Physician-Related Factors Involved in Patient Decisions to Enroll Onto Cancer Clinical Trials

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Abstract

Purpose: To examine the attitudes of the public and cancer survivors toward their health-related decisions and cancer clinical trials (CCT) with a particular emphasis on the role of the physician, building on a 2003 report in *Journal of Clinical Oncology*.

Methods: An Internet-based survey was performed in March through April 2005, using a subsample from Knowledge Networks' national probability sample of adults. One sample of 1,027 adults was selected to reflect a cross-section of the public. A second sample of 2,027 cancer survivors was selected from the Knowledge Networks adult panel, representing a probability sample of adult cancer survivors in 2005.

Results: Both the public and cancer survivors rely mainly on their physicians as a key source of health-related information; their physicians are the most trusted health-care professional source of health information, although other sources such as the National Cancer Institute (NCI) and professional societies are also rated highly. All three sources rank significantly higher than the other 20 sources examined ($P < .05$). Only approximately 10% of survivors reported that they were aware of the possibility of CCT participation at the time of their diagnosis, and only 3% reported participation in a CCT. Seventy-three percent of patients aware of a CCT were made aware by a physician. Participation in a CCT was directly related to the level of physician involvement reported by the survivor ($P < .01$).

Conclusion: The physician plays a critical role in CCT recruitment. Future increases in patient participation in a CCT will depend on the willingness of physicians to present, explain, and encourage patient enrollment when a CCT is a clinically relevant treatment approach.

Introduction

Clinical trials are required to identify and establish the effectiveness of new therapies for all human diseases, including cancer. At present, in the United States, 65% of patients diagnosed with cancer will survive for 5 years or longer, and for the first time in history there has been a decrease in the death rate from cancer.[1] Improvement in cancer patient survival is a result of several factors, including better methods of screening, earlier detection, and development of more effective cancer treatments, the efficacy of which has been demonstrated in cancer clinical trials (CCTs).

Only approximately 3% to 5% of adult cancer patients participate in CCTs.[2] Understanding of the biology of cancer has progressed tremendously in the last several decades,[3] and therapies based on this greater understanding are now available.[4] We are entering an era where the genetic characteristics of an individual patient's disease are an important factor in determining the most effective course of treatment. Increasingly, the development of new cancer therapies based on the understanding of cancer requires additional, and more complex, clinical trials.

Building on an analysis of an earlier study that we conducted in 2000 and reported in *Journal of Clinical Oncology* in 2003,[5] this study was designed to identify and promote an understanding of, on a national level, the attitudes of the public and cancer survivors toward health-related decisions and CCTs to identify the key factors that must be addressed to resolve this chronic problem. This report substantially expands on previous collected measures of physician involvement in the presentation, explanation, and enrollment of patients onto a CCT.

Methods

Sample Selection

This study was conducted online in March and April 2005 using a national probability sample of adults from a panel of households constructed by Knowledge Networks (KN).[6] The KN national master sample includes more than 40,000 adults, all of whom complete one or more baseline surveys, including self-reports about current or previous medical conditions, on entering the KN system. The public and survivor studies were approved as exempt by the institutional review board of Northwestern University.

KN recruits individuals from a national probability sample of households with or without Internet access to participate in a continuing online weekly survey program in exchange for a free MSN box and free Internet service. The KN panel incorporates individuals who would prefer to answer questionnaires using their home computers rather than through their television, and provides a comparable reward structure for these participants. The KN national panel is the only probability-based online sample available in the United States and has been used frequently in national studies conducted by the Centers for Disease Control and Prevention and the National Institutes of Health.[7-11]

The public survey included 1,027 adults older than 18 years who did not have a diagnosis of cancer. An additional, 2,057 KN panel members indicated that they had been diagnosed with cancer at some time in the past; 1,816 of these cancer survivors responded to the initial invitation to participate. On subsequent analysis, 28 respondents were found not to have had

Table 1. 2005 Public Sample Characteristics

Characteristic	Sample (%) (N = 1,027)
Educational attainment	
Less than high school graduation	13
High school diploma or GED	36
Some college	28
Baccalaureate	14
Graduate or professional degree	10
Sex	
Female	52
Male	48
Age, years	
18-24	9
25-34	21
35-44	22
45-54	19
55-64	13
65 or older	16
Cancer experience	
Personally had cancer	3
Family member or close friend has had cancer	75
No personal, family, or close social experience	22
Race/ethnicity	
White, non-Hispanic	72
Black, non-Hispanic	12
Other, non-Hispanic	5
Hispanic	11
Not reported	0

cancer, reducing the final number of participants in the study to 1,788, or approximately 88% of the eligible sample of 2,057. Demographic characteristics of the survey respondents correspond to US Census Bureau reports[12] on educational attainment, sex, age, and race/ethnicity (Table 1). In addition, the incidence of cancer experience among study participants corresponds closely to available demographic data.[1]

Survey Instrument

The questionnaire used in this study was based in part on a questionnaire originally developed by Comis et al[5] for a national study conducted in 2000. The 2005 study included a larger number of open- and closed-ended questions to explore the critical role of the physician as a source of information and as an advisor in clinical trial recruitment. Additional questions were posed to determine the levels of understanding and awareness of clinical trials. Individuals with cancer experience were asked a series of questions about the treatment process, including sources of information, awareness, and attitudes. Those who were aware of clinical trials were also questioned regarding their physicians' level of support and encouragement concerning CCT enrollment.

Statistical Analysis

Statistical analysis was undertaken to characterize statistically significant associations between variances in public and cancer survivor attitudes and information-gathering behaviors, according to the methods of Blaylock et al.[13] Bivariate levels of association regarding physician influence on CCTs and public self-reports about the likelihood of enrolling were measured using an ordinal coefficient γ calculation.[14,15]

Results

Public Attitudes Toward the Role of the Physician

When asked how much participants would rely on their physicians for information about a serious illness and how much they might use other sources of information, a comparison of the 2000 and 2005 results point to a slight shift in expected public behaviors. Looking at the responses to the same question, it appears that a majority of adults in 2005 were willing to rely primarily on their physicians for information about their medical condition and options, but would also consult other sources of information. The proportion of adults who would rely exclusively on their physicians and not examine other information sources decreased from 12% to 6%, and the proportion who would treat their physicians as only one of multiple sources decreased from 43% to 35% (Table 2). Increasingly, the physician appears to be viewed as the quarterback of the health care team.

This emerging role of the physician becomes clearer when we look at the levels of trust accorded various health information sources. Each respondent in 2005 was asked to indicate how much they would trust health information from various sources, and "your physician" was the most trusted source, with a mean score of 8.1 on a zero-to-10 scale (Table 3). Information from the NCI Web site received a mean trust rating of 7.9, and

Table 2. Attitude Toward Physician Direction and Independent Information Seeking, 2000 and 2005

Response	2000	2005
Rely exclusively on doctor	12*	6*
Rely mainly on doctor but do own research	38*	51*
Use doctor as one source among several sources	43*	35*
Not sure	8	8
Total No. of respondents	1,000	1,027

NOTE. The question was presented as follows: Imagine for a moment that you were diagnosed with a serious illness or medical condition. How do you think that you would go about learning more about your condition and the treatments available for this condition? Would you rely exclusively on your own doctor, would you rely mainly on your own doctor but do your own research as well, or would you use your doctor as only one source among a number of sources?
*The difference between 2000 and 2005 is significant at the .05 level.

Table 3. Trust in Information Sources

Source	Public		Survivors	
	Mean	SE of the Mean[13]	Mean	SE of the Mean[13]
Your physician	8.1	0.06	8.6	0.03
Information on the National Cancer Institute Web site	7.9	0.07	8.4	0.04
A report from a society of cancer physicians and researchers	7.8	0.07	8.3	0.04
A brochure from your local hospital or physician's office	6.8	0.07	7.7	0.05
Another member of your family who has had cancer	6.8	0.08	6.3	0.06
Information on the WebMD site or a similar site	6.7	0.08	6.9	0.05
A report on a PBS documentary show	6.6	0.08	70.0	0.05
A brochure from a nonprofit patient support group	6.5	0.08	7.1	0.05
An interview with a well-known cancer survivor	6.5	0.08	6.6	0.06
A staff physician at your local hospital	6.3	0.07	6.8	0.05
A nurse in your physician's office or clinic	6.3	0.07	6.7	0.05
A story in *Time* or *Newsweek*	5.9	0.08	6.2	0.05
A story in a woman's magazine*	5.9	0.11	6.1	0.06
A report on a cable newscast such as CNN or MSNBC	5.8	0.08	5.9	0.06
A report on network evening news show	5.6	0.08	5.6	0.06
A pharmacist	5.5	0.08	6.4	0.05
A brochure from your local pharmacist	5.4	0.08	6.1	0.06
A health story on your local television news	5.3	0.08	5.6	0.06
A health story in your local newspaper	5.3	0.08	5.5	0.05
A story in a major metropolitan newspaper	5.2	0.08	5.2	0.05
Your priest, rabbi, minister, or religious leader	3.8	0.11	3.6	0.07
A television commercial from a pharmaceutical company	3.5	0.08	3.4	0.06
Your insurance company	2.9	0.09	3.4	0.07
Total No. of respondents	1,027		1,786	

NOTE. The question was presented as follows: There is a lot of information about cancer in newspapers and magazines and on television. For each of the information sources listed below, please indicate how much you would trust health information from that source. Please use a 0-to-10 scale, with 0 meaning that you would not trust health information from that source and 10 meaning that you would definitely trust health information from that source. If you are not sure, please check the Not Sure box and do not enter a number.
Abbreviation: PBS, Public Broadcasting System.
*Computed for women respondents only.

information from a "society of cancer physicians and researchers" received a mean trust rating of 7.8. These top three ratings are not significantly different at the .05 level, indicating that many adults trust a combination of information from their physicians, the NCI, and cancer-related professional groups. These results suggest that many adults still look to their physicians as the primary source of information and judgment about serious medical problems, but that they want confirming information from nationally recognized and respected sources. The parallel pattern of information trust among cancer survivors reinforces this finding.

Understanding of Clinical Trials

All respondents were asked a series of questions relating to their awareness of CCTs. Sixty-six percent of public respondents indicated that they "had heard of cancer clinical trials" before completing the questionnaire. When asked about their level of understanding of the term "clinical trial," 13% reported a "clear understanding," 57% reported a general sense, and 29% reported having "not much idea." Using an open-ended question format, 59% of individuals from the public sample had some understanding of the contextual clinical trials framework, ranging from drug testing (14%) to testing drug effects with or without a comparison reference group (26% and 19%, respectively). One third of respondents said they "didn't know," and 6% provided an incorrect answer. Cancer survivors had a greater understanding than the public at large in all categories.

Cancer Survivor Awareness and Attitudes Toward Clinical Trials and Enrollment

To obtain more detailed information about patient awareness of clinical trials at the time of diagnosis, cancer survivors were

asked a series of questions about the process and information provided by medical staff, nurses, family, friends, and others. Initial awareness was measured through two questions: When you were first diagnosed with this cancer, were you aware that you might be able to participate in a clinical trial for a new treatment for cancer? In the days and weeks after your diagnosis of cancer, did anyone tell you that you might be eligible to participate in a clinical trial for a new treatment for cancer?

Survivors who reported more than one cancer diagnosis were asked the same series of questions on their first and most recent diagnosis. Seventy-one percent of respondents had only one cancer diagnosis, 18% had two diagnoses, and 11% had three or more diagnoses.

Nine percent of survivors reported that, at the time of their most recent diagnosis, they were aware that they might be able to participate in a clinical trial. Of the 90% of survivors who were not aware that they might be able to participate in a clinical trial, 65% indicated that they would have been somewhat or very receptive to enrollment if they had become aware of the possibility.

A total of 4% of survivors tried to enroll onto a CCT, but only 3% were found to be eligible and actually enrolled. An equal number (3%) were offered participation and declined. Another 2% reported awareness of the possibility of a clinical trial, but were not offered the chance to enroll. These findings are consistent with other published reports.[16–18] Adults between the ages of 35 to 65 years were the most likely to enroll, whereas survivors in the age 18- to 34-year range and those older than 75 years recorded the lowest levels of enrollment (data not shown). The likelihood of enrollment did not vary by level of formal education or sex.

The reported level of awareness and enrollment depended on the type of treatment a survivor received (Table 4). Survivors who were treated with systemic therapy had the highest level awareness and enrollment, and individuals treated with surgery alone reported the lowest levels of awareness and participation.

Survivors who enrolled onto a clinical trial were asked about what they perceived as the advantages of enrollment: 65% indicated that they enrolled "to increase their personal chances of recovery," and 27% indicated that they wanted to "advance medical science." Conversely, individuals who were aware of the opportunity to participate in a trial were asked why they decided against it: 40% indicated that they were concerned that the new treatment might not be as effective as the standard of care, 18% voiced some concern about random assignment to treatment, and 11% were concerned with adverse effects or safety.

Survivors who participated in a clinical trial were asked a series of questions relating to the clinical trials experience (Table 5). More than 90% of CCT participants reported that they were treated with dignity and respect and had a positive experience. Nine of ten participants said that they would recommend participation in a CCT to others. Only nine percent (9%) "felt like they were treated like a guinea pig."

Role of the Physician in the Enrollment Decision

A primary, referral, or other physician was the source of CCT awareness in the 73% of survivors who knew about the possibility of enrolling onto a clinical trial. The primary physician was the reported source in 11% of those instances, whereas the referral physician accounted for 45% of responses. Except for other health professionals (6%), all other potential sources of awareness (eg, Web sites, newspaper, television, or family) were cited by 5% or fewer of the respondents.

Survivors who were aware of the possibility of a clinical trial at diagnosis reported a wide variation in levels of physician encouragement, education, and assistance with regard to clinical trials (Table 6). Forty-four percent of respondents reported their physicians had encouraged them to participate. Only 4% of respondents said their physicians discouraged enrollment. The majority reported their physicians were neutral about enrolling.

Survivors aware of clinical trials also were asked about the level of effort each patient's physician made to educate about the pros and cons of enrolling onto a clinical trial for their cancer treatment, and 37% of respondents reported that their physicians made a "great deal of effort" in this regard. Approximately 40% said their physicians made "a moderate amount of effort" to educate about the advantages and disadvantages of a clinical trial.

The final step of the enrollment process often involves identifying an appropriate trial for a patient's specific condition and characteristics. Survivors were asked about the level of effort each patient's physician made to help identify a "suitable clinical trial." Approximately 28% of respondents reported that their physician made a great deal of effort to find a suitable clinical trial for them, 41% said their physicians made a "moderate amount of effort," and 31% reported that their physician "made little effort."

To provide a summary measure of physician influence in the decision to enroll, a simple index was constructed, assigning 2 points for physician encouragement to enroll, 2 points for making a great deal of effort to educate the patient about clinical trials, and 2 points for making a great deal of effort to locate an appropriate clinical trial. One point was given for neutrality about clinical trials and for moderate efforts to educate about clinical trials and to locate an appropriate clinical trial. The resulting zero-to-6 Index of Physician Encouragement is a strong predictor of the final decision to enroll (Table 6). The γ for this relationship was 0.70 in the 2005 study, indicating that 70% of the variation in enrollment patterns can be explained by

Table 4. Cancer Clinical Trial Participation According to Therapy Type

Type of Therapy	Adult Survivors (%)				
	Aware	Aware but Not Offered	Offered and Declined	Not Eligible	Enrolled Onto Trial
Drug/chemotherapy (n = 488)	18	2	6	2	8
Radiation only (n = 107)	11	5	0	3	3
Surgery and radiation (n = 181)	7	1	1	2	3
Surgery only (n = 880)	5	1	2	1	1
All adult survivors (n = 1,776)	9	2	3	1	3

the level of physician effort in encouraging and explaining CCT ($P < .05$).

Discussion

These findings indicate that the physician maintains a leadership role when it comes to health care information and decision making in general, and the decision to consider participation in a CCT.

A comparison with our 2000 study indicates that a majority of the public now view their physicians as the most important sources of critical health information, but want to be able to find confirming information from respected national authorities such as the NCI or professional associations. In 2005, only 6% of adults indicated that they thought of their physicians as the sole source of health information, reflecting the growth of public access to the Internet and a growing public awareness of the availability of credible health information sources accessible through various media.[19,20] We are entering a new era in which the physician is the quarterback of the health care team, and physicians will need to recognize and expect that many of their patients will consult other information sources to learn more about their diseases and their options.

Although two thirds of adult public respondents said they had "heard of" CCTs before participating in the survey, only approximately 10% of cancer survivors reported that they were aware that participation in a CCT was an option, either on diagnosis or in the days and weeks thereafter. Cancer survivors in the 2005 study who were aware of the possibility of a CCT listed physicians as the principal source of their information. Awareness of CCT has been associated with positive attitudes toward CCT participation.[21]

Table 5. Satisfaction With Participation in a Cancer Clinical Trial

Response	Adult Survivors Participating in a Clinical Trial (%) (N = 1,776)
Felt they were fully informed on risks and benefits	97
Felt they were treated with dignity and respect	96
Had a positive experience	92
Would recommend a trial to others	91
Felt like a "guinea pig"	9

This study found a significant relationship between patient reports of physician discussion and encouragement of enrollment in a CCT, and patient-reported enrollment. This result is consistent with other studies based primarily in oncology clinics.[21-30]

We recognize that some patients are not eligible for enrollment onto a CCT because of the nature of their diseases and other factors, and many physicians take this into account in deciding whether to mention or offer a CCT to a patient.[17,21,31,32] We previously estimated that approximately 200,000 newly diagnosed patients would be eligible and have some willingness to participate.[5] Currently, only 20,000 to 25,000 patients are enrolled onto clinical trials each year, suggesting that there are many newly diagnosed cancer patients who would be interested in enrolling onto a CCT but are not being informed about the opportunity.[33]

Several studies have evaluated barriers to physician participation in clinical trials, including increased staff time and effort associated with clinical trials; paperwork and regulatory requirements associated with the process; inadequate reimbursement to cover the research costs required to screen, inform, enroll, and observe a patient (particularly on government-sponsored trials); lack of time committed to clinical research in both the academic and community-based oncology practice setting; and the shrinking federal research budget.[34-36] These are all legitimate systemic issues that need to be addressed if participation of adults in CCTs is to increase.

Despite these barriers, continued progress in cancer treatment depends on the enrollment of a significantly higher number of cancer patients onto CCTs. As the number of new therapeutic agents and approaches continues to grow, the importance of CCT enrollment becomes ever more important. The key to progress in the diagnosis and treatment of cancer is successful completion of high-quality clinical trials that define new standards of cancer care. When physicians identified appropriate

Table 6. Role of Physician in Participation in a Cancer Clinical Trial

Response	Trial Mentioned by Physician and Patient			No. of Patients
	Declined	Tried to Enroll	Enrolled	
The physician . . .*				
Discouraged me from participating	100%	0%	0%	4
Was neutral about participating	66	18	16	50
Encouraged me to participate	9	7	84	43
How much effort did any physician make to educate you about the pros and cons of participating . . .*				
Relatively little effort	69	9	22	23
A moderate amount of effort	41	18	41	39
A great deal of effort	25	11	64	36
How much effort did any physician make to help you find a clinical trial that was suitable for you?*				
Relatively little effort	67	10	23	30
A moderate amount of effort	48	13	39	39
A great deal of effort	7	11	82	27
Index of Physician Encouragement*				
0 (negative or no encouragement)	100	0	0	1
1	79	7	14	14
2	66	17	17	18
3	50	25	25	12
4	37	11	52	27
5	20	20	60	5
6 (strong positive encouragement)	0	5	95	20

*Significant at the .01 level.

patients, discussed the possibility of enrollment, and helped the patients identify a possible CCT on which to enroll, more than 90% of the eligible patients enrolled. Just as these data indicate that a majority of patients see their physicians as the quarterback of their health care team, it is essential for the oncology community to recognize that the physician is also the quarterback of the CCT enrollment process.

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