



Barriers for cancer clinical trial enrollment: A qualitative study of the perspectives of healthcare providers

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ABSTRACT

Background: Barriers to clinical trial enrollment have been the subject of extensive research; however, the rate of clinical trial participation has not improved significantly over time. Studies often emphasize patient-related barriers, but institutional and organizational barriers in the health care system may have a more substantial impact on clinical trial participation.

Objective: To qualitatively identify perceived barriers to clinical trial participation based on perspectives from healthcare providers.

Design: Qualitative research design with a phenomenological approach was used. A purposive sample of 18 healthcare providers participated in an in-depth focus group session. Participants were involved in cancer care and clinical research from a large hospital in the United States Midwest region. Data were transcribed, coded, and systematically analyzed through thematic content analysis.

Results: The data revealed four levels of barriers to clinical trial enrollment, with emergent themes within each level: patient (beliefs or trust, distance to trial sites, health insurance coverage, language, and immigration status), provider (limited awareness of trial, time constraint, and non-cooperation from colleagues), clinical (eligibility criteria and clinical design), and institutional (policy and limited logistic support).

Conclusion: Healthcare providers face complex, multifaceted, and interrelated barriers to clinical trial enrollment. To overcome these barriers, health care organizations need to commit more human and financial resources, break down boundaries for more efficient inter-departmental cooperation, develop more coordinated efforts in promoting trial awareness and participation, and remove unnecessary regulatory barriers.

1. Introduction

Clinical trials act as the backbone of cancer clinical research and are critical for developing new treatments and improving health outcomes [1]. However, while most Americans (70%) view clinical trial participation favorably, only 3%–5% of eligible adult cancer patients participate in clinical trials [1,2]. Low enrollment in cancer clinical trials leads to delays in the advancement of cancer research, as well as an escalation in the cost of developing and disseminating effective cancer treatments [3,4].

Researchers have identified a wide range of factors that hinder patient participation in clinical trials [1]. Factors impacting motivation to participate in clinical trials include patient attitudes, perception of clinical trials, limited awareness, and willingness [5,6]. A complex clinical trial design with strict inclusion and exclusion criteria limits the

number of eligible volunteers. Inconsistent trial implementation and inadequate recruitment strategies or planning may result in limited enrollment in clinical trials. Provider familiarity with and access to clinical trials is another often-cited barrier to clinical trial participation [1,2].

Healthcare providers play a vital role in advising, motivating, and directing patient participation in clinical research. Several studies have revealed that patients consider doctors and nurses the most trustworthy source of health and medical information, including clinical trials [6–8]. A majority of patients (84%) suggested that they would consider participating in clinical trials if their physician recommended it [9]. As the number of clinical research activities increases, healthcare professionals are anticipated to play a more significant role in identifying, recruiting, and assisting patient participants in clinical trials [10].

Despite advancements in clinical trial research, limited studies in the

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literature were focused on healthcare providers' perception of and experience with clinical trials [9]. Current research indicates a need for assessment of healthcare provider's attitudes towards clinical trials, as well as their capacity to engage and support patients' clinical trial participation [9,11]. Using a qualitative approach, the present study sought to examine healthcare providers' experiences, perceptions, and recommendations about patient participation in cancer clinical trials.

2. Materials and methods

2.1. Study design and participants

A qualitative phenomenological approach was utilized to understand healthcare providers' roles, feelings, opinions, experiences, and clinical trial enrollment recommendations that are difficult to capture quantitatively [12]. This approach focuses on investigating a phenomenon by illuminating the experience and understanding the meaning attributed to it by participants [13]. It is phenomenologically a social constructivist philosophy and is predicated on the sociocultural and historical interpretation of experiences and life [14]. This involves an iterative process seeking an understanding of a participant's perspective to develop a broader picture of their lived experience [15].

Participation eligibility was limited to individuals who provide direct care and treatment to cancer patients. This population included but was not limited to oncologists, nurses, and surgeons. A purposive sampling method was used to recruit 18 oncology healthcare providers (11 male, 7 female) across various demographic groups from a large hospital in the Midwest region. Participants ranged in age from 30 to 60 years. A majority of the participants were non-Hispanic White (13 out of the 18 participants). Two-thirds of the participants were oncologists, with the other one-third being nurses and oncology surgeons.

2.2. Data collection

Data were collected during the summer of 2016 utilizing a semi-structured focus group discussion lasting approximately 60 min. The discussion questions were developed to elicit participants' perspectives, context, and experiences of clinical trials focusing on perceived barriers/challenges related to recruiting diverse patients in clinical trials. The discussion was facilitated by a moderator and audio-recorded with the permission of the participants. The moderator asked participants a series of questions using a semi-structured interview guide with open-ended questions and additional probes when needed (Table 1).

The interviews were recorded with a digital recorder, and the sound quality was tested and deemed sufficient quality for recording. The focus group moderator made sure to create an atmosphere of respect and openness so that responses would be spontaneous and appropriate without creating any unnecessary conflict or argument. The recordings were transcribed verbatim by the research personnel involved in the study.

Table 1

Focus-group interview key questionnaires with healthcare providers.

1. How did you learn about clinical trials, and overall, what's your general thoughts about them?
2. What do you think most healthcare providers or colleagues in your hospital think about clinical trials?
2a. Follow-up: Can you elaborate?
3. If these are the barriers, then what are some of the solutions? So if you were to change this and improve clinical trials here, what would that process look like?
4. What would you suggest needs to happen for stakeholders to come on board and have same perspective as say you do?
5. Talk about the any barriers or changes with patient recruitment?
5a. Follow-up: what do you think some those challenges are to enrolling minority patients in the protocols?

2.3. Ethical considerations

The Institutional Review Board at the study team's institution approved this study (IRB# 722-15-EX). The study objectives and voluntary participation were explained to participants, and oral informed consent was obtained before the beginning of the focus group. Confidentiality was assured by using numbers instead of names (e.g., Male and Female 1, 2, 3, etc.) and by removing identifying information such as name and affiliation from the transcripts before data analysis. All audio recordings and transcripts were saved on a password-protected computer. The Standards for Reporting Qualitative Research (SRQR) guidelines were followed throughout this study [16].

2.4. Data analysis

The data were analyzed using NVivo version 12. Colaizzi's method [17] was used to analyze the transcript. The analysis consisted of multiple steps, including reading the transcription of the focus group several times to acquire a feeling for the participants and their responses, identifying significant phrases and restating them in general terms, formulating meanings, and validating meanings through research team discussions to reach consensus, identifying, and organizing themes into clusters and categories, and developing a full description of themes.

Two members of the study team (GK and PC) independently coded the transcripts using thematic content analysis [18]. The two members analyzed the transcripts in two stages. First, each member independently analyzed the transcripts and applied initial codes. Then the two members met and discussed their results and recoded the transcripts based on their discussion over the emerging themes. During the second stage, the two members compared their updated codes and established the themes together based on their joint review of the codes. Cohen's kappa was used to quantify the degree of agreement between the two research members in their coding [19]. The kappa score for this study was 0.91, suggesting a high degree of agreement between the two research members in their coding of the transcript.

3. Results

3.1. Introduction to clinical trials

In the focus group discussion, participants were asked to describe how they first learned about clinical trials. Most respondents indicated they were introduced to clinical trials early in their respective schooling, with a few of the participants learning about clinical trials before entering medical or nursing school. For example, two of the respondents were introduced to clinical trials while working as a clinical research assistant and working at a summer internship at the ages of 18 and 20, respectively. Other participants learned about clinical trials during medical or nursing school – "I learned about it as a third-year medical student" [Male 3], "I was a medical student...and a clinical fellow" [Male 11], "I was in nursing school" [Female 3], and "I learned about them in nursing school, of course, [and] I was hired to coordinate them in 1993" [Female 6].

3.2. Barriers to clinical trial recruitment

Four levels of perceived barriers to clinical trial enrollment were identified (Table 2). These perceived barriers included: 1) patient-level barriers related to clinical trial participation (ie. beliefs or trust, distance to trial site, health insurance coverage, language, and immigration status); 2) provider-level barriers (i.e., limited awareness of trial, time, and non-cooperation from colleagues); 3) clinical-level barriers (i.e., restrictive eligibility criteria and complex clinical design); and 4) institutional-level barriers (i.e., lack of policy and logistic support). These barriers can build upon or reinforce each other across all identified levels.

Table 2
Themes and Codes related barriers to clinical trial enrollment.

Level of Barriers	Codes on Specific Barriers
• Patient	• Beliefs/attitude or mistrust, distance to trial site, health insurance coverage, language, and immigration status
• Healthcare providers	• Limited awareness/knowledge of ongoing clinical trials, time constraints, and non-cooperation of colleagues
• Clinical	• Strict eligibility criteria and complex clinical design
• Institutional/Structural	• Policy, limited logistic support (staff, financial, and IRB)

3.2.1. Patient-level barriers

Multiple challenges were identified by the focus group participants at the patient level. Some of these concerns include patient beliefs/trust and were frequently arisen by the participants followed by health insurance coverage, language, and immigration status.

Participants indicated that patients expressed concerns over the potential quality of care they may receive, indicating patients' mistrust of experimental procedures, trust surrounding fair and equitable treatment, and fear. One participant discussed patients fearing "...being treated like a guinea pig. And the number of times that I hear about that can be surprising, and it's more profound with minority groups, because there's an inherent trust issue about how they're being treated, equitably or not" [Male 2]. Participants suggested that patients want assurance that "...the standard of care that they're receiving is in fact already the best care available, and this [clinical trial] may be better or surpass it or, perhaps, not be inferior. And that's really the assurance the patient wants" [Male 11].

Participants also shared patients' concerns about over-relying on the computer for conducting randomization in clinical trials.

"... .. like the randomizations thing. A lot of my patients were all okay with clinical trial, but then they said, "Do you know what? Why don't you decide what I should be on? I don't want the computer to decide. I want you to decide what side I should be on." And so they won't enroll in a clinical trial because they would rather the physician that they know and trust to make the decisions, instead of – and even when we said we don't quite know which side is good, they said, "Well, use your gut instinct. It's better than a computer." So we have that as well, and you can't explain." [Female 7]

Distance or proximity of the patient to the clinical trial location was a common barrier perceived by the focus group participants. One participant stated, "Part of problem I encounter when a patient cannot enroll, it's because of distance... .. probably like 30, 40 percent of our patients travel over 100 miles to come here. And so it's hard for them to travel that distance to get a lot of things done. So a few of them can't be enrolled in a trial because of that" [Female 7].

Focus group participants identified language barriers as an important challenge in gaining patients' trust, especially with regard to minority populations. One participant linked it to the language issue: "[I]f I'm consenting a patient for surgery and the patient speaks Spanish, I have a Spanish consent. But if the patient speaks Vietnamese and Lao or anything else, they use an English consent. So how is that equitable? But if anything else [other than Spanish], I have to use the phone, and that's just the reality of how things are. So if your patient doesn't speak English, like the problem of talking about a clinical trial, like double, triple, it went up exponentially. There's no way you can communicate and explain the risk and benefits of a clinical trial...unless you speak the same language as the patient." [Female 5].

Of note, the Hispanic population in the study area increased from 167,399 to 215,872 between 2010 and 2018 and continues to rise [20]. There is a palpable fear of participating in clinical trials among undocumented immigrant patients: "I did have a minority patient...[who] said to me that there was a fear of going on clinical trials because they were not documented citizens, and that being put in a database would make them more at risk" [Female 3].

Finally, participants mentioned patient insurance does not cover clinical trials due to their experimental nature.

"I had a couple of patients that their insurance wouldn't cover clinical trial." [Female 2]... "Yeah, because it's experimental." [Female 7]

3.3. Provider level barriers

Oncology healthcare providers and staff reported unique challenges at the provider level regarding clinical trial participation. Some of the most frequently cited challenges include time constraints, limited awareness of trial, and non-cooperation from colleagues. In the clinical setting, the expected appointment length is typically only 15–20 min, which is inadequate to verify patient eligibility, explain in detail to the patient about the trial, and answer questions to help the patient make an informed decision.

"And I agree that in a clinical setting, you are expected to see a patient every 15 or 20 minutes or whatever it may be. First of all, those kinds of encounters are rarely, if ever, 15 or 20 minutes. They always go beyond. And now you're talking about doing justice to a clinical trial, and more importantly to the patient (...)." [Male 4]

"I'll see you another time to discuss the clinical trial, rather than having the time or the resources to allocate more time to that. And so you may just choose to go to the next line of therapy off of clinical trial." [Male 1]

Participants identified a lack of awareness of clinical trials as an important barrier to patient engagement and enrollment. For example, one participant stated, "Well, it's also the case that many of us don't realize some of the trials that are in fact ongoing, and not just in our areas, but in other areas." [Male 11].

Finally, some of the focus group participants also struggled with the non-cooperation from departments outside oncology. One of the participants relayed the experience of patients' primary care providers dissuading them from participation in clinical trials: "A couple of people, their primary provider said, 'You really don't want to go on protocols'. I think overall, though, when you look at the non-oncology, they really see it as a pain." [Male 4].

3.4. Clinical level barriers

Participants identified a wide range of clinical trial complexities which hindered patient participation in clinical trials. The eligibility criteria of the trial were most identified by the participants, followed by complex clinical design. Providers were particularly concerned about restrictive eligibility criteria: "Some trials are just harder to enroll because the criteria are so strict." [Female 7].

Providers further identified clinical trial design and implementation complexities as a barrier. "Really, when you're doing informed consent, it involves not only the physician but also the research nurse that's working with the clinical trial to help make sure that they understand the complexity of the logistics and the risk/benefit of the clinical trial, and that takes a lot of time, both within the care encounter, but also potentially multiple encounters that would not otherwise have existed if they weren't going onto a clinical trial." [Male 1].

The issues discussed above culminate in a much larger and overarching issue with clinical trials - recruiting enough patients to meet the target sample size. "I don't know how many of our clinical trials actually get five patients or actually meet their intended goals that we submit to the Institutional Review Board and the Scientific Review Committee... we have to project a magical number of five patients, depending upon the situation, onto a clinical trial, for it to even be considered to move forward." [Male 6].

3.5. Structural/institutional level barriers

Most of the challenges identified by the focus group participants centered on the structural or institutional level and begged the question of defining the institutional identity. As one participant explained, "I think it's a battle for the heart and soul of what the university is going to be.

Are we going to be an academic medical center that's going to generate research and generate new science? Or are we going to count beans with science?" [Male 5]. At the time of the focus group, the university followed a relative-value-units (RVU) remuneration model, where providers' salary is based on RVU production. The focus is placed on events, such as surgeries, whereas most activities related to clinical trial organization and execution do not count towards RVU-based salaries. This disincentivizes practitioners from promoting clinical trials to their patients, as one participant commented:

"If you create a model which is based on event-based remuneration then the cognitive side of things will take a back seat, which means that it's easier for me to convince a patient to go to the operating room than for me to say, Let's stop and not do this. That takes more time. But it does not remunerate me, because I'm not providing that service" [Male 4].

This revenue-based model makes it challenging to get inter-departmental support for clinical trials as well. Clinical trials require inter-departmental cooperation, and cooperation is difficult to obtain because RVUs often do not get equitably disbursed amongst included departments. One participant explained:

"...I needed to go to radiology and have someone help me do measurements for data for a clinical trial, and it was very time-consuming, and they're also incentivized to do certain things. And so when someone comes from a clinical trial where there's no benefit to them [radiology], specifically to their department, they don't see that as valuable use of their time" [Female 3].

Another participant expanded on this:

"You can even lead a horse to water. I mean, there are several times where we'll put in, like, these are the target lesions, you know. I mean, that seems to be just a whole other time-savings – we can try to be proactive, and yet they completely can ignore the mission of yes, this has identified already as a clinical trial patient". [Male 1]

Oncology providers routinely encounter bureaucratic barriers to implementing clinical trials. Without dedicated clinical trial staff or case managers, the bulk of the identification, enrollment, and follow-up sits with the providers themselves. One participant recounted the clinical trial process:

"Every trial that was added to the institution was the purview of a set of dedicated nurses, and every new patient that came to surgical/oncology clinic had their chart reviewed by the nurse to see to what extent the patient was eligible for any of the existing trials, and all I had to do was call that individual and say, 'I have a new patient with this condition. Would they be eligible for some of the trials?' And they would literally come down, review the chart, and say, 'She's eligible for this, this, and that'. And from then on, things were much easier, because they had a dedicated team to do that. For us to stop in the middle of a 20, 25 day patient clinic to talk to one individual who may be a candidate, sometimes all you can say is, 'Would you be interested?' and they say yes, but that's the end of the conversation unless you could make a phone call and have somebody come down, review the chart, and then right then and there tell you the patient is eligible, and subsequent to that, visits could be arranged to make sure". [Male 11]

Participants sounded a cautionary note about the limited support from the institutional side. One participant stated, "I think our organization as a hospital, as an institution, traditionally has not been very helpful with clinical trials. So, there's a bit of a problem there, and that could be improved." [Female 1].

Further, another participant identified limited resource allocation and stated that "We've recently had some changes and transition in my area, and surgical trials are hard to come by, but at the same time, when we went out to look for those resources, those resources have either dissipated or have not been replaced, and then we had to ask for help from a variety of sources. And fortunately, for example,helping me with a whole bunch of stuff ...,

but there's no specific motivation that I see from the institutional side to say, are we going to replenish these resources? So that makes it harder." [Male 4].

Another noteworthy barrier identified by the focus group participants is the institutional review board (IRB) and how it might delay the clinical trial approval process. There have also been instances of clinical trials being closed to enrollment due to delayed IRB review.

"Well, as an IRB number, I think it comes – a lot of it comes down to getting the protocols through the numerous committees in a timely fashion, whereas some institutions have central IRBs or outside – external IRBs, sorry, that the protocols go through faster. They meet more often. They have more of them. They're better at delegating what trials can go outside the institution versus need to be in the institution." [Male 1] "the trial closed by the time we got it through the IRB. It was 14 months." [Male 11].

Another participant quoted that "The other area is we have a second committee, the scientific review committee, which also sometimes slows it down quite a bit, although all NCI cancer centers have the same type of committee structure. But just because of all the various things, and also the contract negotiation for pharmaceutical company trials, and that's very prolonged here as well." [Female 1].

4. Discussion

To our knowledge, this is the first qualitative study that explored the perspectives and experiences of healthcare providers regarding their perceived barriers to cancer clinical trial enrollment and implementation, focusing on the Midwest region of the United States. Our study identified several significant scaffolding barriers at the patient, provider, clinical, and institutional levels. The range and diversity of the emerging themes (patient, healthcare, clinical and institutional) and codes illustrated the complexity of the issue and were generally consistent with the previously proposed cancer clinical trial decision-making framework focusing on patients, healthcare providers, clinical, and structural levels [1,2].

Although minority patients are overall as likely as white patients to enroll in a clinical trial [4], minority patients have unique reasons to decline participation. Some of the barriers to clinical trial participation at the patient level, as revealed by participating oncology care providers in this study, reinforce the importance of addressing patient perceptions of clinical trials including potential distrust in clinical research and fear of becoming a "guinea pig", especially among Black patients. Perception of discrimination was also common among Spanish-speaking patients, and both Latinx and African Americans were more likely to ascribe discriminatory associations to medical researchers than their white peers [21]. Trust was not the only barrier facing minority patients - participants also identified barriers of patient/provider language discordance and insurance coverage, which has been previously documented [22–25].

Multiple other factors also influence a patient's decision to participate in clinical trials. These factors include distance to clinical trial location, financial aspects, limited beliefs/trust in the clinical research, low diversity of staff, and immigrants' legal status and documentation. These findings parallel previous research, further underscoring the need to develop and implement appropriate primary interventions that can facilitate clinical trial participation for minority patients [22,26–28].

Healthcare providers play a critical role in facilitating or inhibiting enrollment in clinical trials. Providers' knowledge and awareness of available trials were identified as an important barrier. Perceived limited awareness of clinical trials at the institutional level was shown to be a major barrier to enrolling breast cancer patients into clinical trials [29]. Limited awareness, coupled with the rarity of clinical trials, has been identified as obstacle to including teenagers and young adults in cancer trials [30]. One study cited interdisciplinary structure at breast specialty clinics as a factor contributing to providers' lack of awareness of trials because such a structure fails to assign patients to a specific

provider [32].

Even when trials are available, providers might be reluctant to enroll their patients in the trials [1,32,33]. Time spent explaining clinical trials to patients and attending to clinical trial details can be a prohibitive time constraint barrier for providers, with the research possibly being construed as burdensome or upsetting due to the required time commitment [34]. One study reported that the burden associated with the clinical trial process was the only significant dimension associated with referring patients to early-phase clinical trials [35]. Physicians who felt burdened with logistical barriers such as diverting time and resources away from their practice were less likely to refer patients than physicians who did not feel burdened.

Non-cooperation from colleagues was another barrier reported by participants. Physicians' reluctance in referring patients to clinical trials may stem from a fear of losing patients to other care providers. One study reported that fear of losing patients was associated with all referral behaviors among physicians; however, this concern was more apparent among physicians from practices with lower levels of accreditation than those from practices with higher levels of accreditation [36]. The study concluded that to alleviate these fears, creative solutions must be identified and appropriately implemented to incentivize providers who feared the loss of patients after referral to clinical trials. Additionally, non-cooperation from departments outside of oncology could be due to a lack of trust and close working relationships. When promoting interdepartmental communication, it is critical to focus on adding value to the provider-patient relationship by expanding treatment options available to patients, as well as establishing a non-competitive relationship while respecting each other's relationships with patients [37,38]. According to the research of the National Cancer Institute's Community Clinical Oncology Program (CCOP), having a team of professionals committed to enrolling patients in control and prevention studies was associated with much higher enrollment than not having any dedicated personnel [39]. For example, research coordinators, patient navigators, and other research staff are needed for the recruitment strategy to be effective.

Healthcare providers in the present study reported trial complexity as an important structural barrier to patient enrollment. Previous research identified restrictive eligibility criteria, complex study design, and time constraints in the consent process as important structural barriers in trial accrual [2]. Specific eligibility requirements including, but are not limited to, age, gender, race and ethnicity, type of cancer, and stage of cancer exclude many patients from participation [40,41]. One study examined barriers to enrollment in non-small cell lung cancer therapeutic clinical trials among 183 patients with appropriate disease and stage of the disease [42]. Over 55% of these patients were ineligible for trial participation because of restrictive eligibility criteria (18%), need for emergent radiation (12%), lack of adequate staging information (6%), and comorbid conditions (4.9%). Findings from another study also suggested that patients with more comorbidities were less likely to qualify for trials [43].

Participating care providers in this study also identified a host of institutional barriers such as bureaucracy, lack of incentives, lack of inter-department support, stringent IRB protocols, insurance denial, and difficulty enrolling patients from another healthcare institution. These barriers were consistent with previous studies, and healthcare providers need to have organizational support from the institution to enroll eligible patients into trials [1,2,22,26,44]. Organizational contextual factors such as the infrastructure for implementing cancer clinical trials (CCTs) and organizational culture are also important in determining physicians' motivation for and success in recruiting patients [31,45]. Based on data collected from 481 physicians who were involved in NCI sponsored CCTs in 2011, one study found that physicians who practiced in programs that had more supportive policies and practices in place to encourage enrollment such as training, administrative support to screen and enroll patients, allocating incentives to enroll patients, and so forth, were able to enroll more patients [46]. This study also found that programs that mandated expectations for enrollment were more successful

in-patient accrual because of a strong sense of organizational commitment and social norms.

A separate study supported the need for a culture change among care providers to enhance clinical trial infrastructure at the organizational level [47]. Recognizing language barriers as cancer clinical trial recruitment barriers, one study highlighted the need for cancer care organizations to become more health literate [48]. Similarly, the Agency for Healthcare Research and Quality (AHRQ) purported language competency and outreach efforts as necessary elements to create health literate organizations [49].

Administrative and institutional support for physician CCT referrals can make a difference in patient accrual. An evaluation of enrollment data from CCTs sponsored by the National Cancer Institute (NCI) identified organizational factors associated with patient accrual among participating healthcare organizations [46]. This study revealed that physicians' participation in CCTs became more likely when organizations were providing consent and enrollment support, enrollment incentives, and mandated expectations for enrollment. Institutional structures such as organizational climate and research-specific resources also play a role in providers' ability to recruit patients to cancer clinical trials [31].

Effective accrual of patients into CCTs often requires close communication between primary care providers (PCPs) who want to refer their patients and oncologists who run clinical trials. Based on qualitative data from 27 PCPs, one study found that the strength of the relationship between PCPs and specialists played an important role in determining the likelihood of referrals [50]. PCPs usually send patients to specialists with whom they previously collaborated or whom they trusted. The study concluded that steps must be taken to strengthen communication between oncologists and referring PCPs to facilitate patient referrals by PCPs.

Dedicated clinical trial teams who are trained in research and dedicated to building and maintaining ethnic and racial diversity (including interpreters for multiple languages) would help reduce barriers identified at all levels. These dedicated teams could also focus on increasing funding from all trial sponsors, so that trial conduct is scalable and sustainable and create and implement protocols to make prescreening incoming patients for trial eligibility more scalable and systematic [51]. However, even multifaceted interventions will have only partial success if they occur in a vacuum; they must be implemented within institutions with the appropriate infrastructure to support trials that match the clinical characteristics of an engaged, diverse patient population [4].

Overall, our findings demonstrate a complex interplay between healthcare providers' perspectives related to the clinical trial recruitment process and factors affecting it. Healthcare providers indicated that institutional or structural factors had the most significant impact on their ability to accrue. Thus, the reallocation of resources and favorable institutional support would create an environment to increase not only clinical trial enrollment but also reduce structural barriers.

5. Strengths and limitations

One strength of this study is the systematic approach used in data collection and analysis to enhance the reliability and validity of the analysis: checking of transcripts against audio recordings and field notes taken and triangulation among coders by consensus to ensure rigor. Also, purposeful sampling was used to choose a wide range of providers with different experiences. Our study is distinct from previous research based on physicians' perceptions because we included diverse healthcare professionals who provide direct care and treatment to cancer patients, including but not limited to oncologists, nurses, and surgeons [28, 44]. The study also represents a rare effort in identifying barriers to cancer clinical trial participation based on perspectives from oncology care providers from the Midwest.

Despite the aforementioned strengths, this study has several limitations that should be considered when interpreting study findings. First,

conducting an hourly focus group discussion involving 18 participants might not be sufficient to give each participant enough time to share their perspectives. Future studies could consider organizing more sessions of focus group discussions with each session involving a smaller number of participants. Second, there is a potential for this study to be expanded by conducting similar focus group discussions amongst cancer patients served by the same hospital to collect additional feedback, which will complement findings from this study and better inform the design of future program efforts in promoting cancer clinical trial participation among diverse patients. Finally, qualitative findings from this study were based on perspectives from oncological care providers from one large hospital in the Midwest and they might not be generalizable to other healthcare institutions and may not represent all oncology healthcare professionals. Future studies can improve the external validity of our conclusions by engaging and collecting perspectives from oncology care providers across clinical settings (e.g. teaching hospitals, non-teaching hospitals, a hospital with a dedicated cancer center versus one without; a site that is deemed high accruing to clinical trials versus one that is low or non-accruing) located in various states, which will facilitate comparative analysis of barriers and facilitators for clinical trial participation across clinical settings as well as the development of tailored strategies for recruiting diverse groups of patients into cancer clinical trials.

6. Conclusion

Healthcare providers offered unique insight and identified scaffolding barriers related to the clinical trial recruitment process, which build upon each other across the patient, provider, clinical, and institutional levels. Addressing these barriers requires that healthcare organizations commit more human and financial resources, break departmental boundaries for more coordinated efforts in promoting trial awareness and participation, and remove specific regulatory barriers that have hindered or discouraged clinical trial enrollment.

Ethics approval and consent to participate

This study was carried out in accordance with the ethical standards at the University of Nebraska Medical Center Institutional Review Board which approved the study protocol (IRB # 722-15-EX). Informed consent was obtained from all participants before they took part in the focus group.

Consent for publication

All authors contributed to the manuscript revision, and read, and approved the submitted version.

Availability of data and materials

Study data have been archived at the Center for Reducing Health Disparities, University of Nebraska Center, and can be requested by contacting Dr. Dejun Su via email at dejun.su@unmc.edu.

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Authors contributions

Gaurav Kumar and Dejun Su contributed to the conception and design of the study. The qualitative data analysis was performed by Gaurav Kumar and Priyanka Chaudhary. The current draft of the

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Declaration of competing interest

All authors declare no conflict of interests.

Data availability

Data will be made available on request.

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