

Gap Analysis/Assessment of Needs

Background

Cancer clinical trials are research studies to evaluate how new diagnostic tests or treatments affect people. The results improve quality of life for people with cancer. People with a cancer diagnosis can participate in clinical trials if they meet the inclusion criteria. However, less than 10% of people eligible for inclusion in cancer trials participate.¹ African American patients with cancer make-up only 5% of the people in clinical trials while people of Hispanic descent comprise 1%.² AT XYZ Cancer Center, Black patients make up 15% of the patients with cancer but only 5% of the center's clinical trial population. If an ethnicity is not represented in a clinical study, extrapolating the study results to that population is difficult and possibly dangerous. Clinical studies involving more people of minority ethnicity, such as Black and Hispanic, are needed to ensure improve quality of life for all cancer patients. Studies suggest that people of minority ethnicity are willing to participate in trials when they are informed about the trials but they face barriers to participation at the systemic and individual level.³

XYZ Cancer Center seeks to increase cancer clinical trial participation among patients of minority ethnicities, especially Black patients, in order to improve patient care. However, hospital leadership (administrators, chiefs of staff, medical managers, and intake staff) are unaware of the trial participation process and what staff attitudes are toward clinical trial participation. Based on an internal staff survey, XYZ Cancer Center found staff unawareness of disparities in clinical trial participation among different ethnicities, staff confusion about their roles and responsibilities, poor communication between clinical intake staff and research staff, and lack of metrics for tracking which patients with cancer have been asked about a clinical trial.

All staff would benefit from knowing what the disparities are for clinical cancer trial participation among ethnic populations, the eligibility criteria for study inclusion, barriers to participation in trials for patients of non-White ethnicity, resources to constructively mitigate those barriers, and technology and other techniques to improve inter-staff communication regarding which patients have been talked to about possible trial participation.

Gap 1: Hospital staff are unaware of the disparities in clinical trial participation among patient populations.

Education Need 1: Hospital staff would benefit from knowing what the disparities are for clinical cancer trial participation among patient populations.

Learning Objective 1: Hospital staff will describe the statistics about clinical cancer trial participation disparities among patient populations and list reasons for those disparities.

In the United States, deaths from cancer are declining but cancer continues to be a cause of morbidity and mortality across ethnicities.⁴ Clinical cancer trials (CCT) lead to new information that improves detection, management, and treatment of cancer.⁵ Since medical advancements may affect people differently depending on their gender, age, and genetics, clinical cancer trials should enroll people with

diverse ethnicities, age, and gender.⁶ But clinical trial participation varies among people of different ethnicities, age, and gender. People racialized as Black are only 5% of clinical trial participants even though they are 12% of the United States population.² Americans of Hispanic descent, while 16% of the US population, are only 1% of clinical participants.² Women comprise 35% of clinical trial participation.⁷ According to the National Cancer Institute (NCI) of the National Institute of Health (NIH), the highest cancer death rates in the United States occur in men and people racialized as Black.⁴ Many factors contribute to the disparities in CCT participation among patients including socioeconomic conditions such as difficulty accessing screening sites, healthcare insurance access problems, lack of paid medical leave, increased environmental exposure to carcinogens, inherited factors, and patient distrust of the healthcare system.^{4,8} Barriers to physician participation in clinical trials include regulatory compliance issues, knowledge of available clinical trials, clinician attitudes toward clinical trials, and reimbursement issues.⁹ While many of these barriers occur at the systemic level and require higher-level intervention, some occur at the individual level and can be mitigated through education.

Gap 2: Staff are unaware of their roles regarding enrolling patients in clinical cancer trials, specifically knowing which patients to talk to about potential trial participation and how to talk with those patients once they're identified.

Education Need 2: Staff would benefit from knowing eligibility criteria for clinical trial participation, having methods for talking with patients about potential trial participation, and understanding barriers to trial participation by Black and Hispanic patients, and how to mitigate those barriers.

Learning Objective 2: Staff will list patient eligibility criteria for clinical trials, describe barriers to trial participation by Black and Hispanic patients and explain strategies for overcoming those barriers.

Healthcare providers must have knowledge of current clinical trials as well as eligibility criteria in order to identify patients they should talk to about possible trial participation. The National Institutes of Health (NIH) has a web page where patients and physicians can find current clinical trials.¹⁰ The American Cancer Society published a synopsis of clinical trial eligibility criteria, guidelines for informed consent, the process once a patient is enrolled, and the patient's right to stop participation at any time without risking interruption of standard treatment for their illness.¹¹

Primary care physicians often diagnose cancer and can be intricately involved in care decisions such as pain management and treatment options.¹² Patients reported that a cancer trial participation recommendation from their physician was the main impetus behind their decision to partake in a clinical trial.¹⁵ Among cancer survivors who were surveyed in one study, 73% reported that they learned about the possibility of participating in CCT from their physician.¹⁶ Bylund et al found that while primary care physicians had positive perceptions of clinical trials, they lacked in-depth knowledge about and experience with clinical trials.¹² Patients of all ethnicities express willingness to participate in clinical trials but barriers to their participation may include patient mistrust of healthcare systems and lack of knowledge of clinical trials.³ "Over the years our data has begun to show us that, for African Americans, it is not so much that we are afraid, but the biggest reason is lack of access and information," according to Patricia Sanders, director of the nonprofit 50 Hoops that educates African Americans about clinical trials. "There are so many things people don't know about clinical trials."¹³ Staff may not understand the

unique reasons why patients that are Black or Hispanic are wary of clinical trial participation.³ “The bottom line is that unfortunately, [Black people have] been misinformed and mistreated. The whole purpose is to ensure that those who do not know are educated around what the truth is by meeting them where they are and showing them that the long-term results of clinical trials can only be positive,” notes Clinical Trial Ambassador Yolanda Murphy.¹⁴ Staff can restore trust by knowing clinical trial eligibility criteria, by understanding that obstacles to trial participation exist for Black and Hispanic patients, and by addressing those obstacles to improve trial participation.³ Providing education to primary care physicians, especially Black and Latino providers, may improve in CCT.¹²

Healthcare providers and patients may hold incorrect beliefs about each other and about clinical trials. Although there is no evidence that physicians actively discriminate against minorities regarding clinical trial participation, studies have suggested that physicians may hold incorrect beliefs about minorities, such as the idea that Black patients are less likely to comply with study treatment protocols, which might preclude physicians from talking to those patients about trial participation.²¹ Patient-centered communication training may help reduce healthcare provider bias regarding patients of minority ethnic descent. Such training focuses on cultivating positive physician-patient relationships, identifying patient needs connected to their ethnicity and culture, and demonstrating the importance of gaining patient trust in successful trials.²¹ Regarding patient misconceptions about healthcare providers and systems, research shows that while Black patients are more likely to fear being treated like “guinea pigs” than other ethnicities, they are just as likely to participate in clinical trials as other groups if they are offered enrollment in a trial.²¹ Lack of knowledge and awareness about clinical trials has been cited as the main reason for low African American participation in clinical trials while recommendations from physicians and community support were cited as the main impetus for trial participation.²¹ Community-centered education programs that focus on training peers of patients in underserved populations about the benefits of participating in clinical trials were found to increase knowledge and improve attitudes toward clinical trials.²² Strategic education planning programs tailored to ethnic minorities have also been shown to increase minority recruitment.²³

Conversations with patients about clinical cancer trial participation can be difficult because patients are emotional about their illness. The gap between clinical knowledge and patient knowledge, or health literacy, can be large and even when it’s not, healthcare staff, especially physicians, may not be communicating effectively with patients.¹⁷ The NCI developed an evidence-based method for staff conversations with patients about clinical trial participation.¹⁸ The method focuses on creating an empowering environment including a private location, encouraging the patient to ask trusted people to attend, empathizing, being respectful, avoiding medical jargon, asking open-ended questions for understanding, and summarizing and repeating key points regularly.¹⁸ The FDA Oncology Center of Excellence Patient-Friendly Language for Cancer clinical Trials provides less academic clinical trial term definitions providers can use when speaking with patients about clinical trials.^{19, 20} Informed consent conversations with prospective clinical trial participants are equally important. Handling them compassionately, clearly, and appropriately while emphasizing the voluntary nature of participation with the option to opt out at any time is paramount to improving patient understanding of the clinical trial

process.¹⁸

Once hospital staff understand the eligibility criteria for clinical cancer trial participation and learn effective communication techniques, they can help increase cancer trial participation. By understanding barriers to trial participation for under-represented populations and individual misconceptions about people, staff can constructively address those barriers and improve participation in clinical trials for patients of Black or Hispanic ethnicity.

Gap 3: Clinical trial research staff and clinical intake staff are unaware of how to share information about patients such as knowing which patients have been talked to about trial.

Education Need 3: Clinical trial research staff and clinical intake staff would benefit from knowing how to efficiently communicate with each other regarding enrolling patients in clinical cancer trials.

Learning Objective 3: Clinical trial research staff and clinical intake staff will organize the communication steps and technology they'll use to inform each other regarding enrolling patients in clinical cancer trial participation.

When communication between healthcare providers breaks down, patient care may suffer.²⁴ Improved communication among members of the healthcare team is linked to better patient outcomes.²⁴ Monica Fradkin, RN, MPH, Smilow Cancer Hospital at Yale-New Haven notes that improving inter-staff communication prioritizes patient safety in clinical trials.²⁵ Using hand-off tools, educating staff, and engaging electronic medical record documentation tools facilitate inter-staff information sharing.²⁵ Strategies for improving communication, such as tracking which patients that have been offered clinical trials, include creating and maintaining a culture of mutual respect among healthcare team members; training team members in improved communication skills such as listening, planning, clarity, empathy, and giving and receiving feedback; and using situation-background-assessment-recommendation (SBAR) structured communication.^{24,26} Technology, such as text messaging and electronic medical records, can enhance communication between staff members.^{24,27}

Summary

Participation in cancer clinical trials by patients of Black and Hispanic ethnicity at this institution, as in general in the United States, is low. Increased participation will improve quality of care for this patient population. XYZ Cancer Center medical staff will benefit from understanding clinical trials and eligibility criteria, knowing why participation by under-represented groups is low and how to mitigate those issues to improve participation in clinical trials by this population at their institution. Finally, implementing new technology and practices for sharing information will help facilitate connectivity between staff regarding patients.

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