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Research Information Knowledge, Perceived Adequacy, and Understanding in Cancer Clinical Trial Participants

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Most people with cancer want to know as much as possible about their type of disease and treatment options (Cox, Jenkins, Catt, Langridge, & Fallowfield, 2005; Jenkins, Fallowfield, & Saul, 2001). A 2007 report from the National Cancer Institute entitled *Patient-Centered Communication in Cancer Care: Promoting Health and Reducing Suffering* (Epstein & Street, 2007) emphasized the critical need for research on outcomes of communication between health professionals and people with cancer. The need to evaluate patient outcomes of receiving education about the opportunity to join a cancer clinical trial is particularly important because of the association of clinical trial participation to better health outcomes (Horstmann et al., 2005). Health professionals often misunderstand patients' perspectives and comprehension about standard treatment options (Janz et al., 2004). Far less is known regarding patients' actual and perceived adequacy of knowledge about a cancer clinical trial prior to deciding whether to join a trial (Biedrzycki, 2010).

The current study describes the relationship between the adequacy of research information (actual knowledge, perceived adequacy of information, and perceived understanding) and the decision to join a cancer clinical trial, as well as satisfaction with this decision. Specifically, the study aimed to describe the relationships between (a) actual knowledge and participation in a cancer clinical trial and satisfaction with this decision, (b) perceived adequacy of information and participation in a cancer clinical trial and satisfaction with this decision, and (c) perceived understanding and participation in a cancer clinical trial and satisfaction with this decision.

Background and Significance

The distinction among the concepts of clinical trial awareness, information, and knowledge is not clearly

Purpose/Objectives: To describe the adequacy of research information among people with cancer at the time they accept or decline participation in a cancer clinical trial.

Design: Cross-sectional, descriptive.

Setting: An urban, academic, National Cancer Institute–designated comprehensive cancer center.

Sample: 197 patients with advanced gastrointestinal cancer.

Methods: Mailed survey; self-reported data.

Main Research Variables: Adequacy of research information (actual knowledge, perceived adequacy of information, and perceived understanding), cancer clinical trial participation, and satisfaction with the decision to participate.

Findings: Most respondents (88%) perceived themselves as having adequate information to make an informed decision regarding cancer clinical trial participation. In addition, 35% demonstrated adequate knowledge of basic clinical research.

Conclusions: Patients decide to accept or decline cancer clinical trials without having adequate knowledge.

Implications for Nursing: Nurses have an important role in educating patients regarding cancer clinical trials. The ideal teachable moment may not occur at the time of diagnosis; other less stressful opportunities may present when the patient is more receptive.

defined in the literature. Collectively, the terms have been associated with cancer clinical trial participation and satisfaction with this decision (Lara et al., 2005; Mathews, Restivo, Raker, Weitzen, & DiSilvestro, 2009; Meropol et al., 2007; Quinn et al., 2007; Umutyran et al., 2008). After a mass multimedia campaign and passage of legislation that mandated third-party reimbursement of cancer clinical trial–related care in California, patients visiting a major cancer center, their families, and friends (N = 1,081) were surveyed (Umutyran et al., 2008). Although knowledge was not tested, cancer clinical trial awareness significantly increased as measured

by recognition of the term *clinical trial* and the association of this term with an experiment (Umutyan et al., 2008). However, significant differences in cancer clinical trial participation rates have not been observed when cancer clinical trial knowledge was measured objectively (Avis, Smith, Link, Hortobagyi, & Rivera, 2006; Davis, Nealon, & Stone, 1993). Even when information was measured objectively, an acceptable score or the adequacy of the research information was not defined in previous studies.

Adequacy of research information has four components: perceived knowledge, actual knowledge, perceived adequacy of information, and perceived understanding. According to Cassileth, Zupkis, Sutton-Smith, and March's (1980) Information of Medical Decisions Survey, *perceived knowledge* is defined as a self-assessment of information needs. In a study of 197 respondents, 178 (90%) perceived a need for more information, reflecting a perceived knowledge deficit; in addition, perceived knowledge was not related to cancer clinical trial participation and satisfaction with this decision (Biedrzycki, in press).

The current study explores the other three components of adequacy of research information: actual knowledge, perceived adequacy of information, and perceived understanding. Actual knowledge measures retention of factual information, whereas the perception of adequacy and understanding of research information captures the individual's assessment of whether the research information is sufficient to make an informed decision for cancer clinical trial participation.

Methods

The Research Decision Making Model (Biedrzycki, 2010) was applied in this study (see Figure 1). In this model, adequacy of research information represents the extent to which an individual perceives that the research information he or she has is sufficient to make an informed decision about cancer clinical trial participation.

Design

The current study examined previously unreported data from a larger cross-sectional research study describing factors related to decision making about cancer clinical trial participation and satisfaction with this decision (Biedrzycki, in press). After obtaining institutional review board approval, the investigator mailed surveys to 443 patients at a large urban, academic cancer center. Inclusion criteria were being aged 18 years or older; being able to speak and read English; having an advanced gastrointestinal diagnosis of pancreatic, colon, or rectal cancer; and having been offered the opportunity to participate in a phase I, II, or III cancer clinical trial.

Table 1 provides sample characteristics. Most survey respondents were employed men with a mean age of 60.5 years (range 25–84) with at least a graduate college degree. Most considered themselves to be financially independent and white-collar workers. In addition, most respondents had stage IV pancreatic cancer and had not previously participated in a clinical trial.

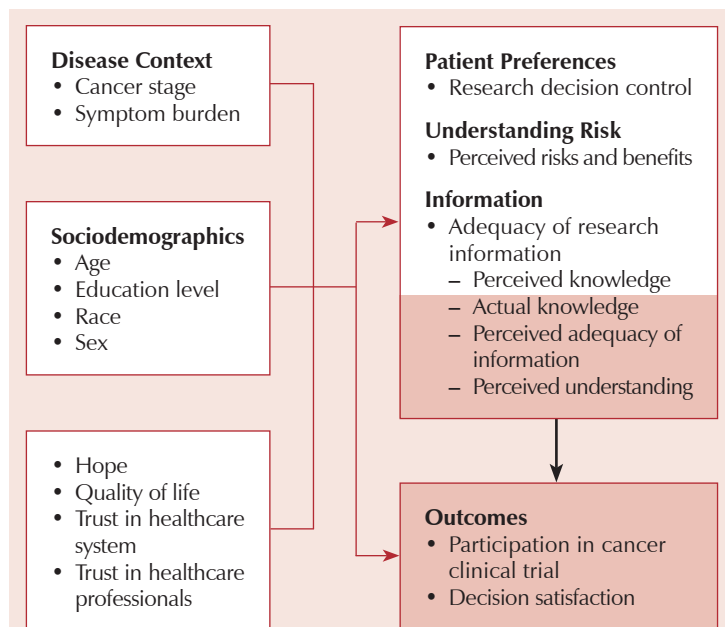
Mailed survey strategies (Cupples, Nolan, Augustine, & Kynock, 1998; Dillman, 2000; Nolan et al., 1992) were used to yield a 46% response rate (205 of 443). Eight survey respondents were excluded; five did not meet diagnostic eligibility criteria and three were excluded because of missing more than 20% of the responses. The final sample size was 197.

Instruments

Age, sex, cancer diagnosis, and cancer stage were obtained from the patients' medical records. Educational level, race, employment status, family income, type of work, and previous clinical trial participation were self-reported on the **Research Decision Survey**, an instrument designed for this study.

The concept of adequacy of research information was operationalized as having both objective and subjective components. Within this study, data on actual knowledge, perceived adequacy of information, and perceived understanding were captured in two instruments.

Actual knowledge was assessed with the **Seven-Item Knowledge Scale**, designed to measure knowledge of cancer clinical trial information (Ellis, Butow,



Note. Shaded items and the black arrow relationship are described in detail in this article.

Figure 1. Research Decision Making Model

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Table 1. Sample Characteristics

Characteristic	\bar{X}	SD	Range
Age (years)	60.5	10.24	25–84
Characteristic	n	%	
Gender			
Male	114	58	
Female	83	42	
Education			
Elementary or grade school	2	1	
High school or less	43	22	
Community or junior college	21	11	
Undergraduate college	54	27	
Graduate college	35	18	
Postgraduate college	41	21	
Missing data	1	1	
Cancer diagnosis			
Pancreatic	146	74	
Colon or rectal	51	26	
Employment			
Working	82	42	
Retired	77	39	
Not working	26	13	
Rather not answer	12	6	
Family income (\$)			
50,000 or less	41	21	
50,001–100,000	49	25	
100,001–150,000	32	16	
150,001 or more	39	20	
Rather not answer	36	18	
Type of work			
Blue collar	43	22	
White collar	142	72	
Missing data	12	6	
Previous clinical trial participation			
Yes	27	14	
No	167	85	
Missing data	3	2	

N = 197

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

Tattersall, Dunn, & Houssami, 2001). The items cover general clinical research statements in which respondents indicate whether a statement is true, false, or unknown. Scoring is based on the number of correct items; therefore, false, unknown, and omitted responses do not count toward the score. A score of 70 or higher indicated adequate knowledge.

Perceived adequacy of information and perceived understanding were captured with two single-item questions within the Research Decision Survey. Survey respondents answered yes or no to the following questions. Did you receive adequate information to make the decision about being in a research study? Do you basically understand the research study? Did you join a cancer clinical trial?

The 16-item **Decisional Conflict Scale** (O'Connor, 1995), evaluates uncertainty and conflict in making a healthcare decision. Respondents rated items on a five-point Likert-type scale with anchors of 1 (strongly

agree), 3 (neither agree nor disagree), and 5 (strongly disagree). Items involve the risks, side effects, benefits, and importance of options and support, pressure, advice, comfort, and satisfaction of decision making. A calculation provided a total score range from 0 (no decisional conflict) to 200 (highest level in decisional conflict). In previous studies, Cronbach alpha for the instrument was 0.72–0.92 (O'Connor, 1995). Cronbach alpha in the current study was 0.94. The total score of the Decisional Conflict Scale in this study represented satisfaction with the cancer clinical trial decision from 0 (greater decisional satisfaction) and 100 (lowest decisional satisfaction).

Findings

Descriptive statistics were used to describe two measures of the perception of knowledge and the adequacy of research information as an actual level. Pearson correlations and chi-square and t tests, as appropriate, were used to describe the relationships between variables of interest.

Among this primarily Caucasian, well-educated, white-collar, and older male sample, only 69 (35%) scored higher than 70% on a knowledge inventory. Most (n = 131; 67%) chose to join a cancer clinical trial, and their satisfaction with their decision was positive based on a low decisional conflict score. Table 2 describes results of chi-square analyses for the dependent variables and cancer clinical trial participation. Table 3 shows t-test results of the dependent variables and decisional satisfaction.

Actual Knowledge

The first aim of the study was to describe the relationship between actual knowledge and participation in a cancer clinical trial and satisfaction with this decision. The Seven-Item Knowledge Scale included questions about basic clinical research. Thirty-five percent of respondents answered 70% or more of the items correctly; that score was defined for this study as adequate knowledge (see Table 4). The two statements that were answered incorrectly most often were "My doctor would know which treatment in a clinical trial was better" (146 [74%] incorrectly answered "true"), and "My doctor would make sure that I got the best treatment in a clinical trial" (141 [72%] incorrectly answered "true"). The statement that was answered correctly most often was "Clinical trials are not appropriate for serious illness like cancer" (172 [87%] correctly answered "false").

On the remaining items, 90 respondents (46%) correctly answered "true" for "Randomized trials are the best way to find out whether one treatment is better than another." Ninety-seven (49%) correctly answered true for "In a randomized trial, the treatment you get is decided by chance." One hundred eleven (56%) correctly answered "false" for "Clinical trials are only used

Table 2. Adequacy of Research Information and Cancer Clinical Trial Participation

Variable and Measure	Total		Accepted		Declined		χ^2	P
	n	%	n	%	n	%		
Actual knowledge (N = 197)^a							3.47	0.063
Adequate (70 or higher)	69	35	40	20	29	15		
Deficit (lower than 70)	128	65	91	46	37	19		
Perceived adequacy (N = 155)^b							2.04	0.153
Yes	137	88	117	75	20	13		
No	18	12	13	8	5	3		
Perceived understanding (N = 156)^c							1.8	0.18
Yes	142	91	121	78	21	14		
No	14	9	10	6	4	3		

^a As measured with the Seven-Item Knowledge Scale (range 0–100)

^b Respondents were asked, “Did you receive adequate information to make the decision about being in a research study?”

^c Respondents were asked, “Do you basically understand the research study?”

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

when standard treatments have not worked.” Finally, 133 respondents (68%) correctly answered “false” for “Clinical trials test treatments which nobody knows anything about.”

Education was positively correlated with actual knowledge ($r = 0.279$, $p < 0.001$). No difference was observed in participation in a cancer clinical trial between participants with adequate knowledge and those without adequate actual knowledge (58% versus 71%, $\chi^2 = 3.465$, $p = 0.063$). In addition, no difference was found in satisfaction with the decision to participate in a clinical trial between participants with adequate knowledge ($\bar{X} = 21.51$, $SD = 19.01$) and those without adequate knowledge of research information ($\bar{X} = 22.38$, $SD = 21.5$; $t = 0.065$, $p = 0.948$).

Perceived Adequacy of Information

The second aim was to describe the relationship between perceived adequacy of information and participation in a cancer clinical trial and satisfaction with this decision. One hundred thirty-seven respondents (88%) perceived that they had received adequate information to make a decision about being in the cancer clinical trial. Having sufficient information to make a decision ($r = 0.344$, $p < 0.001$) correlated with satisfaction with respondents’ cancer clinical trial decision as measured by the Decisional Conflict Scale. No difference was observed in participation in a cancer clinical trial between respondents who perceived they had received adequate information and those without adequate information (85% versus 72%, $\chi^2 = 2.043$, $p = 0.153$). Respondents who perceived that they had received adequate information ($\bar{X} = 18.99$, $SD = 17.67$) were more satisfied than those without such a perception ($\bar{X} = 39.73$, $SD = 22.2$; $t = 4.699$, $p < 0.001$).

Perceived Understanding

The third aim was to describe the relationship between perceived understanding and participation in a cancer clinical trial and satisfaction with this decision. One hundred forty-two respondents (72%) indicated that they understood the study. No difference was found in participation in a cancer clinical trial between respondents who perceived that they had an adequate understanding of the research study and those who did not (72% versus 84%, $\chi^2 = 2.043$, $p = 0.153$). Respondents who perceived that they had an adequate understanding of the research study ($\bar{X} = 20.01$, $SD = 18.82$) were

more satisfied than those who did not ($\bar{X} = 39.69$, $SD = 21.85$; $t = 2.653$, $p = 0.011$).

Discussion

The current study described three components of the adequacy of research information at the time of making a cancer clinical trial decision. Although most participants perceived that they had adequate information (88%) and that they understood the research study (91%), many did not have adequate actual research knowledge (65%).

In this sample of well-educated patients, only 35% had adequate actual knowledge of clinical research; this finding strongly suggests a need for additional education. Knowledge levels in the current study ($\bar{X} = 3.62$, $SD = 1.96$) were similar to the actual knowledge level in a previous study of 83 women with breast cancer ($\bar{X} = 4.1$, SD not reported) (Ellis et al., 2001). However, the participants in Ellis et al.’s (2001) study were not deciding on cancer clinical trial participation.

This study’s findings suggest the need for further research concerning who should educate potential research participants and the best time for this training to be delivered. Although patients have indicated that having desired information in advance reduces stress (Swanson & Koch, 2010; Toubassi, Himel, Winton, &

Table 3. Adequacy of Research Information and Decisional Satisfaction

Item	t	p
Actual knowledge	0.65	0.948
Perceived adequacy of information	4.7	< 0.001
Perceived understanding	2.65	0.011

Table 4. Levels of Actual Knowledge on the Seven-Item Knowledge Scale^a

Number Correct	n	%	Cumulative %
None	12	6	6
14	20	10	16
29	25	13	29
43	40	20	49
57	31	16	65
71	34	17	82
86	16	8	90
100	19	10	100

N = 197

^a Scores range from 0–100. Scores of 70 or higher indicate adequate knowledge; scores lower than 70 indicate a knowledge deficit.

Nyhof-Young, 2006), the time when a patient with a cancer diagnosis is being evaluated for anticancer therapy may not be the ideal teachable moment. Although many factors may influence the effectiveness of patient education, stress associated with the diagnostic phase is a known impediment (Adams, 1991; Treacy & Mayer, 2000; Villejo & Meyers, 1991).

Although the National Cancer Institute and other public and private organizations have advocated for an increased public awareness of cancer clinical trials in general, the current study indicates that more effort is needed. Implementing a clinical trial awareness program may enhance understanding of cancer clinical trial participation.

Patients today are assuming more responsibility for their health than ever before (Institute of Medicine, 2001). Comis, Miller, Aldige, Krebs, and Stoval (2003) projected that 32% of all American adults (estimated by the researchers to be 64 million) would be willing to participate in a cancer clinical trial if invited. Comis et al. (2003) challenged the assumption that not enough people are willing to join a cancer clinical trial by implying that eligibility criteria and a lack of appropriate clinical trials may be the reasons for consistently low national accrual rates. While acknowledging the challenges in identifying appropriate clinical trials and study participants, the basis for the public's willingness to become cancer clinical trial participants must be considered. Comis et al.'s (2003) research sample, obtained through the Harris Interactive poll in 2000, may not have been fully informed about clinical trials. Although 60% of those polled indicated that they understood "what a clinical trial was" (Comis et al., 2003, p. 831), the perceived knowledge was not validated. People may be interested in clinical trials but lack adequate information (Sood et al., 2009). Potential participants are not aware of the knowledge they lack—therefore, healthcare providers must fully inform their clients.

Many patients in the current study did not know why the research was being conducted or were not aware of the basic research concept of equipoise (i.e., that uncertainty exists regarding which treatment arm in a clinical

trial is better). Most participants correctly identified the statement "Clinical trials are not appropriate for serious illness like cancer" as being false. This finding was not surprising because all respondents had cancer and were being offered cancer clinical trial participation. Although consent forms document that patients understand the cancer clinical trial and know their rights as research participants, evidence confirming whether participants actually understand this information is limited.

The knowledge test items most frequently answered incorrectly were related to patients' trust in physicians. One hundred forty-six respondents (74%) incorrectly believed the statement "My doctor would know which treatment in a clinical trial was better" was true. Likewise, 141 respondents (71%) incorrectly believed the statement "My doctor would make sure that I got the best treatment in a clinical trial" was true. Those misconceptions are concerning. Kass, Sugarman, Faden, and Schoch-Spana (1996) concluded that trust in one's physician and in the research institution may actually hinder the informed consent process. The findings may indicate that patients' trust should be reframed as having confidence in their healthcare providers to provide adequate information to make cancer clinical trial participation decisions that are consistent with patients' values and goals. The reframing of trust may lead to improved patient outcomes, increased participation in cancer clinical trials, and greater satisfaction with the decision to participate.

Limitations

Recall bias could have influenced responses. The survey was conducted at least two weeks after the decision for clinical trial participation was made. Social desirability also may have impacted responses, especially on sensitive issues such as knowledge, despite the fact that a mailed survey approach and confirmation of confidentiality and anonymity were reinforced. In addition, this study was the first to test the instruments in the context of adequacy of research information at the time of deciding about cancer clinical trial participation. The study was conducted in a single institution; therefore, the findings may not be generalizable.

Conclusions and Implications for Nursing

Considering the needs of the individual, future research is warranted to evaluate and improve the adequacy of research information. Oncology nurses frequently educate patients about cancer clinical research in general and the specifics of cancer clinical trials. In an effort for social desirability and a need to proceed efficiently with the clinical trial enrollment process, patients may not readily admit to their lack of basic knowledge and understanding about cancer clinical trials. Oncology

nurses should ascertain patients' perceived and actual knowledge and close the gaps to improve the adequacy of research information.

Health policy may answer society's need to advance science through clinical research. Investment in the public's education regarding clinical trials may provide society with long-term investment gains. Scientific data may be generated more rapidly, leading to evidence-based practice that will ultimately reduce the United States' healthcare costs.

Offering clinical trial education within healthcare settings to all patients and their families, even those currently not affected by cancer, may facilitate a common good. Older adult centers, community organizations, and libraries are venues where the public could receive clinical research information. Patients prefer shared

decision making when considering cancer clinical trials (Biedrzycki, in press); therefore, educating the public will facilitate research participation as discussions flourish among patients, families, and healthcare providers. In clinical practice, healthcare providers are challenged to provide general clinical research and specific clinical trial information to patients while ensuring that the information is transformed into actual knowledge.

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Digital Object Identifier: 10.1188/11.ONF.E291-E296

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