CME

Factors that affect infertility patients' decisions about disposition of frozen embryos

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Objective: To describe factors that affect infertility patients' decision making regarding their cryopreserved embryos.
Design: Forty-six semistructured in-depth interviews of individuals and couples participating in IVF programs.
Setting: Two major southeastern academic medical centers.
Patient(s): Fifty-three individuals, including 31 women, 8 men, and 7 couples.
Main Outcome Measure(s): Qualitative analysis of interview transcripts.
Intervention (s): None.
Result(s): Seven broad themes informed participants' decisions about embryo disposition: family and personal issues, trust, definition of the embryo, prospective responsibility to the embryo, responsibility to society, adequacy of information, and lack of acceptable disposition options. Many wished for alternative options, such as a ceremony at the time of disposal or placement of embryos in the woman's body when pregnancy was unlikely.
Conclusion(s): Recent debates regarding embryo disposition do not reflect the range of values that infertility patients consider when deciding about frozen embryos. In addition to questions about the embryo's moral status, decision making about embryos is informed by a range of factors in the lives of individuals who created them. These perspectives may have important implications for the content and timing of informed consent, facilitating embryo disposition, and advancing policy debates about the ethics of frozen embryo use. (Fertil Steril® 2006;85:1623–30. ©2006 by American Society for Reproductive Medicine.)

Key Words: Cryopreserved embryos, embryo disposition, embryo research, stem cell research, embryo donation, qualitative research, interviews, informed consent

Advances in assisted reproductive technologies have expanded procreative options for many people experiencing infertility. With the evolution of in vitro fertilization (IVF), more embryos often result from each cycle of ovarian stimulation than can safely be returned to a woman's uterus for implantation. To reduce multiple gestations and their morbidity, avoid embryo destruction, improve cost effectiveness, and preserve future options for infertile couples, embryo cryopreservation (freezing) has developed as a routine practice in most IVF clinics (1). Once embryos are frozen, they may be used for future pregnancy attempts, donated to another couple, designated for stem cell or other research, or discarded. Evidence suggests, however, that many remain in storage with no specific plans for future use (2–5). Recent reports estimate 400,000 frozen embryos are stored in the United States (6).

Deep moral challenges for understanding and managing obligations to human embryos accompany the advancing science and provision of clinical services (7–10). Human embryonic stem cell research, in particular, has become a divisive issue. Religious groups, politicians, and academics have all participated in the debate (11–14). Yet few data exist regarding the attitudes of those who will face the decision about what to do with frozen embryos, namely, the individuals who underwent IVF or have used assisted reproductive technologies (15–18). As a result, public discourse and policy debates proceed in the absence of an empirical understanding of views of infertility patients and their partners.

The purpose of this study is to describe the factors that affect decision making for individuals considering disposition of their cryopreserved embryos. Such perspectives will inform clinicians working to improve the care delivered to

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infertility patients and facilitate decision making among individuals whose embryos have been frozen for extended periods. Furthermore, these perspectives will inform policymakers developing guidelines for counseling, informed consent, and the ethical conduct of stem cell research.

METHODS

Design

We conducted semistructured in-depth interviews to investigate individuals' attitudes regarding their cryopreserved embryos. The qualitative research methods we employed generate hypotheses and provide rich descriptive information regarding a phenomenon about which little is known or novel understandings are desired (19, 20). Researchers using these methods do not impose or test theoretical assumptions but allow participants to frame questions so that theory can emerge from data collected.

Study design in qualitative research reflects its goals as an inductive theory-building process. The concern is with representativeness of concepts and how concepts vary dimensionally, rather than representativeness of populations (20). Thus sampling, data collection, and analysis are aimed at developing, identifying, and relating the concepts that are the building blocks of theory. To capture and explore all potentially relevant concepts, the timelines of data collection and analysis are merged, allowing researchers to capture and pursue relevant aspects of a topic as soon as they are perceived (21).

Participants

To ensure a breadth of responses, we designed our initial sampling frame to include participants at four stages in IVF: individuals and couples who: 1) had not yet undergone IVF or were early in the IVF process; 2) had undergone IVF and had achieved pregnancy with fresh or frozen embryos; 3) had undergone IVF and had not achieved pregnancy; and 4) had had embryos in storage for more than five years (Table 1). We conducted 46 interviews: 31 with women alone, 8 with men alone, and 7 with couples together.

Sampling was completed when we reached "saturation" with regard to the theoretical categories that emerged from the data collected. Saturation is reached when no new or relevant data emerge regarding a theoretical category, the theoretical category is well developed in terms of its properties or dimensions, and the relationships among theoretical categories are well established (20).

Participants were recruited from the infertility clinics at Johns Hopkins and Duke Universities. Letters were sent to each institution's database of individuals with cryopreserved embryos; flyers also were distributed in clinics. Participants were compensated for their time. The institutional review boards of both institutions (Duke and Johns Hopkins Universities) approved the research.

TABLE 1

Number of participants/couples per category.

Category of interview participant	No.
1—IVF client is new to IVF, has begun within the past year, no successful pregnancy yet	5
2—IVF client has achieved successful pregnancy using either fresh or frozen embryos	21
3—IVF client has been trying IVF for over a year but without a successful pregnancy yet	13
4—IVF client has had embryos cryopreserved for 5 years or more regardless of IVF outcome	7

Lyerly. Decision making about frozen embyros. Fertil Steril 2006.

Data Collection

Interviews took place between September 2002 and May 2004. Using an interview guide, we began each interview by asking participants to answer open-ended questions about their IVF experiences and identify the most positive and negative aspects of their experiences with frozen embryos. Probe questions were used for clarification or elaboration where required. If not covered during open-ended questioning, we asked participants about: 1) information received prior to freezing; 2) the impact on family life of having frozen embryos; 3) their feelings about donating embryos for research; 4) their feelings about donating embryos to another couple; 5) the impact, if any, of other factors on decision making about frozen embryos; and 6) recommendations they would make to doctors or policy makers about embryo freezing. Demographic information including reproductive history also was collected.

Interviews were audiotaped and transcribed for analysis. We took steps to ensure reliability—often termed "exhaustiveness" in qualitative research (20). Two of the investigators read all interviews as they were transcribed, noted and discussed emerging concepts and common themes, and revised the interview guide according to ongoing findings. We conducted interviews until the same themes were being repeated and no new themes emerged. Theme exhaustiveness is reached when similar themes are generated by participants with different backgrounds.

Analysis

All transcripts were entered into a qualitative data analysis software program, N6 (QSR International, Doncaster, Victoria, Australia).

Initially two investigators coded transcripts with a priori codes that captured topics covered in the interviews, then formulated a second, content-driven coding scheme (20). We followed a "grounded theory" approach with a "constant comparisons" method and its related open and axial coding techniques. "Constant comparisons" denotes the iterative process of comparing emerging concepts with the content of previous interviews to provide clarity and make note of similarities and differences.

During open coding, both investigators coded one in five transcripts, compared results for theme agreement and disagreement, and revised the coding scheme when needed. Throughout the coding process, the investigators reviewed decision rules, which served as guides that determined why data fell into one category and not another, as a check on coding validity. During axial coding, three investigators then developed conceptual categories by comparing themes within and between transcripts. We identified 76 elements that affected or informed participants' decision making about frozen embryos, which fell into seven broad themes. Although we identify these broad themes as conceptually distinct, there is some overlap between them.

Illustrative quotations were edited for ease of reading. We did not make substantive changes but deleted repeated words and corrected grammatical inconsistencies. Each quotation is followed in parentheses with the participant's gender, age, and category as defined in Table 1.

RESULTS

Subjects ranged in age from 30 to 48 years. Seventy-two percent of the participants were women; 15% were African American (Table 2). In 34 interviews, individuals currently had between 1 and 23 embryos in storage. Thirty-three individuals or couples expected to use some embryos for future attempts at pregnancy, 18 (39%) indicated willingness to donate unused embryos for research, 13 (28%) indicated willingness to donate unused embryos to another couple, 4 (8%) indicated willingness to thaw and discard unused embryos, and 16 (34%) were undecided about the best option for their unused embryos (Table 3). Seven broad themes emerged as important to decision making about cryopreserved embryos: family and personal issues, trust, definition of the embryo, prospective responsibility to the embryo, responsibility to society, adequacy of information, and lack of acceptable options.

TABLE 2

Participant characteristics.

Characteristic	Value
Age range (mean)	30–48 (37.5)
Gender, no.	
Female	38
Male	15
Interviewed as couple, no.	7
Race/ethnicity, no.	
African American	8
Indian	1
White	44
Religious affiliation, no.	
Protestant	30
Roman Catholic	11
Jewish	3
Greek Orthodox	1
Sikh	1
No affiliation	7
Reason for infertility, no. (not mutually exclusive)	
Unexplained	17
Male factor	11
Tubal factor	9
Age (woman)	5
PCOS	2
Endometriosis	8
Balanced Translocation	1
Other	3
Number of stored embryos/couple	
0	12
1–2	5
3–5	14
6–10	10
11 or greater	3
Unsure	2

Note: PCOS = polycystic ovary syndrome.

Lyerly. Decision making about frozen embryos. Fertil Steril 2006.

Family and Personal Issues

The most immediate issue faced by most participants with frozen embryos was whether or not they wanted additional children. This usually served as a "gate" question; if participants did not want to use their embryos to pursue pregnancy, they would then proceed through some or all of the remaining themes to deliberate disposition.

Decisions whether to seek pregnancy were driven primarily by personal and family issues including age, finances, and health. Although many participants described increasing pressure to use or dispose of embryos as they moved beyond what they felt were their "normal" reproductive years, the very situation of having frozen embryos meant that age was not entirely decisive. For some, frozen embryos were a "security blanket" that allowed maintenance of reproductive potential:

> [I]f we want to have more children, I can do that at any time because I don't have to worry about my age. (F, age 47, category 4)

Financial considerations also affected decisions about frozen embryos. Some thought the expense of future IVF cycles

TABLE 3

Disposition options identified as potentially acceptable.

Category	Keep/use	Donate*	Research	Thaw	Undecided
	Options for embryo disposition (not mutually exclusive)				
1	4	2	2	0	2
2	18	6	7	2	8
3	9	5	6	1	3
4	2	0	3	1	3
Total	33	13	18	4	16

Note: N = 46 interviews of individuals and couples; categories as defined in Table 1; *Donate to another couple.

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with frozen embryos would be better spent supporting their existing children.

Participants also spoke about the potential impact of more IVF cycles on the woman's physical and emotional health:

> The negative aspect of [frozen embryos] is trying to determine if you really want to go through [IVF] again—if you want to choose to risk having multiples again or . . . go through the whole experience of getting your hopes up and then nothing happening. (F, age 30, category 2)

Once participants decided not to use embryos for pregnancy attempts, they often expressed uncertainty about disposition. Several factors, detailed in the themes following, affected views about remaining options.

Trust

Many participants noted their decision making was affected by trust of physicians, researchers, and others responsible for their embryos. Comments reflected how trust, or lack of trust, can generate problems in clinical care. Too much trust was blamed for an uncritical acceptance of cryopreservation practices:

> We really trusted the clinic . . . that never wavered. We met all the doctors, and they were all just fabulous. So I think that might have been part of the reason that we just bought into the process—because we really trusted them. (M, age 41, category 2)

Alternatively, lack of trust, manifesting as concern about misuse of embryos by physicians or researchers, made some participants uncomfortable about donation for research:

> I could understand being able to donate embryos for [research], but you know you'd probably always have that irrational fear of two things: one is that, no they're going to let it grow anyway, or the other fear, frankly, that I've always had, even though I trust [the institution] immensely, was the fear that someone needed an embryo and they would give it to somebody, or they would mix it up. (F, age 44, category 2)

Even for those who considered research a reasonable option, trust remained an important consideration—at times one that precluded disposition decisions, particularly given fears that researchers would allow the embryo they donated to develop into a child:

> I just don't want my embryos in someone else's body. I don't want to look at other children for the rest of my life and think that they could be mine. So, if I knew they were researching . . . as long as they didn't turn into people. (F, age 33, category 4)

Thus, both trust and lack of trust heightened fears that potentially interfered with embryo disposition.

Defining the Embryo

For a few participants, decisions turned on their views about the nature of the embryo itself—whether or not they considered the embryo a human being or a person, deserving of the same rights, respect and protection owed to a child or adult. This consideration, often referred to in ethical analyses as the question of "moral status," held particular force for the few participants explicitly holding the view that embryos are "life" or have a "right to life":

> I would like to think the policy would be that we don't destroy these; [the freezer] is like an orphanage for children; these need to go somewhere and be utilized in the natural way that's intended. (F, age 35, category 2)

For these participants, destruction, including research, was prohibited; all noted that religion had a significant impact on their decision making and identified themselves as Catholic, (Evangelical) Christian, or Baptist.

Many participants, however, expressed a view of the embryo as an entity that did not command the same moral obligations as a person who had been born. Some thought of the embryo as a cluster of cells without uniquely human moral rights or interests:

> To me [the embryo] is just another laboratory specimen . . . no more or less valuable than a laboratory mouse or anything else that's giving up its life for research. (F, age 41, category 3)

Others felt their obligations to embryos would begin only after implantation. Thus disparate views regarding the definition of the embryo guided a few participants' decisions about acceptable options for embryo disposition.

Prospective Responsibility to the Embryo

For the majority of participants, however, beliefs about the intrinsic nature of the embryo were not at the center of their moral deliberation. Instead of discussing the embryo's status in abstract terms, they spoke about particular responsibilities to their own embryos. Several respondents who preferred embryo destruction or research over donation to another couple described special obligations felt toward the embryos they had created:

> [T]hough I empathize tremendously with what it's like to not be able to have a child, I just feel that I have a responsibility towards this embryo and I don't have the right to put it in an unknown situation. (F, age 44, category 2)

Another woman's comment reflected a deeply felt responsibility that did not depend on—in fact stood in opposition to—the question of an embryo's "right to life":

> I admire women who can give up their children . . . I couldn't do it. I'd rather have [the embryos] destroyed than born. (F, age 33, category 2)

Moral responsibility as understood by many of the participants was marked by concerns not about embryo destruction but about the embryo developing into a human being without their knowledge or further participation.

Responsibility to Society

Participants noted that in some contexts altruism drove decisions. Some were interested in donating embryos for research to make a contribution to society:

> Research made me more comfortable because . . . at least that was a way I could give back. I may not be here to see it, but . . . hey I did contribute to make this world a healthier place than it was when I lived in it. (F, age 37, category 2)

Others were particularly interested in contributing their embryos for fertility research, having experienced the hardship of infertility or having benefited from treatment:

> I'm sure they've done research in the past and that's how they were able to help me, so I would love to be able to help . . . women in the future. (F, age 34, category 1)

When pressed about whether the type of research proposed would influence decision making about whether to donate, most respondents noted that the type of research did not matter as long as it had the potential to benefit others.

Adequacy of Information

Many participants commented that they did not feel prepared to make decisions about their frozen embryos because they had not received much information about cryopreservation before IVF:

> I don't think they give you a lot of counseling . . . and it's something that you have to figure out on your own. And I don't know how to get there because I don't have the tools. (F, age 45, category 2)

Many, however, stated they were overwhelmed by the volume of information they were asked to absorb. They reflected that in the early stages of IVF, they were not in a state of mind to consider what they might do in the future should they be fortunate enough to achieve all the pregnancies they desired:

> Early on there is just too much information as you are going through it. When you are just trying to achieve an egg, the last thing you want to hear about is how to dispose of it. (F, age 37, category 2)

Most participants noted that at the time of freezing their intention was to use all embryos for pregnancy attempts and tht they seriously considered other choices only when pregnancy was no longer desired. Even those who considered other options before freezing noted that going through IVF changed their feelings:

> When I was going through [IVF] I didn't even think of them as embryos, what they really can become, I just thought of them more scientifically as just cells that potentially could develop, whereas now the realization of oh my gosh what a beautiful human being can be created; it changes your emotions just a little bit . . . maybe they are less cut and dried. (F, age 37, category 2)

The majority of participants at each institution noted little ongoing contact with the clinic when they were not actively pursuing pregnancy with IVF. Contact consisted almost exclusively of a bill for embryo storage. Some admitted they had temporarily forgotten about the embryos. Many wanted more information following cryopreservation—even a periodic letter indicating the number of embryos in storage and available disposition options.

Lack of Acceptable Options

Many individuals not desiring future pregnancies but having stored embryos found themselves in an unanticipated situation in which none of the available choices for embryo disposition was ideal or even acceptable. Reflecting on this, several women expressed desire for one of two alternative disposition options. Some wished for a ceremony which would enable a respectful "goodbye" to the embryos or impart a sense of closure:

> You could go into a hospital chapel . . . with them in a little box and half an hour later, go out . . . just something

> where you could have a quiet few minutes to think about it . . . kind of mourn for those children that will not exist. (F, age 35, category 2)

In addition, participants noted that being present during a ceremony might placate concerns that their wishes would not be carried out.

For many, a notion of physical connectedness informed another alternative option—that the embryos be returned to their body at a time when pregnancy was unlikely. Some felt that transfer to the woman's body would be more humane or natural than disposal of embryos in the laboratory:

> The ultimate thing would be [to] have them put into your body when you are not ovulating for your body to dissolve, naturally . . .. I think if you ask ten women in my situation they probably would tell you the same thing: they don't want them flushed down the toilet . . .. If you think about it where would you want them? So I just think that would be the most humane natural thing to do. Let your body absorb them. (F, age 33, category 4)

Though women imagined and felt comfortable with these alternatives, they did not feel that these options were available to them and, therefore, continued to maintain embryos in storage indefinitely.

DISCUSSION

The disposition of frozen embryos remaining after IVF has been the subject of a vigorous and polarized debate. Some view embryos as potential sources of stem cells, crucial to promising research. Others view embryos as human life and their destruction for any purpose a deep moral wrong. Significant numbers of stored embryos and a growing demand for embryos as a source of stem cells has made embryo disposition a critical issue for clinicians, scientists, and policy makers. Our data qualitatively describe the issues important to individuals considering disposition of their frozen embryos. These data offer important perspectives to guide both physicians in the timing and content of their conversations with patients and policy makers in the development of guidelines for counseling, informed consent, and the ethical conduct of research.

Not surprisingly, almost all participants noted that aspects of their personal situation, including age, finances, and health, influenced disposition decisions, particularly about use of embryos for further attempts at pregnancy. Although such considerations inform procreative decision making generally, they are frequently overlooked in public debates about embryo disposition, which have instead focused on what philosophers and others have termed "moral status" (22–24). In such debates, the central ethical question has been whether the embryo is deserving of the same rights and protections as a child or adult person. In contrast, study participants' initial decisions about frozen embryos were often informed by a range of more personal values, including values about family, parenting, health, and well-being.

When participants decided not to use their embryos for further pregnancy attempts, they typically cared deeply about what would become of them. Notably, concern for the embryo did not necessarily reflect beliefs about the embryo's right to life, nor did it translate into a desire to ensure the embryo had a chance at gestation. Though seemingly consistent with a broadly held view that embryos are deserving of "special respect" (25, 26), our data revealed a distinctive conceptualization of what respect might entail: for many participants, responsibility entailed that the embryo not ever be allowed to develop into a human being. Theirs was primarily a concern about the embryos becoming babies in other women's bodies and growing up in families other than their own.

Whether or not the preference for embryo destruction based on to prospective responsibility to one's own embryo is a defensible moral position is an important question for future debate. Nevertheless, alternatives to options necessitating development of an embryo into a person may be most consistent with preferences of many individuals deciding about embryo disposition. To meet such preferences, clinicians and policymakers should ensure that the option to discard embryos or donate them for research purposes remain available to infertility patients.

Several participants, however, noted that none of the disposition options were appealing. Often, this view was also motivated by a notion of responsibility to the embryo they intended to discard, rather than a conviction about its right to life. For instance, participants were reluctant to discard embryos, because the process failed to meet their needs for closure or honor emotional or physical connections with the embryos. Several participants noted that a ceremony at the time of thawing or placement of the embryos in the woman's body at a time pregnancy was unlikely might alleviate these concerns. Furthermore, reluctance to donate embryos for research stemmed in part from concerns that one of their embryos would be allowed to develop into a person. Policies that address patients' concerns about embryo misuse and make available methods of disposal that meet individuals' needs may help facilitate disposition of stored embryos.

Consistent with views that the ethics of embryo research should be evaluated from a range of values, including reduction of human suffering or advancement of applied scientific knowledge (23, 24), several participants' decisions were influenced by broader societal values. Having suffered infertility, they wanted to "give back"—to help other patients or benefit humanity. In contrast to what has been discussed in the literature (25, 27), participants either supported embryo research or they did not; the type of research (stem cell or otherwise) was less salient in the formation of their opinions.

As with previous research in other areas of medicine (28), study participants cited trust as important to decision making about their embryos. Not only do our data highlight the harm that can result from a lack of trust, but they also underscore the potential dangers of too much trust. Participants admitted they had not considered long-term consequences of embryo cryopreservation because they trusted physicians' guidance. Clinicians should understand that IVF patients' willingness to participate in embryo cryopreservation does not necessarily indicate a reasoned and reflective decision to do so.

The importance of meaningful informed decision making has been emphasized in the assisted reproductive technologies (29), particularly for technologies potentially leading to the use of embryos for research (15, 30). Although some centers request embryo disposition decisions only after completion of pregnancy attempts, others require decision making early in IVF. To avoid problems of long-term embryo storage, some have proposed standardized consent for disposition of unused frozen embryos before embryo freezing (31). Two findings of this study call into question the feasibility of informed decision making about disposition at the time of cryopreservation.

First, we identified what we will call a "cognitive-affective dissonance": While managing the strain of infertility, some participants were not in a suitable affective state to meet the cognitive demand of carefully considering the eventuality of "spare" embryos. It therefore may be unrealistic to expect people beginning the process of creating embryos to be able to reflect seriously about whether or how they might eventually dispose of them. Second, consistent with findings of other studies (32), individuals' preferences for disposition of embryos reportedly changed over time. When many individuals start IVF, they do not appear to have settled moral views or reflective preferences about their embryos. Our data suggest that the process of infertility treatment, whether successful or not, profoundly influences what these preferences turn out to be.

These findings have important implications for the timing and content of the informed consent process. Because individuals may not be prepared to make disposition decisions at the time of cryopreservation, it is unlikely that agreements made before freezing will solve the problem of excess embryos in ways that respect the subsequent preferences of those who created them. The goal of discussions held before cryopreservation therefore should not be to secure a patient's commitment to a particular course of action regarding "spare" embryos, but to communicate that embryo cryopreservation may have untoward consequences, among which is the burden of facing what may be a morally difficult decision in the future.

Our study has several limitations. Participants were recruited from infertility clinics in two major medical centers, which may limit the generalizability of results. This setting, as opposed to a private practice setting, may have resulted in over-representation of individuals with favorable views of research. Participants were similar in age and did not represent an ethnically or socioeconomically diverse sample. Though narrow, this represents the population currently engaging in infertility treatment. Finally, our cross-sectional sampling method suggested that individuals' attitudes toward cryopreserved embryos shift over time; to assess this properly a longitudinal method should be employed. Given the exploratory nature of our qualitative methods, larger studies involving a diverse national sample and quantitative methodologies are needed to assess prevalence of the elicited views. In addition to validating our findings, quantitative data will permit an empirical assessment of the relative importance of factors affecting decision making across groups of individuals receiving infertility care.

The seven themes identified in this study provide an initial framework for evaluating and improving informed consent and advancing policy debates about frozen embryo disposition. Offering disposition options that take into account this array of considerations and providing appropriate counseling and contemporaneous consent for disposition may facilitate timely, reasoned, and reflective decisions about cryopreserved embryos. Ultimately, moving away from narrow assertions about the moral status of the embryo and incorporating a broader range of considerations in the public debate about frozen embryos may better inform practices and policies that satisfy a divided public, whether infertility patients or not.

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