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Identifying Patient Information Needs about Cancer Clinical Trials Using a Question Prompt List

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Abstract

Objective—Question Prompt Lists (QPLs) have demonstrated significant promise in facilitating communication in general, surgical and palliative oncology settings yet have not been tested in the oncology clinical trial setting. We aimed to develop a targeted QPL for Clinical Trials (QPL-CT)

Methods—Breast Lung, and Genitourinary cancer patients who either had (trial experienced) or had not (trial naive) participated in a clinical trial joined focus groups to help develop and explore the acceptability of a QPL-CT.

Clinicians also participated in separated focus groups—Focus groups were audio-recorded and transcribed. We explored patients' trial information needs and views about the utility of the QPL-CT.

Results—Patients focused on four trial information needs: understanding foundational information, conflict of interest issues and financial implications of trial participation. Of note, experienced patients need to personalize foundational information.

Conclusion—Patient information needs varied considerably and were influenced by trial experience. Patients valued the QPL –CT as an aid to gathering new trial information and ensuring that their information needs were met.

Practice Implications—Physicians need to carefully elicit patient information needs and tailor trial information to meet these needs. The QPL-CT, may be of great benefit during clinical trial discussions

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.

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1. Introduction

Low rates of patient accrual to cancer clinical trials are regarded as one of the greatest barriers to the development of effective cancer treatments. Less than 5% of all adult cancer patients enroll in clinical trials.(1–3) As such, there is a critical need to identify and address modifiable institutional, physician and patient barriers to accrual for all phases of clinical trials. High quality communication has been identified as key to successfully seeking informed consent and trial accrual. Oncologists need to have excellent communication skills if patients' informational needs are to be met and informed consent achieved.(4)

The World Health Organization (WHO) specifies that patients must be informed about the clinical trial's aims, methods, anticipated benefits and potential side effects, as well as their rights to refuse or withdraw from the clinical trial(5): however, the type and amount of information provided is not monitored. Research focusing on patient understanding of clinical trial information across trial types shows that critical information is often omitted or poorly presented (6) leading to variable patient understanding of clinical trial information. (7–9) It is imperative that physicians be cognizant of patients' informational needs regarding trials that they are asked to consider if communication is to be improved.

Active patient participation in health care consultations has been shown to have several important benefits.(10–12) One method proposed to encourage patient activity is increased patient question asking using a Question Prompt List (QPL). These are structured lists of questions that aid patients' information seeking. Patients who actively ask questions of their doctor are able to change the focus of the consultation and control the content, duration and the amount of information provided.(13) Attempts to influence patient question asking behavior have met with some success in the medical oncology setting.(11,14–16) as well as the palliative and surgical oncology clinical care contexts.(17,18). To date, prior studies have shown these QPLs to be acceptable, understandable and valued by patients.

There is a mounting body of evidence about the communication challenges present in doctor-patient consultations about clinical trials. A QPL that targets patient information needs in this specific context is a promising method for improving this communication and subsequently the quality of informed consent. The first author (RB) previously collaborated to develop and conduct initial testing of a QPL that targeted patient information needs specific to informed consent to cancer clinical trials in an Australian oncology setting. Due to cultural and health system differences, the results of this preliminary work needed replication in the U.S setting.

Thus, to develop further a clinical trial-specific QPL, we conducted focus groups with two distinct groups of cancer patients, those who had participated (*trial experienced*) and those who had not participated (*trial naïve*) in a clinical trial. Our goal was to explore a broad range of patient views about their clinical trial information needs and obtain feedback about the utility and completeness of the previously developed QPL. Trial experienced patients were asked to review the QPL retrospectively to detail their actual unmet needs during the trial recruitment process. Trial naïve patients were asked to review the QPL prospectively to provide information about their hypothetical information needs if they were to consider trial participation (i.e. as someone who is in the same position as a patient being asked to join a trial who has not been exposed to this idea before). In addition, we recruited a variety of cancer clinicians currently involved in helping cancer patients make clinical trial decisions to separate focus groups. Our goal was to explore the different views of patients and clinicians about the potential utility of the QPL. In this manuscript, we present qualitative themes regarding patient clinical trial information needs from these distinct perspectives and the perceived role of the QPL in information seeking.

2. Methods

2.1 Participants

2.1.1 Oncologists—Six medical oncologists from three Services, Breast, Lung and Genitourinary oncology (two from each Service) at a Comprehensive Cancer Center in New York City gave permission for us to recruit study participants from their outpatient clinics.

2.1.2 Patients—Participants were adult cancer patients diagnosed and treated for lung, breast or genitourinary (GU) cancer who were recruited consecutively during follow up visits. All participants were classified as either “trial experienced” or “trial naïve.” Exclusion criteria consisted of: a) age less than 18 years, b) not English speaking, c) cognitive or physical impairment rendering the patient incapable of providing informed consent to participate in this study.

2.1.3 Clinicians—Clinician health care professionals including oncologists, oncology research nurses and oncology social workers, psychiatrists and clinical psychologists were invited to join focus groups. Eligibility requirements were that the clinicians was: a) a current health care professional at the institution; b) currently involved in recruiting patients with lung, prostate or breast cancer to Phase I, II, or III clinical trials at the institution; c) fluent in English; and d) able to provide informed consent.

2.2 Procedure

2.2.1 Patient recruitment procedure—One hundred and fifteen eligible patients treated or receiving treatment within 12 months prior to commencement of the study were randomly selected from the six participating oncologists' lists of patients who either had or had not participated in a clinical trial. Of these 115, 55 had participated in a clinical trial (trial experienced) and 60 patients had not (trial naïve). From this available pool of 115 patients, we aimed to recruit between 24–32 patients (See sample size calculation below). The Research Assistant (RA) mailed a recruitment letter to patients that included an explanation of the study purpose, an invitation to attend a focus group and a response form patients could return via a pre-paid envelope if they did not wish to be contacted about the study. The RA called those patients who had not returned a response form within two weeks of the initial mailing and discussed study participation. Interested patients gave verbal assent to participate and were scheduled for a focus group session stratified by whether patients had participated in a prior clinical trial. Patients who attended a focus group were compensated \$25 for their time and effort.

2.2.2 Clinician recruitment procedure—Clinician leaders in the lung, genitourinary and breast services identified seventy-three eligible participants. The recruitment procedure was identical for clinicians to the method described above for patients although there no compensation provided for participation.

2.2.3 Focus group procedure—The focus groups were designed and conducted according to well established methodologies.^{(19),(20)} The investigators developed guides for each focus group containing a set of relevant topics and subsidiary questions. The focus group guide questions covered: patient needs for information when making trial decisions, the process of trial decision-making and feedback regarding the utility of the QPL. The guide questions were modified to be specific to either patient group or health care professionals. See Table 1 for a list of sample questions.

Two authors (ES and RB) jointly moderated each focus group. Immediately prior to the focus group, participants signed an informed consent form and completed a brief

demographic questionnaire. The discussion then commenced. The focus group guides were used as tools to moderate the discussions and allowed unstructured time for participants to discuss issues that were not included in the question prompts. Clinicians reviewed the QPL for potential utility to patients. Participants were provided with a copy of the QPL after a discussion of patient information needs when considering participation in a clinical trial, and trial participation decision-making processes had occurred. The QPL is presented as Appendix 1.

Each focus group was audio-recorded and subsequently transcribed. The study received approval by the Institutional Review Board at the participating institution.

2.3 Qualitative Analysis Plan

The research team reviewed and interpreted narrative data using thematic text analysis with an inductive, data-driven approach.(21–23) Atlas.ti was used to manage the data coding. (24) Consistent with this method, each member independently developed codes to represent the underlying meaning of the text. The research team then met regularly to compare codes and achieve consensus about code names and meanings. We ultimately created a codebook consisting of 90 descriptive codes. Our codes described distinct phenomena identified through the coding process.(23) We identified 29 codes relating to 1) patient information needs when considering clinical trial participation and 2) eight codes focusing on patient assessment of the QPL. We generated reports from Atlas.ti that contained all data coded related to these two areas and subsequently read these data as a team to describe recurrent themes and provide illustrative examples of each theme. Rigor in our qualitative analysis was derived from successive rounds of iterative consensus work among multiple team members who analyzed the focus group transcripts.(25)

2.4 Sample size consideration

Based on established sample size recommendations for focus groups (19,20) with the goal to achieve theoretical saturation (no new themes emerging) we aimed to recruit eleven patients each to four focus groups resulting in 44 potential participants. We similarly estimated a sample size of twenty-two clinician participants to two focus groups. We estimated an attrition (no show) rate of approximately 20% leaving six to eight participants per group. Thus our expected sample size was 24–32 participating patients and 12–16 participating clinicians,

3. Results

3.1 Participant characteristics

Twenty patients were recruited for four focus groups (two trial experienced and two trial naïve). We recruited 9/55 (16%) trial experienced patients and 11/60 (18%) trial naïve patients. An overview of our recruitment process, including reasons for non-participation is presented in Figure 1. After four focus groups no new themes emerged; therefore, as we had achieved our aim of theoretical saturation, recruitment ceased.

Patients were mostly female (70%), with an average age of 60 years. Eight patients had been diagnosed with lung cancer, eight with breast cancer, and four with GU cancer. Most patients, (12/20) had advanced disease. Of nine trial experienced patients, 6 had participated in a Phase II trial and 3 in a Phase I trial. Five of the 55 trial experienced patients had participated in a Phase III study; however, none agreed to participate in the focus groups (See Table 2 for demographics of Trial naïve patients and Table 3 for demographics of trial experienced patients).

Twenty-four clinicians agreed to be contacted. We recruited 13/24 of these clinicians to one of three focus groups. As with the patient focus group our decision to cease recruitment was based on achieving theoretical saturation. Clinician demographics and professional information are detailed in Table 3.

3.2 Themes about information needs

Our qualitative analysis revealed that patients had four types of information needs regarding clinical trials when considering trial participation, including a need to: understand foundational information about clinical trials; personalize foundational information regarding trials; understand conflict of interest issues; and understand financial implications of trial participation. We present below themes within each type of information need for both trial naïve and trial experienced patients.

3.2.1 Trial naïve participants

Foundational questions: Trial naïve patients expressed interest in asking about the following four foundational information areas: purpose of a clinical trial, benefits of a trial, a trial's procedure, and any side effects. For some naïve patients, gaining an understanding of these types of information would be central and sufficient in their process of educating themselves if faced with a trial decision. For example, one trial naïve patient stated, *"You give me the purpose of the trial...you tell me how long it's going to take. You give me the negative and the positive. What more do I want?"* Naïve patients' level of interest in receiving in depth information regarding trial side effects varied across the sample. Some naïve patients did not desire to receive extensive information about potential side effects, as expressed by the patient below.

"I am a realist and you know the way I look at it if you're giving me something fine. You'll give it to me. And then when I say, 'well geez I got pains here'. and the doctor then says that's one of the side effects. Okay fine. I would rather have it that way."

In contrast, other naïve patients reported wanting to understand potential side effects in great detail, as shared by the following patient, *"You're a realist and I'm a lawyer. If someone is not going to tell me what the side effects are I'm going to be very concerned."*

Personalization questions: A need to personalize foundational trial information was the most prominent information need for trial naïve patients. Patients used personalization questions in an attempt to have their physician present trial-related information, such as trial benefits or side effects, as targeted or unique to their own personal medical situation. Trial naïve patients' personalization questions consisted of three separate information needs.

Firstly, many naïve patients had negative perceptions of clinical trials that a clinical trial—represented a last resort in cancer treatment—and thus stated they may become anxious or concerned that their disease had progressed if their physicians talked to them about participating in a trial. Learning the reasons why their physicians presented them with a clinical trial opportunity may alleviate their concerns or anxiety. Secondly, many naïve patients sought to understand their personal survival benefit from participating in a particular clinical trial. One trial naïve patient commented, *"I keep thinking will this trial help extend my life?"* Similarly, a third personalization information need was patients' interest in learning whether a clinical trial was the best treatment option for them. For example, after viewing the QPL, a naïve patient stated, *"By participating in this trial, am I foreclosing myself the opportunity to participate in another one? And so if the answer is yes, I would want to know that this is really particularly well suited for me..."*

Conflict of interest questions: A desire to understand conflict of interest issues seemed to be more important for trial naïve patients than for trial experienced patients. Common conflict of interest issues included, “*who is the staff running the trial;*” “*what are the safeguards for study data;*” and “*whether the doctor has any financial interest in the trial outcome.*” One trial naïve patient in particular described their information needs surrounding conflict of interest issues in great detail:

I think that’s (conflict of interest questions) is a reasonable question and I think as a participant, you’d want to know what those conflicts are. Whose going to be doing the testing, the monitoring, the evaluation of the data including your data...that would tell me a lot about how well designed the study was...that would affect whether I would want to be part of it.

Financial concerns: Trial naïve patients also described information needs regarding financial concerns associated with trial participation. One naïve patient did not find personal financial obligation associated with trial participation was important to know and shared, “*that to me is secondary unless you’re willing to put a dollar sign on your life.*” On the other hand, another trial naïve patient felt differently about financial concerns and specifically explained that:

It (personal financial obligation) would be a primary concern for me too but it would be related to exactly what they were for. What type of monitoring it was and so forth...the more individually tailored the monitoring was, the better follow-up there was, the more willing I would be able to pay for it.

3.2.2 Trial experienced participants

Foundational questions: Foundational information needs of trial experienced patients were similar in content to the foundational needs of trial naïve patients, but in some cases were more personal in tone than those expressed by naïve patients. As with trial naïve patients, variability existed among trial experienced patients regarding their interest in understanding trial side effects. While some experienced patients reported that learning about potential side effects was central to their trial decision-making, others said that learning about all possible side effects was “scary,” and wasn’t that relevant to them, as they were focused on surviving their disease and would join a trial regardless of possible severe side effects. In contrast to naïve patients, trial experienced patients expressed an interest in understanding what their personal burden would be if they joined in a trial. For example, as expressed below, one experienced patient wished that his physician had asked him about his personal everyday life responsibilities when presenting the trial opportunity to him, so that he could assess whether he could manage his unique burden from participation prior to joining a trial.

How am I going to manage my life and return to my life after undergoing this treatment?...What are the practical ways it’s going to affect my life?

Personalization questions: As with the trial naïve patients, a desire to personalize foundational trial information was important to trial experienced patients. As observed with foundational information needs, trial experienced patients’ personalization questions were more personal in nature than those expressed by naïve patients. Experienced patients also stated their interest in understanding their likely survival benefit, wondering “*if this clinical trial is the best treatment option for me.*” While trial naïve patients would ask their physicians why they had approached them to join in a trial, trial experienced patients instead generated proxy questions in the hope of obtaining direct physician guidance as to whether they should join a trial. A commonly used proxy question was asking physicians whether they would recommend that their own loved one participate in the trial, evidenced by the patient comment below.

One question that's not on here (the QPL) that I can tell you was asked of every physician that my husband and I met was... 'If it was your wife, your family member, your daughter, your son, would you put them in this?' ...It's almost like the question: 'Is this worth me going forward with?'

Trial experienced patients assumed that a physician would be motivated to provide their own family members with the best medical care, thus learning whether they would ask their loved ones to join the trial would lend great confidence that the trial was a worthy treatment option to consider.

Finally, trial experienced patients needed to understand how other trial participants with similar characteristics fared with regard to benefits and side effects. These patients sought such information to learn what a similar group of former patients had encountered so as to anticipate their likely outcomes based on the group's outcomes. For example, a trial experienced patient commented:

"I would like to know what has happened to other guys in the same situation. Are they getting as tired as I am or is it just a few of us? Are they gaining weight or losing weight? Or how am I fitting in with the rest of the group?"

Conflict of interest questions: While some trial naïve patients were interested in learning about potential trial-related conflict of interest issues, the majority of trial experienced patients' felt that conflict of interest questions were secondary. Several of these experienced patients indicated that including such questions might be counterproductive, raising concerns about their physician's intentions behind offering a trial. The comment below exemplifies this concern.

"About the whole money thing...I think that even putting it out there. Not that it wasn't a person's business but then the response back that'll be like: 'Well, we really can't disclose that' because they probably don't even really know. And then it almost makes you feel like 'oh are they hiding something?' ...I mean it's almost being suggestive that it could be even suspicious."

In contrast, as described below, other trial experienced patients felt confident in their own judgment to find a reputable, trustworthy physician, one whom they felt would not offer a clinical trial for their own financial benefit.

"If you're a good doctor, you would not be putting me in this because you're getting paid to do this...And I guess I'm relying on myself to put myself in a good place with a good physician that I trust...If I have to ask the question, I ought to not be talking to you."

Financial issues: Few trial experienced patients reported an interest in learning about personal financial responsibility from joining a clinical trial. The common sentiment was that it would be nice to know financial costs resulting from participating in a trial, but that it would not be a prominent decision-making factor. One experienced patient stated, *"It was a question but I don't think it was a concern. No, we would've paid what we had to pay. But yeah of course we wanted to know. But that's it. Whatever it takes to survive. I think that's our ultimate goal."*

3.3 Utility of the QPL in assisting patient information seeking

Overall, the majority of both trial naïve and experienced patients regarded the QPL to be a highly comprehensive useful tool for assisting them in asking physicians questions regarding trials. Several naïve patients noted that the QPL questions contained terminology that was educational and could therefore broaden their knowledge and ability to ask doctors more

nuanced questions. A number of both naïve and experienced patients identified the questions on the QPL regarding side effects and conflict of interest issues to be potentially threatening or too risky to ask.

Clinicians expressed concerns about the potential for the QPL questions to overburden patients through the quantity and complexity of the questions and that some questions could cause heightened anxiety in already vulnerable patients. One oncologist expressed this concern by saying

“Patients should leave our office feeling better than when they came in. That’s what our job is. We happen to deal with clinical research which makes it very hard. ‘Cause they can leave feeling worse...overwhelmed. So there is a scenario where they can feel overwhelmed by them (the questions) and leave feeling confused or worse off. That’s what I would worry about...I could identify patients who I wouldn’t go near with this”.

Clinicians were also concerned that the use of the QPL could lengthen their consultations adding to their existing time pressures.

As a physician..I want people to really understand..(the clinical trials) but we are under a lot of time pressure. And when I have to answer the same question 3 or 4 times because it’s just being asked in a slightly different way, it starts to make me irritable

4. Discussion and conclusions

4.1 Discussion

The aim of this study was to further develop a clinical trial specific QPL to help patients seek salient trial information. We sought trial naïve and experienced cancer patient perceptions of their information needs and the utility of the QPL-CT to ensure that these needs are expressed and met. The information needs of naïve patients in our sample were similar to the needs of other cancer patients facing a trial for the first time. (26) Trial naïve patients believed that asking these general foundational questions would help them gain additional information enabling them to better understand the trial and determine whether it was their best choice.

Trial experienced patients expressed their information needs differently, wanting to provide personal lifestyle details and information about their treatment values so as to aid the decision making process. This is in line with previous suggestions that clinicians allow time during discussions of clinical trial participation for patients to have a voice and provide such information.(27) Experienced patients felt they needed to probe indirectly to gain an accurate understanding of their oncologist’s opinion about the worthiness of the trial suggesting that these patients needed a clear personal recommendation from their physicians. Patients rely heavily on their doctors in making treatment decisions(28) and accept treatment recommendations primarily based on a belief in the benefit of the treatment.(8) Thus, it may cause undue influence, violating ethical principles of voluntary trial participation, for oncologists to provide a trial recommendations based on their own personal views. Yet, some cancer patients in our sample, as in others, prefer a paternalistic decision making style and this may be particularly true in patients with severe disease facing trial participation.(28,29) (30)The benefits and pitfalls of clinicians providing a trial recommendation have been discussed in other studies.(26,27,31) Strong clinician endorsement of a trial is somewhat different from clinician recommendations as endorsement supports the value of the study question, the methods and possible benefits rather than presenting a belief about the best course of action for a particular patient. Future

research could usefully explore this distinction and suggest strategies for achieving a balance between meeting patients needs and complying with ethical principles as a solution to ethical discomfort concerning potentially coercive recommendations.(31)

Another important finding is that trial experienced patients had greater needs to receive personalized information about risks and benefits of trial participation. They desired information about prior experiences of other trial participants and may desire direct contact with actual participants to seek additional information and endorsement of the trial. These patients most likely need to personalize information to help understand their own likelihood of a negative trial experience. These results warrant future investigation as providing such comparative information may have a powerful impact on decision-making. Patients felt that the QPL was a useful tool to aid them in asking questions that would help personalize information.

Our finding that patients had varying information needs is in line with other studies.(32) Patients had differing needs for information about the possibility of side effects with some desiring direct and precise information while others found this information frightening and only wanted to deal with such side effects discussions if they actually experienced the side effects. Most patients in our sample had been diagnosed with advanced disease and it is likely that, as in other studies, patients will overlook high possibilities of toxic side effects even when the likelihood of treatment benefit from the trial is low.(5) Nonetheless, patients valued the QPL as a means of posing difficult questions. On the other hand, although patients felt that the QPL would enhance their ability to achieve information needs, clinicians expressed significant concerns about the potential for the QPL to overburden patients with too much information and extend consultation length. Our results concur with other studies that show that Oncologists underestimate patients information needs (33) The QPL has the potential to help overcome this discordance as patients can elect how many questions they would like to ask and have some control over the flow of information and topics covered,

Both naïve and experienced patients felt that the QPL generated an awareness of questions about potential conflict of interest and financial concerns. Again patients' views about their needs for this type of information varied. A noteworthy finding is that patients were concerned about potentially undermining their trusting relationship with their oncologist by inquiring about conflict of interest, yet for others such questions were seen as very important. Both trial naive and experienced patients considered questions about personal costs to be secondary. It is likely that this reflects the view of this study's participants who tended to be well insured. Future studies are planned to test the QPL in more diverse minority and low-income cancer populations.

Finally, although our recruitment strategy did not restrict phase of prior clinical trial participation, no patients with prior experience participating in Phase III trials agreed to participate. Additionally our sample was mostly comprised of patients with advanced disease. Our future research involves pilot testing the utility of the QPL during actual physician – patient consultations in which a clinical trial is to be discussed. To improve the generalizability of the QPL findings, this work is now being conducted at two sites and will include more diverse patients with early stage disease considering a randomized trial.

4.2 Conclusions

Cancer patients have distinct needs for trial information. Patients have varying needs for the amount and type of information they require. In addition, patients express their needs for information and utilize information in different ways. The QPL-CT is a promising step forward to help meet patients' information needs.

4.3 Practice Implications

These preliminary findings suggest that physicians need to carefully elicit patient information needs and tailor trial information to meet these needs. The QPL-CT, a simple paper and pen resource may be of benefit during clinical trial discussions.

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Appendix 1 Question Prompt List

“I went into the consultation room and forgot every question I had.”

Introduction

People are often anxious when given the diagnosis of cancer and faced with making decisions about treatment. Being invited to join a clinical trial can make this process more difficult as there are extra options and concepts to think about. People come to the specialist to have the benefit of his/her knowledge, expertise and care. Often with the stress of the moment important questions can be forgotten.

The purpose of this question list is to

1. act as a prompt, if you so desire, in gaining relevant and important information about the clinical trial being considered and
2. assist you to make an informed decision regarding your treatment.

These questions have been developed after much discussion with patients who have been through the experience of participating in a clinical trial. They have been reviewed by oncologists and other health professionals who are involved in the care of people diagnosed with cancer faced with making a decision about trial participation. Your specialist will be pleased to answer any questions you may have and additional space has been included for you to jot down your own questions or concerns that you may wish to discuss in your consultation.

You may wish to use this prompt list during the first consultation where your specialist invites you to participate in a trial or you may choose to ask some of the questions at a later stage. Different people want different things at different times. You or your family may find it helpful as a reference, it is up to you. Please do not feel you should ask questions just because they are listed.

We have organised the list under headings. You may find that some are very relevant to you, and others are not.

If you have any further questions or comments on this brochure please do not hesitate to contact me, Dr Richard Brown at 646 888 0011.

Understanding my choices

1. What is the usual (standard) treatment for people in my situation?
2. Why are you offering me this particular trial? Does it ask an important question in cancer treatment?
3. Are there choices other than the trial and the standard treatment?
4. What other trials am I eligible for? What makes me eligible (or not)?

Finding out more information about this trial

5. How can I learn more about the trial? Can I speak to someone who is already participating in this trial?

Understanding the trial's purpose and background

6. What is the purpose of this trial?
7. What is already known about this treatment's success?
8. How does the treatment work?

Understanding the possible benefits

9. What benefits could I possibly get if I join the trial?
10. If I join this trial how might others benefit?
11. Has the benefit of the new treatment already been proven in people like me?
12. (If doctor describes response to treatment) What does response rate mean? How long would a response last?

Understanding the possible risks

13. What are the risks of taking the new treatment? Are there any long-term or permanent side effects from the treatment? Are there any serious or rare side effects that I should know about?
14. Will there be side effects on the trial which I won't get on the standard treatment? Are there different side effects depending on which arm I am randomised to receive?
15. Whom can I call if something goes wrong?
16. If I get a side effect or injury because of being in the trial, will I get compensation?

The differences between going on the trial and having the standard treatment

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?)
18. How often will I need to come in for treatment, and is that different from if I took the standard treatment?
19. Will the treatment be given by experienced staff? Where will the treatment be given?

Understanding how the trial is being carried out

20. Is the new treatment only available through joining in the trial?

21. How long has the trial been going on? How many people will be studied and how many are on the trial already? Are there any concerns about the trial or treatment so far?
22. Apart from the hospital staff, will other people have access to my medical records? Who? How will my confidentiality be protected?
23. If the new treatment is beneficial, how can I get it (if I am not already on it)? How will I be informed of the results of the trial?
24. How will the results of the trial be used?

Understanding randomization and blinding

25. Is this trial randomised? What does that mean and why is it important?
26. Will I know what treatment I am getting, or is this trial blinded? What does that mean and why is it important in this trial? Will I ever know what treatment I am getting?

Understanding possible conflicts of interest

27. Are you in charge of the trial (the principal investigator)? If not, what's your role in the trial?
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? Could you tell me how much money and is this usual? How is the money spent?

Understanding my right to join or not to join the trial

29. Will you still treat me if I decide not to go on the trial?
30. Do I have time to think about whether to go on the trial (a day or two, or a week)? Will taking time to decide affect how well the treatment works?
31. If I join the trial, but later change my mind, how can I stop? Will I be penalised in any way?
32. If I join the trial will I be losing out on any new treatment opportunities (such as another trial or standard treatment later)?

Alternative Therapies

33. Can I still have alternative therapies if I go on the trial (eg vitamins, herbal remedies, naturopathy, dietary changes)?

Your own questions: (Please write down any questions not listed).

Figure 1.
Sampling Schema and Flowchart of Recruitment for Question Prompt List Focus Groups

Table 1**Focus Group Probes****Experience of the clinical trial.**

I'd like to talk about your experiences with the clinical trial you participated in.

Thinking back,

What were your thoughts and feelings about the clinical trial?

What were your impressions of the trial?

How did your experience meet your expectations?

Did you find it difficult to ask questions about the clinical trial? Why or why not.

Information needs about trials.

Now I would like to talk with you about particular issues you wanted to know about before you joined the trial.

What were some of the issues you were interested in finding out about the clinical trial?

Did you find it difficult to get information about the trial?

Were you left with questions about the trial at the time you gave consent?

Thinking back, were there issues that you would have like to have been covered about the trial that came up for you after you had joined or once you completed the trial?

What are the important issues about clinical trials you would tell someone who was facing trial decision?

Here is the Question prompt list. Please take a moment to read through it.

Completeness of the Question Prompt List. (QPL)

Now that you have reviewed the Question Prompt List I would like to find out about your impressions of the completeness of the list.

In what ways does the QPL provide a good coverage of the issues that you were interested in either before you joined the trial or after you joined?

What topics are not covered that in your experience would be good to include on the list?

Acceptability of the Question Prompt List.

I am interested in your thoughts about whether you would have found the Question Prompt List useful when you were considering participating in the clinical trial.

Do you think you would have tried to use the QPL in your consultations where you were discussing a clinical trial with your oncologist? If you had used it how would you have found it useful?

If you do not think it would be useful what are your reasons?

What kinds of issues do you think would have prevented you from using the QPL?

Ending/Conclusion of Focus Group

Okay, we've covered all the issues that I wanted to discuss. Before we finish, I want to give you the opportunity to reflect on our discussion and share anything that you think is relevant to the Question Prompt List that didn't come up during the conversation.

Again, thank you very much for your honesty and willingness to participate in this group. We have learned a lot today, and this will help us with helping patients' communication with their doctors about clinical trials. If you'd like, please feel free to stay a bit if you have any questions about our research, or have any other comments you'd like to share.

Table 2

Demographic and disease characteristics of naïve patient sample

Gender (n = 11)	
Female	7 (64%)
Male	4 (36%)
Average Age (n = 11)	63 years (Range: 47–74)
Education (n = 11)	
Junior High School	0 (0%)
Senior High School	2 (18%)
High School equivalency (GED)	2 (18%)
Technical degree	0 (0%)
Junior College Degree	0 (0%)
Undergraduate degree	1 (9%)
Higher Degree (post Graduate)	6 (55%)
Marital Status (n = 11)	
Single	1 (9%)
Living together with partner	0 (0%)
Married	9 (82%)
Widowed	1 (9%)
Divorced/Separated	0 (0%)
Other	0 (0%)
Primary tumor site (n = 11)	
GU oncology	2 (18%)
Breast	4 (36%)
Lung	5 (45%)
Stage of disease (n = 11)	
<i>GU oncology (n=2)</i>	
Stage I	0
Stage II	1
Stage III	0
Stage IV	1
<i>Breast (n=4)</i>	
Stage I	2
Stage II	1
Stage III	1
Stage IV	0
<i>Lung (n=5)</i>	
Stage I	0
Stage II	2
Stage III	1
Stage IV	2

Table 3

Demographic and disease characteristics of Experienced patient sample

Gender (n = 9)	
Female	6 (67%)
Male	3 (33%)
Average Age (n = 9)	57 years (Range: 36–83)
Education (n = 9)	
Junior High School	0 (0%)
Senior High School	1 (11%)
High School equivalency (GED)	0 (0%)
Technical degree	1 (11%)
Junior College Degree	0 (0%)
Undergraduate degree	3 (33%)
Higher Degree (post Graduate)	4 (44%)
Marital Status (n = 9)	
Single	(11%)
Living together with partner	0 (0%)
Married	6 (66%)
Widowed	0 (0%)
Divorced/Separated	1 (11%)
Other	0 (0%)
Primary tumor site (n =9)	
GU oncology	2 (22%)
Breast	4 (44%)
Lung	3 (33%)
Stage of disease (n = 9)	
<i>GU oncology (n=2)</i>	
Stage I	0
Stage II	0
Stage III	0
Stage IV	2
<i>Breast (n=4)</i>	
Stage I	0
Stage II	2
Stage III	2
Stage IV	0
<i>Lung (n=3)</i>	
Stage I	1
Stage II	0
Stage III	0
Stage IV	2
Phase of trial (n= 9)	

Phase I	3 (33.3%)
Phase II	5 (55.5%)
Phase III	0 (0%)
Other	1 (11.1%)

Table 4

Demographic and career characteristics of clinician sample

Gender (n =13)	
Female	7 (54%)
Male	6 (46%)
Average Age (n = 13)	44 years (Range: 26–61)
Average Years of Oncology Experience (n = 13)	14 years (Range: 2–32)
Specialty (n = 13)	
Medical Oncologist	5 (38%)
Psychiatrist	0 (0%)
Psychologist	1 (8%)
Nurse	4 (31%)
Social Worker	3 (23%)
Other	0 (0%)
Service (n =13)	
GU oncology	3 (23%)
Breast	5 (38%)
Lung	4 (31%)
All services	1 (8%)