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Cancer Patients' Fears Related to Clinical Trial Participation: A Qualitative Study

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Abstract

Patient-related barriers have hindered cancer patients' abilities to participate in the decision-making processes to participate in clinical trials. However, little is known about patients' emotional barrier of fear and how physicians influence this barrier. We conducted 48 in-depth interviews with cancer patients to determine their knowledge and attitudes about participating in

clinical trials, transcribed interviews verbatim, and qualitatively analyzed the transcripts using content analysis. For the purpose of this manuscript, we focused on findings related to the role of the emotional barrier of fear in cancer patients' perceptions of participating in clinical trials. The majority of cancer patients ($n=40$, 83.3%) discussed fears surrounding clinical trials, particularly as it related to cancer diagnosis, clinical trial participation, and fear of the unknown. In conclusion, providers might consider addressing the role of fear in patients' considering participating in a clinical trial.

Keywords

Cancer clinical trials; Fear; Decision making; Patient-provider communication

Introduction

Although clinical research trials for cancer patients have low accrual rates, clinical trial participation might improve patients' overall quality of life [1]. Much has been written about the processes cancer patients use when making a decision regarding whether to participate in a clinical trial, with a particular focus on reasons why patients accept or decline to participate in a clinical trial [2–4]. More often, these studies have identified key structural (i.e., lack of transportation, lack of physician's recommendation to participate) and personal-related (i.e., distrust of medical provider, lack of knowledge of clinical trials, fear of receiving the placebo, etc.) barriers to participating in clinical trials [1, 2, 5]. Additionally, researchers have identified emotional barriers as the single largest inhibitor of cancer patients' decisions regarding their cancer treatment [6].

Although it often goes unaddressed, many patients experience fear and distress related to cancer diagnosis, symptoms, and treatment [7]. At times, such anxiety motivates patients to perform positive health behaviors; however, overwhelming anxiety or fear often lead to patients' feeling of loss of control and, in turn, may make it difficult to make decisions rationally [8]. Physicians may lessen patients' distress and empower them to understand their health and treatment options by building a relationship with the patient and sharing health information [8].

Patient-provider communication serves as a key component of cancer patients' selection of medical treatments, particularly in clinical trial participation [9]. Patients vary in their preferences of who should direct their medical treatment (i.e., physician-directed or patient-physician shared decision); therefore, providers need to identify and clarify patients' values regarding decision-making procedures [10]. For example, past studies have demonstrated cancer patients' preference to simply receive health instructions from their physicians rather than actually participating in shared decision making [11, 12]. Beaver and colleagues found that when colorectal cancer patients were encouraged to share in their personal treatment-related decision-making process, they felt there was a "right" medical decision [10]. That being the case, they trusted the doctor to supply that decision for them and preferred physicians to inform and update them on their medical treatment and outcomes.

Although some studies have demonstrated patients' preferences to share the decision-making processes, patient-provider power differentials serve as a barrier for their participation in treatment decisions [13, 14]. In a health care realm filled with difficult-to-understand medical terminology and complex health instructions and forms, and trying to navigate a complicated health care system, limited health literacy skills serve as an additional challenge in patients' ability to understand and therefore decide to participate in a clinical trial [21]. However, physicians' use of supportive communication might facilitate patient understanding and involvement, and physicians' explicit encouragement to participate in decision-making processes in health treatment might foster patient participation in medical decision making [15]. Despite all that is known about patient-provider communication and clinical trials, little is known about the specific fears patients experience regarding deciding to enroll in clinical trials and how their physicians can influence such fears. Therefore, using a qualitative approach, we examined the role of fear in cancer patients' perceptions of participating in cancer clinical trials and what role clinicians play in addressing or perpetuating this.

Methods

In preparation for the development of a media product designed to inform patients about clinical trials, we interviewed cancer patients about their overall knowledge, attitudes, and perceptions of participating in clinical trials (Table 1). A study coordinator contacted cancer patients receiving care at a comprehensive cancer center to assess their interest in participating in a brief interview about clinical trials. There was a deliberate effort as part of the recruitment strategy to include: patients who agreed to participate in clinical trials, patients who declined to participate in clinical trials, and patients who never asked to participate in clinical trials.

A total of 57 patients were contacted; however, nine refused, all citing lack of time to participate in the interview. Those who agreed were administered an informed consent form and participated in a 30–45-min qualitative interview using a semi-structured in-depth interview guide. Respondents were paid \$25 as compensation for their time. This study was approved by the University of South Florida Institutional Review Board.

Analysis

All interviews were audio-taped and transcribed verbatim. One researcher read all transcripts and generated an initial list of codes. Next, the research team was assigned one interview transcript to independently code using the initial list and also to look for possible other interview themes. On meeting to discuss codes, they refined the coding scheme by expanding, merging, and renaming the initial codes into "axial codes" [16]. Three members of the research team independently coded a different interview transcript and submitted their coded interviews to one researcher who calculated interrater reliability of .90. Researchers then independently analyzed the remaining transcripts and organized codes into ATLAS.ti software. After coding the data, the research team met to discuss interpretations of the qualitative results. For the purpose of the current research study, we focused on those

responses related to fear (use of the word fear or similar words) and patient–provider communication.

Results

Of the 48 patients interviewed ($M=30$, 62.5%; $F=18$, 37.5%), 25 had previously participated in a clinical trial, 10 had been offered a trial and refused, and 13 had never been offered a trial. Participants ranged in age from 32–75 years old (mean age=66). Patients had a diagnosis of lung cancer ($n=22$), breast cancer ($n=9$), hematological cancer ($n=6$), genitourinary cancer ($n=5$), and head and neck cancer ($n=4$) or did not disclose the cancer type ($n=6$).

Most of the interview participants ($n=40$, 83.3%) mentioned the word “fear” at some point during their interviews, 38 (79.2%) of whom used the word fear three or more times. Respondents spoke about fear in at least three different contexts. One context was fear related to the cancer diagnosis, the second was fear of clinical trials, and the third was an overall general fear of unknowns associated with cancer, cancer treatment, and clinical trials. Patients also discussed physicians’ roles in sharing information and communicating risks and benefits to participating in clinical trials.

Fear and Cancer Diagnosis

Respondents were asked to describe how they would make a decision to participate in a clinical trial if the offer were presented to them. In the context of this question, the majority of respondents first described their experience of receiving their cancer diagnosis. They used such words as “afraid,” “fear,” “terror,” and “scared” to describe how they felt about learning they had cancer. One patient described

“Everyone is afraid of the word cancer. I was terrified when I found out; it was hard to think about anything else.”

Rather than describing the evaluation processes of entering a clinical trial, this patient was more consumed with processing the cancer diagnosis. Another patient also noted a similar initial reaction to receiving a cancer diagnosis:

“My family and I were so scared when the doctor said ‘cancer’; I don’t think I heard anything else that was said. I really couldn’t think about a clinical trial at that time. I had to digest how scared I was to know I had cancer.”

In this case, overwhelming fear of cancer hindered the patient’s ability to immediately make health-related decisions.

Other patients described their fear of dying. Receiving the cancer diagnosis was a death sentence, and many patients immediately feared dying, thus leaving behind loved ones.

“Of course I was so afraid. I was sure I was going to die when I found out I had cancer. It was terrifying. I could not think about anything but what I was going to miss—seeing my grandchildren grow up.”

Clinical Trials and Fear of the Unknown

Respondents were asked “What images or thoughts come to mind when you hear the words ‘clinical trial’?” All respondents had heard of a clinical trial or research study and had a combination of negative and positive images associated with the terms. Those who negatively perceived clinical trials discussed the fear of being the subjects of experimental testing and often compared this to animal studies.

“It brings up fear, it is frightening—animal testing and the unknown and pain.”

Others described similar fear of being a test subject, lacking control over the testing and health-related outcomes.

“Testing, it’s scary. It is like you are a guinea pig and have no control over what will happen.”

Another patient described refusing trial participation as a means to have control over some aspect of her cancer experience.

“Maybe in the future I will have to think about it again but for now, saying no gave me some control.”

Respondents who had both participated in and refused a clinical trial were asked to predict why people might not choose to participate in a clinical trial. Also, patients who had not been offered a trial were asked to describe some of the reasons they might not consider a trial if one were offered to them in the future. The majority of respondents gave answers that focused on lack of time and the fear of not experiencing a positive health outcome because of the trial. Patients believed that participating in clinical trials is time consuming, so they prefer to spend the rest of their lives with loved ones rather than in participating in a clinical trial which is not guaranteed to produce major health improvements.

“I was afraid to take a chance. If I only have a limited time left I don’t want to waste my time with research where the outcome is unknown.”

Patients who had previously participated in a clinical trial and also those who expressed interest in future participation clarified that along with the feeling of fear, there was also a sense of hope associated with participating in clinical trials.

“It’s going where no person has gone before—and that is frightening, but clinical trials are a way to test and develop new cures. So they sound like hope.”

Although patients believed that clinical trials could lead to the creation of new cancer cures, they were still apprehensive about participating in an experimental treatment option.

“Well, you are a guinea pig, that’s for sure... but a guinea pig to help find a better cure.”

Provider’s Influence in Trial Participation

Patients described the roles health care providers play in their decision to participate in clinical trials. In some cases, patients accepted physicians’ recommendations to enroll in clinical trials because of their relationship and trust in their physician.

“We were scared to hear about a clinical trial because it sounded like a death sentence, like there were no other options for me. In the end we made this decision because we had faith in our doctor, and she told us this may be our only hope.”

In other cases, physicians’ warnings of negative health outcomes dissuaded patients to enroll in clinical trials.

“I did not do a clinical trial. I was told to be wary of a trial (by diagnosing physician).”

All of the respondents in the groups who had participated in a clinical trial and those who had not been offered the trials said they ultimately made (or would make) their decision based on physician recommendation. In addition, patients recommended that physicians first inform them of the importance and purpose of clinical trials and then details regarding specific trials.

“There has to be a way to talk about research as a treatment option... I thought clinical trials were a last resort for people who had no other options. When I was presented with [information about] a trial I learned that was not always the case. I never would have known that.”

Moreover, those who had previously refused a trial said they would consider it for the future if their physician provided information about the trial and then strongly recommended it, particularly if there were no other treatment options (they had failed standard treatment).

Discussion and Conclusion

Discussion

The current study revealed the types of fear cancer patients experience associated with clinical trials, which suggests that cancer treatment decision making involves strong emotional responses. This study reveals that both the initial fear resulting from a diagnosis of cancer and fears related to various aspects of clinical trials are barriers to clinical trial participation. It is interesting to note that when patients were asked how they would or did make a decision about participating in a clinical trial, most of the respondents discussed the fear they felt during and after being diagnosed with cancer. At first glance, it seemed their responses were not related to the question asked; however, this may demonstrate that the emotion of fear was so overwhelming that patients could not process thinking about alternative approaches to treatment [17]. Indeed, distress might hamper cancer patients’ capacity to process information [6]. Also consistent with previous research findings, fear of the unknown, particularly lacking control of cancer treatment options, and fear of being a medical “guinea pig” were major reasons to decline participation in a clinical trial cited by the cancer patient [1, 18].

Although fear was present in their responses, many participants mentioned taking chances by enrolling in clinical trials to help future cancer patients. Patients faced difficulties in making the decision of enrolling in a clinical trial particularly since clinical trials do not guarantee positive health outcomes. However, similar to past research studies, altruism was

cited as a major reason to participate in clinical trials, as patients believed that it would help future cancer patients [19, 20].

Physician recommendation to participate seemed to be the deciding factor in most of the cases, whether it was in favor of or against participating in a clinical trial. Patients preferred their physicians to be the primary decision maker for their treatment decisions. This is similar to past research that questioned the superiority of patient autonomy in health decision making since some patients might perceive making health-related decisions as an added burden rather than a good option [21].

Patients suggested that their health care providers offer both general information about clinical trials and detailed information about specific trials in which they might be asked to enroll. Consistent with previous research, patients viewed their physicians as a principal source for their health information and trusted their physicians' recommendations regarding whether or not to enroll in a clinical trial [22].

Limitations

As with all qualitative research, this study's findings are not generalizable to other settings or patient populations. Participants were conveniently selected, and lung cancer patients were over sampled. Also, certain demographic data such as marital status were not collected from the sample. The original purpose of the data collection was to gather information for the development of several media products related to improving awareness of clinical trials.

Future Research and Practical Implications

The results of the overall study regarding patients' informational needs regarding clinical trials led to the development of a visual medial product designed to "prime" patients about clinical trials. These overall results are available in another publication [9]. Future research will examine the impact of priming and reducing fears as well as quantitatively assessing if the level of fear experienced impacts cognitions about trial information. Other research studies could explore physicians' perceptions and behaviors of addressing cancer patients' fear of participating in both the medical treatment decision-making process and of clinical trials.

It appears the general fear of the concept of clinical trials is typically assuaged by trust in a specific health care provider or clinical setting. It is important that health care providers determine patients' preferences for their preferred degree of involvement in their cancer treatment decision-making processes [23]. It is also critical that they consider patients' fear related to cancer to further develop therapeutic relationships with their patients and, therefore, enhance decision-making processes [8]. Additionally, physicians should acknowledge patients' concerns and fears about clinical trial participation when developing a cancer treatment plan. For example, physicians can dispel myths (i.e., being a "human guinea pig") and provide corrective information which may ease patients' feelings of fear and anxiety towards participating in clinical trials [24]. Patients may have unmet emotional needs during the time when they are considering cancer treatments. Psychosocial services such as counseling have been proven to help patients cope with their cancer diagnosis, treatment, and health outcomes [25].

Conclusion

Fear is a common reaction to both the cancer diagnosis and the presentation of alternative treatment options such as clinical trials. Acknowledgement of patient fear, from general fears of the unknown to specific fears about the uncertainties of clinical trials, might facilitate decision making. It appears the general fear of the concept of clinical trials is typically surpassed by specific trust in a health care provider or clinical setting. It is critical that health care providers assist patients in informing them of the option of participating in clinical trials, describing the processes of such trials, thus eliminating the fear of participating in possible life-saving trials.

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Table 1

Interview guide sample questions

How did you receive your cancer diagnosis?

Have you ever had any other type of cancer?

How has your health been for most of your life?

Why did you decide to receive care at this cancer center?

At any point in your treatment was a clinical trial discussed?

If so, how did you make a decision about the clinical trial?

If you participated in a clinical trial, please describe the clinical trial experience.

If you were offered to participate in a clinical trial, did you feel comfortable with your decision?

 Did that change at any time during the trial?

 Did you have any concerns about the trial?

 How do you feel now about your decision?

For those of you not offered participation in a clinical trial, what have you heard about clinical trials?

 Would you have considered participating if your physician had offered?

What would you tell a friend who came to you for advice about participating in a trial? What would you advise?
