Strategic Physician Communication and Oncology Clinical Trials

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Purpose: **Clinical trials are the primary means for determining new, effective treatments for cancer patients, yet the number of patients that accrue is relatively limited. The purpose of this study was to explore the relationship between physician behavior and patient accrual to a clinical trial by videotaping the interaction.**

Patients and Methods: **Forty-eight patient-physician interactions involving 12 different oncologists were videotaped in several clinics at the H. Lee Moffitt Cancer Center and Research Institute (Tampa, FL). The purpose of each interaction was to present the possibility of a clinical trial to the patient. A coding system, the Moffitt Accrual Analysis System, was developed by the authors to code behaviors that represented both the legal-informational and social influence models of communication behavior. Thirty-two patients agreed to participate in the clinical trial.**

Results: **Videotaping was found to be a viable, valid, and reliable method for studying the interaction. Physicians who were observed to use both models of influence were found to enroll more patients. Thus, patients were more likely to accrue to the trial when their physician verbally presented items normally included in an informed consent document and when they behaved in a reflective, patient-centered, supportive, and responsive manner. Discussion of benefits, side effects, patient concerns and resources to manage the concerns were all associated with accrual.**

Conclusion: **This research has implications for modifying physician behavior and, thus, increasing the numbers of patients accruing to oncology clinical trials.**

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CLINICAL TRIALS continue to be the primary means for determining the most effective treatments for cancer patients. Yet, reports consistently show that the number of patients that accrue and maintain an active status in clinical trials is inadequate for efficiently advancing the accumulation of scientific knowledge.[1-4] Learning why patients choose not to participate in a trial is crucial for ensuring the ability to generalize trials to larger cancer patient populations (integrity) and for assuring that the logistics of clinical trial participation are not excessive (viability).[5]

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The option of a clinical trial is only presented to those patients for whom a trial is available and for which they meet the eligibility criteria. Patients agree to enroll onto a study for many reasons,[6-10] including trust in the physician[2]; the physician recommended the study[5]; physician resolved questions/issues[11]; encouragement by family members, positive perceptions of the study (eg, the study is viewed as ''best'' treatment option or ''latest'' medical care)[2]; side effects of the treatment are perceived as ''manageable''; altruism (future cancer patients will benefit from knowledge gained)[12]; a desire to live; and a willingness to participate to receive care at the particular clinic.

Conversely, patients choose not to enroll onto studies because they perceive that their needs are no longer the physician's primary priority[5]; impingement on quality of life and functional abilities; they want to choose their own pattern of care[13,14]; unwillingness to be randomized to a treatment condition[15]; the study might not be the best treatment; logistical difficulties exist in getting the treatment and problems related to insurance[16]; excessive toxicity; poor understanding of the study[17]; they have tried ''enough'' treatments; the family is against study participation[18]; sufficient survival benefits are expected from standard therapy[19]; and participation in the study may involve excessive burden on friends and family as caregivers. In addition, racial and ethnic minority groups are underrepresented in clinical trials because they lack opportunities to participate, have minimal information about the availability of trials, and distrust white majority groups conducting test procedures.[20,21]

The presentation of a study option to a patient may occur during an initial encounter or in the middle of an existing relationship, depending on disease stage, patient eligibility, and trial availability. Regardless, accruing a patient to participate in a research study, as part of the treatment plan, is an event that occurs when uncertainty for the patient's outcome is likely to be relatively high. This exacerbates the patient's perceived stress level. How the physician communicates with the patient about this as a treatment option will likely impact how well the patient judges the risks, benefits, and barriers of entering a clinical trial.

Because the focus is the interaction occurring between the patient and physician, we videotaped the patients and physicians together to record and analyze real-time communication patterns. Outside the medical context, videotaping has been used to study such social psychologic processes as deception detection in relationships[22] and motor mimicry as a reflection of empathy in interpersonal encounters.[23] Although there have been a variety of studies using audio tape to study the patient-physician interaction,[24,25] this is the first study, to our knowledge, that has used videotaping technology to fully capture the patient-oncologist transaction and focus on the relationship as the unit of analysis.[26] Thus, a key goal of our study was to explore whether this methodology was feasible, reliable, and valid.

Two models conceptualize the presentation of a clinical trial. The legal-informational model is a framework represented by a legal document, the informed consent form. Informed consent is, by and large, a process that describes the study's purpose, procedures, and the medical risks of participation.

The social influence model, based on persuasion and marketing principles, is a complementary strategy for inducing patient participation.[27-29] Accruing patients to clinical trials is an influence situation similar to other persuasive communication encounters, such as those of a buyer-seller transaction. The physician's focus, then, is not on the quantity of information that he/she should present to the patient but on how usefully he/she can frame participation in the clinical trial in terms of the patient's needs and concerns (whether stress-related, logistical, and so on) about the progression of the disease and the treatment process. Equally important, the physician should learn what the patient perceives as obstacles to participation (eg, increased transportation needs, extensive hair loss) and actively address those obstacles with resources.[30] If possible, such resourceful activities could include arranging for some tests to occur closer to the patient's home, consolidate appointments, provide timely wig prescriptions, and so on). Patients will not likely enroll onto clinical trials unless they perceive the benefits to outweigh the risks for them personally.[31] Perceived benefits may include believing that the study is sound, the side effects are tolerable, the financial burden is reasonable, and the logistics of participating in the trial are workable. Patients generally want to feel that the physician hears their concerns and questions and satisfactorily answers them.[32]

It should be noted that the social influence perspective does place the physician in the position of potentially benefiting from the patient's choice. This benefit is not as direct as in other ''buyer-seller'' relationships, but the potential for indirect benefits, such as additional institutional support for travel and data management and enhancement of the institution's research reputation, do exist. At major National Cancer Institute designated cancer centers such as H. Lee Moffitt Cancer Center, research is expected and necessary in the quest for cancer cures. The potential for conflicts of interest to arise for physicians presenting studies that may indirectly benefit them might be minimized when the scientific integrity of the study is carefully monitored and several physicians (in addition to the principal investigators) are accruing patients to a given study.

In sum, it is expected that patients who choose to participate in clinical trials will be those whose physicians present protocols conforming to legal/informational (and ethical) guidelines and are sensitive to patient concerns, emphasize patient-relevant benefits for participating in the study, usefully assist and support patients in facing stress and uncertainty,[26,33,34] and help patients overcome perceived obstacles to study participation (such as excessive side effects and transportation to and from treatment sessions). Legal/informational messages should not excessively tax the patient's understanding.[35] They do necessarily meet an ethical mandate by conveying relevant medical knowledge and, therefore, can strengthen the physician's medical credibility.[10] However, it is information about the study benefits and the physician's responsiveness to the patient's concerns (eg, offering resources and reassurance) that specifically provide emotional support to the patient. Such messages enable the patient to frame the medical information about the protocol in terms of his/her own situation and needs.[36,37] This is also a way for the patient to experience a supportive alliance with the physician, also termed a ''therapeutic alliance,'' in facing the treatment process and aftermath.[38,39] In short, such interactional support may increase the patient's trust in the physician. ''Trust in the physician'' was the most frequent reason given by patients for agreeing to participate in a chemotherapy protocol.[10]

It has been shown that physicians influence patient decisions to enroll onto trials.[8-10] However, studies are lacking that examine the impact of specific physician behaviors, particularly communication behaviors, on patients' decision making. The purpose of this study is to investigate whether a detectable relationship exists between physician communication behavior and patient accrual to clinical trials. Our effort has been to identify, during real-time interaction, particular physician communication strategies and aspects of the physician-patient encounter to determine whether they systematically vary with patient choices regarding the selection among treatment options. It is our hypothesis that physicians who use a direct social influence approach to complement the legal/informational content will be most successful in accruing patients to clinical trials.

PATIENTS AND METHODS

Patients/Physicians

Patients attending one of several multidisciplinary clinics at the H. Lee Moffitt Cancer Center and Research Institute were selected based on their eligibility for a phase II or phase III clinical trial. The clinics represented thoracic, malignant hematology, breast, neuro-oncology, pain management, senior adult, and gastrointestinal oncology programs. In most instances, the patient was told that a clinical trial was a possible treatment option (before consent was sought to videotape the more formal process). The study included 12 medical oncologists (two women, 10 men; average age, 55 years; all those approached agreed to participate in the study). Three research nurses assisted in four interactions, although each nurse was under the supervision of one of the 12 oncologists in the study. Fifty patients were approached to participate in the videotaping study; one patient declined. Because of technical problems with the taping of one patient, the final sample consisted of 48 videotaped provider-patient interactions.

Interactions between physicians and patients were videotaped during the time the eligible patient was formally presented with the option to participate in a clinical trial. Patients, family members, significant others, oncologists, and other health care providers (research nurses, primary nurses) were included in the videotaping, if present. The protocol for the videotaping was described to each participant, and informed consent was obtained. The patient was also offered (without cost) a copy of the videotape of the physician explaining the study (mailed to the patient at home within 2 weeks after the session).

Two small video cameras were subsequently set to record the physician and the patient, and the tapes were reviewed multiple times for analysis through two videocassette recorders connected to a digital audiovisual mixer unit. Using digital processing technology, this unit enabled simultaneous viewing of the tape of the physician/health care provider and the patient via a split-screen format on a single video monitor. We were thus able to track how the individuals adapted to and reciprocated communication patterns. The split view was then recorded onto a standard VHS videocassette. Coders then inserted the videocassettes into standard VCR units, to code the interactions.

Coding

The videotaped interaction data were reviewed and coded by four trained analysts (three research assistants and a senior researcher in behavioral medicine). The coders used the Moffitt Accrual Analysis System (MAAS), an original coding system developed by the study investigators. This system was developed after review and initial testing of extant coding systems (eg, the Roter Interaction Analysis System, the Stiles Verbal Response Mode, the Multidimensional Interaction Analysis System, and the Davis Observation Code),[24,25,39-43] showed they lacked sufficient scope and sensitivity to the strategic communication context of accruing patients to clinical trials in the context of a life-threatening disease.[26] This is not surprising, given that most of these earlier coding systems were primarily developed for application in the primary care setting. The MAAS coding system was developed to address both content and strategic influence aspects of the accrual interaction. It was necessary to include a broad range of topics, given the legal requirements for written informed consent documents to cover specific content areas such as randomization, side effects and study procedures. We were also interested in the specific strategies used by the physician to influence the patient to enroll onto the protocol (eg, ''We can easily help you get an attractive wig'' or ''Our staff can help you arrange to have your tests done at a clinic closer to your home'').

The MAAS coding system was developed by the study investigators during January to April, 1996, on the basis of four initial videotaped interactions and consists of two major sections. The first is a comprehensive checklist for coders to record the occurrence or nonoccurrence of key messages and behaviors relating to the legal/informational requirements of the informed consent process. The second section includes a series of global judgments by coders for rating the effectiveness of the physician-patient communication process, including aspects of rapport, trust, language, responsiveness of the physician to the patient's concerns, adequacy of information given, and manner/style of managing the encounter. (The coding system is available on request from the authors.)

RESULTS

Study Participants

The breakdown of patients by their subsequent accrual status and study type is as follows: Forty-five patients were white (not of Hispanic origin), two patients were black (not of Hispanic origin), and one patient was Hispanic. Accrued patients were 28% men and 72% women. Of the patients who did not accrue to clinical trials, 23% were men and 76% were women. Accrued and nonaccrued patients were similar in age (average age of accrued patients was 57.8 years, SD = 12.34 years; average age of nonaccrued patients was 59 years, SD = 10.36 years).

The 16 patients who accrued to phase II studies were distributed across 13 different protocols. The five patients who did not accrue to phase II studies were each presented one of five additional protocols. The 15 patients who accrued to phase III studies were distributed across eight different protocols. The 12 patients who did not participate in phase III studies were presented one of eight additional protocols (Table 1). Of note, there was one phase II and one

Table 1. Profile of Study Patients and Number of Protocols Presented to Patients (accrued and nonaccrued) to Clinical Trials

Trial Type	No. of Patients Accrued	No. of Protocols Presented	No. of Patients Not Accrued	No. of Protocols Presented
Phase II	16	13	5	5
Phase III	15	8	12	8
Total	31 (65%)	21	17 (35%)	13

phase III protocol where one patient accrued and one chose not to accrue. Six patients chose to accrue to one phase III protocol, but two patients chose not to accrue to the same protocol. One phase III protocol was presented to which two patients accrued and one did not.

A range of physicians interacted with the patients who did and who did not accrue. The breakdown of the numbers of patients interacting with each physician (and supervised research nurse) in the study is listed Table 2.

Reliability and Validity of the Coding System

Preliminary reliabilities were computed to determine intercoder agreement of the MAAS coding guide. These analyses were conducted on a randomly drawn set of approximately 15% of the videotaped interactions. Results of the Cohen's kappa reliability assessments[43] for the checklist items average 0.67 (SD, 0.16; range, 0.30 to 0.0) across 73 items. Kappa coefficients for the global judgment items averaged 0.64 (SD, 0.11; range, 0.53 to 0.82) across 17 items measured on 7-point scales. Kappa coefficients of 0.40 to 0.60 have been judged as fair, 0.60 to 0.75 as good, and 0.75 or greater as excellent, according to Fleiss.[44-46]

Table 2. Breakdown of Physicians by Participation in Number of Accrued and Nonaccrued Interactions

Physician	Accrued Interactions	Nonaccrued Interactions
A	1	–
B	1	1
C	6	–
D	4	–
E	–	1
F	–	2
G	6	3
G: RSN 1*	1	–
G: RSN 2	1	1
H	1	–
I	1	–
I: RSN 3	1	–
J	2	–
K	2	3
L	5	5
Total MDs/RSNs	13	7
Total interactions	32	16

Abbreviations: RSN, research nurse; MD, physician.

*Research Nurses 1 and 2 were supervised by Physician G; Research Nurse 3 was supervised by Physician I.

Validity of the global judgment items on the MAAS scoring system was assessed in two ways. Convergent and discriminant validity were evaluated by whether the items correlated in expected ways in a multitrait-multimethod analysis. (Results from the analysis are in matrices and available from the authors.) The results generally provide empirical evidence of acceptable convergent validity for the scoring system.[47,48] For example, as would be predicted, coder judgments concerning hierarchical rapport between physician and patient, connection/closeness between physician and patient, trust, and physician responsiveness to patient concerns show intercorrelations of 0.69 to 0.78 ($P <$ .01). Conversely, negative associations among judgment items were as predicted. That is, judgments of physicians who present primarily a data-based style when giving information (as shown on the videotapes by physician comments such as ''The data show...'' and ''We know from recent studies that...'') is negatively related ($r = -0.33$, $P <$ .05) to judgments of those same physicians communicating primarily based on their personal opinions (demonstrated by statements on the videotape such as ''I think...'' or ''In my personal view...'' and so on). Divergent validity was demonstrated by the low correlations between global judgment scores on the MAAS coding system and global affect ratings from the Roter Interaction Analysis System (RIAS) coding system.[21] The correlations ranged from −0.27 to 0.22, which were not significant (NS). (Though the RIAS system has been used recently in the cancer setting,[49] the system was originally designed to code primary care physician-patient interactions. Thus, many of the RIAS items are conceptually distinct from the MAAS items [which were developed to focus specifically on the accrual context in life-threatening illness]. And, with the exception of the physician-related items, the MAAS system is geared toward rating the physician-patient relationship as the level of analysis, as opposed to the judgments of individual behavior as the unit of analysis. In contrast, the RIAS is designed for coders to score patients and physicians separately on each item. Thus, it is largely focused at the individual level.)

Initial results for global judgments of the patient-physician interaction and relationship are presented in Table 3. Accrued patients can be characterized as having significantly higher average scores for hierarchical rapport based on cordiality, patient-physician connection, trust, and greater physician responsiveness to patient concerns. In addition, the physicians of accrued patients were judged to adhere

Table 3. Means and Standard Deviations of Coder-Rated Global Judgments, Accrued Versus Nonaccrued Interactions

MAAS Global Judgments‡	Nonaccured Patients (n = 14)		Accrued Patients (n = 31)		
	Mean	SD	Mean	SD	*t**
Hierarchical rapport	4.21	1.42	5.87	0.99	3.98†
Connection, MD-PT	3.21	1.48	5.06	1.06	20.55†
Trust, MD-PT	3.92	1.71	5.29	1.01	13.70†
MD code	4.57	1.28	5.26	0.82	NS
PT code	5.64	0.93	5.74	0.93	NS
MD responsiveness to PT concerns	4.64	1.55	5.77	1.23	12.55†
MD directed toward signed consent	4.64	1.60	5.71	1.24	NS
Conformity to legal consent form	3.33	1.69	5.00	3.00	9.82†
Sharing of floor time	3.29	0.99	3.42	1.23	NS
Amount info given	3.86	1.66	5.55	1.41	16.90†
MD information orientation, opinion-based	3.07	1.98	2.94	1.29	NS
MD information orientation, data-based	4.57	1.55	4.35	1.70	NS

Abbreviations: MD, physician; PT, patient.

*Degrees of freedom = 43.

†$P < .01$.

‡MAAS terms and scales are as follows:

Hierarchical rapport: Extent to which the physician preserved his/her status as the medical expert with arrogance or with cordiality shown toward the patient (relationship variable). 1 = status preservation with arrogance; 7 = status preservation with cordiality.

Connectedness: Connectedness/closeness; the extent to which there appears to be a warm relationship between the physician and patient during the interaction (relationship variable). 1 = low; 7 = high.

Trust: Trust level between physician and patient; the degree to which the patient appears to have confidence in the physician's integrity, ability, and judgment and the extent to which the physician seems to recognize and respond to that trust (relationship variable). 1 = low; 7 = high.

MD code: Physician's speech code; degree to which physician uses technical, medical language in conversing with the patient versus using nontechnical, jargon-free, layperson-oriented language/terminology (individual variable). 1 = technical/syntactic; 7 = lay, pragmatic.

PT code: Patient's speech code; degree to which patient uses technical, medical language in conversing with the physician versus using non-technical, jargon-free, layperson-oriented language/terminology (individual variable). 1 = technical/syntactic; 7 = lay, pragmatic.

MD responsiveness to PT concerns: Physician's responsiveness to patient's concerns/questions; extent to which the physician invites and responds with reassurance/resources to patient comments, questions, and concerns regarding the trial option (individual variable). 1 = low; 7 = high.

MD directed toward signed consent: Physician's directedness/momentum for consent; extent to which physician seems to move the discussion along toward directing and providing the impetus for the patient to sign the consent form (individual variable). 1 = low; 7 = high.

Conformity to legal consent form: Degree to which physician's discourse conforms to the language, structure and format of the formal consent form (individual variable). 1 = low; 7 = high.

Sharing of floor time: Sharing of floor time (between MD and patient); degree to which physician and patient engage in conversational turn taking (relationship variable). 1 = low; 7 = high.

Amount info given: Amount of information given by physician; extent to which the information given to the patient by the physician is judged by coders as appropriate or inappropriate (either too little or too much) for the patient's needs (relationship variable). 1 = inappropriate; 7 = appropriate.

MD info orientation opinion-based: The extent to which evaluations or conclusions provided by the physician to the patient is based in his/her personal opinion (individual variable). 1 = low; 7 = high.

MD info orientation data-based: The extent to which evaluations or conclusions provided by the physician to the patient are based on accepted scientific findings (individual variable). 1 = low; 7 = high.

more closely to the legal consent form (providing more legal/informational messages) and to give more appropriate amounts of information. Overall, 10 of the 12 differences in the means are in the predicted direction (the exceptions are physician information orientation-opinion based and physician information orientation-data based). A sign test[50] negates the probability that this pattern of mean differences occurred solely by chance ($P < .019$, one-tailed test; see also *t* values in Table 3).

The types of physician behaviors that occurred with patients who accrued include defining the study as ''research,'' reviewing the nature of confidentiality of participation, telling patients that participation is voluntary and that they can ''withdraw from the trial at any time,'' giving patients the names of persons to contact while they were enrolled in the trial, explaining why their signatures are needed on the informed consent document, and discussing the nature of randomization procedures for specific phase III protocols (see Table 4).

Study Benefits, Side Effects, and Patient Concerns

Physicians interacting with accrued patients tend to mention study benefits more often than do physicians interacting with patients who do not accrue to trials (physi-

Table 4. Differences in Coder-Rated Checklist Results (Legal/Informational Items) for Accrued and Nonaccrued Patient Interactions*

Checklist Item	Nonaccrued (n = 13) Yes (%)	Nonaccrued (n = 13) No (%)	Accrued (n = 31) Yes (%)	Accrued (n = 31) No (%)
Is study defined as research?	8	92	45	55
Confidentiality reviewed?	15	85	35	68
Patient told participation is voluntary?	52	38	65	35
Patient told he/she might withdraw at any time?	38	62	48	52
Persons to contact about study reviewed?	15	85	39	64
Need for consent signature explained?	31	69	35	65
Clinical concept defined?	38	62	39	61
Study purpose described?	92	8	93	7
Treatments, tests, procedures reviewed?	100	0	93	7
Alternatives to study reviewed?	85	15	81	19
Publication of results reviewed?	0	100	19	83
Specific study procedures reviewed?	92	8	81	19
Time frame of study clarified	69	31	71	29
Randomization explained?	40	60	53	47
Random procedures described?	50	50	89	11

*Percentages in this table represent whether or not the physicians mentioned each of the issues listed in the table.

cians mention an average of 2.35 benefits per accrued patient *v* an average of 1.77 benefits for nonaccrued patients). Physicians also tend to discuss more potential side effects of study treatments for patients who accrue (mean ± SD, 7.32 ± 6.81), than for patients who do not accrue (6.00 ± 3.06; $t = 3.47$; df = 42; $P < .05$). However, physicians do not tend to offer significantly more resources to handle the side effects mentioned (eg, referral to wig salons for hair loss) to patients who accrue to trials.

On average, accrued patients and nonaccrued patients raise approximately the same number of concerns about the protocols presented to them (mean ± SD, 4.11 ± 2.62 for nonaccrued; 4.16 ± 2.91 for accrued). However, physicians are more likely to offer a larger percentage of resources in response to the concerns raised by patients who later accrue to clinical trial than to patients who do not accrue (0.26 ± 0.28 accrued; 0.18 ± 0.21 nonaccrued; $t = 4.0$; df = 43; $P < .05$). Responding to patient concerns with tangible resources, even more than emotional support, tends to be associated with patient decisions to accrue to trials.

The average length of the interaction (in minutes) did not differ between accrued versus nonaccrued physician-patient interactions for the presentation of phase III trials (accrued phase III, 24.31 minutes; SD, 12.97; nonaccrued phase III, 23.75 minutes; SD, 11.41; $t = 0.11$, NS). However, physicians generally took longer to present phase II studies to accrued patients than to nonaccrued patients (accrued, 18.56 minutes; SD, 12.16; and nonaccrued, 15.75 minutes; SD, 7.80; $t = 0.83$, NS).

DISCUSSION

In general, these results show that patients were more likely to accrue to cancer clinical trials when their physician verbally presented items normally included in an informed consent document and when their physicians communicated in a reflective, patient-centered, supportive, and responsive manner. Discussion of the benefits of the protocol, the side effects, addressing patient concerns, and offering resources to manage the concerns raised by patients was each associated with patient decisions to accrue to a trial as a treatment option. As shown in our videotaped data, physicians differ in their behaviors and abilities to connect and support their patients in ways that positively affect the therapeutic alliance, a dynamic clearly important for patients in coping with the burden of uncertainty regarding treatment decisions.

Although the physician-patient relationship has been frequently studied, we do not know of other research that has examined the interaction of the physician and the patient in the discussion of the presentation of a clinical trial. We have demonstrated that patients will agree to be videotaped and that a reliable, valid coding system (the MAAS) has been developed for analyzing such interactions. As shown in the social scientific literature on interaction analysis, it is unlikely that the attention given to the interaction by the presence of the cameras significantly altered the interaction.[51,52] Our procedures are consistent with guidelines for unobtrusive video observation, and several comments by patients and physicians after the taping suggest they forgot about the cameras once the discussion began. In addition, the use of this methodology allowed for the eventual investigation of the role of nonverbal communication behaviors that may or may not be consistent with verbal behaviors and analysis of the role and influence of third parties, such as family members, in the accrual process.

The percentage of eligible patients (65%) who agreed to participate in a clinical trial is significantly higher than the percentage generally quoted nationally.[4] This may reflect screening; those most likely to participate will be presented with the option, and/or the higher accrual rate may reflect a generally higher rate unique to comprehensive, research-oriented cancer centers. Additionally, physicians' attitudes toward research are more likely to be positive at a comprehensive research center. The research of Taylor and Kelner[53]

supports the expectation that physicians' orientation toward research is likely to be related to the presentation of a protocol to a patient.

The percentage of those agreeing to participate was higher for phase II than for phase III trials, possibly reflecting the difficulty of randomization for patients. The importance of randomization in the decision-making process for patients was reported by McQuellon et al[15] when they presented hypothetical treatment scenarios to 115 early-stage breast cancer patients. Approximately 76% of the patients in their sample reported that they would prefer standard treatment or an experimental agent to reduce symptoms, even if the treatment did not prolong life. However, only 10% would allow randomization to a clinical trial comparing high-dose with standard chemotherapy. In addition, further research is needed to determine whether the magnitude of the perceived differences in the treatment arms of a randomized trial (one drug *v* another as compared with radical surgery *v* drug therapy) also impact a patient's view of risk and participation in the trial.

Our results demonstrate that accrual to clinical trials is higher when physicians use both the legal-informational and the social influence models of communication. Additional studies will examine the role of nonverbal behaviors in oncologist-patient interactions. Certainly nonverbal communication is a way in which meaning is co-constructed between a physician and a patient. Typically, communication occurs on a content level as well as a relational level.[54] Relational messages are often communicated at the nonverbal level. How people feel about one another at a relational level (close/distant, dominant/submissive, caring/uncaring, and so on) can filter the topic or content of discussion. For example, if the physician is verbally presenting the option of a clinical trial but through gestures, body posture, facial expression, eye contact, and voice inflection seems cool, distant, aloof, or impatient, the patient may feel that his/her individual needs are being ignored. This is likely to add to his/her anxiety about the treatment decision. Thus it will be important to explore whether nonverbal behaviors enhance or detract from the legal-informational content.

Further, investigation is needed regarding the impact of a third party companion accompanying the patient. We found that family members were present in 68% of the interactions where patients accrued and present in 81% of the interactions where patients chose not to accrue.

The drawbacks of this study include a relatively limited number of interactions studied and an exclusive focus on interaction coding by the observers. This study also did not include post-hoc interviews with patients regarding their reasons for accruing or not accruing. Finally, it should be noted that those who rated the physician-patient interactions were blind to 63% of the interactions. The patients could be observed on the videotape signing the consent forms for participating in the clinical trials in 37% of the interactions. However, for the interactions where the outcome was observed (one third of the total), 89% of those patients accrued, and 11% did not accrue. For the blind interactions (two-thirds of the rated interactions) 57% of the patients accrued and 43% did not. A χ^2 test ($\chi = 1.49$, df = 1, NS) shows the two distributions do not significantly differ.

To the extent that these results are replicable, the findings will assist in developing and testing intervention strategies to use in physician training. Legal constraints clearly stipulate the text that is to be included on informed consent forms. Guidelines for instructing physicians in what to say to patients about participating in a trial are less clear. Given the range of physicians observed in this research and their broad pattern of behavior, this research suggests that physicians who talk about study procedures and side effects and respond to patient concerns are more likely to accrue patients to studies. These behaviors could be relatively easily included in a busy clinic either by the physician addressing them directly or by providing referrals to institutional resource centers, other staff members, or even community sources. Our research provides some initial guidelines for physicians to use in presenting clinical trials to their patients. Training programs to help physicians use these strategies could include such techniques as CD-ROM interactive technology, role-playing, and observational feedback.

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