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Barriers to Recruitment and Retention Among Underrepresented Populations in Cancer Clinical Trials: A Qualitative Study of the Perspectives of Clinical Trial Research Coordinating Staff at a Cancer Center

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Background: Although US research agencies have instituted peer review processes to require participant diversity in clinical trials before funding decisions are made, the underrepresentation of certain populations (eg, racial and ethnic minorities) in clinical trials remains a persistent challenge in biomedical research. This issue has the potential to affect the generalizability of findings and impede efforts to ensure the provision of high-quality healthcare across all populations. In this study, we examined barriers to the recruitment and retention of underrepresented populations in cancer clinical trials from the perspective of research coordinating staff.

Methods: Semi-structured interviews were conducted at a US-based academic cancer center and included 6 patient-facing staff (clinical research coordinators) and 6 non-patient-facing staff (regulatory and financial specialists). Interview data were subjected to thematic analysis. To provide additional organizational context, descriptive data were obtained on the characteristics of clinical trials undertaken at the cancer center.

Results: The following themes emerged from the staff interviews: 1) absence of a consistent structure for decision-making and problem-solving related to recruitment and retention, 2) staff shortages, 3) administrative burden, and 4) lack of resources. In addition, descriptive data revealed that nearly half the trials, 64/134 (48%), offered informed consent only in English, and only 3/134 (2%) offered participant incentives or reimbursement (eg, for transportation). These interrelated organizational issues were indicative of inadequate systems for ensuring diverse and equitable representation in cancer clinical trials.

Conclusion: Results indicate that overcoming barriers to underrepresentation may require dedicated support from sponsoring agencies in the form of evidence-based guidelines, learning collaboratives to facilitate implementation, technical support, resources, and oversight. For progress to be made therefore, both sponsors and cancer centers may need to assume joint responsibility for the implementation of effective systems for ensuring diverse and equitable representation in cancer clinical trials.

Keywords: clinical trials, academic cancer centers, underrepresented populations, recruitment and retention, health disparities, diversity, equity, inclusion

Introduction

Clinical trials play a crucial role in advancing scientific knowledge and providing evidence for patient treatments. While these trials have led to today's standards of care, ensuring diversity in recruitment remains challenging in the United States (US). Underrepresentation of certain populations persists, as they face intersecting barriers like race, ethnicity, socioeconomic status, language, and access to healthcare. These barriers, often interconnected, contribute to compounding the challenges these groups face in clinical trial participation.[1–5]

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Racial and ethnic minorities, especially African American and Hispanic populations, are underrepresented in oncology trials despite bearing a disproportionate disease burden. For instance, African Americans, who have a higher incidence of multiple myeloma, often face exclusion due to restrictive criteria, mistrust, and limited trial site access.[6,7] Socioeconomic factors, such as income and education, intersect with racial disparities, further compounding these challenges.[8,9]

It is noteworthy that in recent years, US federal agencies sponsoring clinical trials, like the National Institutes of Health (NIH), the Food and Drug Administration (FDA), and the Centers for Disease Control and Prevention (CDC) have developed their own policies and guidelines aimed at improving the representation of diverse populations; however, the emphasis and stipulations may vary. For example, NIH review of grant proposals will include information about inclusion of participants by gender, race, and ethnicity. If the proposal does not include an explicit plan to recruit a diverse, or at least representative, sample, this issue may reduce fundability or lead to feedback to improve this aspect of the work, which in turn may include translation of materials and reimbursement of costs to participants related to the study.[10] While the NIH puts forth statutory requirements to include women and minorities in clinical trials, the FDA encourages diversity through guidance and regulatory pathways but relies on voluntary compliance by industry sponsors, and the CDC emphasizes health equity and inclusion in research, especially in public health and epidemiology studies. So far, however, such efforts by regulatory bodies to expand eligibility criteria and boost diversity have not helped to resolve the challenge of underrepresentation in clinical trials.[4,5]

The underrepresentation of populations at higher risk for chronic and infectious disease in clinical trials can have significant adverse consequences.[3] In addition to the limited generalizability of results to underrepresented populations, it could result in medications and treatments being less effective or potentially harmful for underrepresented groups, due to differences in lived experiences, daily living conditions, environmental exposures, and other factors.[11] It could also perpetuate existing healthcare disparities by not addressing the unique needs of all populations. To ensure the safety and efficacy of treatment for everyone, therefore, it is essential to have diverse and equitable representation across all populations in clinical trials.

Review of Literature and Development of Conceptual Framework

The United Nations Human Rights Council[12] defines minority groups as any group comprising less than 50% of the total population on a state's territory and whose members share a similar culture, religion, or language. Such groups may be described as ethnic, religious, or linguistic minority groups. Racial and ethnic minority groups include African Americans, Asian Americans, Pacific Islanders, American Indians, and Hispanic Americans. These populations are often underrepresented in clinical trials and more likely to experience health disparities.[4,5,9,12] It has been observed that minority groups are often disproportionately impacted by cancer incidence, burden, and mortality.[13–15] Clinical trials are critical for generating high-quality evidence about interventions to improve patient care and health outcomes for all.[2,16,17] Therefore, diverse, equitable, and inclusive representation in clinical trials is fundamental to ensuring that the results are generalizable across all patient populations.[2,18,19]

The National Comprehensive Cancer Network asserts that optimal care for patients with cancer is achieved through active patient participation in clinical trials,[2] yet most adult cancer patients do not participate.[1,20,21] In 2020, 18 new cancer drugs were approved by the US Food and Drug Administration.[22] Only 11% of the 4922 clinical trial participants were African American or Hispanic; combined, both groups account for approximately 40% of the population of the US.[20] On the other hand, while non-Hispanic White individuals comprise approximately 59% of the total population, they accounted for 75% of the participants in clinical trials exploring innovative pharmaceuticals in 2020.[21] Based on an analysis conducted on cancer therapeutic trials, 4–6% of the participants in such trials were African American, while they accounted for 13.4% of the overall population of cancer patients, and 3–6% of the participants in such trials were Hispanic, while Hispanic patients accounted for 18.5% of the overall population of cancer patients.[23] The limited diversity of participants in turn creates a data deficiency and disparity that affects the accuracy of medical evidence and hinders the development of innovative therapies.[24] These concerns were heightened during the COVID-19 pandemic, when enrollment in clinical trials was low across all populations and significantly lower among racial and ethnic minority populations.[25] Summarized below are the key themes in the existing literature related to both the barriers identified and the solutions proposed for the recruitment and retention of underrepresented populations in clinical trials.

Socioeconomic Disparities

Socioeconomic status (SES) influences trial participation, as individuals from lower SES backgrounds face challenges like inadequate transportation, insufficient insurance, and limited childcare.[18,26,27] These barriers complicate trial enrollment and retention. Addressing individual needs, such as providing transportation support, can alleviate these challenges and improve participation.[28–30]

With respect to recommended solutions, the literature has proposed that accommodating individual needs can alleviate burdens and facilitate the recruitment and retention of patients in clinical trials.[29,30] Providers report that transportation is one of the most frequently encountered barriers to enrollment or sustained participation in clinical trials.[31] Patients are more interested in participating if transportation alternatives or reimbursement options are offered for transportation to any trial-related events.[29] Therefore, being transparent about the structure of reimbursement for transportation could be helpful in incentivizing and motivating patients to participate in clinical trials.[32]

Mistrust and Lack of Knowledge or Awareness

Mistrust in the US healthcare system is a major barrier for underrepresented populations. Mistrust may stem from fear of exploitation or inadequate information, exacerbated by a lack of cultural diversity among clinical trial staff.[23,33–35] Addressing this requires cultural inclusivity and education for both providers and patients to build trust and understanding.[29,36] Most patients learn about cancer clinical trials through their providers; but these providers do not always have access to appropriate trials to refer patients to for their specific disease.[29] Guerra et al[23] reported that only 20% of patients had discussed clinical trials with their providers, suggesting more cancer clinical trial knowledge and awareness is needed for both providers and patients. Patients with low health literacy are at a greater disadvantage since they are disproportionately burdened by complex medical and legal jargon.[27] Trust between provider and patient is the foundation of a healthy doctor-patient relationship; providing culturally appropriate materials to highlight the logistics and objectives of relevant clinical trials has the potential to increase patient understanding and trust.[29,36]

With respect to recommended solutions, health educators and educational interventions have been proposed to help increase comprehension of and participation in clinical trials among underrepresented populations.[13] Also, diversifying the clinical trial research team has been shown to help build trust by incorporating cultural congruence, increasing engagement, and addressing social barriers.[30] Finally, patient navigators have been found to be helpful in minority recruitment as they can assist in improving health literacy by serving as patient advocates, which in turn can help to build trust and transparency in the doctor-patient relationship.[13,23]

Language and Communication Barriers

Language and communication barriers are frequently encountered challenges among underrepresented populations. Providers report that minority patients with low English proficiency have difficulty comprehending the logistics of cancer clinical trials despite the use of translators, leading to minority patients being recruited less often due to the higher administrative burden imposed on clinical trial coordination staff.[1] Often, there is insufficient institutional support for translating consent forms or study materials; when these materials are not available, providers may be less likely to refer patients for clinical trials.[37] When language translation is requested, the translation needs to be completed quickly to enroll the patient while they are interested and eligible, which can be a time-consuming and financially burdensome process.

With respect to recommended solutions, providing interpreters and linguistically appropriate materials can allow patients to gain full comprehension which in turn can help to build mutual trust.[36] Research aimed at enhancing cultural sensitivity in academic health centers demonstrated a significant increase in the involvement of underrepresented groups in non-therapeutic clinical trials for cancer from 20% to 62%.[38,39] Additionally, integrating cultural and linguistic modifications into existing educational interventions has been found to be effective in increasing patients' likelihood of enrolling in clinical trials.[40] Huang et al[41] have emphasized the importance of culturally sensitivity training of clinical trial research teams and the provision of recruitment materials written for a 5th-grade reading level to maximize comprehension among prospective participants. Based on the above discussion, Figure 1 summarizes the framework

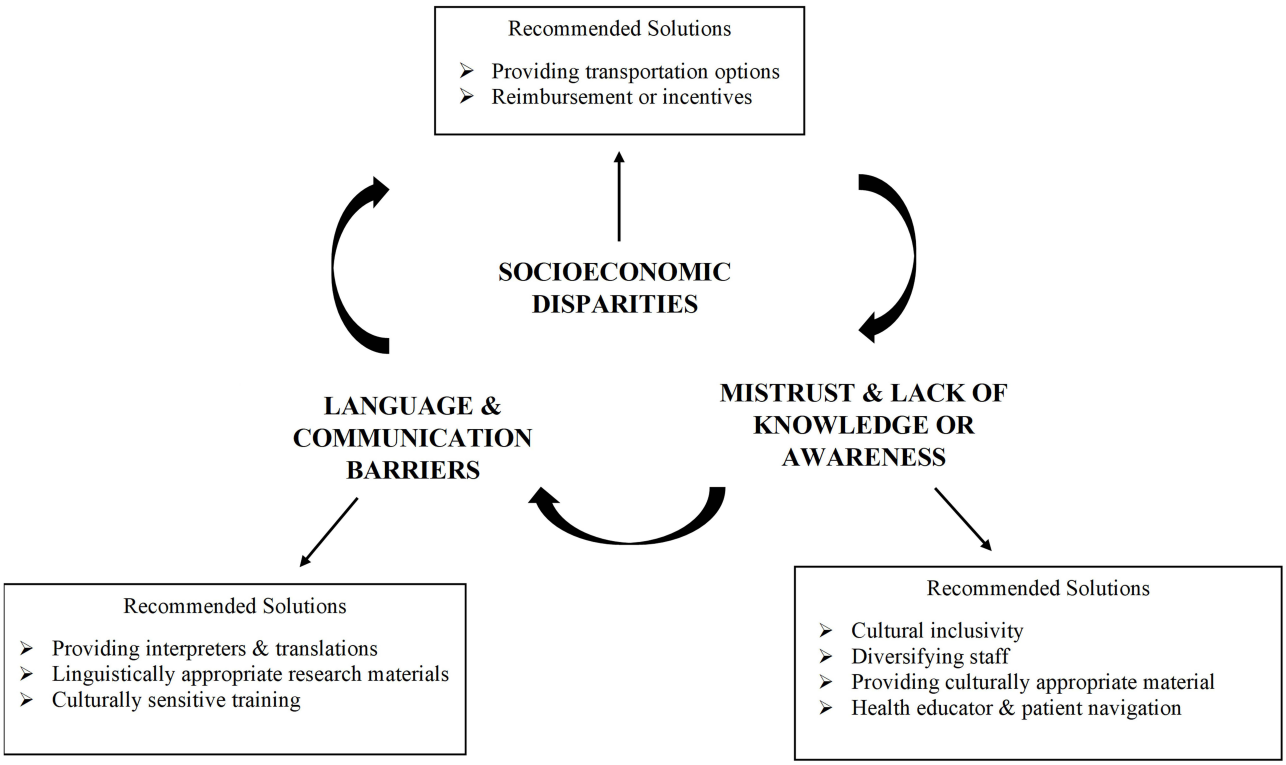


Figure 1 Conceptual framework of barriers to recruitment and retention of underrepresented populations and recommended solutions.

of challenges and proposed solutions identified in the existing literature, for the recruitment and retention of underrepresented populations in clinical trials.

Research Questions

Existing studies have sought to describe the challenges of underrepresentation in clinical trials through cross-sectional analyses[42] and qualitative studies to elicit the perspectives of providers, patients, and community participants, eg, faith-based groups.[43,44] However, there has been limited exploration of these challenges from the perspective of the research team, including clinical trial coordinating staff. This study sought to address this gap by investigating the barriers to the recruitment and retention of underrepresented groups in cancer clinical trials from the perspective of clinical trial research coordinating staff, including patient-facing staff (eg, clinical research coordinators) and non-patient-facing staff (eg, regulatory and financial specialists) at a cancer center. In doing so, this study sought to identify reasons for the persistent challenge of underrepresentation of certain populations in clinical trials, despite the significant attempts in the existing literature to put forth solutions for addressing these challenges. The specific research questions are outlined below.

1. What are the barriers to recruitment and retention among underrepresented populations in cancer clinical trials from the perspectives of clinical trial research coordinating staff?
2. What are the barriers to implementing the solutions proposed in the existing literature for the recruitment and retention of underrepresented populations from the perspective of clinical trial research coordinating staff?

Methodology

This study used qualitative methods to address the research questions. Semi-structured interviews informed by the literature were conducted with consenting clinical trial research coordinating staff at a US-based academic cancer center. An organizational database (OnCore) was leveraged to generate descriptive data on the characteristics of clinical trials

being undertaken at the cancer center, which in turn helped to provide additional organizational context for the staff interviews. Data obtained from the interviews were subjected to thematic analysis to capture emergent themes.

Recruitment and Informed Consent Process

Following approvals from Institutional Review Boards (IRBs) at both the authors' university and the study site (Approval # 2023–066), the Principal Investigator reached out to the director of the Cancer Clinical Trials Office at the study site to inform them of their intent to interview members of the clinical trial research coordinating staff as part of the study, including clinical research nurse coordinators, clinical research coordinators, regulatory coordinators, and finance and budget specialists. In effect, these four types of staff positions encompassed the existing range of clinical and non-clinical staff roles in cancer clinical trials, thereby enabling the researchers to tap into staff's varied exposure to the challenges of conducting such trials. An initial Email about the study was sent out to the full department of 35 clinical research coordinating staff members. We estimated that approximately 21 staff members were eligible in terms of meeting eligibility criteria related to work experience of two or more years of full-time experience at the cancer center (study site). Upon receipt of the initial Email, 15 eligible staff members stepped forward to indicate interest in participating in the study. Purposive sampling techniques were used to screen interested participants (to ensure that they met the eligibility criteria), after which, three staff members from each of the four categories of staff roles (indicated earlier), were shortlisted based on scheduling availability, while prioritizing those with greater experience.

All 12 staff members who were invited replied by Email agreeing to participate in the study. The Principal Investigator then sent a second Email to all 12 prospective participants to provide information related to the study purpose, procedures, potential risks and benefits, confidentiality measures, and their rights as participants. The Email also included the consent form and study information for review. Prospective participants were informed that study participation would be purely voluntary and were given an opportunity to ask questions. Interviews were then scheduled at the convenience of participating staff. After those 12 staff members were interviewed, interviews were examined for data redundancy to assess saturation. The potential for bias was minimized by sampling across staff roles. Data saturation was the main goal of the interview process, and recruitment would have continued had it not been met.

Data Collection

The organizational OnCore database collects descriptive data related to clinical trials for planning purposes. For this study, data collected over a three-year period from September 2020 to September 2023 were leveraged to describe the clinical trial characteristics at the study institution, including the number of available trials per disease group, sponsor type, protocol type, and trial phase. Data were also obtained on whether the trials offered informed consent forms in languages other than English and offered any incentives or reimbursements for patients. The descriptive data on clinical trial characteristics were intended to provide broad contextual information of the type of trials being undertaken by the cancer center (study site). The breakdown by sponsor helps to characterize the proportion of federally sponsored vs industry-sponsored trials at the site; similarly, the breakdown by disease type helps to understand the types of cancer typically treated by the cancer center. Additionally, the descriptive data pertaining to informed consent translation and participant incentives at the study site, served a dual purpose in providing a springboard for interviews with staff on barriers to recruitment and retention in the specific contexts of language translation and availability of participant incentives. The rationale for collecting descriptive data over a three-year period as opposed to a single year, was to obtain a robust and reliable context for the types of clinical trials undertaken at the cancer center. Although the COVID-19 pandemic may have played a role in impacting the logistics of studies conducted during the height of the pandemic with respect to start and end dates, we do not expect it to have substantively impacted the characteristics of clinical trials undertaken by the cancer center.

Qualitative data were collected through semi-structured individual interviews on Microsoft Teams with 12 clinical trial research coordinating staff who consented to participate in the study. Participants' informed consent included publication of anonymized responses/direct quotes. The timeframe for qualitative data collection was September 2023 through December 2023. As indicated earlier, participants included six patient-facing staff (three clinical research nurse coordinators, three clinical research coordinators) and six non-patient-facing, administrative staff (three regulatory

coordinators, three finance and budget specialists). The average interview duration was 30 minutes. A semi-structured interview guide (Appendix 1) was used with the flexibility to explore topics and follow-up questions based on the responses received. The purpose of the interview guide was to enable the interviewer to get started with anchoring information about existing trials and characteristics. This in turn enabled the interviewer to use the descriptive data as a springboard for a discussion about barriers to using available resources (eg, participant incentives, language translation services) and their knowledge associated with implementing those services. The interview guide was informed by both the literature and the descriptive data on clinical trial characteristics obtained from OnCore. The guide was designed to balance structure and flexibility, and allow a deeper understanding of the participant's experience, perspective, and insight. Notes were taken during each interview to support and facilitate thematic analysis.

Data Analysis

The descriptive data obtained from OnCore helped to summarize the key characteristics of clinical trials undertaken at the study site, including: the available number of trials per disease group, sponsor types, protocol types, and the phases of each trial. The OnCore system also included information on availability of informed consent forms in languages other than English, as well as the availability of incentives and reimbursements for participants. Data obtained from OnCore were summarized to establish the organizational context with respect to clinical trial characteristics which in turn served to support the data collection and analysis from interviews.

Upon completion of each interview, the audio transcription from Microsoft Teams was exported to a Microsoft Word document. The text was reviewed while listening to the audio to ensure details were captured accurately. Once the transcription was proofread and determined to be accurate and coherent, it was imported to DeDoose Version 7 (a qualitative analysis tool) for coding and identification of emergent themes related to barriers to recruitment and retention of underrepresented populations in cancer clinical trials from the perspective of clinical trial research coordinating staff. Notes taken during the interview also helped to track the flow of conversation and support the thematic analysis of interview data. The concurrent collection and analysis of the qualitative data from interviews enabled the determination of data saturation by identifying and organizing the thematic categories after coding each interview.

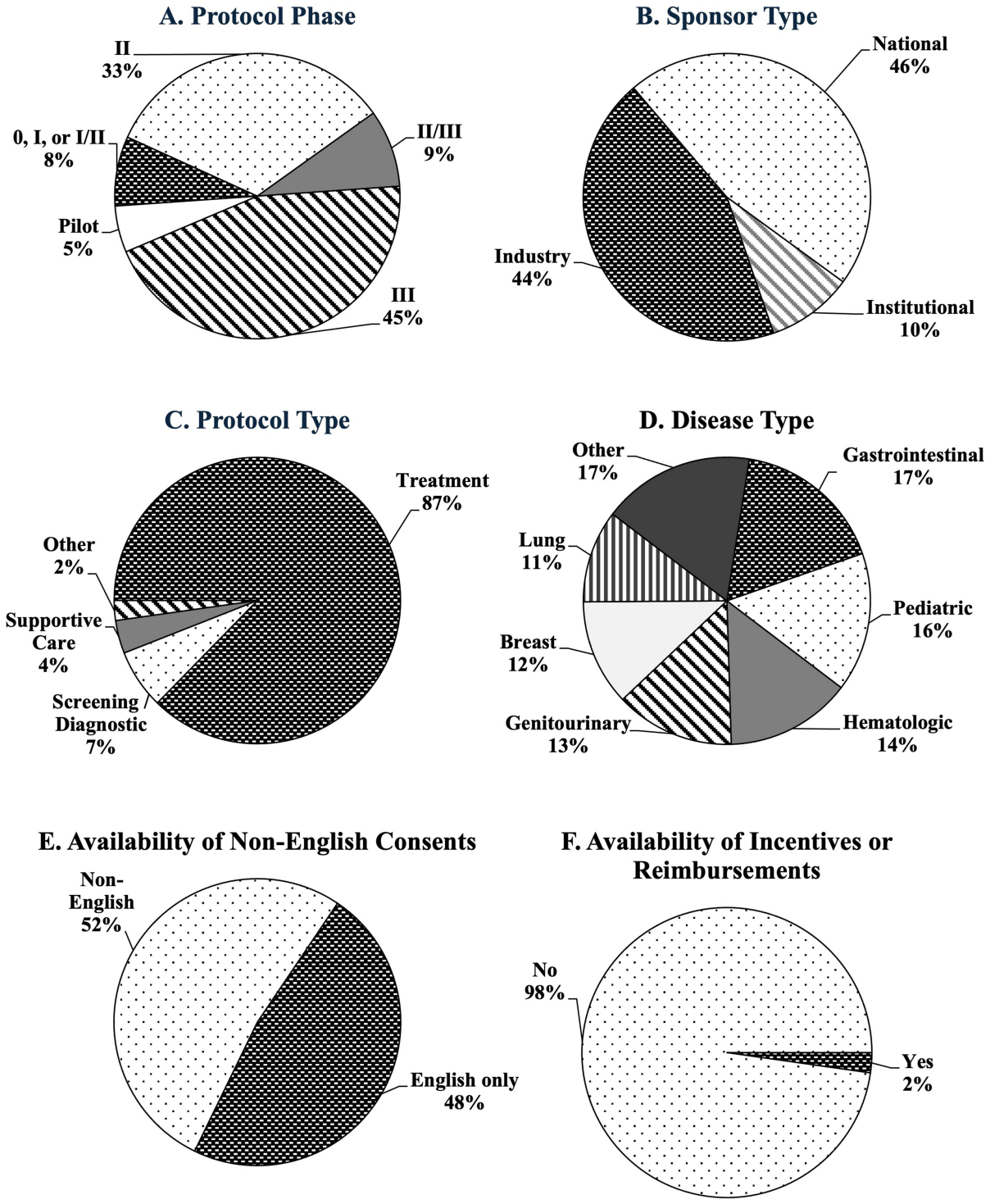
Results

Descriptive Data on Clinical Trial Characteristics

Figure 2 includes several pie charts summarizing the descriptive data related to clinical trials at the cancer center obtained from OnCore, including the protocol phase (A), protocol sponsor type (B), protocol type (C), disease type (D), availability of non-English informed consent (E), and availability of incentives and reimbursement for clinical trial participants (F). Of the 134 clinical trials reviewed, most studies were Phase II (33%) or Phase III (45%; Figure 2, Panel A). Most protocols were sponsored by national agencies (46%) or industry (44%; Figure 2, Panel B). A majority (87%) were treatment trials, while a small proportion were screening or diagnostic (7%) or supportive care (4%; Figure 2, Panel C). The studies focused on a variety of disease types (Figure 2, Panel D). About half of the studies had only English language consent forms (48%; Figure 2, Panel E); of the remaining 52% (70), 69 offered Spanish consent, 2 offered Chinese and Russian consent, and 1 offered Nepali and Bengali consent. Few studies had incentives or reimbursements available (eg, for transportation; 2%; Figure 2, Panel F).

Qualitative Data from Semi-Structured Interviews

The following themes emerged from thematic analysis of interview data: 1) absence of a consistent structure for decision-making and problem solving related to the recruitment and retention of underrepresented populations, 2) staff shortages, 3) administrative burden, and 4) lack of resources for recruitment and retention. These are discussed below in greater detail. Table 1 provides a summary of participant demographics. It is noteworthy that by *Ethnicity*, there were 3 participants reporting Indian ethnicity and one reporting Chinese ethnicity. However, under *Race*, the total number for "Asian" is reported as 3 instead of 4 because one participant with Chinese ethnicity, identified as Caucasian.



Note: For Panel C, other protocol types include health services research, basic science, and not specified. For Panel D, other includes diseases with fewer than 10 studies (7%) each: bone marrow transplant, gynecological, head & neck, melanoma/skin, neurological, and surgical.

Figure 2 Dashboard overview of clinical trial characteristics at the cancer center. (**A**) Protocol Phase; (**B**) Protocol Sponsor Type; (**C**) Protocol Type; (**D**) Disease Type; (**E**) Availability of Non-English Informed Consent; (**F**) Availability of Incentives and Reimbursement.

Table 1 Participant Demographics

Demographic	Number of Participants	Percentage
Gender		
Male	5	42%
Female	7	58%
Race		
Caucasian	7	58%
African-American	2	17%
Asian	3	25%
Ethnicity		
Non-Hispanic	9	75%
Hispanic	3	25%
Academic Background		
Undergraduate	9	75%
Graduate	3	25%
Work Experience		
2–5 years	6	50%
5+ years	3	25%
10+ years	3	25%
Clinical vs Non-Clinical		
Clinical	6	50%
Non-clinical	6	50%
Primary Language Spoken		
English	7	58%
Spanish	3	25%
Hindi	2	17%

Theme 1: Absence of a Consistent Structure for Decision-Making and Problem-Solving

A key theme that emerged from the interviews was the absence of a consistent structure for decision making and problem solving. Participants felt that the absence of a structure for decision-making related to the recruitment and retention of underrepresented populations resulted in unclear direction and inconsistent guidance or support. One patient-facing (clinical) staff member stated:

> most or all our issues here are related to a lack of consistent attention to these challenges. Having support and coordination from leadership can solve most of our problems related to the recruitment and retention of minorities.

Administrative staff also expressed the need for additional support for the finance team so that the workload is more evenly distributed. One non-patient-facing staff member stated that "the responsibility to solve this problem rests with the current leadership, however, they have not approved of additional staff roles to help us." Administrative staff members also indicated that no initiative had been taken to implement processes or provide resources to alleviate challenges associated with the recruitment and retention of underrepresented populations. One staff member stated: "limitations come from understaffing, small budget, and honestly upper leadership support." Overall, both patient-facing and non-patient-facing participants vocalized their need for a consistent structure for decision making and problem solving regarding the recruitment and retention of underrepresented populations. They also shared that the absence of a consistent structure to address these challenges could eventually lead to low staff morale, ultimately impacting patient care and organizational effectiveness.

Theme 2: Staff Shortages

An overarching theme that emerged from the interview data was staff shortages. Both the patient-facing and the non-patient-facing staff expressed that staff shortage was the primary reason why the cancer clinical trials office could not provide the services needed to increase recruitment and retention of underrepresented populations. Due to the shortage of staff resources, patient care was affected by longer wait times to screen and enroll patients, decreased time to attend to individual needs, and greater scope for errors due to overworked staff. The shortage of resources also helped to explain inadequate training of staff and feelings of burnout expressed by staff. One patient-facing staff member stated: "there are so many things we could accomplish as a team, but we cannot do it right now because we are so short-staffed." The clinical team would only prescreen some patients at times, thereby missing the opportunity for all eligible patients to be aware of and enrolled in the clinical trial. One patient-facing staff member stated "…and again, to reimburse patients means to offer the service throughout all the study protocol which is unlikely here because of inadequate staffing." The finance team could not provide the option to reimburse or incentivize patients due to its administrative burden as one non-patient-facing staff reported:

> we do not offer any kind of incentives or compensation for patients, the limitation is staffing for the finance team and the more stipends we offer, the more staff time is needed from the finance team.

Each clinical trial has a budget sheet that is closely and thoroughly negotiated and takes months to approve. If the Cancer Clinical Trials Office agrees to offer patients incentives or reimbursements from the sponsor, they may not be able to fulfill the administrative responsibilities due to the greater burden and increased complexity of reporting.

Theme 3: Administrative Burden

Participants often expressed frustration with the higher administrative burden emanating from budgetary constraints experienced by the cancer center and the consequent limitations in department funding for staff resources. Participants felt that this administrative burden could be alleviated through advocacy for additional resources or even leadership engagement and collaboration in setting priorities and allocating resources. With respect to the solutions proposed for addressing underrepresentation in the existing literature, one clinical research staff member observed, "these are great ideas, but they would impose a huge financial burden on the sponsor and an administrative burden for us." Both patient-facing and non-patient-facing staff felt that creating additional job roles would necessitate additional departmental funding for staff salaries, training, and staff retention. The process of translating consent to other language in turn comes with an administrative burden that often cannot be handled due to staff shortage; it also comes with a financial burden due to the cost of professional translation services, the need for multiple reviews by both sponsor and the IRB, and the potential need for legal review.

Theme 4: Lack of Resources for Recruitment and Retention

Both patient-facing and non-patient facing staff members expressed concerns related to the lack of resources for recruitment and retention, including translation services and reimbursement for transportation. Patients may struggle to find transportation to their treatments, and without translation services they may face language barriers, making it difficult for them to provide informed consent. One patient-facing staff member stated:

> offering support for transportation is indeed important. If the sponsors offer a stipend, patients could use that towards their travel expenses, but it would be just a few dollars.

Another patient-facing staff member stated, "we do offer support for transportation, but it is capped and can only be use so many times per patient." Even with available resources for translation, coordinating translation services for multiple languages and dialects can be logistically challenging. Overall, the absence of systematic approach to recruitment and retention of underrepresented patients can decrease the number of such patients in the trial due to the lack of awareness of clinical trials. This can cause delays and difficulty in meeting enrollment targets and increased costs. One patient-facing staff member stated:

> Patient education is so important here; it can solve a lot of the issues. We can have diverse staff but we also need to give patients reading materials and information on clinical trials so they can take home and read and understand before deciding. It's all about having the right resources, this also means allocating resources to develop recruitment materials, which is where leadership support would be valuable. If our clinical trial advertisements are made available in multiple languages, I believe we can attract more underrepresented patients be part of our trials.

Clinical research staff expressed that the Cancer Clinical Trials Office does not provide any recruitment materials unless the sponsor provides it; however, the translated documents are either non-existent or limited in translations due to costs. The Cancer Clinical Trials Office also has no social media presence, nor does it take advantage of social media to inform patients of cancer clinical trials. One patient-facing staff member stated:

> Something we don't do here is advertise clinical trials, some patients don't even know that we offer them. This is a disadvantage here at our site, but we are hoping it changes. I know pre-pandemic there were talks to go out into the community and provide information but then nothing happened afterwards. We can certainly use more social media now; it would help educate patients, but this can be costly which then can create other issues for leadership.

Overall, the thematic analysis helped to capture interrelated organizational issues that were indicative of inadequate systems for ensuring diverse representation in cancer clinical trials. A key takeaway from staff interviews was that the leadership could do more to prioritize recruitment and retention among underrepresented populations, even amidst resource constraints such as community education and workflow changes, to prioritize recruitment and retention among underrepresented populations. It would also be relevant to note that there was a broad concordance in feedback received from patient-facing and non-patient-facing staff across all themes, although there were subtle distinctions. Patient-facing staff provided feedback based on their interaction with patients participating in the clinical trials and their understanding of patient care, whereas the non-patient facing staff provided feedback based on administrative logistics.

Discussion

Summary of results

Participant responses revealed four emergent themes related to barriers to recruitment and retention of underrepresented populations in cancer clinical trials: 1) absence of a consistent structure for decision-making and problem-solving related to recruitment and retention, 2) staff shortages, 3) administrative burden, and 4) lack of resources for recruitment and retention of underrepresented populations. These four emergent themes not only helped to explain the barriers to recruitment and retention among underrepresented populations from the perspective of research staff, but also the challenges frequently encountered in implementing the solutions proposed in the existing literature. In essence, the four themes that emerged represent interrelated organizational issues that were indicative of inadequate systems for ensuring diverse representation in cancer clinical trials.

The absence of a consistent structure for problem solving can result in a lack of strategic direction and inadequate resource allocation for conducting the trials. Staff shortages in conducting clinical trials in turn can lead to increased workloads, burnout, and compromised patient care. Staff shortages can moreover result in decreased efficiency, adding to the financial burden imposed by departmental budgetary constraints governed by sponsor funding. The absence of adequate systems and strategies for recruitment and retention in turn can thwart the timely and effective implementation of clinical trials, ultimately affecting patient access to potentially lifesaving treatments. These issues in turn can inhibit the ability to address the challenge of recruitment and retention systematically, which could ultimately affect enrollment and lead to the potential failure of clinical trials. Descriptive data from OnCore revealed that many clinical trials were missing items that could improve recruitment and retention, including non-English informed consent forms and incentives or reimbursements for participants.

Implications for Policy

The results suggest that for progress to be made, both research sponsoring agencies and cancer center organizations (clinical trial sites) may need to assume joint responsibility for the implementation of effective systems for the

recruitment and retention of underrepresented populations in clinical trials. Despite efforts being undertaken by US research agencies to monitor and enforce diversity in clinical trial participation prior to funding, the commitment to diversity expressed by clinical trial sites at the time of the funding application may not necessarily translate to effective implementation during the trial. At a minimum, the results of this study suggest that it is possible for cancer centers to encounter challenges in designing and implementing effective systems for ensuring diverse representation in clinical trials. Therefore, an implication for policy is that sponsoring agencies could extend more direct and systematic support for ensuring the effective implementation of systems for ensuring diverse representation in clinical trials in the form of evidence-based guidelines for effective system implementation, learning collaboratives to facilitate implementation, technical support, resources, and oversight. These proposed solutions emanate directly from the wider literature on Implementation Science, a formal field of study that emerged in the early 2000s out of the recognition that there is often a significant gap between what scientific research demonstrates as effective (evidence-based practices) and what is routinely implemented in real-world settings, particularly in healthcare.

One strategy to further elucidate the barriers and facilitators is to utilize the Consolidated Framework for Implementation Research (CFIR), a comprehensive framework well-established in implementation research that is used to systematically assess factors that influence the implementation of innovations in health services.[45] The CFIR has been applied to study the implementation of healthcare innovations such as electronic health records, evidence based clinical practices, and telehealth. Healthcare providers' familiarity with technology and their confidence in using telehealth tools have been found to be critical facilitators, while lack of training has been identified a key barrier. Therefore, engaging clinicians early in the design and rollout process mitigates resistance, and ongoing feedback mechanisms helps refine telehealth implementation.[46] Organizational readiness, leadership support, and a culture that promotes innovation have also been identified as strong facilitators for telehealth implementation.[47] Similar investment in implementation research surrounding the development of effective systems for recruiting and retaining underrepresented populations in cancer clinical trials, can help to generate evidence-based management guidelines for cancer center organizations to use in this context.

Sponsoring agencies could invest in research to generate recruitment and retention guidelines and make them available to cancer centers alongside learning collaboratives, technical support, resources, and oversight, to facilitate uptake and enable the successful and sustainable implementation of systems for the recruitment and retention of underrepresented populations in cancer clinical trials. To address concerns related to tokenistic efforts from sponsoring agencies related to recruitment challenges, the sponsor could encourage and enable clinical trial sites to obtain more "representative samples" rather than simply instituting standardized or minimum requirements. To clarify, if the sponsor and site do assume joint responsibility, and agree to work collaboratively to address implementation issues, that has the potential to alleviate challenges such as "lack of resources" being experienced at the clinical trial site which in turn could facilitate adoption of best practices such as population health approaches to recruitment and retention (eg, community engagement and culturally competent recruitment). To achieve substantial change, sponsoring agencies need to be committed to providing sufficient funding so that these efforts are sustainable.

Having a structured framework of expectations related to diversity and equity in clinical trial participation from funding agencies could go a long way in motivating cancer center organizations to make this issue a priority. Healthcare organizations need to have policies in place to support and prioritize diverse, equitable, and inclusive representation in clinical trials. This includes providing adequate funding, resources, and infrastructure to facilitate recruitment and retention efforts. Priority setting equitable representation across all populations at the level of the sponsor could go a long way in laying the foundation for effective attention to these challenges at the cancer center (organizational) level.

Implications for Practice

A key takeaway from the staff interviews was that more could be done by the cancer center to improve the recruitment and retention of underrepresented populations through changes to resource allocation, workflow and processes improvements, and community education.

Although it may be possible for cancer centers to be engaged in addressing this problem even in the absence of external pressures, the experience at the study institution suggests that some organizations may find it challenging to

institute effective systems for diverse representation in clinical trials, in the absence of more systematic support from the sponsor.

With impetus for diverse representation from the funding agencies, it would behoove cancer center organizations to have protocols in place for ensuring minority representation, including adequate resources, collaborations, and infrastructure to facilitate recruitment and retention efforts. It would be important for the cancer center leadership to undertake systematic efforts to investigate each department and examine what areas are lacking in funding and resources and what areas need to be prioritized to bridge these gaps. For example, the leadership could also investigate how the research team could provide population-based solutions for ensuring success with the recruitment and retention of underrepresented populations. The Cancer Clinical Trials Office staff could organize a monthly community outreach program where the staff goes out into the community and provides education related to clinical trials and their importance. The staff in turn could form a taskforce team whose main responsibility would be to brainstorm and implement changes in the workflow and processes to address challenges inherent in recruiting and retaining underrepresented populations in cancer clinical trials. These proposed solutions (eg, monthly community outreach program) would be directly aligned with the results theme of "lack of resources" since such approaches have potential to greatly increase efficiency in resource use through a population health approach to recruitment by engaging the community and facilitating culturally competent recruiting with less effort and more efficient use of available resources.

Implications for Future Research

Future research is needed to explore the specific barriers to underrepresentation from the perspectives of the decision makers at cancer centers. Understanding the perspectives of cancer center leaders can help to supplement data collected from research coordinating staff to inform holistic strategies for overcoming the barriers to recruitment and retention of underrepresented populations in cancer clinical trials. One potential tool to improve recruitment and retention of underrepresented groups in the context of limited resources and staff shortages is artificial intelligence (AI). AI-based tools can help to improve the diversity of participants by identifying and engaging with potential candidates from underrepresented populations more effectively and efficiently, through analysis of trends to help target specific populations and automated communication.[48] Overall, the integration of AI can contribute to increasing diversity in clinical trials and improving underrepresented populations. It is also noteworthy that the purpose of this study was to capture the broad challenges inherent in the recruitment and retention of underrepresented population at an organizational level regardless of sponsor, and the results reflect that challenges to recruitment and retention of underrepresented populations persist across the board regardless of sponsor; for example, only 2% of all 134 trials included participant incentives. Given the study purpose, a detailed scrutiny of the recruitment and retention plans and outcomes by sponsor was beyond the scope of this paper. However, this could be a fruitful avenue for future research to understand if variations exist in organizational recruitment and retention outcomes by sponsor.

Study Limitations

The study is restricted to a single organization with a relatively small sample size of interview participants, which in turn restricts the potential for generalizability of the results. While the study site is broadly similar in structure and function to other cancer center organizations, there may be cultural differences that may impact the workflow of clinical trial research coordinating staff. Successfully recruiting 12 interview participants with diverse backgrounds and expertise helped to ensure that the data collected and analyzed were comprehensive in addressing the research objectives and questions when data saturation was reached. Additionally, while the results of this study may not be generalizable to all cancer center clinical trial sites, the experience at the organization provided valuable insight into the need for both sponsoring agencies and cancer centers to assume joint responsibility for implementing effective systems to ensure progress with the recruitment and retention of underrepresented populations in clinical trials.

Conclusion

Ensuring participant diversity in clinical trials should contribute to equitable healthcare for all patients. The current challenges of underrepresentation limit the generalizability of cancer clinical trial study findings and create disparities in

healthcare outcomes. This study addressed a gap in the literature by understanding the barriers to recruitment and retention of underrepresented populations from the perspective of clinical trial research coordinating staff. At a broader level, this study provided a deeper insight into why such barriers persist despite knowledge of proposed solutions. The study identified interrelated organizational issues that were indicative of inadequate systems for ensuring diverse representation in cancer clinical trials. From a policy perspective, the results suggest that, for progress to be made, both research sponsoring agencies and cancer center organizations (clinical trial sites) may need to assume joint responsibility for the implementation of effective systems for the recruitment and retention of underrepresented populations in clinical trials. From a practice perspective, it is important for cancer centers to have protocols in place for ensuring diverse, equitable, and inclusive representation across all populations, including adequate resources, collaborations, and infrastructure to facilitate recruitment and retention efforts as well as looking into a population-based solution. Future research should include the perspectives of decision makers at cancers and consider the use of AI to improve recruitment and retention. Overall, the results indicate that addressing the barriers to clinical trial recruitment and retention may require a multifaceted approach involving policy and practice changes and future research.

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References

1. Niranjan SJ, Martin MY, Fouad MN, et al. Bias and stereotyping among research and clinical professionals: perspectives on minority recruitment for oncology clinical trials. *Cancer*. 2020;126(9):1958–1968. doi:10.1002/cncr.32755
2. Clark LT, Watkins L, Piña IL, et al. Increasing diversity in clinical trials: overcoming critical barriers. *Curr Prob Cardiol*. 2019;44(5):148–172. doi:10.1016/j.cpcardiol.2018.11.002
3. Nipp RD, Hong K, Paskett ED. Overcoming barriers to clinical trial enrollment. *Am Soc Clin Oncol Educ Book*. 2019;39:105–114. doi:10.1200/edbk_243729
4. American Association for Cancer Research (AACR) Cancer Disparities Progress Report. Disparities in clinical research and cancer treatment. 2023. Available from: https://cancerprogressreport.aacr.org/disparities/cdpr24-contents/cdpr24-disparities-in-clinical-research-and-cancer-treatment/. Accessed September 12, 2024.
5. National Academies. Lack of equitable representation in clinical trials compounds disparities in health and will Cost U.S. hundreds of billions of dollars; urgent actions needed by NIH, FDA, others to boost representation. 2022. Available from: https://www.nationalacademies.org/news/2022/05/lack-of-equitable-representation-in-clinical-trials-compounds-disparities-in-health-and-will-cost-u-s-hundreds-of-billions-of-dollars-urgent-actions-needed-by-nih-fda-others-to-boost-representation. Accessed September 12, 2024.
6. Alqazaqi R, Schinke C, Thanendrarajan S, et al. Geographic and racial disparities in access to chimeric antigen receptor-T cells and bispecific antibodies trials for multiple myeloma. *JAMA Network Open*. 2022;5(8):e2228877. PMID: 36018590; PMCID: PMC9419017. doi:10.1001/jamanetworkopen.2022.28877
7. Kanapuru B, Fernandes LL, Baines A, et al. Eligibility criteria and enrollment of a diverse racial and ethnic population in multiple myeloma clinical trials. *Blood*. 2023;142(3):235–243. PMID: 37140031. doi:10.1182/blood.2022018657
8. Caston NE, Lalor F, Wall J, et al. Ineligible, unaware, or uninterested? Associations between underrepresented patient populations and retention in the pathway to cancer clinical trial enrollment. *JCO Oncol Pract*. 2022;18(11):e1854–e1865. PMID: 36178922; PMCID: PMC9653198. doi:10.1200/OP.22.00359
9. NIH Office of Research on Women's Health. Review of literature: primary barriers and facilitators to participation in clinical research. 2024. Available from: https://orwh.od.nih.gov/sites/orwh/files/docs/orwh_outreach_toolkit_litreview.pdf. Accessed September 12, 2024.
10. National Institutes of Health (NIH) Central Resource for Grants and Funding Information. Inclusion of women and minorities as participants in research involving human subjects. Available from: https://grants.nih.gov/policy/inclusion/women-and-minorities.htm. Accessed July 15, 2024.
11. National Institutes of Health (NIH) National Institute on Minority Health and Health Disparities. Available from: https://www.nimhd.nih.gov/resources/understanding-health-disparities/diversity-and-inclusion-in-clinical-trials.html#:~:text=People%20may%20experience%20the%20same,can%20benefit%20from%20scientific%20advances. Accessed July 15, 2024.

12. About minorities and human rights. United Nations Human Rights Office of the High Commissioner. Available from: https://www.ohchr.org/en/minorities#:~:text=Minority%20rights%20are%20an%20integral,Discrimination%20and%20Protection%20of%20Minorities. Accessed October 26, 2024.
13. Habr D, Ferdinand R. Addressing racial/ethnic disparities in cancer clinical trials: everyone has a role to play. *Cancer*. 2021;127(18):3282–3289. doi:10.1002/cncr.33600
14. Hwang DA, Lee A, Song JM, Han HR. Recruitment and retention strategies among racial and ethnic minorities in web-based intervention trials: retrospective qualitative analysis. *J Med Internet Res*. 2021;23(7):e23959. doi:10.2196/23959
15. Kelsey MD, Patrick-Lake B, Abdulai R, et al. Inclusion and diversity in clinical trials: actionable steps to drive lasting change. *Contemp Clin Trials*. 2022;116:106740. doi:10.1016/j.cct.2022.106740
16. Natale P, Gutman T, Howell M, et al. Recruitment and retention in clinical trials in chronic kidney disease: report from national workshops with patients, caregivers and health professionals. *Nephrol Dial Transplant*. 2020;35(5):755–764. doi:10.1093/ndt/gfaa044
17. Unger JM, Hershman DL, Till C, et al. "When offered to participate": a systematic review and meta-analysis of patient agreement to participate in cancer clinical trials. *J Natl Cancer Inst*. 2020;113(3):244–257. doi:10.1093/jnci/djaa155
18. Shi JJ, Lei X, Chen YS, et al. Socioeconomic barriers to randomized clinical trial retention in patients treated with adjuvant radiation for early-stage breast cancer. *Int J Radiat Oncol Biol Phys*. 2023;116(1):122–131. doi:10.1016/j.ijrobp.2023.01.037
19. Wieland ML, Njeru JW, Alahdab F, Doubeni CA, Sia IG. Community-engaged approaches for minority recruitment into clinical research: a scoping review of the literature. *Mayo Clin Proc*. 2021;96(3):733–743. doi:10.1016/j.mayocp.2020.03.028
20. Jyoti P Addressing the barriers to minority participation in cancer clinical trials. Cancer.Net. Available from: https://www.cancer.net/blog/2021-12/addressing-barriersminority-participation-cancer-clinicaltrials#:~:text=And%20although%20minority%20racial%20and,FDA)%20were%20Blac k%20or%20Hispanic. Accessed October 26, 2024.
21. Roy E, Chino F, King B, et al. Increasing diversity of patients in radiation oncology clinical trials. *Int J Radiat Oncol Biol Phys*. 2023;116(1):103–114. doi:10.1016/j.ijrobp.2022.11.044
22. Recent Cancer Drugs Approved by the FDA. Available from: https://jhoponline.com/issue-archive/2020-issues/february-2020-vol-10-no-1/18024:recent-cancer-drugs-approved-by-The-fda-2020. Accessed September 10, 2024.
23. Guerra CE, Fleury ME, Byatt LP, Lian T, Pierce L. Strategies to advance equity in cancer clinical trials. *Am Soc Clin Oncol Educ Book*. 2022;42:127–137. doi:10.1200/edbk_350565
24. Cahan EM, Hernandez-Boussard T, Thadaney-Israni S, Rubin DL. Putting the data before the algorithm in big data addressing personalized healthcare. *Npj Digital Med*. 2019;2(1). doi:10.1038/s41746-019-0157-2
25. North C, Dougan M, Sacks C. Improving clinical trial enrollment - in the COVID-19 era and beyond. 2020. Available from: https://api.semanticscholar.org/CorpusID:220584896. Accessed October 26, 2024.
26. Indorewalla KK, O'Connor MK, Budson AE, Guess C, Jackson J. Modifiable barriers for recruitment and retention of older adults participants from underrepresented minorities in Alzheimer's disease research. *J Alzheimers Dis*. 2021;80(3):927–940. doi:10.3233/jad-201081
27. Barry D, Steinberg JR, Towner M, Barber EL, Simon MA, Roque DR. Enrollment of racial and ethnic minoritized groups in gynecologic oncology clinical trials: a review of the scope of the problem, contributing factors, and strategies to improve inclusion. *Clin Obstet Gynecol*. 2022;66(1):22–35. doi:10.1097/grf.0000000000000765
28. Miller BC, Bowers JM, Payne JB, Moyer A. Barriers to mammography screening among racial and ethnic minority women. *Soc Sci Med*. 2019;239:112494. doi:10.1016/j.socscimed.2019.112494
29. Anderson T. Barriers and facilitators to the recruitment of underrepresented populations in health research: a narrative review. *Undergrad Res*. 2023;3(1). doi:10.58361/2766-3590.1054
30. Thakur N, Lovinsky-Desir S, Appell D, et al. Enhancing recruitment and retention of minority populations for clinical research in pulmonary, critical care, and sleep medicine: an official American Thoracic Society Research statement. *Am J Respir Crit Care Med*. 2021;204(3):e26–e50. doi:10.1164/rccm.202105-1210st
31. Versavel S, Subasinghe A, Johnson K, et al. Diversity, equity, and inclusion in clinical trials: a practical guide from the perspective of a trial sponsor. *Contemp Clin Trials*. 2023;126:107092. doi:10.1016/j.cct.2023.107092
32. Parkinson B, Meacock R, Sutton M, et al. Designing and using incentives to support recruitment and retention in clinical trials: a scoping review and a checklist for design. *Trials*. 2019;20(1). doi:10.1186/s13063-019-3710-z
33. Avis-Williams A, Khoury A, Lisovicz N, Graham-Kresge S. Knowledge, attitudes, and practices of underserved women in the rural South toward breast cancer prevention and detection. *Family Commun Health*. 2009;32(3):238–246. PMID: 19525705. doi:10.1097/FCH.0b013e3181ab3bbb
34. Pribulick M, Willams IC, Fahs PS. Strategies to reduce barriers to recruitment and participation. *Online J Rural Nurs Health Care*. 2010;10(1):22–33. PMID: 23641192; PMCID: PMC3639431. doi:10.14574/ojrnhc.v10i1.68
35. Gilmore-Bykovskyi AL, Jin Y, Gleason C, et al. Recruitment and retention of underrepresented populations in Alzheimer's disease research: a systematic review. *Alzheimers Dementia*. 2019;5(1):751–770. doi:10.1016/j.trci.2019.09.018
36. Frierson GM, Pinto BM, Denman DC, Leon PA, Jaffe AD. Bridging the gap: racial concordance as a strategy to increase African American participation in breast cancer research. *J Health Psychol*. 2017;24(11):1548–1561. doi:10.1177/1359105317740736
37. Tilley BC, Mainous AG, Amorrortu RP, et al. Using increased trust in medical researchers to increase minority recruitment: the RECRUIT cluster randomized clinical trial. *Contemp Clin Trials*. 2021;109:106519. doi:10.1016/j.cct.2021.106519
38. Quinn GP, Jimenez J, Meade CD, et al. Enhancing oncology health care provider's sensitivity to cultural communication to reduce cancer disparities: a pilot study. *J Cancer Educ*. 2011;26(2):322–325. doi:10.1007/s13187-011-0223-1
39. Niranjan SJ, Durant RW, Wenzel JA, et al. Training needs of clinical and research professionals to optimize minority recruitment and retention in cancer clinical trials. *J Cancer Educ*. 2017;34(1):26–34. doi:10.1007/s13187-017-1261-0
40. Vuong I, Wright J, Nolan MB, et al. Overcoming barriers: evidence-based strategies to increase enrollment of underrepresented populations in cancer therapeutic clinical trials—a narrative review. *J Cancer Educ*. 2019;35(5):841–849. doi:10.1007/s13187-019-01650-y
41. Huang B, De Vore D, Chirinos C, et al. Strategies for recruitment and retention of underrepresented populations with chronic obstructive pulmonary disease for a clinical trial. *BMC Med Res Methodol*. 2019;19(1). doi:10.1186/s12874-019-0679-y
42. Flores LE, Frontera WR, Andrasik MP, et al. Assessment of the inclusion of racial/ethnic minority, female, and older individuals in vaccine clinical trials. *JAMA Network Open*. 2021;4(2):e2037640. doi:10.1001/jamanetworkopen.2020.37640

43. Davis TC, Arnold CL, Mills G, Miele L. A qualitative study exploring barriers and facilitators of enrolling underrepresented populations in clinical trials and biobanking. *Front Cell Develop Biol*. 2019;7. doi:10.3389/fcell.2019.00074
44. Fenech M, Miklas M, El-Abed Y, et al. Identifying and addressing a new barrier to community-based patients accessing cancer clinical trials. *SSRN*. 2023. doi:10.2139/ssrn.4415423
45. Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander JA, Lowery JC. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. *Implement Sci*. 2009;4:50. PMID: 19664226; PMCID: PMC2736161. doi:10.1186/1748-5908-4-50
46. Van Dyk L. A review of telehealth service implementation frameworks. *Int J Environ Res Public Health*. 2014;11(2):1279–1298. PMID: 24464237; PMCID: PMC3945538. doi:10.3390/ijerph110201279
47. Rangachari P, Mushiana SS, Herbert K. A scoping review of applications of the consolidated framework for implementation research (CFIR) to telehealth service implementation initiatives. *BMC Health Serv Res*. 2022;22(1):1450. PMID: 36447279; PMCID: PMC9708146. doi:10.1186/s12913-022-08871-w
48. Daugherty PR, Wilson HJ, Chowdhury R. Using artificial intelligence to promote diversity. In: *The MIT Press eBooks*. 2020:15–22. doi:10.7551/mitpress/12588.003.0006