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PATIENT AND FAMILY MEMBER PERSPECTIVES ON SEARCHING FOR CANCER CLINICAL TRIALS: A QUALITATIVE INTERVIEW STUDY

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Abstract

Objective—Clinical trials are vital in the context of ovarian cancer and may offer further treatment options during disease recurrence, yet enrollment remains low. Understanding patient and family member experiences with identifying trials can inform engagement and education efforts.

Methods—Interviews were conducted with 33 patients who had experience with clinical trial conversations and 39 **nominated** family members. Thematic analysis examined experiences and generated findings for clinical practice.

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Patient details

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.

Disclosure

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Conflicts of Interest

There exist no conflicts of interest between authors and any persons or institutions involved in this research.

Results—Trial conversations with providers at diagnosis were uncommon and often overwhelming. Most participants delayed engagement until later in the disease course. With hindsight, though, some wished they considered trials earlier. Difficulty identifying appropriate trials led some to defer searching to providers, but then they worried about missed opportunities. Most family members felt unqualified to search.

Conclusion—Trial conversations during clinical encounters should start early and include specifying search responsibilities of providers, patients, and family. Patients and family members can be engaged in searches but need guidance.

Practice Implications—Trials should be discussed throughout the disease course, even if patients are not ready to participate or are not making a treatment decision. Education should focus on identifying trials that meet search criteria. Transparency regarding each individual's role in identifying trials is critical.

Keywords

Oncology; ovarian cancer; clinical trials; women; qualitative research

Introduction

Clinical trials advance the science of prevention, detection, treatment, and quality of life [1]. They may be especially important in the context of ovarian cancer (OC), a disease characterized by late-stage diagnosis [2], persistently high mortality rates [3,4], and high rates of drug resistance and tumor recurrence [2]. Clinical trials may expand the number of available treatment options for OC patients [5,6] while advancing scientific discovery.

Only about 5% of adult cancer patients enroll in trials [7,8], and **existing literature has identified several** barriers [9-13]. Less attention has been given to questions of how and when patients search **for trial opportunities even though** lack of awareness about trials is an enrollment barrier [9]. Understanding patient information-seeking behaviors is critical because providers' negative attitudes about trials **can be a limiting factor in trial conversations** [14,15]. This is especially important **for** patients with OC **who** need access to the full range of treatment options at the time of diagnosis [16], in part because early treatment choices may preclude later trial participation [17].

Publicly-available websites are one avenue for disseminating clinical trial information. [ClinicalTrials.gov](https://www.clinicaltrials.gov) **indicates** it “provides patients, their family members, health care professionals, researchers, and the public with easy access to information on publicly and privately supported clinical studies.” However, little is known about how patients and family members perceive their role in trial searches. The purpose of this study was to examine OC patients' and their family members' experiences of learning about trials **and to better understand** whether they actively search for trial opportunities. This **research** was performed as part of a **study designed to describe OC patient and family member** experiences with learning about trials and making decisions about trial enrollment. The perspective of family members is important because they can play information support roles for cancer patients [18]. However, little research extends to their role in identifying trial opportunities.

1. Methods

Qualitative inquiry is useful for understanding individuals' accounts of their realities, including **myriad** factors that occur outside the clinical setting [19]. This study uses an approach similar to applied thematic analysis [20], **which** proposes systematic, inductive research for the purpose of addressing practical problems. In addition to disseminating results to a broad audience interested in clinical trials and patient education, we aimed to inform clinical practice.

Data collection **occurred** January 2012 to December 2014. Patients were referred by gynecologic oncology providers at Mayo Clinic (**MC**) (Rochester, Minnesota) and the University of Chicago Medicine (UC) (Chicago, Illinois) using a purposeful sampling strategy [21]. Eligible patients had a diagnosis of epithelial ovarian, primary peritoneal, or fallopian tube carcinoma; had been presented a trial opportunity at one of the institutions; and were able to nominate at least one family member (biological relative or "social family" member) **who** was important to their decision making to potentially participate in a separate interview. This study was approved by the institutional review boards of **MC** and **UC**; all participants provided informed consent prior to being interviewed.

The primary method of data collection was semi-structured individual interviews using a guide reviewed by OC patient advocates (see Table 1 for specific questions related to learning about trials; data from other interview questions were also analyzed). Interviews were conducted by investigators not involved in patient care, and field notes were recorded immediately following each interview to begin reflection on the data [21]. Audio files were transcribed and reviewed for accuracy. Participant demographics were ascertained through a survey; patient disease characteristics, including stage at diagnosis and diagnosis at interview (initial diagnosis, recurrence or remission), were collected through electronic health record review. Participant recruitment ceased when the **investigators** (through concurrent interviewing and analysis) determined that data saturation had been achieved.

Investigators included experts in psychology, sociology, family studies, and health services research. The inclusion of multiple individuals with different theoretical backgrounds allowed interpretation from different disciplinary perspectives [21]. Oncology providers aided in interpretation. The **investigators** reviewed transcripts and field notes, and discussed potential codes to segment and organize the data; these codes were documented in a detailed codebook. At least two individuals independently coded each transcript; **they subsequently** met to discuss **and harmonize** coding before transcripts were entered into qualitative analysis software (NVivo 10.1, QSR International Pty Ltd.). Interpretation involved re-reading segments of coded data for particular topics or domains, writing analytic memos, grounding findings in the existing literature, and identifying areas for action or further **inquiry**. Participant characteristics were used to aid in interpretation as appropriate. Findings from the two sites were not distinctly different, so they are reported in aggregate.

2. Results

Thirty-three patients (27 MC and 6 UC) and 39 family members (35 MC and 4 UC) participated. **Individual** interviews were conducted in-person (n=15) or by telephone (n=57) per participant preference. The mean **interview** duration (including all questions outlined in the study) was 48 minutes (range 20-77). Patients' mean age was 59.2 ± 9.9 (range 36-76); 93.9% (n=31) self-identified as white, non-Hispanic. Fifty-five percent had a bachelor's degree or higher (n=18). Mean age at diagnosis was 56.6 ± 10.9 (range 34-76). Seventy percent were diagnosed with Stage 3 cancer (n=23) and 18.2% were diagnosed at Stage 4 (n=6). The remaining patients were Stage 1 or 2. At the time of their interview, 69.7% were experiencing a cancer recurrence (n=23), 21.2% (n=7) were in remission or showing no evidence of disease, and 9.1% (n=3) had received an initial diagnosis.

Family members included spouses/partners (n=13), adult children (n=9), siblings (n=6), parents (n=3), friends (n=6), and others (n=2). Family members' mean age was 56.0 ± 13.4 (range 25-81); all family members self-identified as white, non-Hispanic. Fifty-nine percent had a bachelor's degree or higher (n=23).

Thematic analysis yielded findings in three overarching areas: timing and hindsight; trusted sources and gatekeepers; and cautious family support. Themes are summarized below along with representative quotes. Patient quotes include age at diagnosis in years (y), stage at diagnosis, and diagnosis at interview. Family member quotes are identified by relationship to the patient.

Timing and hindsight

Participants often responded to questions regarding how they learned about trials and whether they searched for them by telling stories about their first experience hearing about a trial in a clinical context. Although most patients had general knowledge of trials, one-third of patients reported that their first direct exposure to a trial was when one was offered as a treatment option at diagnosis. These patients were typically given a trial option alongside other chemotherapy options in the period just following surgery; this was consistently described as an emotionally overwhelming and confusing time. One patient described being in the hospital, and her confusion about the options presented, some of which required placing a chemotherapy port. Another patient **described her oncology appointment**: "So I had to decide right then and there the frequency of my chemo treatment, whether I wanted to do it once a week for 6 weeks or once every three weeks for the next 18 weeks. So I had to decide that and I had to decide whether I wanted to be on the clinical trial... That was my first visit with the oncologist [after surgery] and I mean, I literally had no idea what was going on." (50 y, Stage 3C, recurrence) Only three patients reported actively searching for trials or asking healthcare providers about trials at diagnosis. Two had backgrounds in the sciences.

In contrast to the limited active searching taking place at diagnosis, **patients reported increased receptivity and action** at disease recurrence or progression. Some of these participants lamented that they wished they had started considering trials earlier, especially those who **learned** eligibility may be limited by treatment experience, such as this spouse:

“Being she has already had 8 different chemos, you know, that normally eliminates her right away for anything.” Another spouse said he and his wife had started to think about trials as a way to reserve other treatment options: “I mean we have done great for 9½ years, but we know there are only so many drugs to fight this, so anytime you can get on something outside of the normal, you know, it can leave some of those other normal drugs as still an option down the road - where the trials may or may not be available down the road.” None of the participants talked about having this foresight at diagnosis.

Trusted sources and gatekeepers

Overwhelmingly, when patients commented on where they would go for trial information or how researchers should promote trial opportunities, they cited doctors as the most trusted source. Following initial treatment, though, patients also reported searching out information from other sources, including other patients. Talking with other patients increased understanding of clinical trials and changed perceptions of them as “last resort” options. Several patients talked about joining advocacy or support groups. Hearing about successful trials left them feeling energized and excited about scientific discovery. Several women said they went online or approached providers about trials after hearing these stories.

“I attended a national conference and they talked a lot about clinical trials and the importance of trying to find one because they use the latest and the best treatments. And, so I read up on it; I went online about it; I talked to friends about it, and I was convinced that that was probably an option for me.” (70 y, Stage 3, recurrence)

Despite growing interest in trials, most patients said it was difficult to sift through search results to identify appropriate trials, so many eventually deferred the role of gathering information to their healthcare providers, even if they wanted to be involved. Several patients described their search strategy as asking providers about available opportunities at each office visit. They **deemed** providers better able to make sense of the information and filter it to identify appropriate trials. That was true for the following patient, who described having spent months looking for trials. She wanted to be engaged in trial searches, but she said she needed more help understanding how to search for trials that met her disease criteria.

“You read them and they are pages and pages, and then you get down and you find that, oh, no, I don't qualify for this one. Or they ask you for like your biomarkers or if you had a gene test and then you don't know.” (70 y, Stage 3, recurrence)

Participants worried their lack of knowledge would result in missed opportunities; they assumed providers were knowledgeable about new scientific developments at various institutions. Some described providers as advocates who searched for trials on their behalf. Others, especially **patients** being treated in facilities without trials, voiced concern that their provider left them to their own devices. More than half of the patients in this study (n=19) were initially diagnosed outside of the two comprehensive cancer centers.

“I asked my own doctor, do you know of any clinical trials at this time? And he said, ‘no, I do not, but you can go online at such and such’...And I tried to do that’...So I did get a second opinion and he said to me, ‘there are no clinical trials

for you at this time that I know about, but you could keep calling and keep trying to see if you qualify for something.” (70 y, Stage 3, recurrence)

One spouse, who along with his wife was searching nationwide for available treatment options, noted the potential for missed opportunities from being in the wrong place: “We were worried that we were going to miss the boat – that somebody may have something really good somewhere that could save her, and we were in the wrong place...As science is, it's a crapshoot. She says, ‘you know, it is geographical.’”

At least two participants questioned whether providers should have raised the possibility of trials earlier. The following spouse suggested that doctors were the best avenue for informing patients about available trials, but at the same time, he questioned whether his wife's doctor waited too long to present the option.

“And in [patient's] case, using so many different [chemos] that she didn't qualify for trials. You know, it seemed to me a little backwards that we weren't aware of that and it wasn't even suggested to us that trials might be a way to go to start with. And then, you know, fall back on the chemo regimes if that isn't working out.”

Several patients said they were uncertain whether their provider was actively searching on their behalf, although some assumed a behind-the-scenes process. Patients consistently talked about long-term relationships with trusted providers. That trust potentially extended to information filtering for this participant: “I had to bring information to my doctor and I was kind of disappointed in that. But, you know, she also protects you, too...not protects you from trials, but I'm sure timing is everything and you have to be at a certain stage or certain place. You know, trials aren't for everybody.” Despite this sentiment, the participant later said she was unsure whether her provider remembered that she was interested in trials, and she noted that she would feel more reassured if her provider revisited the topic of trials with her.

Several **participants, including the following spouse**, said they wished they would receive targeted trial notifications from providers; e.g., emails, when potentially appropriate trials became available. “You know, even a newsletter or just some kind of mailing or update to say this is what we are working on. One, it kind of keeps giving you that hope that there is new stuff coming...and at some point that may lead to a conversation of, hey, I've been on this for a while, but it looks like there is some trial open – what do you think? And that kind of opens the conversation with the doctor. And, obviously, it has to keep the doctors on their toes to be able to *respond to all of those as they go*.” Another spouse said communication about trials at various institutions should be an expectation.

Cautious family support

Only one family member reported actively looking for trials for the patient at the time of diagnosis, and only two reported attempting internet searches on behalf of the patient after disease recurrence. Spouses in particular talked about searching for trials alongside the patient **rather than separately**: “We tried to look online for trials. Her brother looked online to see what might be available... I didn't find a lot – too much online myself, her brother is really investigative and he found some stuff and referred it to us.”

Family members often expressed concern about their ability to understand trial information, and almost no family members stated they would be able to identify appropriate trials. However, while active searching for opportunities was rare, searching for specific information was more common; almost all respondents answered affirmatively that they would seek out information if they heard about a new drug trial, primarily by turning to the internet to learn more about it before passing information along to the patient. Some said they worried about raising patients' hopes only to find out the trial was not available or not appropriate, as was the case with this sister who shared information from a news story with the patient, but only after calling trial staff to learn more: "Because I didn't really want to do anything if she wasn't, my feeling was that she would want to, but also from another standpoint, she has just been through so much, for so long before ...then I'd start feeling...that I was the one who told her about it."

Most family members deferred the role of identifying trials to providers or the patients themselves, who were seen as being more knowledgeable of search criteria like disease characteristics and treatment history. However, not all family members closed the door completely to this role, including the following friend: "...because I know that she felt – that made her feel more alone. I think if there is a way to kind of hold the friend's and family's hand to learning about clinical trials too, or feeling confident enough to research them, that would be really a bonus to the patient."

4. Discussion and Conclusion

4.1 Discussion

This study provides first-hand insights into OC patients' and their family members' experiences regarding how they **learn about or** search for clinical trials. These perspectives further our understanding of barriers to trial enrollment by examining the necessary precursors to successful enrollment, such as exposure to trial information and identification of appropriate trial opportunities. Patients can be informed of trials in clinical encounters, but this study also aimed to understand whether they engage in their own trial searches and if their family members participate.

Similar to other studies [22-25], this study found that there may be times, such as at diagnosis, when patients are too overwhelmed to consider trial information. However, patients in this study also talked about "planting the seed early," **regardless of readiness to participate**. Some suggested newsletters or mass media human interest stories as a way of raising clinical trial consciousness. When patients in this study were presented trials at diagnosis, it was done in the context of treatment decision making rather than education. Our findings suggest that *routine* conversations about trials might change perceptions of trials as "last resorts" or at least pave the way for future conversations.

Likewise, our finding that women are particularly interested in trials at recurrence is consistent with others [26], but reserving trials for later in the disease course may actually limit trial opportunities [27,28]. Two-thirds of patients did not report being offered a trial at diagnosis, and with the benefit of hindsight, these participants wondered if trials should have been brought up earlier. It is important to note that none of the participants reported having

that foresight at diagnosis; this is critical in a disease like OC. Extensive treatment with multiple lines of chemotherapy did preclude some study participants from available clinical trials.

It is important to address the perception among healthcare providers and patients that trials should be reserved for advanced disease. This recommendation is in line with the American Society of Clinical Oncology's call for new educational strategies aimed at changing providers' perceptions: "Determining a patient's needs, values, and preferences requires that the clinician present the option of participating in a trial during initial care planning, rather than after all other treatment options have failed" [16]. We found that one active strategy held by patients later in the disease course was to ask providers at each clinic appointment whether a trial was available. Some participants suggested that they trusted their providers, as most had been involved in their care for an extended time, and patients assumed he or she would tell them if a trial was available. However, lack of transparency left some participants wondering if the provider was filtering information and ascertaining nothing was available or whether the patient's interest had been forgotten. **This is a key and novel finding from our study.**

Having providers share responsibility for initiating the topic early could allay concerns that providers would not be receptive to their involvement in trial searches. Healthcare provider referral may also be important for identifying reputable information sources [29]. Interaction with other patients (e.g., in support groups and conferences) also prompted some patients to actively search for and talk with providers about trials. Provider referrals to these groups might provide another avenue for patient education.

Websites such as [ClinicalTrials.gov](https://www.clinicaltrials.gov) have been developed to provide access to trial information [30], but our findings reveal that individuals continue to face substantial burden searching for trials on their own. Even though most participants in this study had high levels of educational attainment, many were frustrated by the experience. These participants may serve as a best case scenario in terms of education and search skills, but even the two patients with scientific backgrounds said they needed providers to help them filter the information they found online. Participants in this study provided practical recommendations for future patient education interventions, including informational DVDs and personal demonstrations of how to search websites for trials that matched disease criteria. Three patients said they had individuals at the American Cancer Society® perform trial searches for them, but these searches were not integrated into clinical conversations and patients did not report learning search skills.

Importantly, several patients were uncertain about whether their healthcare provider was keeping them in mind for trial opportunities, or they assumed providers were searching on their behalf. Explicit conversations about the extent to which the clinical team and patients or family members will search for trials within the institution or at other health care institutions may allay worries about "missed opportunities" and protect against incorrect assumptions. Moreover, explicit conversations with every patient about their preferences would allow them to participate to the extent they choose. This is necessary to address known disparities in who is invited to be in clinical trials [31,32].

This study included the perspective of family members, which is important because they can potentially alleviate some of the trial search burden for patients. [Clinicaltrials.gov](https://www.clinicaltrials.gov) lists family members as a potential audience for its trial information. However, our data reveal similar barriers to trial searching and filtering **among** family members, especially if they have less knowledge of patient disease characteristics related to trial eligibility. While family members rarely searched for trial opportunities for patients, several noted they would potentially pass along information that they heard about, possibly after conducting an internet search on the trial. Our findings put actual family member voices behind calls to pay greater attention to caregiver cancer literacy and the role caregivers play in providing high-quality information to patients [33,34], especially in light of family participants' fears about worsening the patients' situation or raising false hopes.

This study's strengths include use of an interview guide informed by OC patient advocates/survivors who themselves had experience searching for clinical trials. We used a systematic analytic approach [20] **that benefitted** from multiple disciplinary **perspectives and** investigator triangulation [21]. Our study also has caveats. First, our findings describe changing perspectives across the disease trajectory, yet our study design was not longitudinal. This was possible because patients **shared their history of** trial experiences. Second, this study was conducted at two comprehensive cancer centers in the Midwest **and** is limited by sample homogeneity, including racial and ethnic homogeneity. Patients facing the greatest barriers to clinical trial information may not have been included in this study. **Continued efforts are needed** to address unequal access to and enrollment in clinical trials. Recruitment in two settings that serve a different overall patient demographic **attempted to** achieve greater diversity, but limited numbers of open trials at UC and a shorter recruitment period hampered enrollment; **moreover**, it likely limited our ability to see differences between settings. The sample was also relatively homogeneous in terms of the disease profile of patients; 88% were diagnosed with Stage 3 or 4 disease. While this is consistent with national statistics showing only 15% of OC cases are diagnosed **at the earliest stages** [2], we had a limited ability to understand the experiences of patients with early stage diagnoses. Finally, our study focused on OC, as this particular cancer provides an excellent context in which to study clinical trial issues. Findings from this study may be transferable to other disease contexts marked by late diagnosis and high rates of recurrence.

4.2 Conclusion

This study extends what is currently known about patient exposure to clinical trial information and patient and family member engagement in trial searches. Most notably, patients may not search for trials at diagnosis, but in hindsight wished they had been exposed to them earlier. Even with interest in trials, many patients and family members may lack self-efficacy to search for them and instead defer searches to providers. Importantly, there can be lack of clarity regarding expectations, and some patients may make (incorrect) assumptions about healthcare providers' roles in identifying trial opportunities. The recommendation to create explicit conversations with patients represents a modifiable pathway to avoid missed opportunities. Conversations in the clinical context can address both providers' responsibilities to present trials and opportunities to engage patients outside the clinical context.

4.3 Practice implications

Providers should engage patients in early and on-going conversations about trials, be transparent about roles and responsibilities, and encourage patients to actively look for trials if they choose. Education should focus on identifying trials that meet search criteria. On-going conversations about trials, including those identified by patients or family members, may allay worries about being unqualified to perform searches and potential missed opportunities. These findings are critical **given** efforts to increase individual access to trial information using platforms like the internet.

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Highlights

- Patients may delay trial searches but regret it later in the disease course
- Patients may want to learn about trials even if they are not ready to participate
- Patients may make assumptions about provider roles in extensive trial searches
- Family members may provide support for searches, but they worry about raising hopes

Table 1

Interview Questions Related to How Patients and Family Members Learn About Clinical Trials

<p>1. How do patients and family members find out about clinical trials that may be going on?</p> <p>2. Have you ever tried to find information on research opportunities or clinical trials on your own?</p> <p>(If yes): Describe your experience to me.</p> <p>(If no): Okay. Imagine you heard about a new cancer drug being developed in a clinical trial. How would you go about getting information on it?</p> <p>3. What do you think would be good ways to get the word out about new clinical trials that are just starting to enroll patients?</p>

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