II. The cryopreservation of human embryos

ESHRE Task Force on Ethics and Law

The general ethical considerations concerning the cryopreservation and ultimate fate of human embryos produced during IVF treatments are discussed. The discussion is centred around two general questions: who should decide and what should be done with the embryos? Special attention is given to the necessity of consent of both intended parents and to the practical solutions in case of disagreement. This problem is linked to the question of the validity and revocability of the prior agreement or contract signed by the intended parents concerning the ultimate fate of these embryos.

Key words: cryopreservation/ESHRE/ethics/human embryos

Introduction

The occurrence of supernumerary human embryos is an inevitable consequence of routine IVF. For safety reasons only a limited number of embryos can be replaced during the fresh cycle. In almost all centres, the remaining embryos are cryopreserved for later use. Two general questions are raised by this practice:

(i) who should decide what happens with these embryos;
(ii) what should be done with these embryos?

The Ethics Task Force presents the following ethical considerations as an answer to these questions.

1. A written agreement before initiation of treatment or before freezing between the intended parents and the centre concerning the fate of the supernumerary cryopreserved embryos is mandatory. This position is founded on the basic principle that patients have the right to decide the fate of their genetic material and, by extension, the right to decide about their reproduction.

2. There should be a written agreement, in order:
   - to confront the patients and the centre with their responsibility for the disposition of the embryos;
   - to detect and prevent, as far as possible, conflicts regarding the fate of the cryopreserved supernumary embryos (e.g. what will happen in case of death, or disagreement between the partners);
   - to state clearly all possible future dispositions regarding the embryos.

3. The options among which the intended parents may choose are:
   - replacement within the parental project;
   - authorization for research;
   - authorization for donation to others;
   - donation to the surviving partner for replacement;
   - disposal.

4. The extent of the cryopreservation period.

   The period during which embryos can be cryopreserved should be clearly limited. The Ethics Task Force equally accepts two options: a standard period of 5 years that can be renewed on the patients’ demand for one term (a total of 10 years) or a standard period of 3 years that can be renewed twice (a total of 9 years). The latter position decreases the possibility of losing contact with the patients and increases the validity of the prior agreements. The maximum storage period can be extended beyond the periods mentioned above if there are medical reasons for storing the embryos. Embryos should only remain stored up to the age at which the establishment of pregnancy is medically advisable.

5. The decision about the disposal of the embryos is attributed solely to the intended parents. If a gamete donor is involved, the donor relinquishes all rights and duties from the moment that the embryo is created. When embryos are donated, all rights and obligations end at the moment of transfer to the recipient woman. Attributing ‘extended’ rights to the donors would run counter to the whole concept that frames the meaning of the donation.

6. A person’s position regarding the moral status of the disposition of cryopreserved embryos is to a large extent based on the view he or she adopts on the autonomy of the patient. One expression of autonomy is the ability to bind oneself in the future. Directives by means of which the couple stipulates what should be done with their embryos at the end of the storage period are binding, just like a contract or a promise. The other expression of a person’s autonomy is the ability to change one’s mind on the basis of new experiences and new information. A person should always be able to alter his or her decision when intervening events change the circumstances in such a way that the originally signed contract is not relevant.

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to the new situation. The view on autonomy determines whether the advance directives for the disposition of embryos are considered enforceable in some situations.

6.1. Concerning the application of the prior agreements or contracts at the end of the period of preservation, two general positions can be adopted:

- the terms of agreement apply when the period of preservation expires, unless the intended parents take the initiative themselves to modify the terms;
- the terms of agreement apply only after the centre has made a reasonable effort to contact the intended parents to confirm their initial decision.

The first position states that the directives of the patients are valid as long as they are not revoked. If the patients do not take steps to review their initial instructions, there is no reason to doubt their moral validity. The second position accepts that people have to be encouraged to make a decision and to impart their decision to the clinic. If the patient is competent at the end of the storage period, the decision taken at that moment overrides the one made at the start of the treatment or the freezing.

The second position has far-reaching practical implications. The experience of the fertility centres shows that a large number of patients cannot be reached due to a change of address or do not answer the requests by the clinic to declare the disposition of their embryos. Both the clinic and the intended parents have an obligation of care towards the cryopreserved embryos. Some members think that a registered letter to the last address communicated by the parents fulfills the obligation of the clinic and expresses a reasonable effort on its part. This letter informs the parents that the storage period is about to end and urges them to confirm their previous directive or to indicate an alternative. The obligation of the parents is fulfilled by keeping in contact with the clinic and by making a decision about the disposition of their embryos. If no confirmation from the couple can be obtained by this procedure, the originally stated disposition will be carried out.

6.2. In case of disagreement between the intended parents (e.g. separation, divorce) about the disposition, four options can be considered:

- the initial agreement should be implemented;
- the court should decide (in those countries where there are no legally enforceable provisions);
- the embryos are kept in storage until the partners reach a new agreement;
- the embryos should be disposed of.

The view on the validity and enforceability of the prior agreements determines the option one favours. According to some members, the prior agreement can be overridden by other ethical considerations in the case of later disagreement between the partners. The first consideration is the conviction that parenthood should never be imposed on a person against his or her will. This possibility is excluded when the embryos are destroyed or used for research when no joint decision can be reached. Consequently, when a request for procreation by one partner is weighted, the terms of agreement apply only after the centre has made a reasonable effort to contact the intended parents to confirm their initial decision.

Other members think that the original advance directive should be enforced in all circumstances. This is a foreseeable consequence of the voluntary choice that was made when the agreement was reached.

7. The disposition of the embryos after the death of one of the partners is a particularly delicate issue. Regarding the issue of post-mortem reproduction, two sources of disagreement are present: the position on whether or not such treatment can be part of a parental project and the decisional authority of a person over his/her genetic material after his or her death. Since the Ethics Task Force did not wish to address the issue of surrogacy, the following options only concern the situation when the male partner dies:

- the surviving intended parent decides among the standard options of replacement, donation to others, donation for research or disposal;
- the surviving intended parent can only choose replacement with mandatory prior written consent of the deceased partner. If the deceased partner did not consent to replacement, he could indicate that the embryos may be used for research or that they should be disposed of;
- no replacement is possible as the parental project ends with the death of a partner.

The members of the Task Force are reserved regarding the possibility of post-mortem reproduction. Considering the decisional authority of the person over his or her gametes and taking into consideration the principle that parenthood should not be imposed on a person against his will, the written and explicit consent by the deceased should be available for replacement by his partner as well as for donation to others.