Published in final edited form as:
J Clin Oncol. 2008 June 1; 26(16): . doi:10.1200/JCO.2007.14.8114.

Influence of Clinical Communication on Patients' Decision Making on Participation in Clinical Trials

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Abstract

Purpose—To investigate how communication among physicians, patients, and family/companions influences patients' decision making about participation in clinical trials.

Patients and Methods—We video recorded 235 outpatient interactions occurring among oncologists, patients, and family/companions (if present) at two comprehensive cancer centers. We combined interaction analysis of the real-time video-recorded observations (collected at Time 1) with patient self-reports (Time 2) to determine how communication about trial offers influenced accrual decisions.

Results—Clinical trials were explicitly offered in 20% of the interactions. When offers were made and patients perceived they were offered a trial, 75% of patients assented. Observed messages (at Time 1) directly related to patients' self-reports regarding their decisions (2 weeks later), and how they felt about their decisions and their physicians. Specifically, messages that help build a sense of an alliance (among all parties, including the family/companions), provide support (tangible assistance and reassurance about managing adverse effects), and provide medical

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Presented in part at the 4th Annual American Association of Cancer Research International Frontiers in Cancer Prevention Research Conference, October 30-November 2, 2005, and the 42nd Annual Meeting of the American Society of Clinical Oncology, June 2–6, 2006, Atlanta, GA.

AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

Although all authors completed the disclosure declaration, the following author(s) indicated a financial or other interest that is relevant to the subject matter under consideration in this article. Certain relationships marked with a "U" are those for which no compensation was received; those relationships marked with a "C" were compensated. For a detailed description of the disclosure categories, or for more information about ASCO's conflict of interest policy, please refer to the Author Disclosure Declaration and the Disclosures of Potential Conflicts of Interest section in Information for Contributors.

Employment or Leadership Position: None **Consultant or Advisory Role:** Terrance L. Albrecht, Pfizer (C) **Stock Ownership:** None **Honoraria:** Terrance L. Albrecht, Pfizer **Research Funding:** None **Expert Testimony:** None **Other Remuneration:** None

AUTHOR CONTRIBUTIONS

Conception and design: Terrance L. Albrecht, Louis A. Penner, John C. Ruckdeschel
Financial support: Terrance L. Albrecht, John C. Ruckdeschel
Administrative support: Terrance L. Albrecht, Susan S. Eggly, John C. Ruckdeschel
Provision of study materials or patients: Terrance L. Albrecht, John C. Ruckdeschel
Collection and assembly of data: Terrance L. Albrecht, Susan S. Eggly, Felicity W.K. Harper, Tanina S. Foster, Amy M. Peterson, Heather Orom, Louis A. Penner, John C. Ruckdeschel
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Manuscript writing: Terrance L. Albrecht, Susan S. Eggly, Marci E.J. Gleason, Felicity W.K. Harper, Tanina S. Foster, Amy M. Peterson, Heather Orom, Louis A. Penner, John C. Ruckdeschel
Final approval of manuscript: Terrance L. Albrecht, Susan S. Eggly, Marci E.J. Gleason, John C. Ruckdeschel

content in language that patients and family/companions understand are associated with the patient's decision and decision-making process.

Conclusion—In two urban, National Cancer Institute–designated comprehensive cancer centers, a large percentage of patients are not offered trials. When offered a trial, most patients enroll. The quality and quantity of communication occurring among the oncologist, patient, and family/companion when trials are discussed matter in the patient's decision-making process. These findings can help increase physician awareness of the ways that messages and communication behaviors can be observed and evaluated to improve clinical practice and research.

INTRODUCTION

Accrual rates for oncology trials are inadequate, causing delays in scientific progress against cancer.[1,2] Low accrual is attributed to factors that decrease the pool of eligible patients and inhibit patients from participating.[3–6] The reduced pool has been ascribed to a lack of available trials, overly stringent eligibility criteria, and complex social and institutional barriers delaying trial implementation.[7–11] To understand why patients who are eligible for an available, clinically appropriate trial do not participate, it is critical to assess the actual process of physician-patient interactions that influence patients' accrual.

When offered enrollment, a patient's perceptions of the oncologist and the quality of the physician-patient interaction during which the trial is discussed affect the decision to accept.[12–17] However, few studies address what oncologists do and say during the course of the discussion that influences patients' decisions and vice versa.[15,18] This high-stakes discussion is further complicated by the presence of family members and companions, who often actively participate in interactions with the oncologist[19] and assist patients in making decisions.[12] Clearly, the oncology interaction is a process of mutual influence experienced by all parties during the exchange of verbal and nonverbal messages throughout the clinical discussion.

Traditional models of human interaction posit that communication occurs on content (ie, transfer of information) and relational levels (ie, how individuals view each other and build their relationship through interaction).[20] In clinic visits, content and relational messages comprise the verbal and nonverbal communication in which physicians influence patients' decisions.[18] To effectively communicate content messages, oncologists must meet ethical mandates,[21] convey medical knowledge,[22] and demonstrate professional credibility,[23,24] without causing misunderstanding or information overload.[25] To effectively communicate on a relational level, oncologists must use alliance-building messages to reassure the patient and family/companions (eg, "We're here to take care of you and help you best manage your treatment"). Effective alliance-building messages increase the patient's confidence in the physician and the treatment decision. A physician who describes potential adverse effects of an experimental agent, and also a treatment plan for managing those toxicities, is signaling that he/she is anticipating and managing the individual patient's medical situation and needs. Such "patient-centered communication"[26] that informs and builds relationships also helps all parties converge on a sense of shared meaning and understanding,[27] particularly helpful in the face of the inherent medical and psychological uncertainties regarding whether to join a trial.[18] This communication strategy helps physicians provide patients with tangible and emotional support and respond to patients' and family/companions' concerns in understandable language, thereby helping patients overcome many perceived barriers to enrollment.

The purpose of this study was to investigate how communication among physicians, patients, and family/companions influences patients' decision making about clinical trials. We combined interaction analysis of real-time observations (collected at Time 1) with

analysis of patient self-reports (collected at Time 2) to understand the influence process and its outcomes.

PATIENTS AND METHODS

Data were collected between April 2002 and March 2006 in the multidisci-plinary outpatient clinics at two National Cancer Institute– designated comprehensive cancer centers, located in the Southeast and the Midwest United States. Participants were patients potentially eligible for phase II or III clinical trials (and their families/companions, if present). Inclusion criteria were age 18 years or older, visiting a physician who had consented to participate in our study, and ability to speak and read English.

Institutional approval

The study was approved by the institutional review boards at the universities affiliated with both sites and underwent protocol review and monitoring at both cancer centers. All patients, families/ companions, physicians, and other medical providers (if present) signed consent forms giving permission to be video recorded; patients also reviewed and signed Health Insurance Portability and Accountability Act (HIPAA) forms.

Procedures

Eligible patients were identified by oncologists or their nurses before their scheduled appointment. When patients arrived, staff asked their permission for a research assistant to approach them (in compliance with HIPAA guidelines). If they agreed, our study was explained to the patients and family/companions, and they were asked to participate. Those who consented signed consent forms and completed background questionnaires (regarding their sociodemographic characteristics and primary information sources) while they waited for the oncologist.

Research assistants video and audio recorded the entire clinical interaction with the oncologist using a remote-controlled, portable digital system (Time 1 data collection).[28] The system includes high-resolution, digital video cameras with wide-angle lenses housed in cylinders, external microphones, and remote monitoring and recording capabilities. After placing the camera units in the examination room, research assistants moved to a private, secured site elsewhere in the clinic to monitor the audio and video recording of the interaction as it occurred. Camera angles were controlled using a touch panel/ liquid crystal display monitor and directed to pan, tilt, and/or zoom as necessary to capture movement in the room. Extensive testing by the authors has empirically established the need for video and audio recording (rather than only audio recording)[29] as well as the lack of research participant reactance to being recorded.[30]

The signal was recorded onto MiniDV format tapes, edited using an HP XW8000 workstation (Hewlett-Packard, Palo Alto, CA) with Xpress Pro software (Avid Technology, Tewksbury, MA). Resulting files were converted to MPEG2 formats and loaded onto DVDs for subsequent coding, using the Observer Video-Pro software analysis program (Noldus, Leesburg, VA) for digital on-screen playback and user-defined coding for data analysis.

Within 2 weeks of each interaction, a research assistant contacted the patient by telephone to conduct a follow-up interview (Time 2).

Study Measures

The Karmanos Accrual Analysis System (KAAS) is an observational coding system used to assess the multiparticipant interaction in which a clinical trial is offered. The KAAS, a

revision of the Moffitt Accrual Analysis System,[18] assesses relational and content messages communicated in the context of clinical trial offers (described later herein).

Independent, trained coders completed each section of the KAAS.[19] We used a group consensus process, whereby three coders independently reviewed and rated each interaction, but resolved disagreements as a group.[19]

Relational communication—This section of the KAAS consists of relational communication items (Global Judgments) rated on 7-point scales with end point descriptors for each item (Table 1). Separate ratings were completed for oncologist-patient and oncologist-family/companion pairs. Principal components exploratory factor analyses with varimax (orthogonal) rotations were conducted separately for the oncologist-patient and the oncologist-family/companion ratings for all cases (N = 226). Using the criteria of eigenvalues greater than 1, visual inspection of plots of these values (ie, scree criteria) and theoretical coherence of the factors, we selected a two-factor solution for patients and a two-factor solution for family/companions. (Item factor loadings in the two analyses were similar.) Individual items were weighted (0 or 1), depending on the factor loading (> 0.50 =1). Weighted raw scores were then summed to form a total score on that factor. Oncologist-patient factors were labeled “oncologist-patient alliance” and “oncologist-patient conversation control.” Oncologist-family/companion factors were comparably labeled “oncologist-family/companion alliance” and “oncologist-family/companion conversation control.” “Alliance” is the extent to which the physician and patient (or family member/companion) are judged to have a trusting, cordial, and engaging relationship. “Conversation control” is the extent to which the physician and patient (or family member/companion) share talk time and speak on the same level to one another.

Content messages—Five checklists from the KAAS were used to assess the information communicated by the physician (Table 2). They include the sum of messages regarding: legal information describing the nature of the protocol, adverse effects, support about the patient’s trial enrollment status, support (reassurance and help) regarding adverse effects, and benefits regarding trial participation.

Decision-related outcomes—We assessed three decision-related patient outcomes in the follow-up interview: the patient’s decision whether to enroll, decision-related affect and cognition (how patients felt and thought about the decision and the physician), and reasons for the decision[31] (Table 3).

RESULTS

Participants

Patient selection—Because our interest was in the process by which a patient who was already declared eligible is in fact offered a trial, only patients who were explicitly offered a trial were included in our final sample. To identify such interactions, observers categorized all video recorded interactions according to one of several categories, ranging from “no mention of a trial by any participant” to “explicit offer of a clinical trial” (Table 4). For coding the classification, two trained coders made independent classification judgments for each interaction; disagreements were resolved by a third coder. Although patients were referred to our study because they were potentially eligible for a clinical trial, in most cases (76%), the oncologist did not make a trial offer. In some cases, a trial was discussed, but the patient was not invited to enroll. Actual offers to participate in a clinical trial were identified in only 47 interactions (20%).

We were unable to contact seven patients for the follow-up interview. Reasons for attrition included changes in health status, difficulty reaching patients by telephone, and/or family member interference that precluded direct interviews with the patient. Finally, among those who did participate in the follow-up interview, five reported that they had not been offered a clinical trial. Henceforward, "patients in this study" refers to those who were explicitly offered a trial, who participated in the follow-up interview, and who reported they were offered trial enrollment. The resulting sample size was 35.

Sociodemographic characteristics—Mean patient age was 58.9 years (standard deviation [SD], 11.2 years); average age of family/ companions was 50.8 years (SD, 13.6 years). Forty-six percent of patients were female; 68% of family/companions were female. Sixtynine percent of patients and 91% of family/companions were white. The largest reported minority group was African American (17% of patients, 6% of family/ companions). Nearly all patients (89%) and family/companions (92%) had completed high school. Approximately 29% of patients and 54% of family/companions were employed. Median annual household income was $60,000.

Patients in our final sample (n = 35) were compared with all other patients in our study (n = 191). χ^2 analyses revealed no differences in ethnicity, sex, level of education, employment situation, or family income and an independent samples *t* test showed no age differences. Most patients were accompanied by at least one family/ companion (n = 26 [74%]; eg, spouses, n = 17 [49%]; children, n = 13 [37%]; or friends/others, n = 5 [14%]).

Fifteen physicians participated. All were male; mean age was 47 years (SD, 12.40 years). Each physician had an average of 2.33 patients (SD, 2.09 patients) enrolled in our study. All physicians had more than 1 year of experience offering clinical trials; 60% had been offering trials for at least 10 years.

Patient Decisions

More than three fourths of the patients (77%; n = 27) decided to enroll on the clinical trial offered to them. Relative to patients who declined to enroll or were undecided at Time 2, independent samples *t* tests showed that patients who decided to enroll based their decisions on personal reasons and their physician's communication behavior during the discussion (belief that the physician listened to them and was supportive; Table 5). Patients who enrolled also reported significantly more confidence in their physicians and shared a greater level of agreement regarding the decision with their physicians and family/ companions than did those who declined to enroll or were undecided. A sign test comparing all the means of the two patient groups showed that seven of the eight means for the patient self-reported decision-related outcomes were higher for patients who chose to enroll versus patients who were undecided or decided not to enroll ($P < .05$).

Influence of Communication on Patients' Decision-Related Outcomes

We examined Pearson product-moment correlations between observed communication behaviors occurring among oncologists, patients, and family/companions (Time 1) and patient decisions reported during the follow-up interview (Time 2). Greater shared conversation control with the physician (Factor 2 on the KAAS) was associated with the patient's decision to enroll and the patient's confidence in the decision and the oncologist. Greater shared control also was related to the extent to which the patient felt there was shared agreement regarding the decision (Table 6).

The communication process also affected the patient's reasons for the decision. The more alliance-building was observed (Factor 1 on the KAAS), the less family opinions and cost

issues influenced the patient's decision. The more information that was conveyed about the trial and the benefits of participation, the more the patient based his/her decision on the belief that the physician listened and was supportive. Adverse effects and costs of the trial were also less likely to influence the patient's decision when physicians reassured the patient that enrollment or nonenrollment would not affect his/her level of care or status at the cancer center.

DISCUSSION

Communication among physicians, patients, and family/companions in the clinical setting influences cancer patients' decisions regarding accrual to a clinical trial and how patients think and feel about their decisions as they enter a trial. The study illuminates the general features of the clinical trial accrual process at two comprehensive cancer centers. An important and somewhat unexpected finding is that few patients were offered a clinical trial, despite the fact that patients were specifically referred to our study because they potentially qualified for one. Trials were never mentioned in 43% of the interactions. The issue of a trial was raised in another 30% of the discussions and either overtly rejected by the physician or not followed up (likely because of physician rejection that was not expressed verbally or because the patient was ineligible for a trial on the basis of performance status or other clinical criteria).[32] Notably, when a suitable trial was available and the physician explicitly invited the patient to participate (20% of the time), three of four patients assented. This finding points to the need to investigate ways to increase the number of trial offers made to patients to increase the number of trial participants.

Observed ratings of physician-patient and physician-family member/companion communication during discussions of trials differed from those interactions in which trials were not discussed. Discussions of offers showed more alliance-building between physicians and patients (mean, 5.38 ± 0.44 *v* 5.11 ± 0.63; $t[df = 212] = 2.36$; $P < .05$), although somewhat less shared conversational control between physicians and patients (mean, 3.89 ± .66 *v* 4.09 ± .62; $t[df = 212] = 2.80$; $P < .07$) and significantly less shared conversational control between physicians and family members (mean, 3.69 ± 0.57 *v* 3.97 ± 0.61; $t[df = 173] = 2.17$, $P < .05$). This suggests that clinical discussions that include trial offers are characterized by significantly higher levels of physician-patient relational trust and mutual positive regard. At the same time, physicians retain greater control over the content and flow of the dialogue with all parties.

Shared conversational control between physicians and patients and physicians and family/companions influenced patients' decisions to enroll. Patients and family/companions who are visibly engaged in interacting with their doctors are likely to be more engaged in the topic at hand (in these cases, clinical trials). Patients' reasons for their decisions demonstrated the importance of both content and relational communication between the physician and the patient to the patient's decision-making experience. Messages exchanged during the encounter that conveyed content about the trial and adverse effects reduced the issue of cost as a factor for patients, reassured patients that adverse effects and toxicities would be manageable, and helped patients feel that the physician was listening and supportive. These results indicate that full and clear communication about the clinical trial has benefits for patients.[22]

Alliance-building and reassurance by physicians also helped ease concerns about treatment costs and potential adverse effects. It seems that more information and an increased alliance[33] helps patients reach a decision in which they can have confidence. These findings also suggest that the patient's cognitions and emotions about the decision are important

outcomes,[34] perhaps even influencing whether the patient follows through with entering the trial and maintaining enrollment.[35]

In sum, oncologist messages that help build a sense of an alliance (among all parties, including family/companions), provide support (such as tangible assistance and reassurance about managing adverse effects), and provide medical information in understandable language, are associated with the patient's decision-making process. These are communication behaviors that can be observed, evaluated, and taught to physicians in training as competencies to improve clinical practice and research.

This study should help clarify the reasons for the persistent problem of low clinical trial enrollment rates. Among patients for whom a trial was available and clear offers to participate were made, 77% accepted. Patient refusal rates may be less of a problem than low rates of trial offers. Currently, the reasons for the relative dearth of trial offers (ie, only to about one quarter of the patients) are unclear. There may have been too few trials available or overly stringent eligibility criteria for those that were open.[36] Alternatively, physicians may have made decisions that certain patients were inappropriate for open trials, or physicians may not have clearly communicated that a trial was an option for the patient to consider. Increasing the numbers of trials, encouraging more investigator-initiated studies, and streamlining the implementation of new studies may help, but further exploration of the reasons physicians do not recommend a trial to a patient who is potentially eligible may be even more essential.

Five of the patients explicitly offered trials did not think they had the option of a trial. Of the 44 patients who only discussed the possibility of a clinical trial with their oncologist, 25% said they were offered a trial (and indicated a decision about enrollment when interviewed). This is disconcerting, given the documented efforts involved in the informed consent process.[21] Effective communication with patients and family/companions is critical for informed consent and informed refusal.[37] Errors in understanding can seriously impair how patients evaluate their options and the quality of their decisions regarding treatment.

These findings should be considered in light of limitations that included a relatively small sample size (increasing the possibility of type II error), presence of only male physicians in the final sample, and the difficulty of obtaining complete data on those patients who were unavailable for follow-up. Nonetheless, this study responds to recent calls in the literature for research on improving communication about trials with patients.[38] The results suggest ways to help physicians become more effective communicators. When behaviors that can be reliably observed and measured empirically relate to patients' reports about treatment decision making, the persistent problem of trial accrual can be addressed through practical and measurable behavior changes. The most dramatic changes may occur when we better understand, and thus eliminate, barriers preventing physicians from offering trials to their patients.

Acknowledgments

Supported by the National Cancer Institute (Grant No. R01CA75003).

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Table 1

KAAS Items for Global Judgment Factors

Factor and Items	Patient			Family/Companion		
	Factor Loading	Mean	SD	Factor Loading	Mean	SD
Alliance* (factor 1)		5.38	0.44		5.31	0.60
Hierarchical rapport: Extent to which MD was arrogant (1) *v* cordial (7) throughout the interaction	0.72	5.57	0.66	0.79	5.35	0.94
Connectedness: Extent to which the MD and patient (or F/C) were distant (1) *v* close (7) throughout the interaction	0.68	5.40	0.78	0.75	4.81	1.02
Trust: Observed level of trust with MD was low (1) *v* high (7)	0.61	5.40	0.81	0.74	5.15	0.73
Responsiveness: MD responsiveness to questions was low (1) *v* high (7)	0.72	5.77	0.73	0.80	5.65	0.80
Information giving: Amount of information presented by MD was unreasonable (1) *v* reasonable (7)	0.79	5.86	0.65	0.68	5.69	0.68
Organization: MD was disorganized (1) *v* organized (7)	0.67	5.54	0.82	0.65	5.31	0.93
Data orientation: MD did not present examples, facts, and statistics (1) *v* did present (7)	0.65	5.26	0.78	0.67	5.19	0.75
Hope: MD did not provide hope (1) *v* provided hope (7)†	0.54	4.20	0.96			
Conversation control‡ (factor 2)		3.89	0.66		3.69	0.57
MD language level: MD explained diagnosis, treatment, and prognosis using technical language/jargon (1) *v* lay language (7)	0.63	3.46	0.95	0.57	3.38	0.70
Language similarity: MD and patient (or F/C) spoke at different language levels (1) *v* same level (7)	0.76	4.86	0.81	0.76	4.73	0.87
Conversation dominance: MD dominated conversation (1) *v* patient (or F/C) dominated the conversation (7)	0.55	3.34	1.16	0.54	2.96	1.11

NOTE. Factor loadings are from varimax rotations on available data (N = 226). Means and standard deviations are for patients reporting they were offered clinical trials (n = 35).

Abbreviations: KAAS, Karmanos Accrual Analysis System; SD, standard deviation; MD, oncologist; FM/C, family member/companion.

*Accounted for 31% of variance in patient items; family/companions: 33%.

†Item did not load on a factor for family/companions.

‡Accounted for 12% of variance in patient items; family/companions: 13%.

Table 2

Mean Number of Content Messages Observed for Each Category of the KAAS Observational Checklist

Checklist and Example Items	Mean*	Standard Deviation
Legal information—eg, items usually on formal consent document such as: clinical trial concept defined, purpose of study stated, alternatives explained, procedures specified, time frame clarified, etc. Score = sum of 19 possible items mentioned by oncologist	7.43	2.28
Adverse effects—eg, hair loss, fatigue, changes in blood counts, fever/chills, etc. Score = sum of 38+ possible items mentioned by oncologist	4.77	4.22
Reassurance/support regarding enrollment status—eg, “Won’t hurt my feelings if you don’t participate in the study,” “If you are not doing well on study we will stop and reevaluate,” If you don’t participate or withdraw from the study it won’t prejudice your care,” “If you don’t participate we will continue to see you.” Score = sum of 6 possible items mentioned by oncologist	0.97	0.95
Reassurance/support regarding adverse effects—Coded as a statement of reassurance (eg, “Don’t worry, the soreness will be mild”) and/or a resource (eg, “We’ll give you some ointment to reduce the pain and redness”) offered for each adverse effect mentioned. Score = sum of total messages of reassurance and/or resources offered by oncologist across all adverse effects mentioned	2.94	4.24
Benefits regarding clinical trial participation—eg, no cost, new treatment, good study, good treatment, will help others, less risk of recurrence. Score = sum of 9+ possible items mentioned by oncologist	1.54	1.22

Abbreviation: KAAS, Karmanos Accrual Analysis System.

*No mean differences found for enrolled versus nonenrolled patients.

Table 3

Patient-Reported Decision-Related Outcomes

Variable and Measure	α	Mean	Standard Deviation
Patient's decision*—Response to question: "Did you decide to enroll in the clinical trial offered to you?" (0 = decided not to enroll; 1 = undecided; 2 = decided to enroll)			
Patient's decision-related affect/cognition			
Confidence in decision—Average reported agreement (4 = strongly agree; 1 = strongly disagree) with statements: "I am comfortable with the treatment decision I have made" and "I have no second thoughts about the decision"		3.42	0.69
Confidence in oncologist—Average reported agreement (4 = strongly agree; 1 = strongly disagree) with statements: "I have confidence in Dr. ___at this time," "Dr. ___and I are partners together in treating my disease," and "I trust Dr. ___'s judgment about my care"	.81	3.51	0.54
Oncologist-patient-family/companion relationship quality—Summed rating (4 = very positive; 1 = very negative) of each dyadic relationship during the visit: "During your discussion with Dr. ___, would you describe the relationship between you and doctor as ___?"; "The relationship between Dr. ___and your family/companion as ___? 0"; and "The relationship between yourself and your family/companion as ___?"	.83	3.50	0.50
Oncologist-patient-family/companion decision agreement—Summed rating (4 = strongly disagree; 1 = strongly agree) of agreement about decision for each dyadic relationship: "Regarding your decision about the clinical trial, how would you rate the level of agreement between yourself and Dr. ___?"; "Between Dr. ___and your family/companion?"; and "Between yourself and your family/companion?"	.75	3.57	0.53
Patient's reasons for decision			
Personal factors—Extent to which each item influenced the decision (1 = no influence on decision; 2 = some influence; 3 = major influence on decision): "Extent to which the trial would increase your quality of life," "Participation in the trial would extend your life," and "Participating in the trial would help fight your cancer"	.79	2.58	0.47
Physician communication behaviors—Extent to which each item influenced the decision (1 = no influence on decision; 2 = some influence; 3 = major influence on decision): "Physician listened to you during the discussion" and "Physician was supportive of you"		2.52	0.51
Family members' opinions—Extent to which the family member (present or not present during the visit) influenced the decision (1 = no influence on decision; 2 = some influence; 3 = major influence on decision)		2.21	0.62
Costs manageable—Extent to which the perception that costs of participating in the trial were manageable influenced the decision (1 = no influence on decision; 2 = some influence; 3 = major influence on decision)		2.04	0.85
Adverse effects manageable—Extent to which perception that adverse effects were manageable influenced the decision (1 = no influence on decision; 2 = some influence; 3 = major influence on decision)		2.07	0.84

*Twenty-seven patients (77%) decided to enroll in the clinical trial offered to them; four (11.4%) decided not to enroll, and four (11.4%) were undecided at the time of the follow-up interview.

Table 4

Typology of Video Recorded Patient-Physician Interactions

Type of Visit*	No.	%
Clinical trial never mentioned	100	43
Clinical trial mentioned, physician rejects trial option	27	11
Clinical trial mentioned, patient rejects trial option	0	00
Clinical trial discussed, no offer made	44	19
Clinical trial discussed, explicit offer made (where patient can respond either “yes” or “no” to the opportunity)	47	20
Other	8	03
Video/audio recording problems (not useable)	9	04
Total	235†	100

NOTE. Sample size includes both study sites. Refusal rates were unavailable for the first cancer center. At the second cancer center, 151 patients and their family/ companions were invited to participate in the project, and 108 (72%) agreed.

*There were no instances in which a physician mentioned a clinical trial (or began to discuss it) and the patient rejected the option outright. Of visits observed, 84% were first visits; 72% of visits where clinical trials were explicitly offered were first visits. Ninety-four percent of the patients were in interactions where trials were offered; 77% of patients in interactions where trials were not explicitly offered knew they had a cancer diagnosis, and treatment options were discussed.

†The majority of patients were diagnosed with respiratory cancers (42%), followed by digestive (22%), leukemia/myeloma/lymphoma (14%); breast (5%); male genital (5%); other (5%); and not cancer/unconfirmed (7%; classified by Surveillance, Epidemiology, and End Results categories). Patients receiving a trial offer were diagnosed as follows: respiratory cancers (23%); digestive (30%); leukemia/myeloma/lymphoma (11%); breast (8%); other (17%); and no cancer/not confirmed (0%).

Table 5

Independent Samples *t* Test Examining Factors Associated With Decision to Enroll

Patient-Reported Outcome	Decided to Enroll		Undecided or Decided Not to Enroll		*t*	*df*	*P*
	Mean	SD	Mean	SD			
Decision-related affect/cognition							
Confidence in decision	3.52	0.71	3.04	0.46	1.55	27	.13
Confidence in oncologist	3.62	0.51	3.10	0.46	2.43	31	.02*
Oncologist-patient-family/companion relationship quality	3.48	0.50	3.67	0.58	.61	22	.55
Oncologist-patient-family/companion decision agreement	3.65	0.53	3.11	0.19	3.14†	9.02	.01*
Reasons for decision							
Personal	2.67	0.44	2.00	0.00	2.56	22	.02*
Physician communication	2.54	0.64	1.67	0.29	2.30	25	.03*
Family opinions	2.28	0.55	1.83	1.04	1.15	19	.26
Cost manageability	2.09	0.85	1.75	0.96	.72	25	.48
Adverse effects manageability	2.08	0.86	2.00	0.82	.17	27	.86

Abbreviation: SD, standard deviation.

*$P < .05$.

†Levene's test for equality of variances was significant, so corrected *t* value and *df* are reported.

Table 6

Pearson Product-Moment Correlations Between Observed Communication and Patient Self-Reports

	Observed Oncologist-Patient-Family/Companion Communication (Time 1)								
Decision-Related Outcome (Time 2)	**MD-PT Alliance**	**MD-FM/C Alliance**	**MD-PT Conversation Control**	**MD-PT-FM/C Conversation Control**	**No. of LIM**	**No. of AE**	**No. Trial Benefits Mentioned**	**Reassurance About Enrollment Status**	**AE-Related Support**
Decision	0.06	0.03	0.28*	0.40‡	0.04	0.13	−0.19	0.03	0.13
Decision-related affect/cognition									
Confidence in decision	0.15	0.27	0.40†	0.27	0.10	0.02	0.03	−0.10	0.22
Confidence in MD	0.16	0.22	0.42†	0.37*	0.14	−0.02	0.11	0.14	0.12
MD-PT-FM/C relationship quality	0.20	0.34	0.25	0.21	0.06	−0.03	−0.06	0.18	0.22
MD-PT-FM/C decision agreement	−0.01	0.15	0.40*	0.51†	0.11	−0.03	−.22	0.08	0.19
Reasons for decision									
Personal	−0.08	−0.07	−0.01	0.26	0.09	−0.15	0.03	−0.05	0.07
MD communication	−0.12	0.02	−0.21	0.08	0.53‡	−0.09	0.38‡	0.23	0.18
Family opinions	−0.28	−0.49‡	−0.20	−0.37	0.04	−0.26	0.22	−0.27	0.01
Cost manageability	−0.58‡	−0.58‡	0.04	0.10	−.37*	−0.29	0.02	−0.46‡	−0.32*
AE manageable	0.26	0.04	−0.25	0.06	0.29	0.39‡	0.28	−0.49‡	0.42‡

Abbreviations: MD, oncologist; PT, patient; FM/C, family member/companion; LIM, legal/informational messages; AE, adverse effects messages.

*P < .10.

†*P* < .05.

‡*P* < .01.