INCREASING PARTICIPATION RATES OF BLACK PATIENTS IN CANCER CLINICAL TRIALS

Executive Summary

The low participation rates of Black patients in clinical trials remains a significant concern for cancer clinical trial management, sponsors, and drug manufacturers. Clinical trials are the foundation on which new treatments emerge. New drugs are evaluated for efficacy and safety in a representative sample of the population before they can be approved for broader use in clinical practice. Clinical trial participation rates must therefore be representative of the demographic distribution of the target population. This process ensures the benefits and harms of participating in clinical trials are evenly distributed among the population to benefit from the new therapy.

In today's era of precision medicine, diversity in the enrolled patient population in which new drugs are evaluated has become even more critical. Genetics can affect how individuals from one demographic respond to a certain drug compared to another group. It is, therefore, critical that new drugs are tested in genetically diverse populations for the benefits of new medicines to accrue to diverse populations.

Although clinical trial participation rates have increased over the years, the representativeness of clinical trial population has remained a concern. Despite efforts to make clinical trial participation equitable, many trial populations do not represent the population they are intended to serve. Preliminary clinical trial enrollment statistics from a Community Cancer Centre show that only 5% of patients enrolled in the ongoing cancer trials are Black, compared to 16% of the population. To better understand and address the reasons for the discrepancies in the enrollment statistics, management at the Cancer Centre commissioned a needs analysis to be implemented during the three-month period between October and December 2022.

Introduction

Clinical trials remain critical for identifying and characterizing the medical interventions required for diagnosing, preventing, and treating disease.[1] Participation in clinical trials is essential to ensure that medicines are tested for safety and efficacy in a smaller population first.[2] The representative participation of patients in clinical trials remains a cornerstone for successful implementation of clinical trials and the advancement of new therapies.[3,4] Participation of a diverse group of individuals is essential, especially as precision medicine has shown that genetic variation may play a role in individual predisposition to disease and response to medications.[5]

To ensure equal benefits from future cancer therapies, an in-depth understanding of clinical trial enrollment patterns and barriers is critical.[3] In recent years, there have been intensified efforts to remove barriers to clinical trial participation among under-represented populations in the US.[2] Factors including institutional, clinical, or physical barriers to patient involvement in clinical trials have been identified as potential barriers.[4] Given the importance of diversity in clinical trial participation, research aimed at eliminating these barriers has been the subject of intense investigation by cancer investigators worldwide.[6] Not surprisingly, disparities in healthcare and the low participation rates of racially underrepresented populations in clinical trials have been consistently shown to translate to healthcare inequity in various oncology trials.[7]

Disparities in clinical trial participation rates

Internal data on file for the Cancer Centre shows that only 5% of patients enrolled in the ongoing cancer trials are Black, compared to 16% of the population. Given the importance of ensuring that the clinical trial population is representative of the source population for data to be generalizable, the center's management is concerned about this finding.

Most studies investigating barriers to clinical participation have focussed on patient-related factors that preclude patient participation in clinical trials, with little emphasis placed on physician-related obstacles.[4,6] The role of physicians and healthcare staff in clinical trial participation is indisputable; they are the bridge between patients and access to cancer care.[3] Multiple studies have shown that physician decision or preference was the primary reason for non-participation in more than half of the patients eligible for enrollment according to the protocol.[3] Physicians often decide whom to enroll in a clinical trial based on several factors, such as time, reimbursement constraints, or other pragmatic reasons.[6]

A testimonial from one patient illustrates how a doctor's decisions or indecision can impact a patient's journey.

"The doctor told me I had three options to consider. The first was a wait-and-see approach, which was essentially to do nothing. The other two were surgery and radiation. I had no idea what I was supposed to do and no context about the options," said the patient.[8]

After visiting a different center, the same patient reported a completely dissimilar experience.

"It was clear that the focus here was all about the patient. I got to meet my care team, and I immediately connected with them. The doctors gave me confidence that I had a chance of survival," he concluded."[8]

Unconscious bias

Equally important in determining who is offered enrollment into clinical trials is the role of implicit bias that can affect how a physician interacts with community members perceived to be "different" [9]. When a White doctor interacts with a patient of color, distrust, and bias toward either party may unintentionally sway the treatment decision.[10]

Left unchecked, biases can result in discriminatory practices by patient-provider interactions, potentially impacting treatment options offered to patients, including trial participation, ultimately resulting in poorer health outcomes for minority populations.[9] In their work aimed at characterizing barriers to clinical trial participation, Unger and colleagues demonstrated a compelling relationship between clinical trial enrollment and improved cancer population outcomes in the enrolled population groups.[3]

Unequal representation

The substantial cancer burden borne by underrepresented populations and the elderly makes it a compelling reason for policies and initiatives that ensure inclusivity in accessing clinical trial participation by diverse participants to ensure broad applicability of their results.[11]

Many clinical trials in the US have demonstrated an overrepresentation of White participants. In particular, the lower enrollment rates of elderly Black males in cancer clinical trials have previously been noted.[12] Black and Hispanic patients are consistently underrepresented in oncology trials used for FDA cancer drug approval compared to the rest of the population.[12,13] To increase the enrollment

of underrepresented populations, there is a need to be agile and employ multiple strategies targeting providers and participants at clinical trial sites and within communities.[14,15]

Gap identification and evidence

Practice gaps and educational needs were determined based on the survey conducted by the Cancer Centre. Data was gathered from clinical staff interviews and publicly available sources.

Gap 1: Low awareness about disparities in clinical trial participation rates among clinical trial staff

Low awareness of participation rates demographic disparities was gathered from reported clinical trial staff survey responses (verbalized). According to the preliminary survey conducted by the Cancer Centre management, clinical trial staff are unaware of the low participation rates of Black patients. It is critical for trial staff to be sensitized to the low enrollment of Black male participants in cancer trials at the Cancer Centre. Based on the literature, unconscious bias may also contribute to non-White participants not being offered the opportunity to participate in the clinical trial.[7,16]

Gap 2: Unconscious bias among clinical trial staff about lack of awareness impacts trial participant enrollment

Unconscious bias has been shown to be a factor that may impact how physicians interact with patients of a different race.[9] It is common for people to be blind to their biases and how this may impact patient care, including who is offered participation in clinical trials.

"Categorizing people without realizing it is as natural as breathing and allows us to navigate the world."[9]

For this reason, this is a critical inferred gap that can be addressed by providing training and refresher workshops among staff to pre-empty any biases that may impact clinical practice.

Gap 3: Staff members are not clear about their roles and responsibilities

Based on verbalized responses from staff, the cancer trial site has several concurrent clinical trials running. Clinical trial recruitment staff are expected to keep abreast of the ongoing clinical trials and the recruitment process for each one, resulting in confusion and poor implementation of the enrollment process. The data from the survey points to a gap in the trial staff's knowledge of their roles and responsibilities in facilitating participant recruitment. Practising recruitment role-play exercises is a proven, effective way of helping clinical staff members to understand recruitment procedures and promote ease with the recruitment process.[17]

Gap 4: Disconnected workflow and unclear communication channels among clinical trial recruitment staff

Verbalized responses from surveys and interviews conducted among clinical trial research staff and clinical intake staff suggest that they need clear communication channels and are unaware of the workflow to be followed in the recruitment process. Poor understanding of the workflow and transparent communication channels among staff will result in potentially eligible participants being lost in the system. The deficit in understanding the recruitment workflow among clinical staff will filter through to the participants, who often need clarification on their eligibility for enrollment. Some studies have pointed to providing clinical trial recruitment staff with a succinct script as a viable strategy to improve clinical trial participation rates.[17]

Gap 5: Poor Audit System of clinical participation data by clinical trial data management staff

Statistics gathered from the center's data sources point to an unclear audit system of how patients are enrolled in the clinical trial. Without good data, it is challenging to implement changes, including increasing the enrollment of Black males in the center's clinical trials. Several studies have shown how clinical trial participation rates significantly perpetuate health disparities.[11] Workshops and training sessions among the clinical trial data management staff and a system to audit or keep track of participant enrolment rates could address this gap.

Practice Gaps and Educational Needs

Practice Gap	Educational Need	Learning Objective	Anticipated Outcomes
Gap 1: Low awareness about disparities in clinical trial participation rates	Facilitate training of clinical trial staff on the ethical responsibility and importance of racial representativeness in clinical trials	Describe the racial and ethnic characteristics of clinical trial participants	Trial staff will articulate the importance of having racially diverse participants included in clinical trials.
Gap 2: Unconscious bias among clinical trial staff about how lack of self-awareness impacts trial participant enrollment	Workshops aimed at educating clinical staff about unconscious bias and how it negatively impacts participant recruitment	Increase awareness of unconscious bias and its impact on clinical trial staff	Raised awareness of unconscious biases among staff and the ability to make an active effort to avoid bias in recruiting clinical trial participants
Gap 3: Staff members are not clear about their roles and responsibilities	Training sessions for clinical staff on the recruitment procedures and eligibility criteria of the ongoing clinical trials	Distinguish between the roles and responsibilities expected to be fulfilled for each category of staff members involved in the clinical trial enrollment process	Acquire an enhanced understanding of the responsibilities as assessed by before and after surveys among clinical staff
Gap 4: Disconnected workflow and unclear communication channels.	Staff needs education and training to enable them to communicate with each other and visual reminders of appropriate communication channels and workflow	Describe the recruitment workflow and the communication channels in detail	Staff will route patients who are interested in clinical trial participation to appropriate personnel
Gap 5: Poor Audit System for the clinical participation data	Education and training of the clinical data management and	Evaluate clinical trial participation data every quarter	Monthly summary statistics and reports reported

	reporting staff to record and regularly audit recruitment statistics		via a user-friendly dashboard made available to all key trial staff

Conclusions

Our needs analysis shows the need to conduct training of clinical staff at different levels. First, there is a need to educate clinical trial staff on the importance of ensuring that clinical trial enrollment is representative of the population for the data to be valid and generalizable to the entire population. This would ensure equitable healthcare, as new therapies, when eventually discovered, would not exclude anyone.

Secondly, staff must be aware of unconscious biases, which may result in patients from a specific demographic being offered enrollment into clinical trials at the expense of other groups. Furthermore, clinical trial staff need to be trained on the recruitment process as well as the communication processes to ensure clear communication and that every eligible patient is offered a chance to participate in a clinical trial.

Finally, it is essential for clinical trial staff to be updated with the recruitment statistics. Knowing these statistics regularly may help staff be more intentional in interacting with patients and equitably enrolling eligible patients.

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