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Consent agreements for cryopreserved embryos: the case for choice

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ABSTRACT

Under current UK law, an embryo cannot be transferred to a woman's uterus without the consent of both of its genetic parents, that is both of the people from whose gametes the embryo was created. This consent can be withdrawn at any time before the embryo transfer procedure. Withdrawal of consent by one genetic parent can result in the other genetic parent losing the opportunity to have their own genetic children. We argue that offering couples only one type of consent agreement, as happens at present, is too restrictive. An alternative form of agreement, in which one genetic parent agrees to forego the right to future withdrawal of consent, should be available alongside the current form of agreement. Giving couples such a choice will better enable them to store embryos under a consent agreement that is appropriate for their circumstances. Allowing such a choice, with robust procedures in place to ensure the validity of consent, is the best way to respect patient autonomy.

Human embryos created by in-vitro fertilisation (IVF) can be cryopreserved in order to have the opportunity of using them in future fertility treatment. The individual circumstances of people choosing to have embryos cryopreserved vary considerably. In routine IVF treatment, it is normal for several embryos to be created, while in the UK the number of embryos transferred to a woman at one time usually does not exceed two. IVF thus commonly produces spare embryos that can be stored for use in subsequent treatment cycles. However, it is also possible for embryos to be created solely for future use, with no intention to produce an immediate pregnancy. For example, if a woman is to undergo medical treatment that risks damaging her fertility, she and her partner may choose to use IVF specifically to create embryos with a view to their future use, after the medical treatment is completed. Cryopreservation of embryos has historically been more successful than cryopreservation of unfertilised oocytes,[1] and despite recent progress in oocyte storage techniques[2] this is generally believed to remain the case. In comparison, if a man is to undergo treatment that risks damaging his fertility, samples of his sperm can generally be stored for future use in a process that is effective, usually non-invasive and inexpensive. A man with cryopreserved sperm and a fertile female partner will generally have a higher chance of achieving genetic parenthood than a woman with either cryopreserved embryos or cryopreserved oocytes and a fertile male partner.

Couples who store embryos may later separate, leading to possible disagreements about the use of their embryos. Since 1990, UK law has stipulated that embryos cannot be stored or transferred without the ongoing consent of both genetic parents, and consent can be withdrawn any time before the embryos are to be used.[3] This rule applies universally, regardless of people's circumstances or wishes at the time the embryos are created. The law was tested by the case of Natallie Evans.[4 5] In 2001, Evans and her then fiancé, Howard Johnston, had embryos created from their gametes and then cryopreserved, before she underwent urgent cancer treatment that included the removal of her ovaries. Evans' relationship with Johnston subsequently ended and he withdrew consent for the continued storage of the embryos. Evans opposed the destruction of the embryos and embarked on a legal battle that ended in the Grand Chamber of the European Court of Human Rights, where she lost her case and, thereby, her sole remaining chance of having her own genetic children.[6]

Evans' predicament sparked a lively debate about consent rules,[7–9] particularly in view of the opportunity for change afforded by the lengthy review process that was eventually to lead to the Human Fertilisation and Embryology Act (2008). From October 2009, if one genetic parent withdraws consent to continued storage of embryos, a 12-month cooling-off period must be observed. During this period, embryos cannot be destroyed unless both parties consent.[10] This provision both allows time for counselling and discussion of the changed consent (if the parties will engage), and removes the technical illegality of maintaining embryos in storage when it is known that one party has withdrawn consent, during the time that the other party is being contacted and notified by the fertility clinic. It does not, however, end the vulnerability of a woman in Evans' position to her partner withdrawing consent. Even if her partner wished to commit to a form of legal agreement that precludes his subsequent withdrawal of consent, the law does not allow him to do this. Evans had argued that this restriction of the kinds of commitments that individuals might make in these circumstances was a breach of their human rights. If a man wished to reassure a woman that her embryos would always be available for her, she suggested, then it was perverse to prevent him from doing so because of the 'primacy of consent'. This argument did not convince the courts, which determined that this was an area in which it was for parliament to legislate and in which a generous margin of appreciation was appropriate.[6 11 12] In this paper, we accept that this is properly a matter for parliament and we set out the case for an alternative form of consent.

ARGUMENTS FOR AND AGAINST AN ALTERNATIVE FORM OF CONSENT

Suppose that the UK were to adopt an alternative consent law, specifying that once fertilisation has occurred, the genetic mother has sole control over the use of the embryos. This would allow a woman in Evans' situation to maintain her future potential to be a genetic mother, as far as is medically possible, without being dependent on the continuation of the relationship with her partner. There is, however, an unavoidable trade-off between different forms of irreversibility: although allowing a man the option of withdrawing consent to the transfer of embryos by necessity involves allowing a woman in Natallie Evans' position to lose her chance of becoming a genetic mother, stating that a man cannot withdraw consent means that he is irreversibly committed to the possibility of genetic fatherhood from the moment of fertilisation. These considerations have been aired in the literature discussing the Evans case.[4 5 7–9]

It seems to us that there are reasonable arguments on both sides, with no overwhelming argument in favour of one type of agreement that should lead us comprehensively to reject the other in all circumstances. It could be argued that the type of agreement in which either partner can withdraw consent before embryo transfer is relatively more appealing when the embryos are created as part of routine IVF treatment and both partners have future fertility prospects, whereas the type of agreement in which one partner cannot withdraw consent after fertilisation is relatively more appealing in cases in which the embryos represent the other partner's only remaining prospect of genetic parenthood. Not all treatment situations, however, fall neatly into one or other category. For example, if a woman is towards the upper age limit for producing viable eggs (typically in her late 30s or early 40s), then discarding embryos produced when she was younger will result in her prospects of future genetic parenthood being considerably reduced.

When couples have a complex range of medical and social circumstances, we believe that the most important consideration of all in determining the appropriate form of consent agreement for a given couple is the preference of the two individuals concerned.

OUR PROPOSAL

We propose that, when embryos are to be created and there is a prospect of cryopreservation of some or all of the embryos, couples be offered a choice of agreement about their future use. One option would be that consent can be withdrawn by either genetic parent at any time up to embryo transfer, exactly as at present. We propose a second, additional option in which one genetic parent can agree to cede control of the embryos to the other. Under this option, it would be up to the genetic parent who retained control to determine in future whether any of the embryos are transferred, subject to the prevailing regulations for treatment; the other genetic parent would not have a veto over their use. Couples would agree, before fertilisation, whether they choose to share control over the future use of embryos, or alternatively, one of them will have sole control. In the event of the genetic father having sole control, he would be able to seek a surrogate mother to carry the embryos to term. However, it is likely that in most agreements in which one parent has sole control this would be the genetic mother, as she would commonly have more limited future fertility options than her partner (with Natallie Evans' situation representing an extreme example of this). The greater invasiveness of assisted conception methods for women, in comparison with men, may also have an influence.[9]

There are precedents for allowing people a choice of the type of agreement in cooperative matters: under English law, for example, two adults buying a property together can choose whether to do so as joint tenants or as tenants in common. Our proposal does not remove any options currently open to people wishing to store embryos for future use. It simply creates an extra option that they may choose should they both agree to it.

Whereas an agreement in which one genetic parent has sole control over the future transfer of embryos might seem to operate to that genetic parent's advantage, in some situations it may also be to the other genetic parent's benefit to be able to sign away his or her legal right later to withdraw consent for the future use of embryos. Suppose a woman facing the imminent loss of her fertility would like to have embryos created with her partner, but (in the light of Evans' misfortune) is unwilling to do so if he retains the right to withdraw consent. Then it may be in her partner's interest to sign an agreement in which he cedes control of the embryos to her. The scope for a person to benefit from making a commitment can be shown in formal rational choice models of strategic interactions.[13]

On the basis of the above considerations, we suggest that there is a strong case in favour of allowing couples a choice over the future control of stored embryos. We see two possible objections on fundamental grounds of principle that could be made against it and now consider each of these in turn. We also assess the possible practical considerations arising from our proposal.

POSSIBLE OBJECTIONS

The first objection concerns harm to a third party—either the child itself or society as a whole.[14] It is likely that our proposal would result in some instances in which a child is born when its genetic parents are no longer together, when the child would not otherwise have been born. The child welfare objection to our proposal would then be that, given these circumstances of conception, it would be better for the child not to have been born. But whether or not one believes that a child's circumstances are better if its genetic parents are together, it is hardly convincing to claim that a child whose genetic parents separate before his or her birth has a life not worth living.

Furthermore, research indicates that children born to single mothers who conceive by donor insemination perform well against socioeconomic and educational indicators.[15 16] Similarly, children born from cryopreserved embryos are likely to be born into households whose average socioeconomic position is higher than for births in society as a whole. They would, by definition, be planned pregnancies and wanted babies, and would be likely to enjoy high levels of welfare and be unlikely to make a disproportionately negative contribution to society.

In short, then, the available empirical evidence does not support the objection that such children would experience poor welfare or would cause harm to society at large. A further response might also be found in reference to current UK law and accepted practice in fertility treatment. The Human Fertilisation and Embryology Act (2008) removed the requirement that clinicians must consider the 'need for a father' for children created by fertility treatment, replacing it with consideration of their need for 'supportive parenting'. Furthermore, many fertility clinics in the UK routinely and legally treat single women. It would be incongruous to ban agreements in which one genetic parent cedes control over future embryo transfer on the grounds that resulting children might be born to a parent who has separated from her partner, while allowing the

deliberate assisted conception of children who are expected at the time of fertilisation to be born into single parent families.

The second objection to allowing a person to cede control over embryos to his or her partner is that it is wrong to allow someone to sign away his or her rights to future control over such an intimate choice. The thought here would be that there is something so deeply significant and personal about reproductive choices that the law should preserve individuals' rights to change their minds, even if so doing overrides their current wishes. In other words, it would be argued that in this situation it is so important to preserve a person's future autonomy that they should be denied the right to make a choice that limits their future options. The extent, however, to which the law should constrain a person's choices for their own good is a matter of debate. There are various views about exactly when such restrictions can be justified;[17 18] however, it is generally held that such restrictions are more difficult to justify in circumstances in which a person is acting voluntarily and knowledgeably. Furthermore, as we have noted already, the mandatory preservation of one genetic parent's right to veto the future use of embryos is not costless; on the contrary, it results in an enforced vulnerability of the other genetic parent to the possible future loss of the option to use the embryos in fertility treatment.

We believe that any concerns about people acting voluntarily and knowledgeably would be better addressed by strengthening consent procedures than by simply not allowing choice. To argue that an agreement in which a person voluntarily cedes control over the future transfer of embryos can lead to that person being forced to become a genetic parent against his or her will is not valid if he or she freely gave consent, having been well informed of the implications of the agreement. We note also that in sexual intercourse men regularly lose control of their genetic material at the moment of ejaculation and, although there may be some sympathy for the idea that a man has moral interests in a pregnancy, men have not been afforded any legal rights (either of veto or even consultation) in abortion decisions.

Ultimately, any decision about whether the law should fail to allow an agreement with the aim of protecting an individual's best interests or their future autonomy is as much a matter of values as of empirical facts. We would tend to agree with Dworkin[19] that, if it is proposed that the law should deny people choices for their own good, the onus must be on showing why the choice should not be allowed. We see no reasonable basis for forbidding a genetic parent of embryos from signing away the future right to withdraw consent over their use if he or she does this freely and knowledgeably.

PRACTICALITIES

If a choice of agreements was introduced, one practical concern might be that this will introduce additional work for fertility clinics. However, clinics are already required to demonstrate rigorous procedures for providing good quality information and recording patients' decisions. Indeed, the UK Human Fertilisation and Embryology Authority provides forms specifically for the purpose of clearly documenting patient consent decisions. To enhance the consenting process, individual advice to each of the partners may be beneficial, in contrast to the focus on 'couple-centred' treatment that prevailed before the 2008 Act. The revised Human Fertilisation and Embryology Authority Code of Practice (8th edition), applicable from 1 October 2009, places more emphasis on individuals than couples. Another possible concern is that the consent process might take longer than at present. However, it is generally regarded as good practice to allow couples as much time as they need to reach a comfortable conclusion. They would then be in a strong position to decide between themselves their preferred arrangements for the future use or disposal of embryos arising from their genetic material.

It would of course be possible to allow a greater range of possible agreements. Increasing the number of types of agreement recognised in law increases the chance that a couple will find an agreement ideally tailored to their needs, but also increases the complexity of the decision and the risk of litigation arising from difficulties in the precise interpretation of each type of agreement. We believe that the limited increase in choice that we are advocating will result in overall benefits that far exceed the costs. Whether or not increasing people's options beyond this would be beneficial overall is less clear.

A second practical consideration concerns time limits over which an agreement about the use of embryos would apply. It would be possible to stipulate that in an agreement in which one partner has sole control, there is no time limit over the duration of sole control, other than any statutory limits for embryo storage. Alternatively, there could be a specific time limit within which the non-controlling partner would be able to use the embryos, but if he or she wished to use them outside this limit, a new agreement or renewal of the original agreement would be required from the non-controlling partner.

CONSIDERATIONS RELATING TO DONOR GAMETES

We have so far considered embryos created by two genetic parents who are partners. When a gamete donor is used in the UK, by law the donor has the same right to withdraw consent before the use of the gametes, or embryos resulting from them, as does a partner.[10] In our opinion, a distinction can be made, however, between two different categories of gamete donors. The first category is those who are anonymous to the recipients at the time of treatment (children created by fertility treatment in the UK from April 2005 using donated gametes have a statutory right to be given identifying information about the donor when they reach the age of 18 years). Withdrawal of consent by such anonymous sperm donors has occurred in the UK, with serious consequences for patients, including the destruction of embryos.[20] These donors have neither financial obligations nor any social connection to the recipients or resulting children, yet the destruction of embryos may have a devastating impact on the recipients. Moreover, whereas people withdrawing consent because of the breakdown of their own relationships can at least identify a cause within their own lives, patients experiencing an anonymous donor's withdrawal of consent are victims of what is to them an arbitrary event over which they have no control. Given all these considerations, we believe that there may be a case for imposing limits on the circumstances under which anonymous gamete donors should be allowed to withdraw consent; however, this proposition needs a more detailed examination than can be presented in the present article.

The other category of gamete donors is those who are known to the recipients at the time of donation. In many such cases, the donor is a relative or close friend. This leads to the possibility of a material change in the donor's social relationship to a recipient after embryos have been created but before they have been transferred in an IVF treatment cycle. The arguments for different forms of consent agreement for cryopreserved embryos are therefore similar to those previously considered for couples using their own gametes, and there is again a case for offering a choice of consent agreements. Allowing joint control between the donor and the other genetic parent is one logical option;

another is allowing the donor to cede control to the other genetic parent at the time embryos are created. However, because there are potentially three interested parties—the donor, the other genetic parent and the genetic parent's partner—an additional option could be to allow the donor to transfer his or her control to the other genetic parent's partner.

Further research into the incidence of and reasons for withdrawal of consent by gamete donors,[20] and its implications for recipients, siblings, half-siblings, donors and their families would be useful. Nevertheless, we believe that there is a case for consent rules for gamete donors to be examined as part of a general review of consent laws.

CONCLUSION

The present legal framework in the UK allows only a single type of consent agreement for the future use of cryopreserved embryos. We propose allowing people a choice of agreement. We have discussed the advantages of our proposal and possible arguments against it, and concluded that our proposal better recognises and protects individual autonomy than the current legal framework. We also suggest that the current system particularly disadvantages women, whose biological investment in reproduction is more substantial than that of men, and who are more vulnerable to the possible loss of future genetic parenthood as a result of withdrawal of consent by another party. Whereas both men and women could choose an agreement that offered the decision about the use of the embryos to their partner, and the proposal itself is gender neutral, it is likely that the introduction of a choice of consent agreement would particularly benefit women.

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