The fate of cryopreserved human embryos approaching their legal limit of storage within a West Australian in-vitro fertilization clinic

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Human embryos can only be stored in the first instance for 3 years in Western Australia, according to the West Australian Reproductive Technology Act. Thereafter, an application must be made to the local regulatory body, the Reproductive Technology Council, for an extension. Of the 650 batches of embryos frozen between 8 April 1993 and 31 October 1995, 170 (26.2%) batches were still in storage after 2.5 years. A reminding letter was sent at this time to the couples to whom the embryos belonged, i.e. 6 months before the expiry of the initial storage period, asking for clarification of what was to be done with the embryos. A large proportion of patients (64.7%) chose to either extend the storage period or thaw and transfer the embryos. Curiously, more batches of embryos were discarded (18.8%) than donated to other couples (5.9%). Contact with the patients was lost in a small but significant proportion of cases; more of these had been unsuccessful in their treatment (20.4%) than had achieved a pregnancy (4.3%).

Key words: cryopreservation/embryo donation/storage

Introduction

The storage of cryopreserved human embryos has become a routine procedure in many laboratories, resulting in a significant increase in the cumulative pregnancy rate per oocyte collection (Horne et al., 1997). However, the introduction of laws around the world governing the practice of in-vitro fertilization (IVF) and allied techniques has highlighted a new dimension to cryopreservation that is attracting increasing attention: what is to become of the embryos once they are in storage?

The fate of embryos in storage must now be addressed in countries that have maximum storage times built into their legislation, after which extensions have to be applied for. For example, the UK requires an extension to be granted after 5 years of storage (Human Fertilisation and Embryology Act, 1990) and Western Australia has an initial storage period of 3 years [Human Reproductive Technology Act, 1991; Human Reproductive Technology (Amendment) Act, 1996]. The aim of the present study was to identify the fate of embryos in storage within a routine IVF clinic in Western Australia, and to gauge the likelihood of patients donating the embryos to others as the legal limit of storage approached.

Materials and methods

A total of 650 patients in the routine IVF programme at Concept Fertility Centre had embryos frozen during the period 8 April 1993 and 31 October 1995 inclusive. Of these, 170 (26.2%) still had one or more embryos in storage 2.5 years later. All 170 patients were then sent a letter informing them that the state law, the Human Reproductive Technology Act (1991), only allowed embryos to be stored for 3 years in the first instance, and that an application had to be made to the statutory regulatory body (the Reproductive Technology Council) for an extension to be granted. Patients were therefore asked to make a decision on the fate of their embryos and consider (i) using the embryos themselves before the 3 year storage limit expired, (ii) applying for an extension to the allowed storage time, (iii) allowing the embryos to succumb, or (iv) donation of the embryos to another patient. The fate of the embryos over the next 6 months to the 3 year limit was then recorded.

Differences between groups were analysed using $\chi^2$ and considered significant if $P < 0.05$.

Results

The eventual fate of the stored embryos at the end of the statutory 3 year storage period is given in Table I. The results are expressed according to whether a pregnancy occurred or not during the storage period, this being either by IVF or the use of frozen embryos. In essence, 64.7% of patients applied for an extension or used the embryos themselves in the 6 months between the reminder and the expiry date. Only 5.9% patients overall opted to donate embryos to others and the decision was not influenced by pregnancy. This compared with 18.8% of patients who chose to discard their embryos. A total of 9.4% of patients could not be contacted. Interestingly, the proportion of these patients without a pregnancy that lost contact (20.4%) was significantly higher ($P < 0.001$) than for those that did achieve a pregnancy (4.3%).

Table I. The fate of embryos remaining in storage after 3 years for 170 couples, according to whether a pregnancy resulted or not during the period of storage

<table>
<thead>
<tr>
<th>Option taken</th>
<th>Pregnancy during storage period</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Donate</td>
<td>3 (5.6)</td>
<td>7 (6.0)</td>
</tr>
<tr>
<td>Discard</td>
<td>6 (11.1)</td>
<td>26 (22.5)</td>
</tr>
<tr>
<td>Used after reminder</td>
<td>4 (7.4)</td>
<td>10 (8.6)</td>
</tr>
<tr>
<td>Extension granted</td>
<td>28 (51.9)</td>
<td>68 (58.6)</td>
</tr>
<tr>
<td>Exported</td>
<td>2 (3.6)</td>
<td>0 (–)</td>
</tr>
<tr>
<td>No contact</td>
<td>11 (20.4)$^a$</td>
<td>5 (4.3)$^a$</td>
</tr>
<tr>
<td>Total</td>
<td>54 (100)</td>
<td>116 (100)</td>
</tr>
</tbody>
</table>

$^aP < 0.001$.

Values in parentheses are percentages.
During the study period, one husband died and his embryos were discarded, as they cannot be used posthumously according to our local legislation. Four couples separated during this time. Of these, both partners of one couple wished to discard the embryos. The male partners of two couples could not be traced and so the clinic applied for a storage extension until the men could be found. The final couple could not agree whether to donate or discard so they finally discarded the embryos as donation required the consent of both.

Discussion
Several studies have been conducted to determine the fate of cryopreserved embryos. Data was pooled from four clinics in France (Mandelbaum et al., 1998) and it was found that, after a 10 year storage period, only one couple had elected to continue storage of the embryos. The majority (86%) of embryos had been thawed for transfer, but 4.7% of embryos had been destroyed and 3.4% had been donated. A further 5.4% of embryos had not had their fate nominated and remained awaiting a decision. A general survey in France (Federation des BLEFCO, 1996) of actual practice revealed that the vast majority of embryos were transferred to the parental couple but of those remaining, 6% were discarded and only 0.2% were donated to another couple. This pattern was seen in the present study, although it is in contrast with the opinions of a group of Belgian patients that had not yet been treated by IVF (Laruelle and Englert, 1995). When the patients were asked what they thought they would do with embryos that had not been used for their own treatment, 51% of patients said they found donation acceptable whereas 30% said they wished the embryos to be discarded. Of course intentions do not always equate to deeds, and the study by Lornage et al. (1995) illustrated how opinions on the preferred fate of embryos can change (Lornage et al., 1995). A survey was conducted on people that had had embryos in storage for more than 1 year, and it was found that anonymous donation to another couple was chosen initially in preference to destroying the surplus embryos (Lornage et al., 1995). However, the trend was seen to change with time and several people who had chosen donation initially then opted to discard the embryos at a later date. The current practice of our unit in requesting patients to nominate their wishes regarding the fate of the embryos at regular intervals, as prompted by the local legislation, would therefore seem to offer a reasonable opportunity for patients to amend their consent if they choose.

The introduction of legislation regulating the storage time of human embryos can be fraught with difficulties, whereby embryos frozen before the introduction of the legislation are then subject to a new set of rules. This was illustrated in the UK where a large number of embryos had to be discarded because extensions could not be granted due to the clinics losing contact with the patients or not receiving the appropriate indications that an extension was required (Edwards and Beard, 1997). This situation could have been avoided if the correct consent had been in place at the time of the cryopreservation (Dickey and Krentel, 1996), and hopefully such occurrences will become rare in future. In some countries, e.g. France (Bergues and Sele, 1997), the situation is avoided as the law distinguishes between the embryos frozen before the implementation of the law and those frozen afterwards. Here in Western Australia, the initial disposal of embryos due to the patients losing contact with the clinic was circumvented by the regulatory authority, the Reproductive Technology Council, awarding extensions to give the clinics more time to trace the patients. However, there will come a time when the extensions will no longer be awarded in the absence of an application from the patients and these embryos will then have to be discarded as it is an offence for the laboratory to keep them without authorization. A similar fate awaits the embryos in the present study where contact was lost but an interim extension awarded at the request of the clinic.

In summary, the present study has shown that the majority of patients do choose to keep the embryos for their own use. However, those patients not wanting to keep or use their embryos themselves are not a major source of donated embryos as most of them prefer to discard the embryos.

References
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