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## **Abstract**

**BACKGROUND.** The moral status of the human embryo is particularly controversial in the United States, where one debate has centered on embryos created in excess at in vitro fertilization (IVF) clinics. Little has been known about the disposal of these embryos.

**METHODS.** We mailed anonymous, self-administered questionnaires to directors of 341 American IVF clinics.

**RESULTS.** 217 of 341 clinics (64 percent) responded. Nearly all (97 percent) were willing to create and cryopreserve extra embryos. Fewer, but still a majority (59 percent), were explicitly willing to avoid creating extras. When embryos did remain in excess, clinics offered various options: continual cryopreservation for a charge (96 percent) or for no charge (4 percent), donation for reproductive use by other couples (76 percent), disposal prior to (60 percent) or following (54 percent) cryopreservation, and donation for research (60 percent) or embryologist training (19 percent). Qualifications varied widely among those personnel responsible for securing couples' consent for disposal and for conducting disposal itself. Some clinics performed a religious or quasi-religious disposal ceremony. Some clinics required a couple's participation in disposal; some allowed but did not require it; some others discouraged or disallowed it.

**CONCLUSIONS.** The disposal of human embryos created in excess at American IVF clinics varies in ways suggesting both moral sensitivity and ethical divergence.

## **Disciplines**

Bioethics and Medical Ethics

## **Comments**

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## ABSTRACT

**BACKGROUND.** The moral status of the human embryo is particularly controversial in the United States, where one debate has centered on embryos created in excess at *in vitro* fertilization (IVF) clinics. Little has been known about the disposal of these embryos.

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**RESULTS.** 217 of 341 clinics (64 percent) responded. Nearly all (97 percent) were willing to create and cryopreserve extra embryos. Fewer, but still a majority (59 percent), were explicitly willing to avoid creating extras. When embryos did remain in excess, clinics offered various options: continual cryopreservation for a charge (96 percent) or for no charge (4 percent), donation for reproductive use by other couples (76 percent), disposal prior to (60 percent) or following (54 percent) cryopreservation, and donation for research (60 percent) or embryologist training (19 percent). Qualifications varied widely among those personnel responsible for securing couples' consent for disposal and for conducting disposal itself. Some clinics performed a religious or quasi-religious disposal ceremony. Some clinics required a couple's participation in disposal; some allowed but did not require it; some others discouraged or disallowed it.

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The moral status of the human embryo has occasioned all manner of debate worldwide in recent years, as interest in stem-cell research and mammalian cloning has grown.<sup>1, 2, 3, 4</sup> Contributing contentiously to debate has been the large-scale storage of human embryos and the disposal of those not destined for development. As many as 400,000 exist

frozen in storage in the United States, with hundreds of thousands more in other nations.<sup>5, 6, 7</sup>

Consensus on policies for the creation, use, and disposal of human embryos is seemingly impossible. Depending on culture, religion, or location, human embryos are regarded as everything from a mere cluster of cells to an actual human being, and they are treated very

**Table 1. Characteristics of 217 responding IVF clinics and their directors.**

Clinic director female, number (percent)	28 (13)
Years directing clinic, mean $\pm$ SD	10 $\pm$ 6
Reproductive cycles assisted per year, mean $\pm$ SD	277 $\pm$ 364
ASRM membership current, number (percent)	215 (99)

SD = standard deviation.

ASRM = American Society for Reproductive Medicine.

differently. Some believe that couples, or the individuals for whose use embryos may be created, always ought to have the option of disposing of embryos they do not wish to use themselves or do not wish to be used by others for procreative, therapeutic, or research purposes.<sup>8</sup> Others believe that every created human embryo must be implanted in a woman's uterus in order to avoid the moral problems of embryo destruction.<sup>9</sup> Some nations permit the creation of human embryos for the sole purpose of using them for research.<sup>10</sup> In the United Kingdom, legislation has been enacted permitting the destruction of unclaimed embryos—after five years.<sup>11</sup>

Numerous options exist for the management of spare, extra, or unwanted embryos. Embryos can be maintained in a frozen state indefinitely. They can be made available for medical research.<sup>12</sup> They can be given to those in need of donor sperm and egg to reproduce with assisted reproductive technologies (ART). Indeed, in the United States, the Federal government has made funding available to encourage such practice.<sup>10, 13</sup> Finally, the embryos could be destroyed, using various methods.

Little has been known about these practices generally, as previous investigations have focused on single clinics.<sup>14, 15</sup> We herein report the first systematic study of excess-embryo practices employed by *in vitro* fertilization (IVF) clinics throughout the United States.

## Methods

We developed a survey instrument in conjunction with a six-member expert panel, including two infertility specialists, a gynecologist, two bioethicists, and one clinical psychologist who worked in an IVF clinic. Most of the instrument's questions were close-ended to minimize respondent burden. For the sake of simplicity, we referred to embryos as belonging to couples, although we recognized that embryos might sometimes

have been created for individuals; we observe the same convention in this report.

With approval from the University of Pennsylvania Institutional Review Board (IRB), we approached the directors of the 369 clinics associated with the Society for Assisted Reproductive Technology (SART), which represented over 95 percent of all ART clinics in the United States immediately preceding the study period.<sup>16</sup>

Questionnaires were sent initially to 12 directors selected randomly for participation in a pilot study. These 12 were asked to comment on the clarity and relevance of the instrument's questions. Comments were then used to refine the instrument. In June 2002, the questionnaire in final form was mailed to the remaining 357 directors; it was undeliverable to 16. Thus, 341 clinics were eligible for study.

The questionnaire inquired about the responding clinic director's sex, title, degrees, and years in a leadership role; the number of reproductive cycles assisted per year; whether extra embryos were created; whether they were cryopreserved; whether they were destroyed; and, if destroyed, how their destruction—their "disposal"—was typically accomplished. Those who reported disposing of extra embryos were asked about their disposal practices, including the position of the person responsible for carrying out the disposal and the technique used; the existence and nature of ethical or religious concerns about disposal among staff members; the timing of consent-for-disposal requests; the options given to couples for managing extra embryos; participation by couples during disposal; and the performance of a ceremony around the time of disposal. Those directors who reported not disposing of extra embryos were asked whether their practice was attributable to individual clinic practice or to state law.

A postcard returned separately from the questionnaire allowed us to determine which clinics had responded, while maintaining the anonymity of each questionnaire. As approved by the IRB, consent to participation was implied by completion of the questionnaire.

## Results

Of 341 IVF clinic directors contacted, 217 (64 percent) responded by returning completed questionnaires. Respondents' characteristics are shown in Table 1.

Table 2. Options offered to couples for handling their extra embryos.

Options	208 clinics creating extra embryos*	175 clinics disposing of extra embryos	33 clinics not disposing of extra embryos
	Number (percent)	Number (percent)	Number (percent)
Creating no extra embryos	123 (59)	110 (63)	13 (39)
Leaving embryos frozen for a fee	199 (96)	169 (97)	30 (91)
Leaving embryos frozen at no charge	8 (4)	5 (3)	3 (9)
Donating embryos for reproductive use by other couples	158 (76)	131 (75)	27 (82)
Disposing of embryos prior to cryopreservation	125 (60)	125 (71)	0 (0)
Disposing of embryos after a certain period of cryopreservation	113 (54)	113 (65)	0 (0)
Donating embryos for scientific research	124 (60)	112 (64)	12 (36)
Donating embryos for the training of embryologists	39 (19)	37 (21)	2 (6)
Disposing of embryos in other ways	13 (6)	9 (5)	4 (12)

\* While 210 clinic directors reported creating extra embryos, 2 did not fully complete this section of the questionnaire.

### Embryo creation and management practices

Of 217 respondents, 210 (97 percent), reported creating extra embryos, *i.e.*, inseminating more eggs than would be transferred in a given cycle. The 7 (3 percent) that did not create extra embryos cited religious and ethical reasons for not doing so.

Among the 210 clinics that created extra embryos, 204 (97 percent) required couples to designate how they wanted their extra embryos managed. Among these 204 clinics, designation occurred at enrollment in 155 (76 percent), after enrollment but before creation of the embryos in 31 (15 percent), and after creation in 18 (9 percent). Table 2 shows options offered at clinics differing in their policies.

Among the 208 clinics that created extra embryos and responded fully to all questions, 208 (100 percent) were willing to cryopreserve extras. Of these, 175 (84 percent) were also willing to dispose of extras, while 33 (16 percent) were not.

### Disposal practices

175 clinics practiced disposal. Among these, 136 (78 percent) required permission from both members of a couple—assuming joint rather than individual ownership—before proceeding to disposal. 166 clinics (95 percent) attempted to contact a couple to say that disposal was upcoming even if consent to future disposal had previously been granted; 110 of these 166 (66 percent) did not proceed if a previously consenting couple proved unreachable, but the remaining 56 (34 percent) did.

165 of the 175 clinics practicing disposal (94 percent) disposed of embryos as biological waste material, 23 (13 percent) after thawing. Several clinics described disposal practices not listed on the questionnaire. 7 clinics (4 percent) reported first culturing their extra embryos until development ceased, then discarding them. 4 clinics (2 percent) reported giving extra embryos to the involved couples to handle themselves.

165 of the 175 clinics (94 percent) reported that the person responsible for disposal was usually an embryologist, but disposal duty fell to others as well. 11 clinics (6 percent) listed a physician of unspecified specialty; 4 clinics (2 percent) a nurse; 30 clinics (17 percent), a technician. Staffing aside, 4 of the 175 clinics (2 percent) insisted that the involved couple be present at disposal, 23 (13 percent) gave the couple the option of being present, 117 (67 percent) allowed the couple to be present if requested but did not offer the option explicitly, and 25 (14 percent) insisted that the couple not be present. As noted above, 4 clinics (2 percent) noted that they give embryos to couples for disposal, while several other clinics explained that involvement of the couple had never arisen as an issue.

7 of the 175 clinics (4 percent) performed a ceremony upon disposal; each ceremony included prayer.

### Practices at clinics that did not dispose of extra embryos

Of the 208 clinics that created and cryopreserved extra embryos and completed all sections of the questionnaire, 33 (16 percent) reported that they did

not practice disposal. Of these 33 non-disposing clinics, 29 (88 percent) attributed their practice to individual clinic policy and 10 of these 29 (34 percent) attributed their policy to religious considerations. Other factors included hospital rules, liability concerns, ethical arguments, emphasis on embryo donation, and patients' requests. 4 of the 33 (12 percent) cited state law as explanatory.

## Conclusions

This first inquiry into human-embryo disposal practices reveals considerable variability across IVF clinics. Nearly all responding clinics created and cryopreserved extra embryos, but they varied in practices regarding management of extra embryos, the options given to couples for disposal, responsibility for disposal, and use of ceremonies concurrent with disposal. Variation was also seen in clinics' procedures for seeking couples' consent at the time of disposal and for involving couples in the disposal itself.

Our results highlight the importance of fully disclosing extra-embryo disposal options when couples first consider enrollment. Little is known about how clinics deliver this information or about the proportion of couples who in retrospect feel they were not fully informed about practices that may have constrained their values or frustrated their preferences. Our results also suggest the need for long-term follow-up of couples who have experienced the creation and also the disposal of extra embryos using various practices, and of clinic personnel as well.

Our results also raise questions about informed consent practices at the time of disposal. Are clinics that require just one partner's consent for disposal more likely to proceed with the woman's permission or with the man's? And might any such likelihood be affected by the root cause of a couple's infertility, by the source of egg or sperm or whole embryo, or by relational troubles, including separation or divorce? What is the consent process for couples at clinics that do not create extra embryos? Do these clinics tell couples that a no-extra-embryo policy means a lower chance of successful pregnancy?

In light of the controversy surrounding research on human embryos, particularly stem-cell research,<sup>17</sup> it is noteworthy that the majority of clinics include donation-to-research among the options that they offer for

the management of extra embryos. A large majority also offer the option of embryo donation to other couples, also known as "embryo adoption." However, extra embryos from infertility treatment may have gone unused because they seemed less viable than others, making them poor candidates for use by other couples. Perhaps because of this concern, very few couples have used donated embryos to achieve pregnancy.<sup>18, 19</sup>

This study also raises fascinating questions about the rationale behind some clinics' practices. Why do certain clinics allow cryopreserved embryos to thaw and be cultured further prior to their disposal? Do they regard this practice as more natural, more respectful, more seemly, less provocative politically or legally?

Even more interestingly, why do some clinics give couples their own embryos to destroy? Physicians and other clinic personnel, after devoting themselves to the difficult task of creating embryos and ultimately babies, may come to regard "extras" non-instrumentally, even reverently, and may be unwilling to assist their destruction. Or, the practice could reflect a liability concern: if couples themselves conduct disposals, then clinics may be less vulnerable should regrets prompt complaints. Nothing systematic is known about such practices or the couples involved in them.

Our work must be considered within its limitations. First, the views of nonrespondents may have differed significantly from those of respondents. Second, despite the anonymity of the survey, social desirability concerns (*e.g.*, reputation or liability) may have led some respondents not to mention practices that are less than socially acceptable. Third, and finally, although some respondents took the time to describe practices that were not offered as questionnaire response items, such as giving embryos to couples for disposal, other respondents may not have done so.

Despite its limitations, this study provides insights into embryo disposal at IVF clinics in the United States and raises new questions bearing on the standardization and regulation of clinical practices.

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Gurmankin had full access to all data and had final responsibility for the decision to submit for publication.

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