Factors and Outcomes of Decision Making for Cancer Clinical Trial Participation

Barbara A. Biedrzycki, PhD, CRNP, AOCNP®

Purpose/Objectives: To describe factors and outcomes related to the decision-making process regarding participation in a cancer clinical trial.

Design: Cross-sectional, descriptive.

Setting: Urban, academic, National Cancer Institute–designated comprehensive cancer center in the mid-Atlantic United States.

Sample: 197 patients with advanced gastrointestinal cancer.

Methods: Mailed survey using one investigator-developed instrument, eight instruments used in published research, and a medical record review.

Main Research Variables: Independent variables: disease context, sociodemographics, hope, quality of life, trust in healthcare system, trust in health professional, preference for research decision control, understanding risks, and information. Dependent variables: decision to accept or decline research participation and satisfaction with this decision.

Findings: All of the factors within the Research Decision Making Model together predicted cancer clinical trial participation and satisfaction with this decision. The most frequently preferred decision-making style for research participation was shared (collaborative) (83%).

Conclusions: Multiple factors affect decision making for cancer clinical trial participation and satisfaction with this decision. Shared decision making previously was an unrecognized factor and requires further investigation.

Implications for Nursing: Enhancing the process of research decision making may facilitate an increase in cancer clinical trial enrollment rates. Oncology nurses have unique opportunities as educators and researchers to support shared decision making by those who prefer this method for deciding whether to accept or decline cancer clinical trial participation.

The Institute of Medicine (2002), in its report *Responsible Research: A Systems Approach to Protecting Research Participants*, stressed the need for empirical data to evaluate satisfaction with the decision to participate in research. Individuals with advanced cancer may be particularly vulnerable when deciding to join a cancer clinical trial. Although patients with advanced cancer may appropriately decline to participate in clinical trials after weighing the risks and benefits in light of their own values, many have expressed confusion concerning this decision. For example, some individuals joined cancer clinical trials expecting a therapeutic benefit when the purpose of the study was limited to testing for toxicities (Daugherty et al., 1995; Kass, Sugarman, Faden, & Schoch-Spana, 1996). Others declined to participate in therapeutic clinical trials, citing an overwhelming fear of their cancer and limited understanding of the study (Stevens & Ahmedzai, 2004) and decisional conflict (Flynn et al., 2008). A systematic review of patient education revealed that multimedia approaches were ineffective in promoting better patient understanding of clinical trial options or satisfaction with the decision to accept or decline participation in a cancer clinical trial (Flory & Emanuel, 2004).

Many factors may affect satisfaction with the decision to join a cancer clinical trial. Most research participants believe they are helping future patients and contributing to science (Moore, 2001). Potential cancer clinical trial participants declined because of fear of their illness and limited understanding of research and then later regretted not joining the trial (Stevens & Ahmedzai, 2004). More information is known about satisfaction with standard treatment decisions than research decisions. For example, dissatisfied people with cancer did not regret declining an alternative treatment, but rather were dissatisfied because they did not take a more active role in treatment decision making (Hack, Degner, Watson, & Sinha, 2006). Decisional regret can have a long-term effect on quality of life (Clark, Wray, & Ashton, 2001).

Satisfaction with the decision to participate in a cancer clinical trial and actual accrual to cancer clinical trials both are important outcomes of decision making. Therefore, the purpose of this study was to examine the factors and outcomes of decision making for cancer clinical trial participation. The specific aims of this study were (a) to examine the relationship between disease context and sociodemographic factors to patient preferences for research decision control and (b) to identify significant factors that influence the decision to join a cancer clinical trial and the satisfaction with this decision.

Background and Significance

Respect for autonomy has long been a central ethical principle guiding informed consent for research participation. The 1949 Nuremberg Code, developed in response to the research abuses of Nazi physicians, emphasized this principle as a counter to the potential for participant coercion (Beuchamp & Childress, 2001; National Institutes of Health, n.d.). The Nuremberg Code also defined the investigator's obligation to protect research participants from harm.

The World Medical Association's (2008) *Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects*, developed in 1964, emphasized autonomy to a lesser degree than the Nuremberg Code and put greater emphasis on the investigator's obligation to protect the research participant. However, in the early 1990s, the ethical emphasis in research shifted from one of protectionism toward the principle of justice and the need for investigators to ensure equal access to the potential benefits of research participation (Moreno, 2001). Federal guidelines on the mandatory inclusion of women, minorities, children, and those in need of emergency care who do not have the capacity to consent are evidence of the new emphasis on equal access to the potential benefits of research participation. Providing access to the benefits of research while protecting research participants is challenging. However, the challenge is even greater for individuals with cancer who have been shown to have difficulty distinguishing standard therapy from experimental therapy (Joffe, Cook, Cleary, Clark, & Weeks, 2001) and who have declined to participate in research because of the fear of cancer and limited understanding of medical research (Stevens & Ahmedzai, 2004).

Conceptual Model

Decision making for cancer clinical trial participation is the multifaceted process leading to accepting or declining participation in a cancer clinical trial, which may be affected by patient, provider, and treatment factors (Biedrzycki, 2010). Cancer clinical trials are experiments in which drugs or procedures are tested on people with cancer.

The Research Decision Making Model was used to guide this study (see Figure 1). This model was based on the Treatment Decision Model (Bowling & Ebrahim, 2001), which considers how sociodemographics, personality, information, experience, role performance, cost and rationing, setting, disease context, and treatment context interact with understanding risks, patient preferences, and professional preferences in making standard treatment decisions. Based on the literature on decision making for cancer clinical trial participation (Biedrzycki, 2010), 5 of the 12 independent factors from the Treatment Decision Model were included in the Research Decision Making Model: disease context, sociodemographics, patient preferences, understanding risks, and information. Additional concepts obtained from the literature and included in the Research Decision Making Model are quality of life (Cohen et al., 2007; Daugherty et al., 2005; Gaskin et al., 2004; Hlubocky, Ratain, Wen, & Daugherty, 2007), hope (Cox & Avis, 1996; Moore, 2001), and trust in the healthcare system and in the health professional (Avis, Smith, Link, Hortobagyi, & Rivera, 2006; Daugherty et al., 2005; Nguyen, Somkin, Ma, Fung, & Nguyen, 2005). The concept of decision control preference for research also was added, based on the work of Degner and Beaton (1987).

Design

This descriptive, cross-sectional research design used a mailed-survey data collection method to examine factors related to the decision-making process regarding participation in a cancer clinical trial and outcomes of this decision. Self-report and additional medical record reviews provided data for the current study.

Sample and Setting

The convenience sample consisted of patients with advanced gastrointestinal (GI) cancer who were seen at an urban, academic, National Cancer Institute–designated comprehensive cancer center in Baltimore, MD. Inclusion criteria were (a) being aged 18 years or older; (b) understanding the written English language; (c) having an advanced diagnosis of pancreatic, colon, or rectal cancer; and (d) being offered the opportunity to participate in a phase I, II, or III cancer clinical trial.

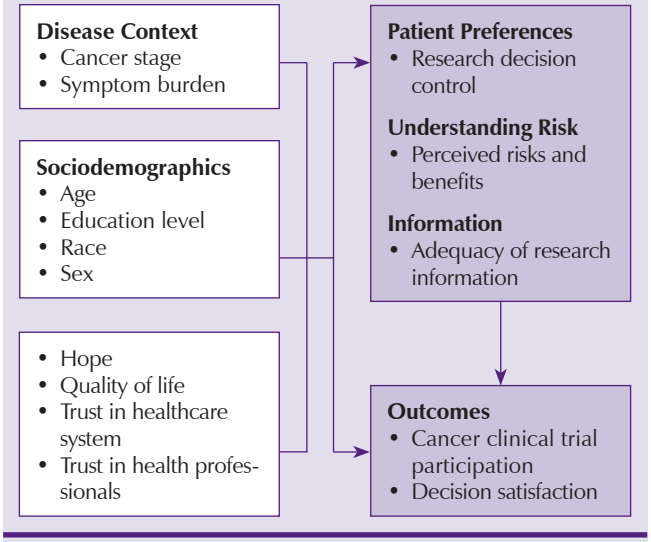

Figure 1. Research Decision Making Model

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Table 1. Sample Characteristics and Cancer Clinical Trial Participation

Variable	Participated in Trial n	Participated in Trial %	Did Not Participate n	Did Not Participate %	N	χ^2	p
Gender						1.355	0.286
Male	72	63	42	37	114		
Female	59	71	24	29	83		
Race						2.103	0.147
Caucasian	115	65	62	35	177		
Not Caucasian	14	82	3	18	17		
Cancer diagnosis						7.437	0.006
Pancreas	105	72	41	28	146		
Colon or rectal	26	51	25	49	51		
Cancer stage						1.646	0.217
Lower than IV	54	72	21	28	75		
IV	77	63	45	37	122		
Family income ($)						0.685	0.953
50,000 or less	28	68	13	32	41		
50,001–100,000	34	69	15	31	49		
100,001–150,000	21	66	11	34	32		
150,001 or higher	24	62	15	38	39		
Rather not answer	24	67	12	33	36		
Employment						0.731	0.694
Working	53	65	29	35	82		
Retired	54	70	23	30	77		
Not working	17	65	9	35	26		
Rather not answer	7	58	5	42	12		
Financial status						0.109	0.741
Independent	99	68	47	32	146		
Dependent	28	65	15	35	43		
Type of work						0.002	0.964
Blue collar	28	65	15	35	43		
White collar	93	65	49	35	142		
Education						4.775	0.092
High school or less	35	78	10	22	45		
Community or undergraduate college	44	59	31	41	75		
Graduate school or higher	52	68	24	32	76		

GI cancer was chosen for its high prevalence in the U.S. population (American Cancer Society, 2011) and because many of those patients initially are diagnosed with advanced disease, which requires them to make research participation decisions over a brief period of time (Miller & Joffe, 2009; Todd et al., 2009). For the current study, advanced cancers were defined as stage III and IV colon or rectal cancer and stage II, III, and IV pancreatic cancer. Including patients with an advanced cancer diagnosis permitted a focus on a vulnerable population with a life-threatening illness.

Cancer clinical trials in phases I, II, and III were selected for this study because all have the potential to benefit the patient. Although phase I trials traditionally have been seen as testing drug safety and not delivering a therapeutic benefit, a review of National Cancer Institute–sponsored phase I cancer clinical trials revealed benefits for about 4%–18% of patients who participated (Horstmann et al., 2005). Phase I, II, and III trials allow for examination of the relationship between understanding of perceived risks and benefits to the decision outcomes.

The sample size was determined by considering that 10 participants are needed to study each variable under investigation (Motulsky, 2010). Because the current study included 14 independent variables, a sample size of 140 was required. However, Thorndike and Dinnel (2000) recommended adding an additional 50 participants to the sample size formula of 10 participants per variable, which totaled 190.

To obtain an ideal sample size of 190 with an expected nonresponse rate of 40%, the investigator anticipated that about 475 surveys would need to be mailed. The expected nonresponse rate was based on the research of Kutner, Vu, Prindiville, and Byers (2000) on patients with stage III colon cancer, as well as on the work of Clark et al. (2001) on patients with metastatic prostate cancer. Those researchers achieved a 56% and 63% response rate, respectively, to a single mailed survey on standard treatment decisions (not cancer clinical trial participation decisions).

Methods

Approval was obtained from the Johns Hopkins University School of Nursing, the Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins, and the John Hopkins Medicine Institutional Review Board. A Health Insurance Portability and Accountability Act waiver was obtained from the institutional review board. The waver permitted access to demographic information contained in the medical record, including the name, address, diagnosis, reason for visit, race, gender, and age of people seen at the Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins, prior to patient consent. The electronic clinical database and medical records were searched daily for potential study participants.

A waiver for written consent also was obtained from the institutional review board. The cover letter mailed with the surveys included information traditionally reviewed as part of the consent process, including the purpose of the study, description of involvement, voluntariness of participation, risks, benefits, confidentiality of records, contact information, the right to withdraw participation, and number of people invited to participate. Participants were not required to sign a written consent form because the return of a completed survey was considered consent.

Table 2. Instrument Descriptive Statistics: Data With Listwise Deletion

Variable	Tool and Reference	Range	$\bar{X}$	Median	Mode	SD	Skewness	Cronbach Alpha	Comments
Adequacy of research information	Information for Medical Decisions Survey (Cassileth et al., 1980)	12–33 (12–33)	15.95 (16.15)	14 (14)	12 (12)	4.58 (4.53)	1.091 (1.21)	0.914 (0.913)	A 12-item measure of the perception of people with cancer on the purpose, content, and implication of an informed consent that they signed for anticancer therapy. The three-point Likert-type scale is scored as 1 (I absolutely need this information), 2 (I would like to have this information), or 3 (I do not want this information). A higher summed score indicates a preference for less information. Psychometric testing for this instrument could not be located.
Hope	Herth Hope Index (Ebright & Lyon, 2002; Herth, 1991, 1992; Wonghongkul et al., 2000)	26–48 (26–48)	40.22 (40.27)	40 (40.27)	36[a] (36)[a]	4.67 (4.62)	–0.236 (–0.256)	0.845 (0.846)	A four-point Likert-type scale with 12 items that measure the cognitive-temporal, affective-contextual, and affiliative-contextual dimensions of hope. Cronbach alpha coefficients have ranged from 0.8–0.97. A higher summed score indicates more hope.
Perceived risks and benefits	Attitudes to Randomized Clinical Trials Scale (Ellis et al., 2002)	4–6.72 (3.74–6.72)	5.49 (5.47)	5.58 (5.52)	4 (4)	0.62 (0.59)	–0.529 (–0.526)	0.85 (0.842)	A 36-item tool that measures perception of loss of control or inconvenience, views about altruism, and the positive and negative aspects of clinical trials. The tool uses a Likert-type scale with 1 (very likely to join a trial), 3 (would not influence my decision), and 5 (very likely to join a trial). A higher mean total correlates with more favorable attitudes toward participating in a clinical trial (i.e., perceived fewer risks and more benefits). Cronbach alpha has been reported as 0.96.
Quality of life	Quality of Life Scale–Patient/Cancer Survivor Version (Ferrell, Hassey-Dow & Grant, 1995; Ferrell, Hassey-Dow, Leigh, et al., 1995)	1.71–8.98 (2.24–9.24)	5.91 (5.89)	5.93 (5.86)	5.98 (5.95)	1.307 (1.305)	–0.035 (0.007)	0.899 (0.893)	A 41-item, 10-point interval level scale. The scale has been used extensively in cancer survivorship studies. It measures overall quality of life ($\alpha = 0.93$), as well as four domains: physical ($\alpha = 0.71$), psychological ($\alpha = 0.77$), social ($\alpha = 0.81$), and spiritual well-being ($\alpha = 0.89$). A higher average score indicates a better quality of life.
Satisfaction	Decisional Conflict Scale (O'Connor, 1995)	0–85.94 (0–85.94)	21.84 (21.85)	15.63 (21.86)	0 (0)	20.71 (19.87)	1.286 (1.287)	0.938 (0.934)	A 16-item, five-point scale. Cronbach alpha ranged from 0.78–0.92, with a test-reliability score of 0.81 when testing was two weeks apart. The scale significantly discriminated people based on decision to accept or decline disease preventive care, including influenza vaccination and breast cancer screening ($p < 0.0002$). For the current study, respondents were specifically advised to consider their cancer clinical trial decision. Options ranged from strongly agree to strongly disagree. The instrument was operationalized as a measure of decision-making satisfaction. A formula provides a calculated score ranging from 0–100, with higher scores indicating more decisional conflict (i.e., less decisional satisfaction).

(Continued on the next page)

[a] Multiple modes exist. The smallest value is presented.

Note. Values in parentheses indicate adjusted data with series means imputed for missing values.

Table 2. Instrument Descriptive Statistics: Data With Listwise Deletion *(Continued)*

Variable	Tool and Reference	Range	$\bar{X}$	Median	Mode	SD	Skewness	Cronbach Alpha	Comments
Symptom burden	Symptom Distress Scale (McCorkle et al., 2000; McCorkle & Young, 1978)	13–59 (13–57)	25.94 (24.43)	25 (23.86)	22[a] (22)[a]	7.51 (7.29)	0.981 (1.039)	0.848 (0.85)	A 13-item Likert-type measure of the frequency and intensity of common cancer-related symptoms. In 23 of 35 (66%) studies, Cronbach alpha for the tool has been 0.8 or higher. The anchors of the five-point scale were 1 (no distress) to 5 (maximum amount of distress). Higher summed scores indicating a greater symptom burden.
Trust in healthcare system	Health Care System Distrust Scale (Rose et al., 2004)	11–49 (12–49)	37.04 (37.24)	38 (38)	42 (42)	6.62 (6.29)	–0.823 (–0.644)	0.712 (0.678)	A 10-item, five-point Likert-type measure of healthcare system–related distrust on dimensions of honesty, confidentiality, competence, and fidelity. Cronbach alpha was reported at 0.74. Higher summed score indicates less trust in the healthcare system.
Trust in health professional	Patient Trust Scale (Kao et al., 1998)	10–48 (10–48)	13.48 (13.34)	11 (11)	10 (10)	5.53 (5.18)	2.746 (2.713)	0.939 (0.931)	A 10-item, five-point Likert-type measure of patients' trust in the physician. The scale has been strongly related to patient satisfaction with medical care ($r = 0.68$, $p < 0.001$). It covers confidentiality, competency, and agency. A higher summed score indicates more distrust (i.e., less trust) in the health professional.

[a] Multiple modes exist. The smallest value is presented.
Note. Values in parentheses indicate adjusted data with series means imputed for missing values.

No in-person recruitment of potential participants was conducted by the investigator or clinical team. The mailed survey approach minimized the threat of coercion to participate (Office for Human Research Protections, 1993). In addition, if the healthcare provider recruited participants, a potential bias would exist in the variable "trust in the health professional," as those who trust their health professional may be more likely to participate.

Evidence-based mailed survey strategies were used (Cupples, Nolan, Augustine, & Kynock, 1998; Dillman, 2000; Nolan et al., 1992). To ensure the confidentiality of eligible patients prior to the mailing of the surveys, an invitation to participate in the research was sent by the director of GI cancer, a medical oncologist who did not have a patient-care relationship with potential participants. An addressed, stamped postcard was included with directions that it was to be mailed if the patient declined to participate. If the postcard was returned, no further contact was made. If the postcard was not received within two weeks of the mailing of the invitation, the surveys were sent with an addressed, stamped return envelope. If the surveys were not returned within two weeks of the initial survey mailing, a second mailing was sent with a reminder and a postcard to be mailed to decline participation or request a replacement survey and envelope.

With each mailing, the potential research participants were reminded of the optional nature of the research and that they need not complete the surveys all at once. On receipt of the completed surveys, participants were compensated for their time with a $20 gift certificate to a grocery store or national retail store and a hand-written thank you note, both mailed to their home.

Response Rate

Invitations to participate in the mailed survey research were sent to 498 patients with advanced GI cancers, specifically pancreatic, colon, or rectal cancers. Fifty-five postcards indicating that the patients did not want to participate were returned. The reasons provided included not being interested in this survey research (n = 24), not being told about any cancer clinical trials (n = 15), other reasons (e.g., too many other problems or things to handle, death, too much pain, difficulty understanding written English, not interested in surveys, nothing of benefit to add, inconvenient, illness makes participation difficult) (n = 11), and no response checked (n = 5).

The first mailing was sent to 443 patients, and 178 surveys were returned (40% response rate). The second mailing was sent to 265 patients, and 15 postcards were returned. Reasons checked on the second mailing postcards were no longer interested in participating in the research project (n = 7), working on survey (n = 5, surveys were never returned), requested replacement

survey packet (n = 2, surveys never returned), and completed survey and needed replacement stamped envelope (n = 1, did return survey). Twenty-seven additional surveys were returned after the second mailing, yielding a 10% response rate. The overall response rate was 46% (205 of 443).

Chi square and t-test analyses were used as appropriate to measure the extent to which those who responded with a completed survey differed from those who did not respond. Respondents did not differ from nonrespondents based on age, gender, cancer diagnosis, and cancer stage. However, Caucasian participants had higher response rates to the mailed research survey than those who were not Caucasian (44% versus 19%, $\chi^2 = 16.32$, degrees of freedom [df] = 1, $p < 0.001$).

Participants

Of the 205 survey respondents, 5 did not meet the eligibility criteria, and 3 surveys were excluded because of excessive missing data: 2 participants completed only the first page of the 12-page survey and 1 person left more than 20% of the survey blank. This resulted in a total sample of 197 for final analysis. The mean age of the sample was 60.5 years (SD = 10.24, range = 25–84) (see Table 1).

Main Research Variables

The independent variables in the current study were disease context (cancer stage and symptom burden), sociodemographic characteristics (age, education level, race, and gender), hope, quality of life, trust in the healthcare system, trust in health professional, patient preferences (research decision control), perceived risks and benefits, and adequacy of research information. The dependent variables were decision to accept or decline research participation and satisfaction with this decision.

Instruments

Participants' cancer stage, age, and gender were obtained from the medical record. Race and educational level were derived from a demographic instrument developed for the current study. Descriptive data for each instrument are reported in Table 2.

Preferences for research decision control were measured with the question, "Which decision making option do you usually prefer when deciding about being in a research study?" Options were 1 (make decisions myself), 2 (make decisions with someone else), 3 (let someone else make decisions for me), and 4 (unsure). Although this item was included on the Decisional Conflict Scale as an optional researcher-generated question, it was scored by itself and was not included in the data for the scale. To the author's knowledge, this question has not been tested previously.

Table 3. Pearson's Correlations of Research Variables

Variable	Stage	Burden	Age	Edu	Race	Gender	Hope	QOL	Trust-HC	Trust-HP	Prefer	Risks	Info	Trial
Burden	0.198[b]													
Age	0.011	−0.131												
Edu	−0.154[a]	0.007	0.042											
Race	−0.207[b]	−0.023	−0.015	0.106										
Gender	−0.051	0.004	−0.072	−0.122	0.107									
Hope	−0.06	−0.394[c]	0.084	0.062	0.04	−0.027								
QOL	−0.135	−0.765[c]	0.113	0.007	−0.045	−0.064	0.612[c]							
Trust-HC	−0.026	−0.155[b]	0	0.046	0.018	−0.018	0.14[a]	0.161[a]						
Trust-HP	0.067	0.121	−0.144[b]	−0.029	−0.062	−0.028	−0.232[b]	−0.228[b]	−0.347[b]					
Pref	0.112	−0.099	0.03	0.024	−0.049	−0.046	0.034	0.134	0.098	−0.093				
Risks	−0.135	0.049	0.182	−0.01	0.074	0.193	0.141	0.099	0.08	−0.272	0.119			
Info	0.036	−0.046	0.064	−0.073	−0.04	−0.203[b]	0.035	0.121	0.045	−0.037	0.122	−0.036		
Trial	0.091	0.05	−0.192[b]	0.052	−0.104	−0.083	−0.015	0.008	0.096	0.111	0.068	−0.083	−0.024	
Sat	0.128	0.057	0.051	0.04	−0.005	−0.029	−0.171[a]	−0.033	−0.228[b]	0.116	0.134	−0.054	−0.002	0.023

[a] Correlation is significant at the 0.05 level (two-tailed).

[b] Correlation is significant at the 0.01 level (two-tailed).

[c] Correlation is significant at the 0.001 level (two-tailed).

Burden—symptom burden; Edu—educational level; Info—adequacy of research information; Prefer—preference for research decision control; QOL—quality of life; Risks—perceived risks and benefits; Sat—satisfaction (dichotomous); Stage—cancer stage; Trial—cancer clinical trial decision; Trust-HC—trust in healthcare system; Trust-HP—trust in health professional

The decision to accept or decline cancer clinical trial participation was measured with a single item. Participants responded yes or no to "Did you decide to join a cancer clinical trial?"

Data Analysis

A descriptive analysis was used to summarize the sample and instrument characteristics. Prior to the main analysis, exploratory analysis was used to examine the findings for missing data and determine their status as random or systematic.

Missing data were 9% or lower for each instrument and were imputed with the mean score of each scale. Most missing data were at random, as indicated by the Missing Completely at Random (MCAR) test ($p > 0.05$); however, the MCAR tests were significant for the Quality of Life Scale–Patient/Cancer Survivor Version (QOL-CS) ($p = 0.013$) and the Attitudes to Randomized Clinical Trials Scale ($p = 0.003$), indicating missing data not at random (Little & Rubin, 1987; SSPS Inc., 2009).

Missing data that were not at random included four items on the QOL-CS with questions about the patient's experience with treatments (items 19, 20, 25, and 31). As participants had not yet started treatments at the time of the survey, those items were not valid and were deleted. Only the remaining 37 items were used for analysis. For the Attitudes to Randomized Clinical Trials scale, page 2 (items 20–36) was omitted inadvertently from 25 surveys. The deletion of three respondents' surveys and four items from the QOL-CS and imputing missing values did not significantly affect the data.

Bivariate correlations among study variables were calculated using Pearson's correlation. Each independent variable was examined for the assumptions for normality and multicollinearity. Sixteen significant bivariate relationships were found among the 15 variables; the correlations are described in Table 3. A significant moderate linear correlation was found for symptom burden and quality of life ($r = –0.765$, $p < 0.001$), hope and quality of life ($r = 0.612$, $p < 0.001$), and hope and symptom burden ($r = –0.394$, $p < 0.001$). However, the variance inflation factor (symptom burden: 2.464; quality of life: 3.325; hope: 1.632) was lower than the usual cut-off value of 5, indicating no serious multicollinearity. Further justification for analyzing the variables included their conceptual importance and the fact that they are being investigated for the first time with the Research Decision Making Model.

Although the intent was to use multiple linear regression with the Decisional Conflict Scale, the data violated the normal distribution assumption. More than 75% of respondents scored lower than 30 on the total calculated score, indicating lower decisional conflict. More than 90% of respondents scored lower than 50. Because the mode was 0, normalizing the data was not possible. The results were transformed into dichotomous categories at the instrument range at the score of 30; therefore, a calculated total score from 0–30 indicated satisfaction with the cancer clinical trial decision and 31–100 indicated dissatisfaction with this decision for purposes of the current study. In addition, multiple logistic regression analyses were performed to identify factors that influenced cancer clinical trial participation and satisfaction with this decision.

Findings

Preferences for Decision Control

The first aim of the study was examine the relationship between disease context and sociodemographic factors to patient preferences for research decision control. No patients indicated that they usually preferred a reliant (passive) role when deciding about research participation. The most frequently preferred decision-making style for research participation was shared (collaborative) (n = 163, 83%), followed by independent (active) (n = 34, 17%).

Table 4. Disease Context, Sociodemographic Factors, and Preference for Research Decision Control

	Collaborative		Independent				
Variable	**$\bar{X}$**	**SD**	**$\bar{X}$**	**SD**	**N**	**t**	**p**
Age (years)[a]	60.64	10.23	59.82	10.41	197	–0.421	0.674
Symptom burden[a]	24.1	7.12	26	7.96	197	1.384	0.168
Variable	**n**	**%**	**n**	**%**	**N**	**χ^2**	**p**
Gender						0.409	0.552
Male	96	84	18	16	114		
Female	67	81	16	19	83		
Self-reported race						0.465	0.495
Caucasian	147	83	30	17	177		
Not Caucasian	13	77	4	24	17		
Cancer stage						2.48	0.115
Lower than IV	58	77	17	23	75		
IV	105	86	17	14	122		
Education						4.218	0.121
High school or less	34	76	11	24	45		
Community or undergraduate college	67	89	8	11	75		
Graduate school or higher	61	80	15	20	76		

[a] Collaborative: N = 163; independent: N = 34

Note. Because of rounding, not all percentages total 100.

Table 5. Bivariate Analyses of Covariates With Research Participation

Variable	Participated in Trial (N = 131) $\bar{X}$	SD	Did Not Participate (N = 66) $\bar{X}$	SD	t	p
Adequacy of research information	16.22	4.59	16	4.42	0.337	0.736
Hope	40.31	4.72	40.17	4.45	0.208	0.85
Perceived risks and benefits	5.5	0.54	5.4	0.68	1.169	0.244
Quality of life	5.87	1.3	5.91	1.32	–0.111	0.912
Symptom burden	24.17	7.46	24.94	6.67	–0.712	0.477
Trust in healthcare system	36.81	6.43	38.08	5.96	–1.376	0.171
Trust in physician	12.93	4.12	14.15	6.81	–1.561	0.12

A series of disease context and sociodemographic variables were examined for their relationships to research decision control preferences. None of those study variables were significantly associated with research decision control (see Table 4).

Cancer Clinical Trial Research Participation and Satisfaction With the Decision

The second aim of the study was to identify significant factors that influence the decision to join a cancer clinical trial and the satisfaction with this decision. Among the 197 participants invited to join a cancer clinical trial, 131 (66%) decided to join and 66 (34%) declined. Of the study variables examined in the Research Decision Making Model (see Table 5), only age was related to this decision. Respondents who joined cancer clinical trials were significantly older in years ($\bar{X}$ = 61.98, SD = 9.5, range = 30–84) than those who did not join ($\bar{X}$ = 57.73, SD = 11.14, range = 25–77) (t = 2.74, p = 0.01). In addition, further analysis regarding the type of gastrointestinal cancer with which the patient was diagnosed revealed that those who had pancreatic cancer were more likely to decide to participate in a cancer clinical trial than patients with colorectal cancer. Respondents with pancreatic cancer also were older ($\bar{X}$ = 62.42, SD = 8.83) than those with colorectal cancer ($\bar{X}$ = 55, SD = 11.99) (t = 4.68, p < 0.001).

Logistic regression was conducted to assess whether the variables within the Research Decision Making Model significantly predicted whether or not a patient participated in a cancer clinical trial. All 13 variables of the Research Decision Making Model predicted cancer clinical trial participation when considered together (see Table 6). Those combined variables significantly predicted whether or not a patient participated in a cancer clinical trial (χ^2 = 23.9, df = 13, N = 193, p = 0.032) with a small explained variance (Nagelkerke R^2 = 0.162). Age was the only individually significant predictor (p = 0.009) of whether a person would join a cancer clinical trial or not. Ninety-two percent of those who accepted cancer clinical trial participation were predicted correctly with this model, whereas only 33% of those who declined participation were predicted correctly. Deletion of variables with backward regression did not improve the regression model by changing the individual significance of additional variables or improving the explained variance.

Logistic regression also was conducted to assess whether the variables significantly predicted satisfaction with this decision. As in the previous logistic regression, all variables significantly predicted whether or not a patient was satisfied with this decision (χ^2 = 28.648, df = 13, N = 193, p = 0.007) with a small explained variance (Nagelkerke R^2 = 0.206) (see Table 7). Hope and trust in the healthcare system were the only individually significant predictors of whether a person would be satisfied with the decision to participate in cancer clinical trial or not. Decisional satisfaction was predicted for 96% by this model, whereas only 19% of those who were not satisfied could be predicted. Deletion of variables with backward regression did not improve the regression model by changing the individual significance of additional variables or improving the explained variance.

Discussion

Shared or collaborative decision making was the preferred style for research participation. When considered

Table 6. Odds Ratios of Association Between Decision-Making Factors and Cancer Clinical Trial Participation

Variable	OR	p	95% CI
Cancer stage	1.37	0.392	[0.67, 2.81]
Symptom burden	1.04	0.332	[0.96, 1.11]
Age[a]	0.95	0.009	[0.92, 0.99]
Educational level	1.26	0.308	[0.81, 1.95]
Race	2.96	0.179	[0.61, 14.37]
Gender	1.37	0.378	[0.68, 2.75]
Hope	0.99	0.848	[0.91, 1.09]
Quality of life	1.22	0.414	[0.76, 1.97]
Trust in healthcare system	1.06	0.065	[1, 1.12]
Trust in health professional	1.07	0.064	[1, 1.15]
Preference for research decision control	1.58	0.348	[0.61, 4.06]
Perceived risks and benefits	0.95	0.86	[0.51, 1.75]
Adequacy of research information	0.98	0.541	[0.91, 1.05]
Constant	0.01	0.137	–

[a] Statistically significant

CI—confidence interval; OR—odds ratio

Note. Referent group was those who agreed to participate in a cancer clinical trial.

Table 7. Odds Ratios of Association Between Decision-Making Factors and Satisfaction With the Decision to Participate in a Clinical Trial

Variable	OR	p	95% CI
Cancer stage	1.98	0.11	[0.86, 4.6]
Symptom burden	1.04	0.351	[0.96, 1.13]
Age	1.02	0.217	[0.99, 1.06]
Educational level	0.91	0.715	[0.56, 1.48]
Race	0.49	0.288	[0.13, 1.84]
Gender	1.11	0.787	[0.51, 2.44]
Hope[a]	0.88	0.019	[0.8, 0.98]
Quality of life	1.64	0.075	[0.95, 2.84]
Trust in healthcare system[a]	0.91	0.003	[0.86, 0.97]
Trust in health professional	1.01	0.88	[0.94, 1.08]
Preference for research decision control	3.09	0.068	[0.92, 10.4]
Perceived risks and benefits	0.72	0.345	[0.37, 1.42]
Adequacy of research information	0.98	0.706	[0.9, 1.07]
Constant	3.94	0.707	–

[a] Statistically significant

CI—confidence interval; OR—odds ratio

Note. Referent group was those who were satisfied with their cancer clinical trial participation decision.

together, all of the variables of the Research Decision Making Model were predictive of cancer clinical trial participation and satisfaction with this decision.

Although models of shared patient-physician and patient-family decision making have been used increasingly in standard treatment decision making (Degner & Beaton, 1987; Degner & Sloan, 1992; Hack et al., 2010; Nolan et al., 2005; Sulmasy et al., 2007), those models and the concept of shared decision making are greatly underdeveloped in the literature. Although individual autonomy in the decision to join an experimental study traditionally has been emphasized in ethical codes, the current study demonstrated that shared (collaborative) decision making is preferred by most patients who consider joining a cancer clinical trial (n = 163, 83%). Clinical research regulations mandate that decision making for cancer clinical trial participation is independent. However, that may not be the preference of the patients who accept and decline cancer clinical trials. Only 17% of participants in the current study preferred the active (independent) role and no one preferred the reliant (passive) role to cancer clinical trial decision making. Patients may prefer sharing decision making for cancer clinical trial participation because many unknowns exist regarding risks and benefits.

In spite of the discordance between the respondents' preferences for shared decision making for participation in cancer clinical trials and regulatory processes promoting autonomous informed consent, respondents were very satisfied with their decisions. Flynn et al. (2008) found that the decliners in their sample of patients with advanced cancer had more decisional conflict than accepters of cancer clinical trials. Flynn et al. (2008) attributed this difference to decliners having more pressure and a lack of understanding and clarity regarding clinical research. Suboptimal decision making and ethical issues could be considered as a rationale for those results (Flynn et al., 2008). In the current study, no differences were found in decisional conflict between accepters and decliners in the sample (acceptors: $\overline{X} = 21.6$; decliners: $\overline{X} = 22.23$; $t = -0.211$, $p = 0.833$).

The sample was surveyed after the decision to participate in a clinical trial was made. The Research Decision Making Model conceptualized that the decision itself and decisional satisfaction are outcomes of the decision-making process. The sample had low levels of decisional conflict scores. Those low levels may be related to the timing of the research, in that participants were past the decision. Respondents may have had a sense of cognitive dissonance or relief after a decision had been made, regardless of whether they accepted or declined research participation. Decisional conflict may have been present at the time that the decision was made.

Most clinical trial participation research has focused on enrollment rates as the primary outcome, not the process of decision making (Biedrzycki, 2010). Exploring this process may advance interventions that currently do not improve the decision-making process, as well as enhance clinical trial enrollment rates and patient satisfaction.

Individuals with advanced cancer may be particularly vulnerable when making decisions about participating in clinical trials that offer little hope for a cure or improvement in their quality of life. Extension of life expectancy does not necessarily translate to improvement in quality of life. Understanding the relationship between patients' research decision-making preferences, trust, hope, and satisfaction with their decision is essential to respect the diversity of patient and family values.

This descriptive research study tested the Research Decision Making Model and identified predicting variables that explain a small portion of variance for predicting participation (16%) and satisfaction (21%) in cancer clinical trials. However, additional variables may add further explanation than those explored in the current study.

Limitations

Multicollinearity among study variables can threaten the validity of study results. Because of multicollinearity, the extent of the association between the predicting factors and outcomes may have been inflated. Some instruments used in the current study have not been tested in samples of patients with cancer, nor in the context of decision making. In addition, psychometrically sound instruments that have been tested in patients with cancer on cancer clinical trial decision making are lacking.

Because of the length of the survey, participants were not only given permission to omit answers, but encouraged to do so. Participants also were encouraged to take breaks as needed, rather than completing the survey at one time. Those strategies were purposefully

incorporated to minimize research participation burden. However, this limited the research findings because of missing values.

To the author's knowledge, the current study was the first to use aspects of Bowling and Ebrahim's (2001) Treatment Decision Model to test research decision-making preference. Lacking a clinical research model, the Treatment Decision Model was a plausible base, as most variables were congruent with those in the clinical research decision-making literature. Nevertheless, several of the Treatment Decision Model's variables were not tested, including cost and rationing, experience, personality, professional preferences, setting, and treatment context. The setting was constant, as all clinical research was conducted at the same institution. An attempt to garner experience information was made through the highest level of education and past clinical trial participation. Future research may consider healthcare insurance coverage, out-of-pocket expenses, and availability of clinical trials to explore the variable of cost and rationing. Professional preferences could be measured by surveying attitudes and referral patterns of health professionals. Setting and treatment context may be important. One should consider the impact of whether research participants need to be hospitalized or whether the research product can be administered on an outpatient basis. The phase of the research study may be considered a measure of treatment context. Not including other potentially important variables was a limitation to the current study.

Although all eligible patients were invited to participate in this mailed research study, a selection bias still existed. Patients seeking care at a large, urban, academic National Cancer Institute–designated cancer center may have unique sociodemographic characteristics, decision-making preferences, hope, trust, and other variables of interest in decision-making research. The findings from the current study cannot be generalized to other settings.

Implications for Nursing

Best practice may be to consider the patient's preference for decision making for cancer clinical trial participation. Implementing the common rule that only the potential research patient can decide whether to participate in cancer clinical trial overlooks the patient's decision-making preference. As a result, implementing a plan to consider patients' decision-making preference may enhance their satisfaction. Until more information is available on cancer clinical trial decision-making preferences, the best practice may be to ask patients about their preferences and to assist individual patients with their decision-making process, as indicated.

Future researchers may consider testing a practice that first explains the study to the patient only, and then, if the patient expresses interest and gives permission, invite family members to join the discussion. Although this practice would increase the time needed to discuss the cancer clinical trial, it would respect patient and family values and enhance information dissemination. Although a shared family decision-making preference may be desired by most, the ultimate effect on clinical trial accrual rates remains unknown.

Additional study is needed for the development of psychometrically sound decision-making instruments and models. Additional research exploring the process of cancer clinical trial decision making will guide the development of interventions to support decision-making preferences that respect patient and family values.

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Barbara A. Biedrzycki, PhD, CRNP, AOCNP®, is a clinical research associate in the Skip Viragh Center for Pancreas Cancer Clinical Research and Patient Care in the Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins in Baltimore, MD. This research was supported, in part, by an American Cancer Society Doctoral Degree Scholarship in Cancer Nursing (DSCN 05-184-01). Biedrzycki can be reached at NPBiedrzycki@aol.com, with copy to editor at ONFEditor@ons.org. (Submitted September 2010. Accepted for publication December 14, 2010.)

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