. Even in clinics allowing self-disposal, it is generally not mentioned in public clinic materials such as brochures or websites. It also appears that there are a number of clinics that oppose the option of removal and self-disposal and do not offer it at all. In our view this is a major omission.

Being Present at Clinic to Watch or Engage in Ceremony

Some participants expressly preferred to have the clinic dispose of their embryos. Views varied as to whether these participants felt that the clinic should provide a ceremony or whether it should be a private matter.

Compassionate/Non-viable Transfer

Non-viable or compassionate transfer is a process in which the embryos are transferred to the woman under conditions where they will not implant. While it does not appear to be generally offered in Australia, several participants raised the prospect of compassionate transfer. Some clinicians believe the process of non-viable transfer would be unethical – because it is a treatment in which pregnancy is not actually being pursued. Moreover, because IVF treatments in Australia attract Medicare funding, it could be considered improper if a rebate were claimed for an embryo transfer which was non-viable. Nonetheless, we believe this option deserves more detailed exploration, and could include consideration of the option of full private funding.

Notification and Information

A number of participants indicated that they wanted specific information about when and how embryos were disposed of. While for some the provision of information was important as it would enable them to mark the moment of destruction in their own way, others regarded the information as procedurally important rather than emotionally significant.

RECOMMENDATIONS

6.1 Development of protocols to ensure that patients are provided with information about the availability of different embryo destruction options.

6.2 Development of protocols to ensure that patients can decide the manner of destruction of their embryos including, but not limited to:
- Removal from the clinic
- Patient presence at the clinic during thawing
- A ceremony

6.3 Consideration of protocols for non-viable or 'compassionate' transfer. This may require consideration of funding and ethical requirements.

6.4 Provide patients with written confirmation of the date, time and manner of destruction.

CHAPTER 7: EMBRYO DONATION

Embryo donation for the reproductive use of others is not commonly practised in Australia. Only around 10 per cent of unused embryos are donated to others, a smaller proportion donated to research, and the rest are destroyed.

While we undertook this research to examine barriers to embryo donation, our findings support the view that donation is not for everyone. For many participants, donating unused embryos was just something that they could not bring themselves to do, regardless of what choices or options were available to them. Nearly all of the reasons expressed by these participants stemmed from their own sense of relatedness to the embryos, and between

the embryos and their existing children. Many of these reasons confirm previous findings of empirical research exploring embryo decision-making.

Thirteen participants in this study had previously donated their embryos to others for reproductive use. In addition to this, there were four participants who strongly wished to donate and had actively pursued this through their clinic, but were ultimately prevented from doing so, and a further five participants who expressed a strong desire to donate but had been told that they were unable to do so because of legal or ethical restrictions. Eight participants had been recipients of donated embryos in the course of their treatment. Taken together, interviews with embryo donors, would-be donors and recipients reported on experiences in five jurisdictions — the Australian Capital Territory, New South Wales, Victoria, South Australia, and Queensland — and across 11 clinical sites.

Why were Donors Willing and Able to Donate?

Donors, like non-donors, felt a deep sense of responsibility for their embryos, but nonetheless indicated a sense of certainty that donation to others was still the best, indeed only, outcome for them. It was striking that many of the same considerations that arose for those opposed to donation were also present for those who did donate. Specifically, the themes of embryos as potential siblings to existing children, the risk of uncaring or abusive recipients and the future prospect of the 'knock on the door' from offspring possibly resentful that they had been 'given away', spontaneously arose in the conversation of embryo donors. Yet, donors were able to overcome these concerns, or weighed them differently in the balance.

The Donation Process

It appears that clinical practice is divided between a traditional donation model (reflecting practice in gamete donation), whereby recipients choose donors, and something more akin to an adoption model, whereby donors choose among recipients. The unique aspects of embryo donation mean that neither model is necessarily suitable if applied without modification and flexibility. We conclude that an adoption model and adoption language should not be imposed upon embryo donation.

Directed Donation

When participant donors were asked by clinics to nominate recipient criteria, they always did. It was clear that age, marital status and sexual orientation were the key areas of distinction. Overwhelmingly, donors favoured married heterosexual recipients who were under 40 years of age.

Future Contact

Almost all donors were open to being contacted before the age of 18 by offspring if there was something that the offspring 'needed' from them, either in terms of health and medical information, or to make sense of the process from a psychological perspective. Many clinics passed letters between donors and recipients and this allowed a range of information

sharing, including photos of children and updates, which did not necessitate identification of the parties. Sometimes these exchanges did lead on to parties choosing to self-identify and make direct contact through phone or email, with varying levels of personal contact and involvement thereafter.

As with gamete recipients, there was some confusion over identity disclosure rules which require that donors must be identifiable once the child turns 16 or 18 (depending upon the jurisdiction). Some donors and recipients mistakenly believed that this meant that any contact before that time was therefore *prohibited*. Of those donors who understood that contact could be made earlier with mutual consent, all believed in leaving that initiative in the hands of the recipients.

Prevented from Donating

A number of participants wanted to donate their embryos for reproduction but were prevented from doing so by law or clinic policy. Some interviewees had actually commenced or proceeded quite some way through the process before their donation was denied.

Three participants were denied the ability to donate because they had genetically affected embryos. In two of these cases this had occurred even though recipients had been informed of the issue and still consented. Recollecting that for embryo donors who are prevented from donating the likeliest outcome is the destruction of their embryos, and for recipients who are prevented from receiving affected embryos a likely outcome is childlessness, risk and impact should be considered as relativities not as absolutes. The stringent clinical standards for the use of donated gametes should not be inflexibly applied to embryo donation.

Several participants had been informed that they were not able to donate their embryos because they had used donor sperm or eggs in their own IVF process. Many were upset that this option was denied to them. The NHMRC Ethical Guidelines in place since 2004 oppose the donation of embryos formed through donated gametes on the basis that it may confuse the identification of genetic parents. With the central donor identity disclosure registers now in three states (soon to be four) and donor family limits throughout Australia, the practical issue of tracing donor identification is now far less problematic. We propose a system to allow for donation of embryos formed with donated gametes in situations in which genetic information is clearly recorded and it is not in breach of the donor's consent or the relevant numerical limit of families born from each donor.

A number of participants reported that they were not offered the option of donating embryos when they commenced treatment. Others were surprised to be refused the option of donating when they requested it upon completing their family. It was notable that many donor interviewees reported that their major source of information about donation came from somewhere other than their clinic, including media reports and friends. The lack of

accessible information about embryo donation for the reproductive use of others was noted by many as a barrier.

RECOMMENDATIONS

7.1 The storage period for donated embryos should be reset at the point of donation.

7.2 No one donation model is workable for all. We propose the development of flexible models for donation, with options for varying degrees of openness or contact explored through counselling so that donors can elect the model which best suits their needs.

7.3 The provision of information to both recipients and donors about each other is highly desirable so that both sets of parties can be more informed and comfortable with the match.

7.4 The option of directed donation should be exercised with great care. While some donors desire choice of recipients, choices should be offered in a way that contextualises information and does not prompt unethical or unlawful discrimination.

7.5 Clinics facilitating donation should have an embryo donor co-ordinator.

7.6 On-going counselling should be available for embryo donors and recipients.

7.7 Voluntary registers (whether managed by clinics or statutory agencies) should be sufficiently flexible to enable both direct and indirect contact between donors and recipients post-donation.

7.8 Current standards regarding what is an acceptable risk of transmission of genetic conditions in gamete donation for IVF treatment should be considered, but not used to overrule the informed consent of patients to embryo donation.

7.9 The donation of affected embryos should be considered using a case-by-case approach. Clinics and regulators should defer to the informed consent of all participants and only interfere if there are very strong grounds. Any decision to refuse a donation should be appealable to the relevant independent dispute resolution body in that jurisdiction.

7.10 Donation of embryos formed with donor sperm or eggs should be permitted as long as all other requirements of legislation and the NHMRC Ethical Guidelines are complied with.

7.11 Embryo donation after separation should be possible with the mutual consent of the woman who underwent the treatment to create the embryos and her former partner.

7.12 Clarify the position in state legislation and the NHMRC Ethical Guidelines of consent requirements for partners who are not gamete providers. We

recommend that they be treated in the same way as partners who are gamete providers.

7.13 The establishment in every jurisdiction of an external organisation, whether state run or licensed, facilitating donation through matching of donors and recipients. This body could also perform functions in Recommendations 2.11, 3.11 and 5.4 (information giving, gamete donation, voluntary registers and embryo storage).

CHAPTER 8: CONCLUSION

Public debate has often characterised embryos in dichotomised terms, as either 'mere' cells or as entities of moral significance: 'life' or potential life. We do not believe that embryos should be granted a moral or legal significance in and of themselves as distinct entities. Rather, their value is relational. Embryos matter because of what they mean to those for whom they were generated. This meaning is intensely personal, and infinitely variable. We seek to develop a framework of law, policy and practice capable of honouring these diverse meanings as much as is possible.

Personal choice and autonomy in the area of reproduction is enormously important. State intervention in decisions about family formation should only occur in pursuit of legitimate objectives, justified by evidence, and intrude only to the extent that is absolutely necessary.

A major emphasis of our recommendations is a radical rethinking of the role of government in regulating ART. We propose a shift away from a focus on prohibition of certain practices and regulation of the activities of providers, in favour of developing more facilitative functions directed towards users. Some recommendations require amendments to legislation governing assisted reproduction in one or more states, or to the current NHMRC Ethical Guidelines. A number of recommendations are directed towards the creation of new agencies to fulfil responsibilities currently undertaken in an ad hoc way by clinics and to address needs that are largely unmet. Other recommendations are directed more to the level of clinic policy and practice and do not require legal change to effect.

National regulation or uniform laws in this field are extremely unlikely. We propose working within the existing system of state based legislation and national ethics guidance. This means we envisage each jurisdiction incorporating our recommendations within their pre-existing legislative framework and organisational bodies and adapting them according to context.

Overall, our recommendations are aimed at producing a more flexible and responsive environment; one which enables IVF participants to make their own decisions on the basis of informed consent.