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Decisional Conflict Among Patients Who Accept or Decline Participation in Phase I Oncology Studies

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Abstract

We compared decisional conflict among adults with advanced cancer who had accepted or declined participation in phase I cancer clinical trials. Respondents completed a 121-item questionnaire that included the Decisional Conflict Scale (DCS), which was designed to measure uncertainty in making health decisions. We used standardized effect sizes to compare the DCS scores of accepters ($n = 250$) and decliners ($n = 65$). Accepters had lower decisional conflict than decliners overall ($d = 0.42$; 95% confidence interval, 0.17-0.68) and on all subscales. Whether greater decisional conflict among decliners represents suboptimal decision-making and is reason for bioethical concern depends on how the results are interpreted. We offer three scenarios to explain the differences and describe opportunities for future empirical work.

Rational decision making combines the best available data and the decision maker's personal values regarding possible outcomes to evaluate the overall worth of an option (Hastie and Dawes 2001). There is concern that patients who agree to participate in phase I oncology studies may not be making optimal decisions. The decision to participate in clinical trials is affected by patients' perceived chance of benefit from the experimental therapy (Meropol et al. 2003). However, patients might have insufficient understanding of potential benefits and risks, may have poorly formed personal values about benefits and risks, or may be vulnerable to undue influence by others. Recent studies have examined patients' knowledge of potential benefits and risks (Meropol et al. 2003; Agrawal et al. 2006; Weinfurt et al. 2005), but there are important complexities involved in determining how patients understand them (Agrawal et al. 2006; Weinfurt 2004; Weinfurt et al. 2008). "Understanding" in the context of informed consent represents the ability to go beyond the recitation of facts in integrating knowledge into a treatment decision.

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We surveyed patients who decided whether to participate in a phase I oncology study to assess their “decisional conflict” (O'Connor 1995), that is, the extent to which they reported unresolved decisional needs such as personal uncertainty and related deficits in knowledge, values clarity, and support or pressure. In this paper, we describe differences in the decisional conflict of patients who enrolled in a phase I trial and those who did not. We also explore the relationship between personal uncertainty and patients' perceived chance of risk and benefit from standard and experimental therapies.

Patients and Methods

Participants were recruited from 4 academic medical centers in the United States to participate in a survey about their perceptions and decision making regarding participation in phase I clinical trials. Participants had been offered an opportunity to enroll in a phase I study and had made a decision about whether to enroll. Patients who had already initiated treatment were excluded. Eligible survey participants were adults who had an advanced malignancy for which there was no standard effective therapy or for which standard therapy had failed; had a life expectancy of at least 3 months; and had an Eastern Cooperative Oncology Group performance status of 0 to 2 (i.e., ambulatory at least 50% of the time). Surveys were conducted either in person or by telephone. The study design and survey instrument were approved by the institutional review boards of the participating sites (Fox Chase Cancer Center, Philadelphia, Pennsylvania; University of Maryland, Baltimore; Georgetown University, Washington, DC; Northwestern University, Chicago, Illinois; and Duke University, Durham, North Carolina [data management center]). Patient recruitment, data collection, and instrument development have been described in greater detail elsewhere (Meropol et al. 2003).

Decisional Conflict Scale

To measure patients' recollections and beliefs about their decision-making process, we used O'Connor's 16-item Decisional Conflict Scale (DCS; version A), which has been used in a variety of health care situations (O'Connor 1995; Goel et al. 2001; O'Connor et al. 1999; Whelan et al. 2004). Response categories are measured on a 5-point scale where 1 indicates “strongly agree” and 5 indicates “strongly disagree.” Items are reverse-scored when necessary, averaged, and transformed into an overall score where 0 indicates low decisional conflict and 100 indicates high decisional conflict.

In addition to the overall score, the instrument has scores for 5 subscales, each of which has 3 items, except for the “Effective Decision” subscale, which has 4 items: (1) “Informed,” which measures awareness of options, benefits, and risks (Cronbach $\alpha = 0.65$ in the current sample); (2) “Values Clarity,” which measures feelings about benefits and risks ($\alpha = 0.34$); (3) “Support,” which measures feelings of support, advice, and pressure from others ($\alpha = 0.48$); (4) “Uncertainty,” which measures the respondent's degree of confidence about the decision ($\alpha = 0.75$); and (5) “Effective Decision,” which has 2 items summarizing the Informed and Values Clarity subscales, an item on the likelihood of adhering to the decision, and an item on satisfaction with the decision ($\alpha = 0.88$). Internal consistency in the overall scale was consistent with previous studies at $\alpha = 0.83$ (O'Connor 1995). Modifications are usually made to the DCS to help respondents focus on a specific decision. Table 2 shows the wording of the items used in this study.

Perceptions of Risk and Benefit

As a measure of patients' perceptions of the risks and benefits of experimental and standard therapies, patients were asked the following 4 questions and instructed to place an X on a horizontal line from 0% to 100% at the appropriate value: (1) “You were asked to participate in a study examining a new experimental therapy for advanced cancer. If you were to receive

this therapy, what do you think are the chances it would control your cancer?” (2) “The experimental therapy you were offered is associated with several potential adverse reactions. These negative effects of the therapy were explained to you in the consent form you read. If you were to receive this therapy, what do you think are the chances that you would experience a severe adverse reaction?” (3) “Standard therapy is offered to some patients with advanced cancer. If you were to receive such therapy, what do you think are the chances it would control your cancer?” and (4) “Standard therapy is associated with several potential adverse reactions, including hair loss, fatigue, mouth sores, and susceptibility to infection. If you were to receive this therapy, what do you think are the chances that you would experience such reactions?” These items were developed and pilot-tested by a multidisciplinary team including medical oncologists, nurses, psychologists, clinical economists, and a medical ethicist.

Statistical Analysis

For patients who completed the DCS, we calculated summary statistics for the total sample and separately for patients who agreed (accepters) and did not agree (decliners) to participate in a phase I trial. We calculated standardized effect sizes (d) by dividing the mean difference between accepters and decliners by the pooled standard deviation (SD). Effect sizes around 0.2, 0.5, and 0.8 are considered small, medium, and large, respectively (Cohen-Mansfield et al. 1992). They correspond to changes in DCS scores that move the average patient from the fiftieth percentile to approximately the fortieth, thirtieth, and twentieth percentiles, respectively. We used a noncentral t distribution to calculate 95% confidence intervals (CIs) around each effect size.

We report the means and SDs of perceived chance of benefit, perceived chance of risk, risk-benefit ratio (i.e., perceived chance of risk divided by perceived chance of benefit for each patient), and the absolute values of the differences in perceived benefits, risks, the difference between benefit and risk, and risk-benefit ratios between the two types of therapy. We used t tests to examine differences between accepters and decliners and between therapies by acceptor/decliner status. We calculated Pearson correlation coefficients and their 95% CIs (Fayers 2008) to illustrate the relationships between the absolute values of the differences between risk-benefit ratios for standard and experimental therapies and personal uncertainty, as measured by the DCS Uncertainty subscale. We used a significance level of $\alpha = 0.05$ for all assessments, and we used SAS statistical software version 9.1 (SAS Institute Inc., Cary, North Carolina) for all analyses.

Results

We invited 593 patients who had been offered enrollment in a phase I study to complete our survey. Of these, 328 (55%) consented. Of the 328 consenters, 260 (79%) chose to participate in a phase I study (accepters) and 68 (21%) did not (decliners). Ninety-six percent of both accepters (250/260) and decliners (65/68) completed the DCS. There were no observed differences in demographic or clinical characteristics between accepters and decliners (Table 1).

Table 2 shows the mean scores for accepters and decliners. Decliners had higher overall decisional conflict scores than accepters, with an effect size of 0.46 (95% CI, 0.18-0.74). Decliners also had higher scores on all subscales, with moderate effects on the Informed ($d = 0.50$; 95% CI, 0.21-0.78), Values Clarity ($d = 0.51$; 95% CI, 0.23-0.80), and Support ($d = 0.43$; 95% CI, 0.15-0.70) subscales. Absolute scores for both groups were highest on the Uncertainty subscale and lowest on the Effective Decision subscale.

Table 3 shows the mean chances of benefit and risk for standard and experimental therapies overall and by acceptor/decliner status, as well as the risk-benefit ratios for each type of therapy.

A risk-benefit ratio less than 1.00 represents a favorable assessment (i.e., low risk relative to high benefit). Patients who accepted participation in a phase I trial perceived greater risk than benefit for standard therapy and greater benefit than risk for experimental therapy (risk-benefit ratio, 2.17 and 0.78, respectively; $p < 0.001$), whereas those who declined participation in a phase I trial saw neither option as having a favorable risk-benefit ratio (1.70 for standard therapy, 2.36 for experimental therapy; $p = 0.61$). We found very low correlations between risk-benefit ratios and the DCS Uncertainty subscale overall (standard therapy, $r = -0.11$ [95% CI, -0.24 to 0.01]; experimental therapy, $r = 0.21$ [95% CI, 0.10 - 0.33]) and by acceptor (standard therapy, $r = -0.14$ [95% CI, -0.28 - 0.003]; experimental therapy, $r = 0.22$ [95% CI, 0.09 - 0.35]) and decliner (standard therapy, $r = 0.05$ [95% CI, -0.23 to 0.31]; experimental therapy, $r = 0.19$ [95% CI, -0.11 to 0.46]) status. There was a statistically significant difference between accepters and decliners in the average difference between perceived chance of benefit for standard versus experimental therapy, with accepters perceiving more difference in benefit between the two types of therapies.

Discussion

Patients who chose to participate in a phase I oncology study experienced less decisional conflict and perceived experimental therapy as more beneficial than patients who declined participation. In particular, accepters reported feeling more informed, having greater clarity about their values, and feeling more support and less pressure from others in the decision-making process. Accepters also reported feeling more certain about their decision and feeling that they had made a more effective decision.

DCS scores of similar level are associated with other difficult medical decisions. For example, the distribution of DCS scores in our study was similar to the distribution of scores among patients with severe chronic obstructive pulmonary disease who had decided with the help of a decision aid whether to receive mechanical ventilation (Dales et al. 1999), a decision that involves substantial tradeoffs of quantity and quality of life. Similar scores were also found among postmenopausal women who had decided with the help of a decision aid whether to take hormone replacement therapy (Clark et al. 2003) at a time when conflicting evidence about the risks of hormone replacement was attracting considerable attention. In contrast, patients facing less complex, less risky medical decisions have lower DCS scores than participants in our study. For example, patients who had decided with the help of a decision aid whether to pre-donate autologous blood before heart surgery had lower DCS scores than patients in the present study (Laupacis et al. 2006). Here the risks and benefits are well described and the tradeoffs are not so difficult. Similarly, men who had decided to undergo vasectomy, a procedure with well-characterized risks and benefits, had lower DCS scores than patients in our study (Balde et al. 2006). These comparisons suggest that the complexity of the decision and outcome uncertainties, rather than the severity of disease, create decisional conflict.

There has been limited research involving patients' decisions to enroll in phase I oncology clinical trials. Previous research found that patients who agreed to enroll in phase I trials reported being well-informed about their alternatives, understanding the risks and benefits of participation, and not experiencing coercive pressure to enroll in a trial (Agrawal et al. 2006). However, this report only included patients who agreed to enroll in a phase I trial. In the present study, which included both accepters and decliners, we found that patients who declined to enroll in a phase I trial felt less informed and less clear in their personal values than did patients who agreed to enroll. Decliners reported having less support in the decision-making process and feeling greater pressure to make a decision. Furthermore, decliners perceived more risk than benefit from experimental therapy, whereas accepters reported the opposite perception.

Although we would expect personal uncertainty about the decision to participate in experimental therapy to be related to perceptions of risk and benefit about therapies, the correlations between the Uncertainty subscale and participants' perceived risk-benefit ratios were weak. This finding cannot be explained by a lack of variation in the measures, both of which show adequate variability, or by a lack of reliability in the Uncertainty subscale, because its reliability is also acceptable.

Better understanding of the differences between accepters and decliners would help to inform the bioethical significance of our findings. One possible interpretation is that decliners had higher DCS scores because they lacked understanding about the benefits and risks of participation and had less clarity about their personal values, whereas accepters had lower scores because they understood the risks and benefits and had greater clarity. In this scenario, there might be an ethical concern about decliners, because they may not have had appropriate decision-making support.

However, a different interpretation would stem from the observation that for phase I studies there is often no reliable information about benefits and risks, especially for studies of agents never before used in humans. From this perspective, an alternative interpretation of our findings is that decliners had higher DCS scores (particularly on the Informed and Values Clarity subscales) because they appreciated the real uncertainty about risks and benefits in phase I trials. In contrast, accepters reported understanding the potential risks and benefits of something for which risks and benefits are uncertain. This interpretation would indicate a problem with the quality of informed consent for patients who agree to enroll in phase I studies.

It is also possible that accepters understand the uncertainties inherent in phase I studies but agree to participate because of the high value they place on the chance of benefit (Agrawal et al. 2006; Rasiel et al. 2005; Weinfurt 2007). Indeed, the absolute value of the difference between the perceived chance of benefit for standard and experimental therapies was nearly twice as high for accepters compared to decliners ($p < 0.001$) (Table 3). Admitting uncertainty about a choice just made would generate cognitive dissonance (Festinger 1957), so people may adjust their beliefs after making a decision to be more consistent with the decision they made. For example, voters leaving a polling place speak more positively about their favored candidate than do voters waiting in line to vote (Frenkel and Doob 1976). In the case of patients enrolling in phase I trials, the fact of having made the decision might influence accepters to downplay doubts about how well they were informed and how clear were their values. Accepters' lower DCS scores would result, therefore, from an effort to minimize inconsistencies between beliefs ("I have great uncertainty regarding possible side effects, and this experimental therapy is unlikely to help me.") and actions (enrolling in the study). If lower reported decisional conflict is a product of patients' efforts to reduce cognitive dissonance, it is not clear that this scenario would present an ethical concern. This interpretation of the findings would simply mean that we do not have direct access to patients' perceptions at the time their decisions are made, but only to the possibly modified beliefs of patients who are motivated to maintain consistency between past actions and present beliefs.

Our study has several limitations. First, although we found moderate differences in decisional conflict between patients who did and did not decide to enroll in a phase I trial, whether these differences reflect a problem with the informed consent process is not clear, because there are multiple possible reasons for our findings. Second, our measures of perceived chance of benefit and risk from standard and experimental therapies have not been formally validated, though they were pilot-tested and have been used previously (Meropol et al. 2003). Third, recall bias may have been an issue, because the participants reported on their decisional conflict and perceived chance of benefits and risks of the therapies after their decision had been made. However, this type of bias, if present, would likely be systematic and should not affect our

results. Finally, since patients uninterested in trial participation may seek care outside the types of academic medical centers where this study was conducted, the participation rate may be higher for accepters than decliners.

Best Practices

This study is novel for its inclusion of both accepters and decliners of participation in phase I trials, and the findings indicate a nearly half SD difference in decisional conflict between these groups. In addition, this is the first time the DCS has been used in a survey of decisions about participation in experimental therapies. Special efforts were made to enroll a wide variety of participants from four geographically diverse locations to improve generalizability. However, due to the multiple and disparate possible reasons for our findings, the implications for informed consent remain limited without further empirical work.

Research Agenda

Given that one of the largest differences between accepters and decliners was for the Informed subscale of the DCS, future empirical work is needed to examine what patients think it means to understand potential benefits and risks, especially when data are unavailable or are characterized by a high level of uncertainty. Likewise, additional work is necessary to determine what patients mean when they answer questions about uncertainty. If patients' self-reported expectations of their chance of benefit and risk from standard and experimental therapies represent more than simple assessments of benefit and risk (Weinfurt et al. 2003), it is unclear how patients' reports about uncertainty should be interpreted. Conceptual work is also needed to reach some consensus in the research ethics community regarding what is meant by understanding and how researchers, ethicists, and clinicians can determine that adequate understanding has been achieved.

To advance this line of work, it is necessary to elaborate on what the differences in decisional conflict between accepters and decliners mean for the informed consent process. Administration of the DCS in this sample was part of a larger interview protocol for which qualitative methods were not used. A complementary next step would be an in-depth interview study with patients who are deciding about participation in early-phase trials to explore themes from the scenarios we outlined above. In addition, a study that evaluated the quality of the informed consent process and the decision support that accepters and decliners received may help clarify whether there is an ethical concern for either group. To determine whether cognitive dissonance is a factor in the lower decisional conflict scores seen among accepters, it may be useful to measure decisional conflict at multiple points in the decision-making process.

Educational Implications

In approaching the informed consent process, clinical trial investigators and their research personnel should be aware that patients who accept or decline investigational therapy may do so because of personal uncertainty that could benefit from additional decision support.

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TABLE 1

Participant Characteristics

Characteristic	Overall (N = 315)	Accepters (n = 250)	Decliners (n = 65)	p-Value for Accepters vs. Decliners
Sex, No. (%)				0.33 [*]
Female	136 (43.2)	110 (44.0)	26 (40.0)	
Male	179 (56.8)	140 (56.0)	39 (60.0)	
Age, mean (SD), y	57.27 (12.08)	57.57 (12.58)	56.16 (9.94)	0.34 [†]
Race/ethnicity, No. (%)				0.84 [‡]
Asian or Pacific Islander	4 (1.3)	3 (1.2)	1 (1.6)	
Black	37 (11.8)	31 (12.5)	6 (9.4)	
Hispanic	3 (1.0)	3 (1.2)	0	
White	268 (85.6)	211 (84.7)	57 (89.1)	
Other	1 (0.3)	1 (0.4)	0	
Highest grade or level of schooling completed, No. (%)				0.94 [§]
8th grade or less	7 (2.2)	5 (2.0)	2 (3.1)	
Some high school	18 (5.8)	16 (6.5)	2 (3.1)	
High school graduate	83 (26.6)	66 (26.7)	17 (26.2)	
Some college	81 (26.0)	61 (24.7)	20 (30.8)	
College graduate or beyond	123 (39.4)	99 (40.1)	24 (36.9)	
Current marital/partnered status, No. (%)				0.67 [‡]
Divorced	22 (7.1)	17 (6.9)	5 (7.7)	
Married/partnered	245 (78.5)	191 (77.3)	54 (83.1)	
Separated	8 (2.6)	6 (2.4)	2 (3.1)	
Single, never married/partnered	19 (6.1)	16 (6.5)	3 (4.6)	
Widowed	17 (5.5)	16 (6.5)	1 (1.5)	
Other	1 (0.3)	1 (0.4)	0	
Monthly household income, No. (%)				0.26 [§]
< \$500	4 (1.6)	4 (2.0)	0	
\$500-\$599	8 (3.2)	6 (3.0)	2 (4.1)	
\$1000-\$1999	42 (16.9)	35 (17.6)	7 (14.3)	
\$2000-\$2999	35 (14.1)	31 (15.6)	4 (8.2)	
\$3000-\$3999	33 (13.3)	28 (14.1)	5 (10.2)	
\$4000-\$4999	25 (10.1)	19 (9.6)	6 (12.2)	
\$5000-\$5999	24 (9.7)	15 (7.5)	9 (18.4)	
\$6000-\$6999	18 (7.3)	15 (7.5)	3 (6.1)	
\$7000-\$7999	17 (6.9)	10 (5.0)	7 (14.3)	
≥ \$8000	42 (16.9)	36 (18.1)	6 (12.2)	
Religious background, No. (%)				0.13 [*]
Atheist/none	45 (14.8)	39 (16.1)	6 (9.5)	
Catholic	115 (37.7)	86 (35.5)	29 (46.0)	
Hindu	8 (2.6)	8 (3.3)	0	
Jewish	22 (7.2)	15 (6.2)	7 (11.1)	
Protestant	115 (37.7)	94 (38.8)	21 (33.3)	
Participated in any other clinical trials, No. (%)				0.48 [*]
No	247 (79.7)	194 (78.9)	53 (82.8)	
Yes	63 (20.3)	52 (21.1)	11 (17.2)	

Abbreviations: SD, standard deviation.

^{*} p-Value from χ^2 test.

⁷ p -Value from t test.
[#] p -Value from exact χ^2 test.
[§] p -Value from Mantel-Haenszel test.

Decisional Conflict Among Patients Considering Participation in Phase I Cancer Clinical Trials

TABLE 2

Scale or Subscale*	Mean Score (SD)		Effect Size (95% CI)
	Accepters (n = 250)	Decliners (n = 65)	
Informed ($\alpha = 0.65$)	26.14 (16.46)	34.43 (17.71)	0.50 (0.21 to 0.78)
I am aware of the choices I have to treat my cancer.			
I feel I know the potential benefits of treatment on this experimental therapy.			
I feel I know the risks and side effects of treatment on this experimental therapy.			
Values Clarity ($\alpha = 0.34$)	30.85 (14.54)	38.17 (13.20)	0.51 (0.23 to 0.80)
I know how important the potential benefits of treatment on this experimental therapy were to me in this decision.			
I know how important the risks and side effects of treatment on this experimental therapy were to me in this decision.			
It was hard to decide if the benefits were more important to me than the risks, or if the risks were more important than the benefits. [†]			
Support ($\alpha = 0.48$)	27.04 (15.41)	33.59 (15.21)	0.43 (0.15 to 0.70)
I had the right amount of support from others in making this choice.			
I felt pressure from others in making this decision. [†]			
I needed more advice and information about the choices. [†]			
Uncertainty ($\alpha = 0.75$)	36.50 (24.00)	42.05 (24.00)	0.23 (−0.04 to 0.50)
It was clear what choice was best for me.			
I was unsure what to do in this decision. [†]			
This decision was hard for me to make. [†]			
Effective Decision ($\alpha = 0.88$)	18.04 (13.62)	21.09 (12.87)	0.23 (−0.05 to 0.50)
I feel I have made an informed choice.			
My decision shows what is most important for me.			
I expect to stick with my decision.			
I am satisfied with my decision.			
Decisional Conflict ($\alpha = 0.83$)	26.47 (12.20)	32.09 (12.05)	0.46 (0.18 to 0.74)

Abbreviations: CI, confidence interval; SD, standard deviation.

* Transformed to a 0-100 scale.

[†] Item was reverse-scored.

TABLE 3

Perceived Chances of Benefit and Risk, Risk-Benefit Ratios, and Differences in Benefit and Risk Among Patients Considering Participation in Phase I Cancer Clinical Trials

Variable	Mean (SD)			<i>p</i> -Value for Accepters vs. Decliners
	Overall (N = 315)	Accepters (n = 250)	Decliners (n = 65)	
Chance of benefit for standard therapy *	41.16 (28.47)	38.95 (28.54)	50.38 (26.53)	0.007
Chance of benefit for experimental therapy *	60.51 (26.64)	64.85 (25.17)	40.04 (23.90)	< 0.001
Chance of risk for standard therapy *	56.56 (29.81)	56.23 (30.15)	57.96 (28.57)	0.69
Chance of risk for experimental therapy *	38.88 (27.41)	36.14 (26.43)	51.76 (28.51)	< 0.001
Risk-benefit ratio for standard therapy	2.07 (2.54)	2.17 (2.70)	1.70 (1.86)	0.15
Risk-benefit ratio for experimental therapy	1.05 (1.64)	0.78 (1.10)	2.36 (2.79)	< 0.001
Absolute value of difference in benefit *	27.38 (25.37)	29.65 (25.82)	17.04 (20.48)	< 0.001
Absolute value of difference in risk *	23.77 (25.91)	24.59 (26.47)	19.89 (22.97)	0.23
Absolute value of difference in the difference between benefit and risk	23.95 (20.75)	24.61 (21.03)	20.79 (19.30)	0.25
Absolute value of difference in risk-benefit ratio between standard and experimental therapies	1.62 (2.67)	1.70 (2.81)	1.24 (1.93)	0.21

Abbreviation: SD, standard deviation.

* Measured on a 0-100 scale.