Original Contribution

Clinical trial awareness, attitudes, and participation among patients with cancer and oncologists

Laurie Fenton,[1] Maureen Rigney, LICSW,[1] and Roy S. Herbst, MD, PhD[2]

[1]Lung Cancer Alliance, Washington, DC; [2]Department of Thoracic/Head and Neck Medical Oncology, The University of Texas M. D. Anderson Cancer Center, Houston, TX

Low accrual rates may affect the completion of clinical trials essential to the development of new cancer therapies. Patient and physician attitudes and awareness of clinical trials directly impact clinical trial participation and are critical for the progress of cancer research. We undertook a study to assess the views of oncology patients and physicians regarding clinical trials. We analyzed data from a US national online survey conducted among 200 patients with lung cancer, 206 patients with other cancers, and 200 oncologists between August 9 and 18, 2006. Participants were consistent as a group, providing a number of perceived advantages and disadvantages to enrolling in trials. Sixteen percent of the patients were aware of relevant clinical trials at the time of treatment decisions, and physicians were cited as the patient's primary source of clinical trial information. Eighty-one percent of the patients reported that they did not discuss clinical trial participation with their physicians, although 84% of oncologists reported that they usually or always discussed clinical trials with patients. The study's findings suggest that low awareness and misperceptions about clinical trials are key barriers to clinical trial participation among patients. Although multiple factors influence patients' and physicians' decisions to participate in clinical trials, better overall communication between patients and oncologists about clinical trials is needed.

Marked improvements in cancer therapy over recent years have been possible with the completion of carefully designed prospective clinical trials.[1,2] Achieving enrollment goals in these trials is critical to establish adequate statistical power and to permit the generalization of results to the overall intended population.[2]

Unfortunately, fewer than 10% of patients with cancer participate in clinical trials.[1–5] Low accrual rates impede the development of new cancer therapies by prolonging the duration of trials, delaying analysis of results, preventing the achievement of statistical goals, and even leading to early closure of important studies.[2,6] The low rate of clinical trial accrual remains a central issue in oncology.

Previous studies have examined the problem of recruitment and participation in oncology trials and have identified enrollment barriers for patients, such as geography, a desire for noninvestigational therapies, fear of randomization, age, socioeconomic status, education level, type of cancer, and difficulties with third-party payers.[2–4,7] As physicians are often an important source of information for patients making decisions regarding clinical trial participation, they have a direct impact on a patient's likelihood of participating in a trial.[7]

Experience from trials to date indicates that it would be valuable to further investigate patient perceptions of the clinical trials process and the role that physicians play in encouraging patients with cancer to participate in these trials.[1,2] We undertook the present study to gain further insight into the predominant barriers to participation by assessing patient and physician views of clinical trials.

The need for clinical trials for lung cancer therapies is particularly strong, because lung cancer is common and associated with short survival times. Therefore, we designed this study to determine whether the views of patients with lung cancer about clinical trials differed from the overall patient population surveyed.[8,9]

Manuscript received November 25, 2008; accepted April 6, 2009.

Correspondence to: Laurie Fenton, Lung Cancer Alliance, 888 16th Street NW, Suite 150, Washington, DC 20006; telephone: 202-463-2080; fax: 202-463-7497; e-mail: lfenton@lungcanceralliance.org.

Commun Oncol 2009;6:207–213, 228

Materials and methods

We analyzed data collected by a private research firm (Shugoll Research, Bethesda, Maryland) through a national US online survey of 406 patients with cancer (200 with lung cancer and 206 with other types) and 200 oncologists from August 9 through August 18, 2006. Survey respondents were part of an online panel of approximately 6 million people (screened on a variety of issues, including diseases they have) who have agreed to participate in online surveys maintained by Harris Interactive. Harris Interactive maintains a specialty panel of people having chronic illnesses, including cancer, who were invited to participate in this survey.

The survey accuracy for the total sample of 406 patients was ±5.0 percentage points at the 95% confidence level. The accuracy for the lung cancer patient sample and the oncologist sample was ±7.0 percentage points at the 95% confidence level. Although patients with all types of cancer participated in the study, we restricted our subanalyses to the patients with lung cancer only.

Two separate surveys with closed-ended questions were used: one for the patients and the other for the oncologists. The patient survey was designed to identify the patient's current and past cancer treatments, to measure awareness of and participation in clinical trials, and to assess attitudes toward clinical trial participation and health-related entities. The oncologist survey was designed to describe the oncologist's type of practice, to measure clinical trial participation, to assess awareness and attitudes toward clinical trials, and to identify information preferences and practices. Of note, the oncologists surveyed were not the oncologists of the patients surveyed. All of the data were analyzed using paired Student *t* tests. We report only those findings that are statistically significant at the 95% confidence level.

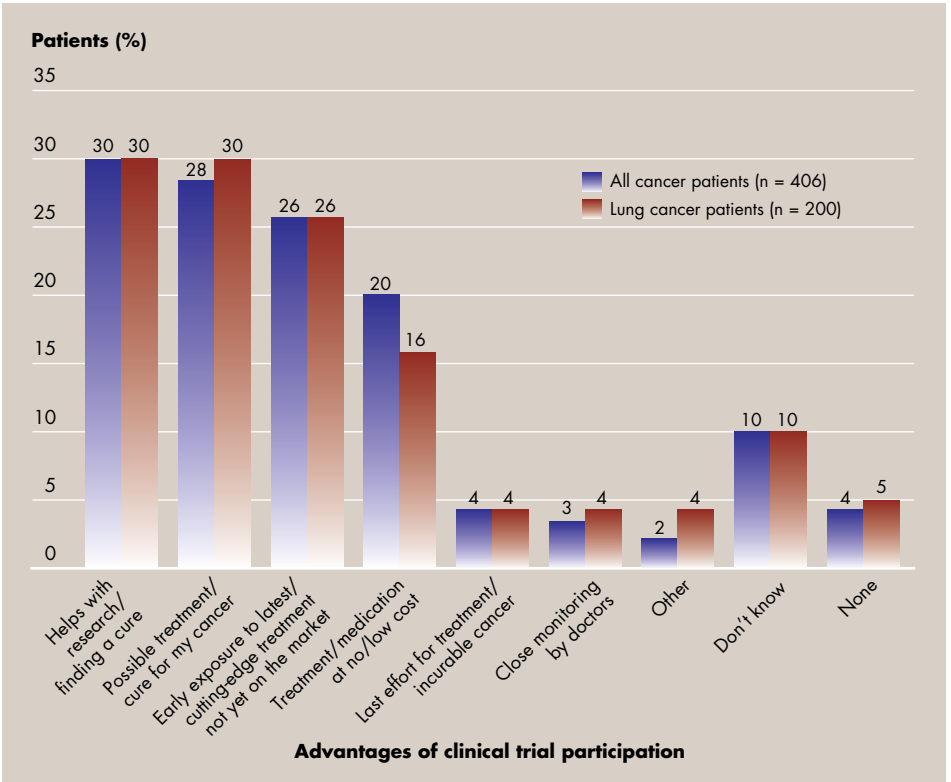

FIGURE 1 Patient-perceived advantages of clinical trial participation. Patients with cancer reported three primary advantages to clinical trial participation. Note: percentages may add up to greater than 100 because multiple responses were accepted.

Results

Patient demographics and treatment history

A total of 406 patients (54% male and 46% female) responded to the survey, 200 (49%) of whom had lung cancer. Ninety-five percent of the respondents were white, and their mean age was 64 years, with the majority (66%) between the ages of 55 and 74 years. Sixty-three percent of all patients had received treatment for their cancer, with the most common treatment modalities being surgery (69%), radiation therapy (50%), and chemotherapy (46%). Additional treatments included other oral medications, targeted therapies, and radioactive seed implants. Patients with lung cancer were more likely to have received chemotherapy (55% vs 38%) and less likely to have used other oral medications (8% vs 20%) than patients with other cancer types.

The majority of patient respondents reported having Medicare or Medicaid (32%) or private health insurance (60%). Patients who required treatment usually received it at a community hospital (41%) or at a major teaching or research hospital (33%). Compared with those with other cancer types, patients with lung cancer were less likely to receive treatment at an outpatient center affiliated with a community hospital (19% vs 32%). The respondents were divided between residing in large (37%), medium (24%), and small (24%) metropolitan areas and rural areas (15%). Sixty-four percent of all patients reported traveling 20 or fewer miles to receive their treatment with 36% travelling more than 20 miles for treatment. Notably, lung cancer patients were more likely to travel more than 20 miles to receive treatment (41%).

Forty-seven percent of patients had received their cancer diagnosis within the past 5 years. However, patients with lung cancer were more likely to have a recent diagnosis (10% within the past year) versus all patients (2% within the past year). The cancer had not spread to other parts of the body in 88% of patients, and 35% of patients had stage I or earlier cancer. Notably, the lung cancer subgroup was more likely than the subgroup with other malignancies to have a diagnosis of stage IV cancer (11% vs 6%) and to indicate that their cancer had spread to other areas of their bodies (8% vs 0%).

Overall, patient respondents were most likely to have received treatment from a radiation oncologist, with 44% of all patients reporting treatment by these specialists. Of note, the patients treated for lung cancer were more likely to be seen by a general or thoracic surgeon than those treated for other types of cancer (46% vs 28%, respectively).

Oncologist demographics and practice types

Ninety-nine percent of responding oncologists were medical oncologists, 60% of whom had been in practice ≥ 11 years (mean, 14 years). Eighty-two percent of the physician respondents were male, 67% were in a private or office-based practice, 41% were affiliated with a major teaching or research hospital, and 79% reported serving as a primary investigator of a clinical trial. These oncologists were located throughout the United States, and 83% were in an urban or suburban practice setting.

On average, the oncologists reported spending 88% of their time with patient care, and 73% reported treating more than 80 patients per month. More than 90% of the oncologists indicated that they treat the more common cancers, including lymphoma and leukemia (96%), breast cancer (95%), colon cancer (95%), lung cancer (93%), and prostate cancer (92%). Forty-eight percent noted that more than half of their patients had cancers that had progressed to advanced stages.

Patient awareness of and participation in clinical trials

Survey results indicated that the large majority of patients with cancer were familiar with the term *clinical trials*, with 82% reporting being either very familiar (32%) or somewhat familiar (50%). However, fewer patients with lung cancer (28%) compared with those with other cancer types (37%) reported that they were very familiar with the term.

Patients were fairly consistent in providing a number of perceived advantages and disadvantages to participating in clinical trials. The three advantages most often mentioned were helping with research and finding a cure, obtaining a possible treatment or cure for their own type of cancer,

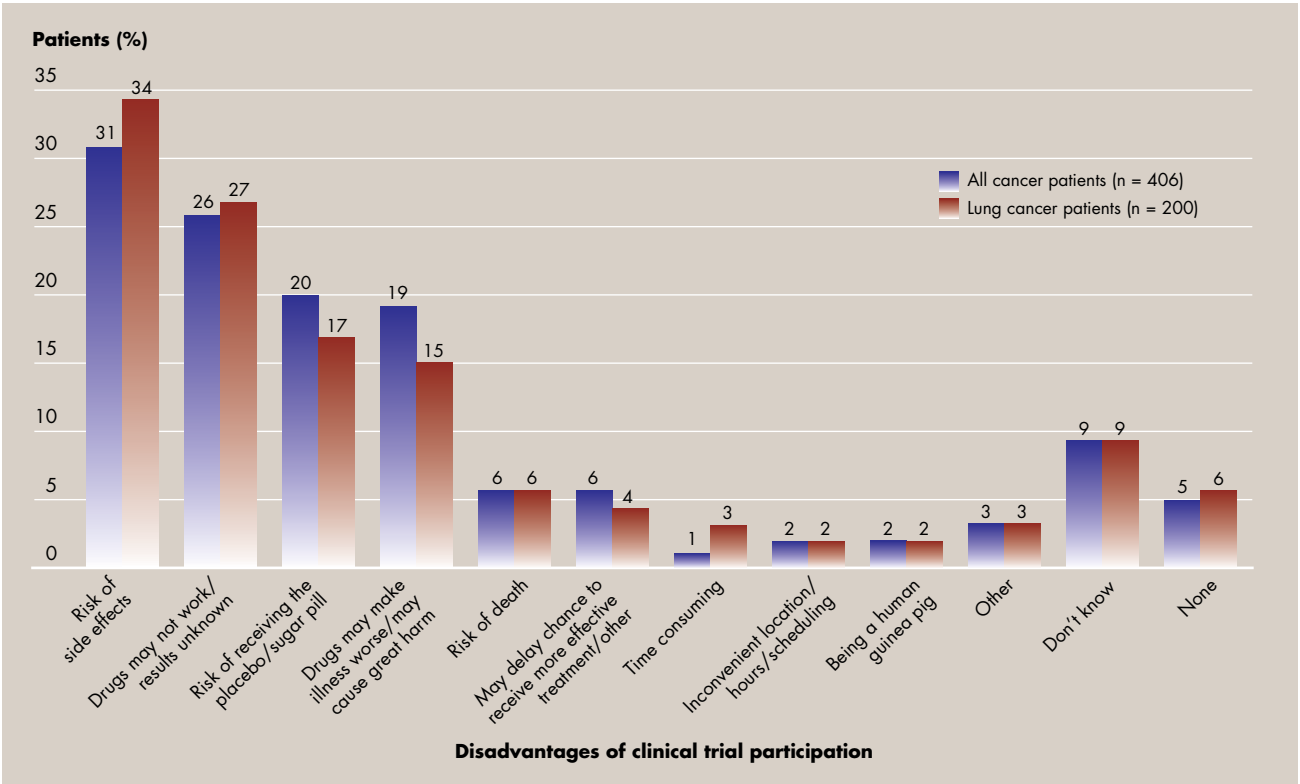

FIGURE 2 Patient-perceived disadvantages of clinical trial participation. Patients with cancer reported four primary disadvantages to clinical trial participation. Note: percentages may add up to greater than 100 because multiple responses were accepted.

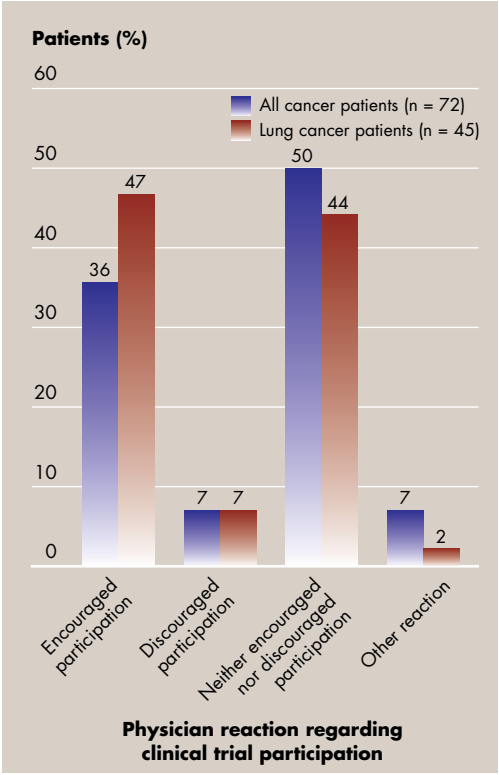

FIGURE 3 Patient-reported physician reaction regarding clinical trial participation among patients who discussed trial participation with their physicians. Although results are based upon a small number of respondents, approximately half of the patients discussing participation with their physicians reported that their physicians remained neutral during the discussion, neither encouraging nor discouraging participation.

and having early exposure to the latest treatments not yet on the market (Figure 1). On the other hand, the patients cited four primary disadvantages to clinical trial participation: the risk of side effects, a concern regarding efficacy of untested agents, the risk of receiving a placebo, and the possibility that the drug may cause harm or make their disease worse (Figure 2).

Overall, 16% of all patients were aware of relevant clinical trials at the time that they were considering treatment options. By far, their main source of information about clinical trials was physicians, cited by 79%. Other sources included the Internet (26%), information at a physician's office (14%), support groups (13%), friends or relatives (11%), and medical journals (11%).

Eighty-one percent of all the patients reported that they did not discuss clinical trial participation with their physicians at the time they were making treatment decisions. The patients with lung cancer were more likely to have had such discussions with their physicians than were the patients with other cancer types (22% vs 13%). Sixty percent of patients reported that their physicians were more likely to initiate a discussion about clinical trials whereas 35% of patients reported that they initiated the discussion. Half of the patients surveyed also reported that their physicians remained neutral during the discussion (Figure 3).

Patient attitudes toward clinical trial participation

Only 7% of all patients surveyed had participated in a clinical trial, although reported participation was more common among the patients with lung cancer than among those with other types of cancer (11% vs 4%). The primary reasons that the patients gave for participating in a trial were that their physicians recommended it (45%), they wanted to help advance the understanding and treatment of cancer (41%), and they considered the trial treatment to be more advanced or state of the art (35%; Table 1). Conversely, the patients cited lack of awareness of appropriate trials as the chief barrier to participation, with 65% of those who had not participated in a trial giving this reason. Other barriers the patients mentioned included satisfaction with their current therapy (23%), fear of possible side effects (14%), and a failure to meet inclusion criteria (13%). Patients with lung cancer were less likely to be concerned about side effects than their peers with other cancer types (10% vs 17%).

The majority of patients expressed interest in clinical trials, with 69% overall indicating that they would be interested in participating if they still required treatment and a new drug was being developed. This number was higher in the subgroup of patients with lung cancer (77%) than in the group with other cancer types (62%).

Oncologist attitudes toward referring patients to clinical trials

Nearly all of the oncologists (95%) had searched for a clinical trial that met the needs of a patient, and only 3% had not referred any patients to clinical trials in the past year. However, 66% of the oncologists reported referring 20 or fewer patients during this time period. Further, few of them referred patients to a hospital other than their own for clinical trials. Among those who had referred patients for trials, 77% reported that only 25% or fewer of their referrals were to a competing or other hospital.

Oncologists reported that the main obstacles to referring patients with cancer to clinical trials were fear or hesitation among patients (50%), the grave condition of patients (49%), lack of interest among patients (44%), and finding clinical trials close enough to be considered (42%). The main obstacles to referring patients with lung cancer were similar (Table 2). Additional obstacles to referral included having to learn about the trials and application and administration issues, among others.

Oncologist clinical trial discussions with patients

The oncologists estimated that about 60% of patients ask about clinical trials. When patients initiate these discussions, the oncologists reported primarily providing objective counseling (79%) and reassurance that the trial is something for the patients to consider (78%). In addition, they mentioned that they provide patients with contact information for the trial leaders (65%), Internet sites or support groups (44%), and their nursing staff (33%), so the patients can gather more information

about a particular trial.

Fully 84% of the oncologist respondents said that they always (43%) or usually (41%) discuss clinical trial participation with a patient if it is appropriate. The chief barriers to such a discussion with a patient who might qualify for a trial were inconvenience of the trial location (25%), lack of patient interest (22%), and time constraints (19%). Other barriers mentioned by the oncologists included the patient not qualifying or the trial not being appropriate for the patient, the possibility that standard therapy might be more appropriate or effective for the patient, and inability of the patient to understand the trial or give informed consent.

Oncologist perceptions of patients' concerns

A large proportion of the oncologists (89%) reported that they had patients who declined to participate in a clinical trial that might have been appropriate for them. According to these respondents, patients hesitate or decline to participate in clinical trials largely because of concerns about being given a placebo, fear of side effects, the inconvenience of the trial location, or the need to relocate away from home or family (Table 3).

Oncologist awareness of and attitudes toward clinical trials

The oncologists surveyed reported being well informed about trials in their general area but also not having time to follow ongoing trials. A total of 50% responded that they are aware of all (7%) or most (43%) clinical trials of new agents in their geographic area. Although most oncologists closely follow the existence and findings of ongoing clinical trials, many noted that they are unable to do so because of time constraints. Specifically, 66% reported following trials in progress closely, whereas only 10% follow them very closely and 24% do not follow them at all. Among those who do not closely follow clinical trials, 87% noted that this was due to a lack of time, and 41% noted that annual symposia and continuing education programs keep them as informed as they need to be.

Many of the oncologists surveyed had not developed strong opinions about criteria to determine whether they would participate in a clinical trial of a particular drug. The majority neither agreed nor disagreed with the following statements: newer drugs must be more convenient to administer; newer drugs must demonstrate progression-free survival; new cancer drugs will replace the need for chemotherapy and will improve overall survival; newer drugs must be targeted to the specific molecular and genetic makeup of a specific type of cancer and show improved survival. However, the oncologists were keenly interested in drugs that will improve the quality of life for their patients, and 72% agreed that if two drugs are equivalent in improving survival rates, the one improving quality of life would be preferred. Further, only 22% agreed that there would be considerable value in a new drug that improves the time to disease progression

TABLE 1

Patient-reported reasons for and barriers to clinical trial participation

Reason for/barrier to participation	All cancer patients, %	Lung cancer patients, %
Reason for participation provided by those who participated in clinical trials (7%), n	29	21
Recommended by doctor	45	48
Advancing the understanding and treatment of cancer	41	48
Trial treatment was considered more state-of-the-art care	35	29
Offered along with the standard course of treatment, so it couldn't hurt	24	29
My costs of care were covered in the trial	21	24
The second or third treatment stopped working	14	14
My first treatment stopped working	7	10
Other	3	0
Barrier to participation cited by those who did not participate in clinical trials (92%), n	374	176
Not aware of any trials appropriate for me	65	64
Current treatment is better/more effective	23	24
Fear of possible side effects	14	10
Did not meet the criteria to participate	13	12
Did not want to change doctors	11	10
Did not want to wait to begin treatment	11	7
Fear of getting a placebo	10	8
Concern about insurance/coverage issues	10	11
Inconvenient follow-up location	6	6
Made an earlier treatment decision that made me unable to meet the criteria to participate	6	5
Trial location would mean relocating or being away from my home/family	6	5
Time commitment was too much	5	5
Out-of-pocket expenses were too high	5	6
My family objected/had some concerns	2	2
Other	5	5

TABLE 2

Oncologist-reported obstacles to referring patients with lung cancer to clinical trials

Obstacle	Oncologists, %
Number of respondents	200
Fear or hesitation among patients	49
Condition of patient is too grave to benefit from trial participation	48
Finding clinical trials close enough to be considered	43
Lack of interest among patients	42
Learning about clinical trials that match the patient's condition (inclusion/exclusion criteria)	33
Ease of application and administration (CROs, forms, etc) for patient's enrollment	21
Coordination of patient care once in a trial	15
Affordability for the patient	15
Loss of patient to another physician/facility	13
I do not treat lung cancer	3
Other	2

CRO = contract research organization

TABLE 3

Oncologist-perceived reasons why patients hesitate or decline to participate in clinical trials

Reason	Oncologists, %
Number of respondents	200
Fear of being given placebo	67
Fear of side effects	61
Inconvenient trial location	59
Trial location means relocating away from home/family	53
Patient too weak or gravely ill to participate	47
Not wanting to delay treatment	45
Health insurance or coverage issues	38
Time commitment for treatment and follow-up	34
Family concerns	33
Out-of-pocket expenses	33
Paperwork or contract issues	28
Belief that current treatment is better	27
Feeling like a guinea pig/being experimented on	4
Other	1

but does not improve quality of life.

Oncologist information preferences and practices

Fully 98% of the surveyed oncologists expressed fair to strong interest in learning about available clinical trials; however, only 37% had a systematic method for remaining current regarding trials. Online databases were overwhelmingly preferred sources of information, cited by 93% of those surveyed. The respondents also cited oncology conferences (66%), the National Cancer Institute (NCI) and National Institutes of Health (NIH) Web sites (55%), oncology medical newsletters (53%), and word of mouth from other oncologists (50%) as their primary sources of clinical trial information. Some 71% of the oncologists rated the opportunity to learn of nearby trials as something that would be particularly helpful, and 57% would find it very helpful to have information available to refer physicians to clinical trials occurring at their facilities.

Discussion

Although measures have been taken to reduce barriers to participation in clinical trials and to better inform patients with cancer about these trials, the results of our survey indicate that the needs of patients with cancer and oncologists still are not being met.

The survey's results indicated a considerable lack of awareness among patients with cancer about the clinical trials that might be available to them. Concerns, fears, and misperceptions about the quality of care and the chances for treatment benefit may deter the few patients who are aware of clinical trials from enrolling in one. Other barriers mentioned by the patients, including preferences for current treatment, distance from the cancer center, relationship with their medical team, and insurance denial, are similar to those described in earlier studies.[2–4] These findings suggest that clear communication between patients and oncologists about clinical trial participation is lacking and that better methods for discussing the option of clinical trial participation with patients are needed. This observation regarding lack of clinical trial awareness among patients and suboptimal communication between patients and physicians about trial participation is supported by previous studies that investigated clinical trial enrollment.[10]

One limitation of our study is that the majority of patients who participated had earlier-stage disease. Many oncology trials, particularly in lung cancer, are conducted in populations with late-stage disease. Hence, the patients surveyed are less likely to have had discussions with their oncologist about clinical trials, and some responses may have differed in a group with more advanced cancer.

In the oncologist portion of the survey, nearly all of the physicians indicated that they search for trials for their patients. Although the oncologists in this study reported that they were aware of most clinical trials for new cancer drugs, their responses also indicate that keeping current on these trials can be challenging for physicians.

This survey revealed important discrepancies between oncologist views of patient beliefs about clinical trials versus patients' actual beliefs about clinical trials. For example, 49% of oncologists indicated that patients' fear of clinical trials is an obstacle to referring them for participation in trials of lung cancer therapies, and a majority believed that patients fear of receiving a placebo (67%) or side effects (61%) is a noteworthy reason why patients hesitate or decline to participate. In contrast, only a minority of patients with lung cancer noted that fear of receiving a placebo (8%) or side effects (10%) was a barrier to their participating in a clinical trial. Taken together, these findings suggest that oncologists believe that patients are more fearful of trial par-

ticipation than patients really are. If oncologists understand that patients are not averse to participating, it is likely that both communication about the existence of trials and overall participation would increase.

Several studies, including this one, have shown that the physician is the main factor in determining a patient's enrollment in a clinical trial.[7] However, some important differences in perceptions exist between patients and physicians. For example, although the survey results suggested that 84% of oncologists believe that they discuss clinical trials with eligible patients, 81% of patients indicated that they were unaware of available and appropriate clinical trials when they were exploring treatment options. Possible explanations for the difference in these responses may be that physicians mention clinical trials only if they believe that the trial has experimental merit, the patient meets ideal eligibility requirements, and trial participation would not be a burden to the patient.[2,11,12]

As suggested by this study and shown in other studies,[13–15] patients are often willing to participate in clinical trials, but a large number do not meet the eligibility criteria. For example, of 1,411 patients treated in the UK National Cancer Research Network in 2002, 40% did not have any trials available to them, and 28% were immediately excluded, as they did not meet entry criteria.[13] In another study conducted at a community-based center in Wisconsin, the center did not have an appropriate trial for the diagnosis and stage of disease for 58% of the 1,012 patients receiving a new diagnosis of cancer between 2003 and 2004.[15]

Although the issues surrounding clinical trial participation may largely transcend cancer type, we found that compared with patients with other types of cancer, patients with lung cancer had more advanced disease at diagnosis, were more likely to have received chemotherapy and to have seen a general or thoracic surgeon, had received their cancer diagnosis more recently, had to travel farther to receive treatment, and were more likely to express interest in clinical trials.

Suggestions for overcoming some barriers to patient awareness and patient accrual to clinical trials include providing consumer-friendly, unbiased information about these trials to patients with cancer. Specifically, patients should be introduced to information about treatment options, including clinical trials, by the oncologist and the clinical research associate.[3] They should also be made aware of the potential benefits of clinical trial participation, as the perception of personal benefit has been significantly correlated with a patient's decision to enter into clinical trials.

In this survey, physicians reported that they would like improved resources to search for trials, which confirms findings of earlier studies suggesting such resources could help engage oncologists in clinical trials.[5] Physicians can search for clinical trials registered on the NCI's Web sites (http://www.cancer.gov or http://www.clinicaltrials.gov), but, because of time constraints and other factors, it may be more useful if current information about trials in the physician's local area were readily accessible.[16] National governmental efforts have also been made to involve physicians in clinical trials through the use of Cooperative Group Outreach Programs by making it easier for physicians to accrue patients to cooperative group studies. Similarly, Community Clinical Oncology Programs allow potential investigators to participate in most cooperative group trials.[5] Community physicians also have the option of joining the Cancer Trials Support Unit, which promotes unrestricted access to NCI-sponsored phase III trials outside of one's cooperative group.[17] In addition, clinical trial nurses may help play a role in recruitment by informing physicians about trials and helping them navigate the enrollment process.[18] Finally, establishing allowances to help maintain the physician-patient relationship when trials are available at other or competing institutions could also decrease barriers to patient enrollment in clinical trials. This would alleviate concerns of physicians who fear losing control of their patients' care and also adequately compensate physicians for the time it takes to refer patients to other centers.

Conclusion

The results of this survey reinforce the notion that the physician has the best opportunity to inform patients about clinical trials and also has the greatest influence on how patients perceive clinical trials. The first step in alleviating many of the barriers to clinical trial enrollment, confirmed by this survey's results, is better communication between patients and their oncologists about clinical trials.

Acknowledgments: We thank Lee Ann Swenson, who provided medical writing support funded by AstraZeneca Pharmaceuticals LP.

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ABOUT THE AUTHORS

Affiliations: Ms. Fenton is President and Chief Executive Officer of the Lung Cancer Alliance, Washington, DC; Ms. Rigney is a Licensed Independent Clinical Social Worker and Director of Patient Services at the Lung Cancer Alliance, Washington, DC; and Dr. Herbst is a Professor of Medicine and of Cancer Biology, in the Department of Thoracic/Head and Neck Medical Oncology, The University of Texas M. D. Anderson Cancer Center, Houston, TX.

Conflicts of interest: Dr. Herbst is an advisor for Amgen, AstraZeneca, Bristol-Myers Squibb, and Prolex. He has received grant and research support from Amgen, AstraZeneca, Bristol-Myers Squibb, Eli Lilly, Genentech, and sanofi-aventis. He is a paid consultant for Amgen, AstraZeneca, Bristol-Myers Squibb, Eli Lilly, Genentech, ImClone Systems, Pfizer Inc, and sanofi-aventis. He has participated in the speaker's bureau for Eli Lilly and Genentech, and has received research funding from Amgen, AstraZeneca, Bristol-Myers Squibb, and Genentech. Ms. Fenton and Ms. Rigney do not have any conflicts of interest to report.