

Decisional conflict and the disposition of frozen embryos: implications for informed consent

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BACKGROUND: Fertility patients often struggle with decisions about disposition of embryos remaining after fertility treatment. We aimed to identify predictors and correlates of decisional conflict among patients facing these decisions.

METHODS: We analyzed results from a survey of 2210 patients from nine geographically diverse US fertility clinics. The main outcome measure was decisional conflict about embryo disposition, as measured by the decisional conflict scale (DCS).

RESULTS: Of 1244 respondents who returned the survey, 1005 with cryopreserved embryos and DCS scores were included in the analysis. Of the respondents, 39% reported high decisional conflict (DCS \geq 37.5). Thoughts about future childbearing were associated with high decisional conflict: respondents who were either uncertain about whether to have a baby in the future or sure they did not want to have a baby were at higher odds of high decisional conflict than participants who desired a baby [adjusted odds ratio (aOR) = 3.93, $P < 0.001$ and aOR = 1.69, $P = 0.04$, respectively]. Also associated with high decisional conflict were being likely to have embryos thawed and discarded (aOR = 2.08, $P < 0.001$), donated for research (aOR = 1.66, $P = 0.01$) or frozen 'forever' (aOR = 1.90, $P = 0.01$); being likely to choose compassionate transfer if it were available (aOR = 1.65, $P = 0.03$); attributing high, but not full, moral status to human embryos; not having enough information; and not being satisfied with the informed consent process.

CONCLUSIONS: Decisional conflict about frozen embryo disposition differs according to reproductive preferences that may vary according to stage of treatment. Informed consent for embryo disposition should be revisited periodically, with serious discussions about disposition after childbearing is complete.

Key words: cryopreserved embryos / ethics / stem cell research / informed consent / embryo disposition

Introduction

The routine practice of freezing excess embryos gives fertility patients the opportunity to use embryos for future attempts at pregnancy. Yet it also creates an unanticipated conundrum for patients who complete treatment with unused embryos remaining. In general, their options include having embryos discarded, donating them for research or donating them to another couple for fertility treatment.

Considerable evidence suggests that patients find these decisions extremely difficult. Qualitative studies report that patients feel 'anguished' and 'agonize' over the decision about what to do with frozen embryos, with many inclined toward perpetual freezing (de Lacey, 2005; Lyerly *et al.*, 2006). As many as 70% of patients with embryos delay their decisions 5 years or more (McMahon *et al.*, 2000). In our recent survey of fertility patients, we found that 40%

of patients who had completed childbearing could not identify a preferred disposition option for their excess embryos; one in five of those individuals indicated they were likely to put off the decision indefinitely (Lyerly *et al.*, 2010). While delayed decisions are due to many factors, including the availability and acceptability of disposition options and barriers to carrying out options once they are identified as preferable (Lyerly *et al.*, 2010), improving information and support for patients in the process of decision-making is likely to alleviate distress and facilitate informed and reasoned decisions and closure with respect to the process of fertility treatment.

Critical to timely and informed decision-making is an informed consent process that meets fertility patients' needs (Fuscaldo *et al.*, 2007). Furthermore, adequate informed consent has been recognized as central to the ethical conduct of research with embryos, with 'voluntary and informed consent' a central and essential feature of

the 2009 NIH regulations for stem cell research in the USA (National Institutes of Health, 2009). However, to our knowledge, no studies have been published that have quantified patients' uncertainty or conflict regarding decisions about embryos, nor have predictors of decisional conflict in the context of fertility care been identified.

As part of a multi-institutional survey of fertility patients with stored cryopreserved embryos in the USA (Lyerly and Faden, 2007; Lyerly et al., 2010), we assessed 'decisional conflict' (O'Connor, 1995) or the extent to which patients with cryopreserved embryos reported personal uncertainty about disposition decisions and related deficits in knowledge and values clarity. High decisional conflict has been associated with delayed decision-making, as well as regret and relevant gaps in knowledge (Brehaut et al., 2003; User Manual, 2006). Although such conflict occurs in part as a consequence of the type of the decision being made (e.g. the morally difficult choices inherent to embryo disposition), several modifiable cognitive, affective and social factors can exacerbate uncertainty; moreover, decisional conflict can be lowered by decision-supporting interventions (O'Connor et al., 2009). In this paper, we describe predictors and correlates of high decisional conflict among fertility patients responding to our survey, and identify specific areas of need for decisional support.

Materials and Methods

Between June 2006 and January 2007 we mailed a confidential 12-page questionnaire to 2210 patients receiving care at one of nine geographically diverse US fertility centers. Potential participants were randomly selected from each center's database. Using an Excel-based standardized randomization and selection protocol, 300 potential participants were selected from each center with >300 patients in their database; the four centers with <300 patients in their databases included all patients in their sample. We sent the first two-thirds of the questionnaires to women intending to become pregnant from IVF and the remaining one-third to each woman's partner (male or female) when information on partner status was available. We sent surveys to only one individual (the woman or her partner) per couple. The study was approved by institutional review boards of all academic centers. Methodology for this study has been described in depth elsewhere (Lyerly and Faden, 2007; Lyerly et al., 2010).

Measurements

The questionnaire was preceded by a qualitative study (Lyerly et al., 2006), which served as the basis for questionnaire language and content. We evaluated and revised questionnaire items based on cognitive interviews (Willis, 2005) with fertility patients and review by an expert panel including fertility specialists and survey methodologists.

Our primary outcome for this analysis was decisional conflict. We used the 12-item version of O'Connor's decisional conflict scale (DCS) (User Manual, 2006), which included four subscales with three questions each addressing (i) uncertainty, (ii) the degree to which the respondent feels informed, (iii) values clarity and (iv) support. We excluded the subscale measuring effectiveness of decision-making because this subscale requires reflection on a decision made in the past, while respondents to our survey currently had embryos and therefore had not yet carried out a decision. We used a statement format, in which respondents were asked to respond to a series of statements using response categories strongly agree, agree, neither agree nor disagree, disagree or strongly disagree. Psychometric assessments of the DCS have established reliability with test-retest correlations and Cronback's alpha that exceed 0.78; DCS > 37.5

has been associated with decision delay or feeling unsure about implementation (User Manual, 2006). Study participants were classified into one of two categories: those with high decisional conflict (DCS > 37.5) and low decisional conflict (DCS ≤ 37.5).

The primary predictor variables for this analysis included patients' responses to the question: 'In terms of how you feel right now, how likely or unlikely are you to choose the following options for your embryos?' Using response categories of very likely, somewhat likely, somewhat unlikely, very unlikely and unsure/do not know, respondents indicated likelihood of choosing each of five conventional options: (i) store for future pregnancy attempts; (ii) thaw and dispose of embryos; (iii) donate to another couple trying to have a baby; (iv) keep the embryos 'frozen forever' (a term articulated by participants in the prior interviews); and (v) donate the embryos to research; and two options not widely available but suggested previously by in-depth interview participants: (i) having embryos placed in the woman's body when she is unlikely to become pregnant ('compassionate transfer') and (ii) being present at a small ceremony during embryo thawing or disposal. Respondents were not forced to choose among options, as our previous qualitative work indicated that many patients with embryos stored had not made a final decision about disposition.

Another predictor variable was reproductive intent (whether the respondent wants more children), which our previous qualitative work indicated as relevant to reasoning about embryo disposition (Lyerly et al., 2006). To elicit such intent, we asked respondents to choose among three options: 'I hope to have a baby/another baby; I am undecided about whether or not I want to have a baby/another baby; I am sure that I do not want to have a baby/another baby'.

To assess patients' experience of the informed consent process, the questionnaire posed two sets of questions pertaining to feelings about the information received, either from respondents' IVF clinic or other sources, using response categories of strongly agree, agree, neither agree nor disagree, disagree and strongly disagree. In the first set, respondents indicated their level of agreement with the statement 'I feel I have enough information about: ...' as it pertained to seven different types of information. These questions together were the basis for the 'content subscale'. In the second set, participants were asked to think back to the time of embryo freezing, and indicate their level of agreement or disagreement with five statements about the nature of that discussion. These questions were the basis for the 'process subscale'. The content and process subscale scores each reflect the mean score of all items in the respective scales. Mean scores ranged from 1 to 5 with 5 reflecting the 'most informed' state according to each response.

An additional potential predictor was beliefs about the moral status of human embryos, measured with a scale previously developed and used on a large population sample (Hudson et al., 2005). Following a detailed description of what is meant by 'moral status', respondents were asked, 'On a scale from 1 to 7 where "1" means "No moral status" and "7" means "Maximum moral status" please check (tick) a number that indicates what you believe to be the moral status of human embryos'. Questions about demographics and IVF and reproductive history also were included to be used as covariates.

Analysis

We began our analysis by calculating means and proportions for the socio-demographic, clinical and attitudinal characteristics of the entire group, as well as for the two groups stratified by high or low DCS scores. We then used t-tests and χ^2 tests to compare these variables by group. In cases where there were more than two possible response categories for demographic, clinical or attitudinal variables, we calculated P-values for overall (omnibus) χ^2 tests. We conducted logistic regression analysis to calculate

adjusted odds ratios (aORs) to explore the relationship between decisional conflict and (i) demographic and clinical characteristics and (ii) attitudes and preferences of participants about embryos, including intentions from frozen embryo disposition, both at the time of freezing and currently; current thinking about childbearing; views on moral status; and experience of information as measured by the content and process subscales. In multivariable logistic regression models we used a backward elimination procedure where predictor variables with $P > 0.20$ were eliminated from the final model. All analyses were carried out using SAS 9.1. (2006; SAS Institute Inc., Cary, NC, USA)

Results

A total of 2210 individuals were sent a questionnaire. We received 1244 returned questionnaires giving an overall response rate of 60%. Of those who responded, 1005 currently had embryos in storage and had decisional conflict scores available, and thus were included in the analytic sample. Of these respondents, 395 (39%) had high decisional conflict scores ($DCS > 37.5$). Decisional conflict did not differ significantly according to whether the respondent was a patient or partner.

Sociodemographic and clinical characteristics of the study sample as a whole, as well as by decisional conflict category, are presented in Table I. As shown, the sample was relatively homogenous and socioeconomically advantaged: 85% were white, 95% were married and 79% had a bachelor's degree or higher. About 87% indicated religion was somewhat or very important to them, and approximately three quarters (76%) reported some religious affiliation. Most had one (36%) or more (43%) children; 75% had children from IVF. Although some differences emerged with respect to pregnancy history, for the most part the two groups did not differ with respect to these characteristics.

A somewhat different picture emerged when the attitudes and preferences of respondents with high decisional conflict were compared with the other respondents: we found that almost all of these items differed by decisional conflict category (Table II). Overall, respondents varied considerably in how much moral status they assigned to their embryos, ranging from no moral status (9.5%) to maximum moral status (18%); most indicated that moral status was a very (47%) or somewhat (31%) important factor in their decision about embryo disposition. Comparing groups stratified by decisional conflict, the percentage of respondents with high decisional conflict generally increased with increasing moral status assigned to embryos and peaked in individuals who assigned embryos a moral status of six out of seven (58%). Notably, however, those who assigned maximum moral status to embryos were least likely to be conflicted (27%) (Table II).

Participants' responses to questions related to how informed they felt revealed a diversity of views (Table III). The percent of respondents disagreeing with items on the content subscale (indicating areas of inadequate information) ranged from 12 to 48%, with the highest percentage indicating they did not have enough information about 'what happens to embryos donated to research'. The percent of respondents citing problems with the process of information disclosure ranged from 13 to 30%, with the highest percentage indicating agreement with the statement 'I was not emotionally prepared to think about or discuss what I would do with embryos not used for pregnancy attempts'.

Results of our analyses of the associations with high decisional conflict are presented in Table IV. As expected based on the intergroup comparisons, numerous significant associations emerged in the bivariate analyses, many of which persisted as significant independent predictors of decisional conflict in the multivariate analyses (Table IV). Three types of intentions for embryo disposition were associated with decisional conflict. Specifically, respondents who indicated they were likely to thaw and discard embryos (aOR = 2.08, 95% CI 1.37–3.15, $P < 0.001$), keep the embryos frozen forever (aOR = 1.90, 95% CI 1.14–3.16, $P = 0.01$) or donate embryos for research (aOR = 1.66, 95% CI 1.12–3.46, $P = 0.01$) were at significantly higher odds of experiencing decisional conflict than those who did not have these intentions. Those who indicated they would choose compassionate transfer if it were available were also at significantly higher odds of having high decisional conflict (aOR = 1.65, 95% CI 1.05–2.61, $P = .03$).

Future childbearing plans also appeared to play a key role in decisional conflict, (omnibus P -value of < 0.001) with indecision about whether to have a baby in the future most strongly associated with high decisional conflict. Compared with respondents who did hope to have a baby/another baby, those who were sure they did not want to have a baby/another baby (aOR = 1.69, 95% CI 1.03–2.78, $P = 0.04$) and those who were undecided about whether they would have a baby/another baby (aOR = 3.93, 95% CI 2.59–5.96, $P < 0.001$) were at significantly higher odds of experiencing high decisional conflict.

Overall, beliefs about the moral status of embryos were significantly associated with decisional conflict (omnibus P -value = 0.002). In particular, those who ascribed high, but not full, moral status to embryos were at significantly higher odds of experiencing high decisional conflict (aOR = 4.22, 95% CI 2.17–8.22, $P < 0.001$) than those who ascribed any other level of moral status to embryos. Finally, both information subscales were associated with DCS scores. Specifically, those with a higher score on the content subscale (indicating they felt more informed about frozen embryo disposition) were at significantly lower odds of having high decisional conflict (aOR = 0.25, 95% CI 0.19–0.34, $P < 0.001$); likewise, those with a higher score on the process subscale (indicating they felt more satisfied with the informed consent process) were at significantly lower odds of having high decisional conflict (aOR = 0.64, 95% CI 0.49–0.82).

Discussion

Deciding about disposition of embryos remaining after IVF often presents a considerable and unexpected challenge for fertility patients. Critical to improving this situation is an informed consent process that meets patients' needs. In the largest multisite survey of fertility patients in the USA, we identified several predictors of decisional conflict regarding frozen embryo disposition, including two scales detailing unmet needs around the content and process of information disclosure about embryo freezing. These data provide information critical to improving the informed consent process for embryo cryopreservation, facilitating informed disposition of excess frozen embryos and redressing the ever growing numbers of embryos in cryostorage.

First, these data have implications for structuring the process of informed consent for embryo cryopreservation and disposition. Notably, the strongest correlate to high decisional conflict was

Table 1 Demographic and clinical characteristics of all participants, and by low versus high decisional conflict scores (n, %).

	Total (n = 1005 ^a)	DCS > 37.5 (n = 395)	DCS ≤ 37.5 (n = 610)	P-value
Female sex	786 (78.4)	315 (40.1)	471 (59.9)	0.27
Age 36 year or older	609 (60.8)	247 (40.6)	362 (59.4)	0.28
Marital status				0.46
Single/divorced/widowed	19 (1.9)	9 (47.4)	10 (52.6)	
Married/live with partner	985 (98.1)	385 (39.1)	600 (60.9)	
Race/ethnicity				0.36
White	840 (83.6)	338 (40.2)	502 (59.8)	
Asian	66 (6.6)	21 (31.8)	45 (68.2)	
Black or African-American	46 (4.6)	19 (41.3)	27 (58.7)	
Latino	19 (1.9)	8 (42.1)	11 (57.9)	
Other	34 (3.4)	9 (26.5)	25 (73.5)	
Highest level of education				0.92
High school diploma, GED or less	122 (12.4)	46 (37.7)	76 (62.3)	
Associate of arts degree	87 (8.8)	34 (39.1)	53 (60.9)	
Bachelor's degree	357 (36.2)	145 (40.6)	212 (59.4)	
Graduate/professional degree	421 (42.7)	162 (38.5)	259 (61.5)	
Annual household income				0.32
\$0–\$49 999	45 (4.7)	21 (46.7)	24 (53.3)	
\$50 000–\$99 999	298 (31.1)	127 (42.6)	171 (57.4)	
\$100 000–\$149 999	267 (27.9)	93 (34.8)	174 (65.2)	
\$150 000–\$199 999	151 (15.8)	59 (39.1)	92 (60.9)	
\$200 000 and up	196 (20.5)	76 (38.8)	120 (61.2)	
Religion				0.22
Protestant ^b	238 (24.3)	101 (42.4)	137 (57.6)	
Roman catholic ^b	236 (24.1)	95 (40.3)	141 (59.7)	
Other christian ^b	172 (17.6)	70 (40.7)	102 (59.3)	
Fundamentalist	85 (8.7)	33 (38.8)	52 (61.2)	
Other/unknown	83 (8.5)	22 (26.5)	61 (73.5)	
None	166 (16.9)	64 (38.6)	102 (61.4)	
Importance of religion				0.80
Very important	425 (43.3)	169 (39.8)	256 (60.2)	
Somewhat important	426 (43.4)	169 (39.7)	257 (60.3)	
Not at all important	131 (13.3)	48 (36.6)	83 (63.4)	
Have been pregnant with fresh embryos	803 (82.2)	327 (40.7)	476 (59.3)	0.07
Have been pregnant with frozen embryos	127 (13.0)	39 (30.7)	88 (69.3)	0.03
Have used donor egg	183 (18.9)	68 (37.2)	115 (62.8)	0.56
Have used donor sperm	38 (3.9)	12 (31.6)	26 (68.4)	0.34
Number of embryos in storage				0.47
1–2	268 (27.1)	95 (35.4)	173 (64.6)	
3–5	363 (36.7)	142 (39.1)	221 (60.9)	
6–10	216 (21.8)	89 (41.2)	127 (58.8)	
11 or greater	100 (10.1)	42 (42.0)	58 (58.0)	
Unsure	42 (4.2)	20 (47.6)	22 (52.4)	
Number of children				0.004
0	194 (19.6)	59 (30.4)	135 (69.6)	
1	362 (36.6)	137 (37.8)	225 (62.2)	
2 or more	434 (43.8)	192 (44.2)	242 (55.8)	

Continued

Table I Continued

	Total (n = 1005 ^a)	DCS > 37.5 (n = 395)	DCS ≤ 37.5 (n = 610)	P-value
Children from IVF (1 or more)	743 (74.7)	313 (42.1)	430 (57.9)	0.002
Fee for storage of embryos	912 (91.2)	365 (40.0)	547 (60.0)	0.13

DCS, decisional conflict score.

P-values are from t-test and χ^2 that examine the difference between groups with high versus low decisional conflict scores for mean (t-test) or distribution (χ^2). Where there are more than two levels in demographic or clinical characteristic variables, the P-value from the overall (or omnibus) χ^2 is presented.

^aItems do not all sum to 1005 because not all respondents answered all questions.

^bNon-fundamentalist.

reproductive intentions, with high DCS most prevalent among respondents who reported being unsure whether they desired future childbearing, followed by those who reported that they were sure that they did not desire future childbearing. These two groups of patients stand in contrast to the respondents who reported that they were sure they wanted a baby, among whom the prevalence of high decisional conflict was much lower. It is striking that the groups who were most likely to report high decisional conflict were the least likely to have had recent access to an informed consent process about frozen embryo disposition. Informed consent for freezing and disposition occurs primarily at the time of freezing—at an early stage of IVF and at the point that reproductive intent is directed squarely in favor of childbearing and the prevalence of high decisional conflict about disposition of potential frozen embryos is the lowest. Indeed, more than 80% of the respondents endorsed having specific plans for their embryos at the time they were frozen. Yet those farther along in their fertility care were more likely to have high decisional conflict: views about embryos and what it is that strikes them as the morally right or best option for disposition evolve; needs around family building and finances change; the disposition decision, once a theoretical possibility, becomes a pressing reality. And yet at this point in the decision process—when they arguably are most in need—fertility patients often have no structured opportunity for an informed consent discussion about embryo disposition.

The above finding highlights one of the most significant challenges to informed consent for embryo cryopreservation and disposition, namely, that individuals' attitudes about embryos change considerably over time (Newton et al., 2007; Nachtigall et al., 2009). Our data indicate that not only do they change, but decisional conflict appears to be higher for patients who have moved farther through the course of treatment. As we and others have argued elsewhere (Newton et al., 2007; Lyerly et al., 2010; Nachtigall et al., 2010). This points to the limitations of the current approach in which discussions about embryo disposition occur primarily at the time of freezing, and which we have shown is a time of lower decisional conflict. Our data, showing higher decisional conflict among patients not intending to become pregnant, highlight the need for a system to revisit discussions about disposition preferences at regular intervals, to engage with patients later on in the process of fertility care, when they themselves can engage with the complexities of embryo disposition decisions and consider them in the contexts of their lives. Standardized procedures and documentation for informed consent and interval follow-up should be a goal for those crafting guidelines and policies for assisted reproduction.

Second, these data have implications for the content of informed consent. Both of our information subscales were based on qualitative

data in which patients themselves articulated items relevant to how they experienced and understood information about embryo disposition. We found that several of these items were not only widely endorsed as relevant, but were also significantly related to decisional conflict. It is likely that incorporating these items into a standardized informed consent will both provide needed information and reduce decisional uncertainty. Indeed, as new approaches to informed consent for embryo disposition are developed and tested, research that measures their comparative effect on decisional conflict among fertility patients will be critical.

Third, our findings further underscore the importance of improving informed consent and alleviating decisional conflict as a means to reduce the accumulation of embryos. High decisional conflict has been associated with delayed decision-making (User Manual, 2006). Delayed decision-making has been shown to characterize embryo disposition decisions (McMahon et al., 2000; Lanzendorf et al., 2009). And in fact we found high decisional conflict to be prevalent among individuals inclined to freeze embryos forever. Yet high decisional conflict was also associated with the option most widely available (thaw and discard), as well as with the option to which the highest percent of fertility patients are inclined (donation to research). Given high decisional conflict around the most widely available option as well as the most widely preferred option, interventions that reduce decisional conflict may be important to facilitating timely embryo disposition.

Despite opportunities for progress, our findings reflect that part of the challenge stems from the nature of the decision (the morally difficult choices inherent to embryo disposition). Interestingly, we found that individuals whose beliefs about moral status fell at the respective poles of our scale—who either assign full moral status or no moral status to embryos—to have the lowest decisional conflict. This finding likely reflects a more settled view in respective groups about what is owed embryos. For those assigning full status to embryos, this would presumably be a chance at life through gestation or reproductive donation; for those assigning no moral status, responsibilities would presumably be minimal. Either view—though diametrically opposed, reflects low conflict, particularly compared with the majority of respondents, whose views about moral status fall between these two extremes. Interestingly, among the latter, we found the highest decisional conflict among individuals who assign high, but not full moral status to embryos. For these individuals, embryos may not demand the same moral stance as a person or child, but do require a level of respect well beyond that applied to human tissue generally. What in particular that respect demands is likely to depend on an individual. Many people who undergo IVF articulate the need for a

Table II Attitudes and preferences of participants about frozen embryos, and by high versus low decisional conflict scores (n, %).

	Total (n = 1005*)	DCS > 37.5 (n = 395)	DCS ≤ 37.5 (n = 610)	P-value
Preferences for embryo disposition				
Intentions at time of freezing				<0.001
Specific plans	811 (81.3)	287 (35.4)	524 (64.6)	
Unsure	186 (18.7)	107 (57.5)	79 (42.5)	
Current intentions—standard options				
Store for future attempts				<0.001
Very/somewhat unlikely + unsure/do not know	322 (32.3)	156 (48.4)	166 (51.6)	
Very/somewhat Likely	675 (67.7)	237 (35.1)	438 (64.9)	
Thaw and discard				<0.001
Very/somewhat unlikely + unsure/do not know	725 (75.7)	253 (34.9)	472 (65.1)	
Very/somewhat likely	233 (24.3)	130 (55.8)	103 (44.2)	
Donate to another couple				0.59
Very/somewhat unlikely + unsure/do not know	750 (77.2)	297 (39.6)	453 (60.4)	
Very/somewhat likely	221 (22.8)	92 (41.6)	129 (58.4)	
Keep frozen forever				<0.001
Very/somewhat unlikely + unsure/do not know	824 (85.4)	309 (37.5)	515 (62.5)	
Very/somewhat likely	141 (14.6)	79 (56.0)	62 (44.0)	
Donate for research				0.10
Very/somewhat unlikely + unsure/do not know	486 (49.9)	180 (37.0)	306 (63.0)	
Very/somewhat likely	488 (50.1)	206 (42.2)	282 (57.8)	
Would be likely to choose if available				
Compassionate transfer				<0.001
Very/somewhat unlikely + unsure/do not know	778 (80.4)	282 (36.2)	496 (63.8)	
Very/somewhat likely	190 (19.6)	99 (52.1)	91 (47.9)	
Ceremony for thawing/disposal				<0.001
Very/somewhat unlikely + unsure/do not know	791 (81.9)	287 (36.3)	504 (63.7)	
Very/somewhat likely	175 (18.1)	94 (53.7)	81 (46.3)	
Current thinking about childbearing				
Hope to have a/another baby	513 (51.2)	140 (27.3)	373 (72.7)	<0.001
Undecided whether or not	298 (29.8)	174 (58.4)	124 (41.6)	
Do not want to have a/another baby	190 (19.0)	79 (41.6)	111 (58.4)	
Beliefs about moral status				
Moral status of embryos				<0.001
1 No moral status	91 (9.5)	26 (28.6)	65 (71.4)	
2	157 (16.4)	56 (35.7)	101 (64.3)	
3	117 (12.2)	51 (43.6)	66 (56.4)	
4	174 (18.1)	71 (40.8)	103 (59.2)	
5	137 (14.3)	61 (44.5)	76 (55.5)	
6	111 (11.6)	65 (58.6)	46 (41.4)	
7 Maximum moral status	173 (18.0)	46 (26.6)	127 (73.4)	
How important is moral status to decision				
Very important factor	456 (47.2)	192 (42.1)	264 (57.9)	<0.001
Somewhat important factor	306 (31.7)	119 (38.9)	187 (61.1)	
Not very important factor	137 (14.2)	58 (42.3)	79 (57.7)	
Factor not important at all	67 (6.9)	11 (16.4)	56 (83.6)	

Continued

Table II *Continued*

	Total (n = 1005*)	DCS > 37.5 (n = 395)	DCS ≤ 37.5 (n = 610)	P-value
Experience of information				
Content subscale ^a				<0.001
Mean (± SD)	3.2 (± 0.8)	2.8 (± 0.7)	3.4 (± 0.8)	
Process subscale ^b				<0.001
Mean (± SD)	3.5 (± 0.8)	3.1 (± 0.7)	3.7 (± 0.8)	

DCS, decisional conflict score.

P-values are from t-test and χ^2 that examine the difference between groups with high versus low decisional conflict scores for mean (t-test) or distribution (χ^2). Where there are more than two levels in attitudinal variables, the P-value from the overall (or omnibus) χ^2 is presented.

*Items do not all sum to 1005 because not all respondents answered all questions.

^aContent subscale: mean score of seven items asking how informed the respondent felt about information received about embryo cryopreservation, where 1 = least informed and 5 = most informed.

^bProcess subscale: mean score of five items asking about how satisfied the respondent was with the informed consent process, where 1 = least satisfied and 5 = most satisfied.

Table III Fertility patients' views about the content and process of information received regarding frozen embryos.

Content subscale items	
I feel I have enough information about:	% Disagree or strongly disagree
What happens to embryos when they are frozen (storage location, monitoring)	26.1
My chances of getting pregnant with a frozen embryo	12.2
Ethical dilemmas some people face when deciding about what to do with embryos that are not transferred	17.1
Support groups for IVF patients with frozen embryos	39.6
What happens to embryos that are donated to another couple	41.6
What happens to embryos when they are donated for research	47.8
What happens to embryos when they are thawed and discarded	41.7
Process subscale items	
At the time of embryo freezing:	% Agree or strongly agree
I felt that the discussion about embryo freezing was rushed	19.9
I felt that the discussion about embryo freezing was impersonal	19.4
I felt that the discussion about embryo freezing was sensitive to my needs	12.6 ^a
It was emotionally difficult for me to think about what I would do with embryos not used for pregnancy attempts	30.3
I felt there was too much information for me to absorb	15.3

^a% disagree or strongly disagree is reported.

respectful disposal process—either compassionate transfer or a disposal ceremony (Lyerly et al., 2010). We found these individuals at higher odds of having high decisional conflict. Others hope to find meaning in disposition through research or reproductive donation (de Lacey, 2007). Still others articulate a responsibility to ensure their embryos do not become children in any family other than their own (Lyerly and Faden, 2007). While the embryo disposition question is intrinsically (and in some respects unyieldingly) difficult, making available a breadth of options which fertility patients understand as responsible and respectful is likely to facilitate embryo disposition and lead to decisions patients can live with.

Our study has several limitations. Although the nine participating centers are diverse with respect to geographic location, size, insurance mandates and affiliation with academia, patients treated at academic centers were over-represented. Nevertheless, this is the largest and only multi-site study directly measuring fertility patient preferences for disposition of cryopreserved embryos in the USA, Australia or Europe. It is also the only study to our knowledge of decision-making around fertility care that incorporated the DCS, a validated scale and predictor of delayed decision making, regret and knowledge gaps. Since the study focused on individuals who currently have embryos stored, our findings may not reflect views of patients who have disposed of embryos or transferred them to a commercial storage facility. However, given the challenges for clinicians and policymakers entailed by currently stored embryos, we chose to focus on the views of individuals situated to decide about accumulated embryos. Finally, although our sample tends to reflect the homogeneous population with access to fertility services, the study group is lacking in socioeconomic and racial diversity, thus limiting power to demonstrate significant differences in attitudes according to racial, ethnic or socioeconomic characteristics.

Notwithstanding these limitations, this study has important implications for clinical care and guidelines for informed consent for embryo disposition. Ethicists and others have emphasized that informed consent should be a process, not an event (Faden and Beauchamp, 1987; Ethics Committee, 2009), and nowhere is this more true than in embryo disposition decisions. Discussions should be facilitated at points where decisional conflict is highest—often long after embryos are frozen, when family building may be nearing its end, through periodic follow-up including discussions regarding

Table IV Unadjusted and aORs of sociodemographic, clinical and attitudinal predictors of high decisional conflict scores (DCS > 37.5).

Predictor	Unadjusted odds ratios		Adjusted odds ratios ^a	
	OR (95 CI%)	P	aOR (95 CI%)	P
Sociodemographics				
Married/living with partner	0.71 (0.29–1.77)	0.47	2.42 (0.66–8.91)	0.18
Have used donor sperm	0.71 (0.35–1.43)	0.34	2.11 (0.84–5.27)	0.11
Have a fee for storage of embryos	1.43 (0.90–2.28)	0.13	1.70 (0.91–3.17)	0.09
Attitudes				
Unsure about disposition at time of freezing	2.47 (1.79–3.42)	<0.001	1.54 (0.99–2.40)	0.06
Current intentions for embryos (somewhat/very likely to choose option)				
Store for future pregnancy	0.58 (0.44–0.75)	<0.001		
Thaw and discard	2.35 (1.74–3.18)	<0.001	2.08 (1.37–3.15)	<0.001
Donate to another couple	1.09 (0.80–1.48)	0.59	1.42 (0.93–2.17)	0.10
Keep frozen forever	2.12 (1.48–3.05)	<0.001	1.90 (1.14–3.16)	0.01
Donate for research	1.24 (0.96–1.61)	0.10	1.66 (1.12–2.46)	0.01
Would be likely to choose if available				
Compassionate transfer	1.91 (1.39–2.64)	<0.001	1.65 (1.05–2.61)	0.03
Ceremony	2.04 (1.46–2.84)	<0.001		
Current thinking about childbearing				
Do not want to have a/another baby	1.90 (1.34–2.68)	<0.001	1.69 (1.03–2.78)	0.04
Undecided whether or not	3.74 (2.77–5.05)	<0.001	3.93 (2.59–5.96)	<0.001
Hope to have a/another baby	Reference		Reference	
Moral Status of embryos				
		<0.001		0.002 ^b
1 No moral status	1.10 (0.63–1.95)	0.73	1.84 (0.79–4.32)	0.16
2	1.53 (0.96–2.45)	0.08	1.29 (0.61–2.72)	0.51
3	2.13 (1.30–3.51)	0.003	1.85 (0.86–3.98)	0.12
4	1.90 (1.21–2.99)	0.005	1.58 (0.80–3.14)	0.19
5	2.22 (1.38–3.57)	0.001	1.36 (0.70–2.64)	0.37
6	3.90 (2.35–6.47)	<0.001	4.22 (2.17–8.22)	<0.001
7 Maximum moral status	Reference		Reference	
Importance of beliefs about moral status in decision making				
		0.002		0.004 ^b
Very important	3.70 (1.89–7.25)	<0.001	3.71 (1.49–9.24)	0.005
Somewhat important	3.24 (1.63–6.43)	<0.001	2.98 (1.20–7.41)	0.02
Not very important	3.74 (1.80–7.75)	<0.001	5.18 (2.03–13.2)	<0.001
Not important at all	Reference		Reference	
Content subscale (Mean score) ^c	0.27 (0.22–0.34)	<0.001	0.25 (0.19–0.34)	<0.001
Process subscale (Mean score) ^d	0.37 (0.31–0.45)	<0.001	0.64 (0.49–0.82)	<0.001

DCS, decisional conflict score.

Final multivariable logistic regression model selected by backward elimination procedure using $P < 0.20$.^aAdjusted ORs are controlling for all predictor variables retained by backward elimination reported in Table IV.^bOmnibus P -values.^cContent subscale: mean score of seven items asking how informed the respondent felt about information received about embryo cryopreservation, where 1 = least informed and 5 = most informed.^dProcess subscale: mean score of five items asking how satisfied the respondent was with the informed consent process, where 1 = least satisfied and 5 = most satisfied with informed consent process.

patients' evolving reproductive goals and values. Given the morally difficult nature of the disposition decision, informed consent is unlikely to be the full solution; ensuring options that patients find responsible and respectful, such as compassionate transfer or a disposal ceremony may benefit those who assign high moral status or value to the embryos but are disinclined to donate them to another couple. These changes may not only reduce the numbers of embryos in storage, but may also facilitate disposition decisions that are morally acceptable to the majority of fertility patients. In the meantime, this study clearly reveals that a considerable proportion of individuals

with cryopreserved embryos have high decisional conflict, and have the potential to benefit from a restructuring of the informed consent process for embryo cryopreservation in fertility care.

Authors' roles

A.D.L. led the conception, development and implementation of the survey, as well as writing and revision of the manuscript. S.N. conducted the statistical analyses and contributed to the writing and revision of the methods and analysis sections. M.K. led the analysis and contributed to the writing and revision of the manuscript.

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