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Testing the utility of a cancer clinical trial specific Question Prompt List (QPL-CT) during oncology consultations

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Abstract

Objective—A Question Prompt List (QPL) is a proven, simple intervention to aid patients to be active participants in consultations with their physicians by asking questions. We aimed to further develop and test the efficacy of a targeted QPL for clinical trials (QPL-CT).

Methods—Breast, Lung and Genitourinary cancer patients who were facing a discussion about a therapeutic clinical trial completed short pre- and post-consultation questionnaires and used the QPL-CT in their discussions with their oncologists.

Results: 30 participants were recruited from 6 oncologists—All QPL-CT questions were selected by at least one-third of participants. Participants mostly wanted and asked questions about personal trial benefit. Oncologists provided information about personal benefit to varying degrees, thus patients did not ask some questions. Patients were still left with some unasked and unanswered questions.

Conclusion—The QPL-CT has potential as a simple, inexpensive intervention to aid such communication. Further investigation is needed to demonstrate the efficacy of the QPL-CT in improving cancer patient outcomes.

Practice Implications—These preliminary finding suggest that important areas of clinical trials are overlooked in clinical consultations. The QPL-CT may be an effective method to encourage oncologists to endorse patient question asking about clinical trials and prompt patient questions.

Keywords

Clinical Trials; Question Prompt Lists; Physician-patient communication

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I confirm all patient/personal identifiers have been removed or disguised so the patient/person(s) described are not identifiable and cannot be identified through the details of the story.

1. Introduction

There is now emerging evidence demonstrating that patient outcomes are improved when oncologists endorse question asking and patients ask questions during their consultation.[1–3] Patients who actively participate in consultations by asking questions are able to change the focus of the consultation and control the amount of information provided by their physicians.[4] Yet patients vary in their ability to be active communicators and those patients who are passive during consultations risk poorer health outcomes than active patients and may be less satisfied with their physician and overall health care.[5]

A Question Prompt List (QPL) is a proven, simple and inexpensive intervention to aid patients to be active participants in consultations with their physician by asking questions. QPLs consist of structured lists of questions that cover prescribed categories developed for specific health related content areas such as treatment, diagnosis and prognosis. Early work demonstrated the efficacy of a QPL in the primary care and general oncology setting[2, 3, 6] as well as the palliative and surgical oncology clinical care contexts [7, 8] and this research has now extended to other health care settings such as pediatrics, geriatrics, coronary and diabetes care and general internal medicine.[9] QPL implementation studies have found that a high proportion, 50–65%, of patients made use of a QPL when it was offered as part of routine clinical practice.[9, 10] One of the most striking results of prior research is that a QPL can successfully encourage patients to ask questions about topics that are known to present significant difficulties during consultation discussions such as prognosis, diagnosis [2] and issues surrounding end of life care.[7]

Although QPLs have been shown to be an effective means of increasing patient participation in other settings, there are no studies demonstrating their efficacy in the context of achieving informed consent to cancer clinical trials. There is a mounting body of evidence about the communication challenges present in physician-patient consultations about clinical trials. [11–17]. The challenges for oncologists are to effectively communicate the purpose, technical aspects and implications of trials to patients [18–20] and to assist patients in decision-making. Yet in many consent interviews critical information is omitted or poorly presented [21] and physicians do not involve patients in decision making.[13–15, 22] This suboptimal physician-patient communication may explain patient misconceptions and gaps in knowledge about clinical trials [23–28].

We have previously developed and conducted initial testing of a clinical trial specific QPL. The QPL contained 33 questions in 11 categories: Understanding My Choices; Finding Out More About the Trial; Understanding the Trial's Purpose and Background; Understanding the Possible Risks; The Difference Between Going on the Trial and Standard Treatment; Understanding How the Trial is Being Carried Out; Understanding Possible Conflicts of Interest; Understanding my Right to Join the Trial or Not; and Alternative Therapies.

To aid in the development of the QPL, focus groups were conducted with two distinct groups of cancer patients, those who had participated *(trial experienced)* and those who had not participated *(trial naive)* in a clinical trial to explore a broad range of patient views about their clinical trial information and decision-making needs and obtain feedback about the utility and completeness of the previously developed QPL. The results of these focus groups and the final QPL-CT have been published elsewhere.[29, 30] In summary, patients felt the QPL-CT could be a useful aid to help them meet their information preferences and also to help them make decisions about joining a trial both during and after the consultation.

Although the focus group data provide preliminary evidence for the acceptability of the QPL-CT, its practical application in clinical encounters has not been tested. Thus, the goal

of the current study was to **conduct a pilot test of** the utility of the QPL-CT in consultations when physicians and patients discussed a clinical trial. The **three**fold aims of the study were to assess first, which questions patients were most interested in asking; second, whether or not these questions were asked, third, in cases when patients *did not* ask the questions they wanted to ask, whether oncologists discussed the information.

2. Methods

2.1 Participants

2.1.1 Oncologists—The study utilized six medical oncologists from three participating services that covered lung, prostate and breast cancer (two from each service) at a Memorial Sloan-Kettering Cancer Center in New York City, who gave permission to recruit participants for the study from their outpatient clinics.

2.1.2 Patients—The participants were considered to be eligible to participate in the study if they : a) were above 18 years of age; b) had been diagnosed with lung, prostate or breast cancer; c) were eligible for a therapeutic Phase I, II, or III clinical trial at the participating cancer center; d) were fluent in English; and e) were capable of providing informed consent.

2.2 Patient Identification and Recruitment

The patient identification process took place either a) at regular multidisciplinary meetings held by the oncology services where individual patient treatment plans were discussed or b) through individual liaison with each oncologist and their clinical research staff. At the time of identification the RA was provided with the date and time of their next clinic appointment. **All eligible patients were approached consecutively and invited to participate.**

On the day of the clinic the RA met each patient and invited the patient to consider participation in the QPL-CT study. The RA was trained by the first author to use sensitive language to describe the QPL-CT study to avoid any distress to patients who may not have expected to discuss a clinical trial. Interested patients were provided with an information sheet that described the study purpose and requirements. After review of the information sheet and consent forms, willing patients signed a written informed consent document that included consent to audio record the consultation.

2.3 Procedure

Once consent was obtained participants completed a short pre-consultation questionnaire that gathered socio-demographic information and preferences for information and involvement in the treatment decision-making process. The participants were then provided with the QPL-CT and instructed to circle the corresponding number of any question they may want to ask in the consultation. Participants were not restricted in the number of questions they could circle and were encouraged to list any additional questions in a blank, lined space provided at the end of the list. The RA immediately made a copy of the completed QPL-CT, returned the original QPL-CT to the patient, and retained the copy for future analysis. Immediately following the consultation, participants completed a validated questionnaire asking about their satisfaction with the communication that occurred in the consultation.[2]

2.3.1 Audio recording—The physician-patient consultation was audio recorded by the RA. Immediately prior to the consultation the RA entered the consulting room with the patient and placed a small digital audio-recorder on the desk. The RA but was not present for the consultation but re-entered the consulting room at the conclusion of the consultation

to retrieve the audio-recorder. **The audio recordings were downloaded and stored on a dedicated, protected server.**

2.4 Measures

2.4.1 Pre-Consultation Information Preferences—Preferences for information were assessed using the Cassileth Information Styles Questionnaire.[31] Participants indicated on a Likert scale the level of detail they require about their illness. Possible responses range between "prefer few details" to "prefer as many details as possible". This scale has good internal reliability with a Cronbach's alpha of 0.89.

2.4.2 Pre Consultation Decision Involvement Preferences—Decision Involvement preferences were assessed using the Control Preference Scale (CPS).[32–34] Participants indicated their preferences on a Likert scale with anchors at 1) The doctor should make the decision using all that is known about the treatments and 5) I should make the decision using all that I know and learn about the treatments. This scale has been used successfully to discriminate levels of congruence between patients' ideal and actual experiences of participation in decision-making during cancer consultations.[35]

2.4.3 Patient satisfaction with the consultation—Patient satisfaction was assessed **using the Patient Satisfaction with the Consultation Scale. Participants completed the scale** immediately after the consultation using a 25 item Likert scale with anchors at 1 – "strongly agree" and 5 – "strongly disagree". [2] The internal reliability of this scale is high (Cronbach's Alpha = 0.91). Raw scores are summed across items to yield a possible range of 25–125 with higher values indicating greater levels of patient satisfaction.[2]

2.5 Analysis

All demographic and questionnaire data were entered into IBM SPSS V 19.0. Frequencies and average scores were calculated for demographic variables and for the Information Preference Scale. As per previous studies,[36] the five CPS response categories were collapsed with categories 1–2 and 4–5 grouped together, resulting in three categories: oncologist directed, shared and patient directed decision-making. A total score for each participant and an average scale score were calculated for the Patient Satisfaction with the Consultation scale.

To meet our first aim we calculated frequencies (gathered from copies of the completed QPL-CTs) for each question that patients wanted to ask from the QPL-CT. **To meet Aims 2 and 3, the research team initially reviewed three audio recordings of the consultations and compared the copy of each participant's QPL-CT with the consultation audio recording. The remaining recordings were reviewed by the RA alone.** For Aim 2, frequencies for each of the 33 questions were noted using a 2 x 2 contingency table:

a) Participant *wanted to ask* (Y) and *asked* (Y)	(YY)
b) Participant *wanted to ask* (Y) and *did not ask* (N)	(YN)
c) Participants *did not want to ask* (N) and *did ask* (Y)	(NY)
d) Patients *did not want to ask* (N) and *did not ask* (N)	(NN)

For Aim 3, we added an additional column to the 2x2 contingency table above that recorded whether the oncologist had already mentioned the information (Y) or not (N).

3. Results

3.1 Participant characteristics

Thirty-eight eligible patients were approached consecutively and eight refused, giving a recruitment rate of 79%. Thirty participants (15 male and 15 female) were recruited, completed the pre- consultation measures and had their consultations audio recorded. Participants had an average age of 63 years, were mostly married (66%) and university educated (66%). Ten participants were recruited from each of the three participating oncology services, Breast, Lung and Genitourinary. Five of the 30 participants were not offered a clinical trial during their consultation and thus did not use the QPL-CT. Of the 25 remaining participants, seven were offered a Phase 1 trial, 12 were offered a Phase II trial and six were offered a Phase III trial (see Table 1 for detailed demographics).

3.2 Pre-Consultation Measures

3.2.1 Information and Involvement preferences—

Eighty-seven percent of participants responded that they preferred as much detail as possible about the clinical trial. Patients' preferences for involvement in making the treatment decision varied with 21% preferring these to be oncologist directed, 46% shared and 33% patient-directed decisions.

3.2.2 Questions Patients Most and Least Wanted to Ask from the QPL-CT—

Participants reported pre-consultation wanting to ask an average of 18.7 questions from the list (sd = 9.7, range 0–33). One participant did not want to ask any questions while five participants wanted to ask all 33 questions during their consultation. There were 14 questions the majority of participants (>60%) wanted to ask. Of these questions, the three questions the most patients (≥75%) wanted to ask were:

1. Question 7 – "What is already known about the treatment success?" (83%)
2. Question 13 – "What are the risks of taking the new treatment?" (80%) and
3. Question 11 – "Has the benefit of the new treatment been proven in people like me?"(77%)

The four questions the fewest participants (≤40%) wanted to ask were:

1. Question 28 – "Is there a payment made by the trial sponsor/company to the hospital or to you as my doctor?" (33%)
2. Question 22 – "Apart from the hospital staff, who will have access to my medical records?" (37%)
3. Question 16 – "If I get a side effect or injury from the trial will I get compensation?" (37%) and
4. Question 10 – "If I join the trial how might others benefit?" (40%)

3.3 Post Consultation – Questions Patients wanted to ask and asked

We determined how many patients asked the most popular questions after the consultation. Half (50%) of the 83% of participants, who wanted to ask Question 7, asked the question. Of 80% of participants who wanted to ask Questions 13, the majority (78%) asked the question. Of 77% of participants who wanted to ask Question 11, less than one third (29%) asked.

Of note, of 60% of participants who wanted to ask Question 20, one participant asked. Table 3 presents frequencies of the 14 questions the majority of participants wanted to ask and asked.

3.4 Post consultation – Questions participants wanted to ask and did not ask

After the consultation, we identified 15 questions the majority of participants (60%) had wanted to ask but did not ask. After reviewing the consultation audio recordings we noted whether oncologists mentioned the specific items related to the question from the list during the consultation, thus most likely eliminating the patients' need to ask the question. Of these 15 questions, the three questions most participants (≥80%) wanted to ask but did not were: 1. Question 24– "How will the results of the trial be used?" There were no cases where the participant did not ask Question 24 and the oncologist mentioned the topic. 2. Question 2– "If I join this trial how might others benefit?" not asked by 92% of participants who had wanted to ask. In 8% of these cases the patient did not ask this as the oncologist had mentioned the topic. 3. Question 17 – "If I enter the clinical trial, will it require me to have extra tests, to attend more clinics and will it cost me extra money?" was not asked by 85 % of participants who had wanted to ask. There were no cases where the participant did not ask Question 17 as the oncologist had mentioned the topic. Overall, there were very few instances where a question was potentially not asked because the oncologist had already asked about it. Table 4 presents frequencies of the 15 questions participants wanted to ask but did not and the frequency with which the oncologist mentioned the topic.

In the case of 3/33 questions we noted that more than 50% of patients who wanted to ask questions 6, 8 and 13, did not ask as the oncologist had already mentioned the topic area. Specifically, in 82% of cases, Question 6 – "What is the purpose of the trial", was not asked as the topic had been mentioned. Question 8. "How does the treatment work?" and Question 13 – " What are the risks of taking the new treatment?" were not asked as they had been mentioned in 61 % and 53% of cases respectively.

3.5 Post Consultation Satisfaction Measure

The average post consultation satisfaction scale score was 101.5 (sd = 6.7, range 89.0–102.0).

4. Discussion and Conclusion

4.1 Discussion

Our understanding of the communication challenges oncologists and cancer patients face as they discuss participation in therapeutic clinical trials is evolving. Research evidence has demonstrated the efficacy of QPLs to aid communication in other clinical settings and that QPLs can be successfully implemented in routine clinical care. [9, 10] Our prior **focus group** research, leading to the development of the clinical trial specific QPL (QPL-CT), indicated that cancer patients (both previous trial participants and non-participants), their caregivers and trial-experienced cancer clinicians found the QPL-CT to be a promising and potentially useful communication aid. [29, 30] Thus, we aimed to test the utility of the QPL-CT by asking a group of cancer patients to use it during their cancer consultation when a clinical trial was discussed.

In this sample of patients with advanced disease, who were mostly facing a Phase I or II clinical trial decision, we observed almost uniformly (90%) high pre-consultation needs for information consistent with the findings of other researchers. [37]. Most participants (79%) preferred participatory decision-making, (either autonomous or shared decisions) which is in line with current trends towards increased patient involvement in decision-making. [27, 36, 38] Participants had similarly high needs to ask questions, with half of participants expressing a desire to ask at least 20 of the 33 questions from the QPL-CT during their consultation. These results may reflect the clinical context in which these patients were asked to consider clinical trial participation as this work was conducted at Memorial Sloan-

Kettering Cancer Center in New York City with a self-selected population of mostly well-educated, affluent, insured patients who likely are expressive of their information and decision making needs. In addition, many patients come to this cancer center seeking out clinical trials.

The questions participants most wanted to ask from the QPL-CT were about the likelihood of personal benefit from joining the trial and the possibility of side effects. Most participants (19/25) were facing decisions about joining Phase I and II trials where the likelihood of personal benefit is very low and the probability of treatment side effects is high. Other research has identified this "therapeutic misconception" [39–42] and shown that the main reason cancer patients enter these studies is the hope for personal benefit including cure from the cancer.[39, 43, 44] Prior research suggests that oncologists do not initiate clear discussions about likely benefit from Phase I therapeutic trials and may promote unrealistic hopefulness.[27] Participants asked benefit and side effect questions suggesting that the QPL-CT may be a useful tool to aid patients to initiate conversations about realistic expectations.

Most participants (>50%) asked questions about the general success of the treatment, potential for side effects and additional burdens of the experimental treatment. Participants who did not ask these questions may have felt there was no need to do so, as their oncologist had already mentioned these topic areas.

Participants commonly indicated a desire to ask about whether the treatment had shown promise in patients in a similar situation, however, in 60% of cases patients who wanted to ask this question did not ask. This is somewhat counterintuitive as personalizing general trial information was suggested by our prior focus group participants as a primary benefit of the QPL-CT.[29, 30] It may be that patients avoided personalized information in order to preserve their sense of optimism and hope. [45]

Questions unrelated to direct personal therapeutic benefit, such as compensation in the event of injury, confidentiality of medical records and oncologists' conflict of interest, were least likely to be desired and asked, yet were selected by at least one third of our participants as questions they would like to ask. Our prior work showed that participants expressed significant discomfort with questions about oncologists' possible conflict of interest, fearing it may damage their therapeutic relationship or might seem critical of the oncologist. As suggested by our focus group participants, it may be that the QPL-CT will aid patients to ask such questions as part of ongoing treatment and the development of a trusting, long-term doctor-patient relationship. [29, 30].

Similarly, our results revealed that patients often did not ask desired questions about financial hardships and additional burdens although the oncologist did not provide that information. It may be that these are particularly difficult questions to ask as they admit vulnerability. Thus it may be that oncologists need to make a point of endorsing all questions and emphasizing, as part of their routine clinical practice, that patients should not be embarrassed to ask any question. In a randomized trial of a general QPL, physician endorsement was successful in prompting patient questions about difficult topic areas.[2] However, it is also possible that once patients received information about their most salient topic areas, such as personal benefit, they were willing to forgo asking additional questions altogether or leave them for a successive consultation. Future research could usefully explore predictors of asking difficult questions (including the quality and depth of the doctor-patient relationship), both in the short and long-term. To our knowledge, no research has yet explored long-term use and effects of a QPL.

A limitation of our study is the homogeneity of our sample who were largely unconcerned about the possibility of additional costs and time burdens associated with trial participation. For other populations, such as minorities, these factors represent major barriers to trial participation and may need a full and open discussion before patients will join a clinical trial. Thus, differential use of the QPL-CT is likely dependent on factors such as race, gender, education, income level, employment and age. In addition, only five participants in our sample were offered a Phase III randomized trial, thus we need to interpret our results regarding questions about randomization and blinding issues with some caution. In future, we plan to conduct a randomized trial of the QPL-CT that will sample from a larger, diverse patient population.

4.2 Conclusion

Physician-patient communication about clinical trials is challenging. The QPL-CT has potential as a simple, inexpensive intervention to aid such communication. Further investigation is needed to demonstrate the efficacy of the QPL-CT to improve cancer patient outcomes.

4.3 Practice Implications

These preliminary finding suggest that several important areas of discussion about clinical trials are being overlooked in clinical consultations. The QPL-CT may be an effective method to encourage oncologists to endorse patient question asking about clinical trials and prompt patient questions.

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References

1. Brown R, Butow PN, Tattersall MHN. Promoting patient participation in the cancer consultation: evaluation of a prompt sheet and coaching in question-asking. British Journal of Cancer. 1999; 80(1/2):242–248. [PubMed: 10390003]
2. Brown RF, Butow P, Dunn S, Tattersall MH. Promoting patient participation and shortening cancer consultations: A randomized trial. British Journal of Cancer. 2001; 85:1273–1279. [PubMed: 11720460]
3. Butow PN, Dunn SM, Tattersall MHN, Jones QJ. Patient involvement in the cancer consultation; evaluation of a question prompt sheet. Annals of Oncology. 1994; 5:199– 204. [PubMed: 8186168]
4. Kaplan SH, Greenfield S, Gandek B, Rogers WH, Ware JE. Characteristics of physicians with participatory decision making styles. Annals of Internal Medicine. 1996; 124:497– 504. [PubMed: 8602709]
5. Epstein, RM.; Street, RL. Vol NIH Publication No 07–6225. Bethesda MD: National Cancer Institute; 2007. Patient-Centered Communication in Cancer Care:Promoting Healing and Reducing Suffering.
6. Roter D. Patient participation in the patient-provider interaction: The effects of patient question asking on the quality of interaction, satisfaction and compliance. Health Education monographs. 1977; 5:281–315. [PubMed: 346537]
7. Clayton J, Butow P, Tattersall MHN, Chye R, Noel M, Davis JM, Glare P. Asking questions can help: development and preliminary evaluation of a question prompt list for palliatve care patients. British Journal of Cancer. 2003; 89:2069– 2077. [PubMed: 14647140]

8. McJannett M, Butow P, Tattersall MHN, Thompson JF. Asking Questions can help: Development of a question prompt list for cancer patients seeing a surgeon. European Journal of Cancer Prevention. 2003; 12:397–405. [PubMed: 14512805]
9. Demoska A, Butow L, Hovey JE, Agar M, Beale P, Tattersall M. Implementing patients question prompt lists into routine cancer care. Patient Education and Counseling. 2011 (In Press). 10.1016/pec.2011.04.020
10. Geest TA, Wetzels R, Wensing M, Castel OC, Olsen F. Evaluation of an intervention designed to enhance involvement of older patients in their own care. European Journal of General Practice. 2006; 12:3– 9. [PubMed: 16945865]
11. Agrawal M, Grady C, Fairclough DL, Meropol NJ, Maynard K, Emanuel EJ. Patient decision making process regarding participation in Phase I oncology research. Journal of Clinical Oncology. 2006; 24(27):4479–4483. [PubMed: 16983117]
12. Albrecht TL, Penner LA, Cline RJW, Eggly S, Ruckdeschel JC. Studying the process of clinical communication: issues of context, concepts and research directions. Journal of Health Comunication. 2009; 14(1):47– 56.
13. Albrecht TL, Ruckdeschel JC, Riddle JC, Blanchard CG, Penner LA, Coovert MD, Quinn G. Communication and decision making about cancer clinical trials. Patient education and counseling. 2003; 50:39– 42. [PubMed: 12767583]
14. Brown RF, Butow PN, Ellis P, Boyle F, Tattersall MHN. Seeking informed consent to cancer clinical trials: describing current practice. Social Science and Medicine. 2004; 58(12):2445– 2457. [PubMed: 15081196]
15. Brown RF, Bylund CL, Siminoff LA, Slovin SF. Seeking informed consent to Phase I cancer clinical trial: Identifying oncologists' communication strategies. Psycho-Oncology. 2010; 20:361–368. [PubMed: 20878842]
16. Fallowfield L, Jenkins V, Farewell V, Saul J, Duffy A, Eves R. Efficacy of a Cancer research UK communication skills training model for oncologists: a randomised controlled trial. Lancet. 2002; 359:650– 656. [PubMed: 11879860]
17. Fallowfield L. Can we improve the professional personal fulfilment of doctors in cancer medicine. British Journal of Cancer. 1995; 71:1132– 1133. [PubMed: 7779699]
18. Fallowfield L, Ratcliffe D, Souhami RL. Clinicians' attitudes to clinical trials of cancer therapy. European Journal of Cancer. 1997; 33:2221– 9. [PubMed: 9470810]
19. Hall, A. The role of effective communication in obtaining informed consent in medical research. Loyal, L.; Tobias, JS., editors. BMJ Books; London: 2001. p. 290-298.
20. Lee JY, Breaux SR. Accrual of Radiotherapy Patients to Clinical Trials. Cancer. 1983; 52:1014–1016. [PubMed: 6883268]
21. Grossman SA, Piantadosi S, Cohavey C. Are informed consent forms that describe clinical oncology research protocols readable by most patients and their families? Journal of Clinical Oncology. 1994; 12:2211– 2215. [PubMed: 7931491]
22. Albrecht TL, Penner LA, Ruckdeschel JC. Understanding patient decisions about clinical trials and the associated communication processes; a preliminary report. Journal of Cancer Education. 2003; 18:210–4. [PubMed: 14766331]
23. Meropol NJ, Weinfurt CB, Balshem A, Benson AB, Castel L, Corbett S, Diefenbach M, Gaskin DJ, Li Y, Manne S, Marshall J, Rowland JH, Slater E, Sulmasy DP, Echo DV, Washington S, Schulman KA. Perceptions of patients and physicians regarding Phase I cancer clinical trials: Implications for physician-patient communication. Journal of Clinical Oncology. 2003; 21(13): 2589–2596. [PubMed: 12829680]
24. Cox K. Informed consent and decision making: patients' experiences of the process of recruitment to phases 1 and 2 anti-cancer drug trials. Patient Education and Counselling. 2002; 46(1):31– 38.
25. Cheng JD, Hitt J, Koczwara B, Schulman KA, Burnett CB, Gaskin DJ, Rowland JH, Meropol NJ. Impact of quality of life on patient expectations regarding Phase I clinical trials. Journal of Clinical Oncology. 2000; 18(2):421–428. [PubMed: 10637258]
26. Daugherty C, Kass NE, Roter D, Larson S, Sugarman J, Kasza M, Ratain MJ, Hlubocky FJ. A study of physician investigator (PI) disclosure of alternatives of care and prognostic information to

advanced cancer patients (ACP) enrolling in Phase I trials. Journal of Clinical Oncology. 2009; 27(15s) p. suppl;abstr 6508.

27. Brown RF, Butow P, Boyle F, Tattersall MHN. Seeking informed consent to cancer clinical trials: evaluating the efficacy of communication skills training. Psycho-oncology. 2007; 16(6):507– 516. [PubMed: 16986176]
28. Brown RF, Butow PN, Butt DG, Moore AR, Tattersall MH. Developing ethical strategies to assist oncologists in seeking informed consent to cancer clinical trials. Social science & medicine. 2004; 58(2):379–90. [PubMed: 14604623]
29. Brown RF, Shuk E, Butow PN, Edgerson S, Tattersall MHN, Ostroff MHN. Identifying patient information needs about cancer clinical trials using a question prompt list. Patient Education and Counselling. 2011; 84:69– 77.
30. Brown RF, Shuk E, Butow PN, Leighl N, Edgerson S, Ostroff J, Tattersall MHN. Enhancing decision making about participation in cancer clinical trials: Development of a question prompt list. Supportive Care in Cancer. 2011; 19(8):1227– 38. [PubMed: 20593202]
31. Cassileth BR, Zupkis RV, Sutton-Smith K, March V. Information and participation preferences among cancer patients. Annals of Internal Medicine. 1980; 92:832–836. [PubMed: 7387025]
32. Strull WM, Lo B, Charles G. Do patients want to participate in medical decision making? Journal of the American Medical Association. 1984; 252(21):2990– 2994. [PubMed: 6502860]
33. Degner LF, Sloan JA, Venkatech P. The Control Preferences Scale. Canadian Journal of Nursing Research. 1997; 29:21– 43. [PubMed: 9505581]
34. Sutherland HJ, Llewellyn-Thomas HA, Lockwood GA, Tritchler DL. Cancer patients: their desire for information and participation in treatment decisions. Journal of the Royal Society of Medicine. 1989 May.82:260– 263. [PubMed: 2754680]
35. Gattellari M, Butow PN, Tattersall MH. Sharing decisions in cancer care. Social Science and Medicine. 2001; 52(12):1865– 1878. [PubMed: 11352412]
36. Ford S, Schofield T, Hope T. Are patients' decision-making preferences being met? Health Expect. 2003; 6(1):72–80. [PubMed: 12603630]
37. Mistry A, Wilson S, Priestman T, Damery S, Haque M. How do the information needs of cancer patients differ at different stages of the cancer journey? A cross-sectional survey. JRSM Short Reports. 2010; 1(4)
38. Chewning B, Bylund LC, Shah B, ANK, Gueguen JA, MG. Patient preferences for shared decision- A systematic review. Patient education and counseling. 2011 In Press. 10.1016/j.pec. 2011.02.004
39. Cox AC, Fallowfield LJ, Jenkins VA. Communication and the informed consent process in Phase I trials: a review of the literature. Supportive care in cancer : official journal of the Multinational Association of Supportive Care in Cancer. 2006; 14:303–309. [PubMed: 16633840]
40. Cohen L, de Moor C, Amato RJ. The Association between treatment specific optimism and depressive symptomatology in patients enrolled in a Phase I cancer clinical trial. Cancer. 2001; 91:1949–55. [PubMed: 11346878]
41. Weinfurt KP, Seils DM, Tzeng JP, Compton KL, Sulmasy DP, Astrow AB, Solinaro NA, Schulman KA, Meropol NJ. Expectations of benefit in early phase clinical trials: Implications for assessing the adequcy of informed consent. Medical Decision Making. 2008; 28:575–581. [PubMed: 18378940]
42. Itoh K, Sasaki Y, Fujii H, Ohtsu T, Wakita H, Igarashi T, Abe K. Patients in Phase I trials of anti cancer agents in Japan,: motivation, comprehension and expectations. British Journal of Cancer. 1997; 76:101–113.
43. Daugherty CK, Ratain MJ, Siegler M. Pushing the envelope: Informed consent to phase 1 trials. Annals of Oncology. 1995; 6:321– 323. [PubMed: 7619746]
44. Jenkins VA, Anferson JL, Fallowfield LJ. Communication and informed consent in Phase I trials: a review of literature from January 2005 - July 2009. Supportive Care in Cancer. 2010; 18:1115–1121. [PubMed: 20204418]
45. Leydon GM, Boulton M, Moynihan C, Mossman JAJ, Boudioni M, McPherson K. Cancer patients information needs and informaion seeking behavior: an in depth interview study. British Medical Journal. 2000; 320:909– 913. [PubMed: 10742000]

Table 1

Demographic and disease information (N = 30)

Variable	N (%)
Gender	
Female	15 (50%)
Male	15 (50%)
Average Age	63 years (Range: 35 – 83)
Education	
Senior high school (12 grade graduate)	10 (33.3 %)
Technical degree	3 (10%)
Undergraduate degree	6 (20%)
Higher degree (postgraduate)	11 (36.7)
Marital Status	
Single	5 (16.7%)
Married	18 (60%)
Divorced/Separated	1 (3.3%)
Widowed	6 (20%)
Primary Tumor Site	
Lung	10 (33.3%)
Breast	10 (33.3%)
Prostate	10 (33.3%)
Phase of Trial (n = 25) *	
Phase I	6 (24%)
Phase II	12 (48%)
Phase III	5 (24%)
Other	1 (4%)

* N=25 for Phase of trials as in five cases a trial was not discussed.

Table 2

Pre consultation frequencies for questions patients wanted to ask (Highest to Lowest Frequency) (N = 30)

Question	Wanted to ask (%)
7 What is already known about the treatments success?	25 (83.3%)
13 What are the risks of taking the new treatment?	24 (80.0%)
21 How long has the trial been going on? Are there any concerns about it?	24 (80.0%)
11 Has the benefit of the new treatment been proven in people like me?	23 (76.7%)
23 If the treatment is beneficial how can I get it, (if I am not already on it)?	23 (76.7%)
18 How often will I need to come in for treatment?	22 (73.3%)
26 Will I know what treatment I am getting, or is the trial blinded?	22 (73.3%)
2 Why are you offering me this particular trial?	20 (66.7%)
1 What is the usual (standard) treatment for people in my situation?	19 (63.3%)
4 What other trials am I eligible for? What makes me eligible?	19 (63.3%)
32 If I join the trial will I be losing out on any new treatment opportunities?	19 (63.3%)
33 Can I have alternative therapies if I go on the trial?	19 (63.3%)
5 How can I learn more about the trial?	18 (60.0%)
20 Is the new treatment only available through joining in the trial?	18 (60.0%)
3 Are there choices other than the trial and the standard treatment?	17 (56.7%)
8 How does the treatment work?	17 (56.7%)
9 What benefits could I possibly get if I join the trial?	17 (56.7%)
12 What does response rate mean?	17 (56.7%)
17 If I enter the clinical trial, will it mean more tests & clinics and cost me extra money?	17 (56.7%)
15 Whom can I call if something goes wrong?	16 (53.3%)
6 What is the purpose of this trial?	15 (50.0%)
14 Will there be side effects on the trial which I won't get on the standard treatment?	15 (50.0%)
29 Will you still treat me if I decide not to go on the trial?	15 (50.0%)
19 Will the treatment be given by experienced staff?	14 (46.7%)
30 Do I have time to think about whether to go on the trial (a day or two, or a week)?	14 (46.7%)
27 Are you in charge of the trial? If not, what's your role in the trial?	13 (43.3%)
10 If I join this trial how might others benefit?	12 (40.0%)
24 How will the results of the trial be used?	12 (40.0%)
25 Is this trial randomized? What does that mean and why is it important?	12 (40.0%)
31 If I join the trial, but later change my mind, how can I stop?	12 (40.0%)
16 If I get a side effect or injury because of being in the trial, will I get compensation?	11 (36.7%)
22 How will my confidentiality be protected?	11 (36.7%)
28 Does the trial sponsor make a payment to the hospital or to you as my doctor?	10 (33.3%)

Table 3

Questions patients most wanted (>60%) to ask from the QPL-CT and asked (N=25)

Question	Wanted to ask and asked (Y/Y) (%)
7 What is already known about the treatment's success?	6/12 (50.0%)
13 What are the risks of taking the new treatment??	7/9 (77.8%)
11 Has the benefit of the new treatment been proven in people like me	5/17 (29.4%)
23 If the treatment is beneficial how can I get it,	9/17 (52.9%)
21 How long has the trial been going on? Are there any concerns about the trial?	10/17 (58.8%)
18 How often will I need to come in for treatment? Is that different from standard?	8/12 (66.6%)
26 Will I know what treatment I am getting, or is the trial blinded?	5/16 (31.2%)
2 Why are you offering me this particular trial?	2/8 (25.0%)
1 What is the usual (standard) treatment for people in my situation?	3/5 (60.0%)
4 What other trials am I eligible for? What makes me eligible (or not)?	5/10 (50.0%)
32 If I join the trial will I be losing out on any new treatment opportunities	3/11 (27.3%)
33 Can I have alternative therapies if I go on the trial?	5/16 (31.3%)
5 How can I learn more about the trial?	3/14 (21.4%)
20 Is the new treatment only available through joining in the trial?	1/12 (8.3%)

Table 4

Questions most participants (> 60%) wanted ask from the QPL-CT and did not ask, wanted to ask and did ask, and Did not ask as the oncologist had mentioned. (N = 25)

Question	Wanted to ask and did not (%)	Wanted to ask and did (%)	Physician mentioned (%)
24 How will the results of the trial be used?	100.0	0	0.0
10 If I join this trial how might others benefit?	91.7	0	8.3
17 If I enter the clinical trial, will it require me to have extra tests, to attend more clinics and will it cost me extra money? (extra parking, extra medication?)	84.6	15.4	0.0
12 (If doctor describes response to treatment) What does response rate mean? How long would a response last?	78.6	14.3	7.1
16 If I get a side effect or injury because of being in the trial, will I get compensation?	77.8	22.2	0.0
22 Apart from the hospital staff, will other people have access to my medical records?	77.8	11.1	11.1
28 Is there a payment made by the trial sponsor/company to the hospital or to you as my doctor if I go on this trial?	77.8	22.2	0.0
5 How can I learn more about the trial? Can I speak to someone who is already participating on the trial?	73.3	20.0	6.7
20 Is the new treatment only available through joining in the trial?	73.3	6.7	20.0
15 Whom can I call if something goes wrong?	69.2	7.7	23.1
29 Will you still treat me if I decide not to go on the trial?	69.2	23.1	7.7
33 Can I have alternative therapies if I go on the trial?	68.8	31.3	0.0
25 Is this trial randomized? What does that mean and why is it important?	63.6	18.2	18.2
31 If I join the trial, but later change my mind, how can I stop?	63.6	27.3	9.1
11 Has the benefit of the new treatment been proven in people like me?	60.0	25.0	15.0

Table 5

Questions physicians provided information about topic (N = 25)

Question	Wanted to ask and did not (%)	Wanted to ask and did (%)	Physician Mentioned (%)
6 What is the purpose of the trial	18.2	0	81.8
8 How does the treatment work	23.1	15.4	61.5
13 What are the risks of taking the new treatment	10.5	36.8	52.6
2 Why are you offering me this trial?	37.5	12.5	50
7 What is already known about the treatments success	30	30	40
32 If I join the trial will I be losing out on any new treatment opportunities	33.3	33.3	33.3
4 What other trials am I eligible for	33.3	33.3	33.3