Building Health Equity through Research Study Design for Multicancer Early Detection Tests:

Key Considerations

A REPORT FROM
The Multicancer Early Detection Consortium
Health Equity Workgroup

Table of Contents

Executive Summary 2
Problem Statement 2
Investigator-level considerations 2
Patient-level considerations 3
Underrepresented groups considerations and implications 3
Implications 4
Recommendations 6

Executive Summary

A primary goal of the Multi Cancer Early Detection (MCED) Health Equity Workgroup is ensuring equitable access to care advancements in cancer prevention, screening, diagnosis, and treatment. This focus on health equity encompasses all parts of research study and design, particularly increasing diversity in research study populations and methods to reflect intended populations of study and document how MCEDs may impact demographic groups differently. Increasing research study population diversity requires leveraging relationships of trust at the patient-provider level as well as collaborating with larger institutions and patients' wider communities to ensure equitable opportunity for research study participation.

Problem Statement

Diverse research study populations and methods are key when investigating the efficacy of clinical drugs and medical screening tools in practice. Ensuring representation of the intended patient population among research study populations increases the safety and context of new medical technologies from point of screening to post-study results. Diversity of study populations not only means racial and ethnic diversity, but also referencing socioeconomic status, disability, gender, sex, pregnancy status, and presence of pre-existing conditions.[1] Increasing trial diversity can also boost public awareness and willingness to try new treatments or tools. Most importantly, increasing trial diversity is another form of health equity, where the scientific community can better understand how clinical treatments affect underrepresented groups ethically and increase access to potentially life-saving health care.[2] By also focusing on research methodologies beyond clinical trials to include participant surveys, interviews, and discussion groups, researchers can also gain a more nuanced understanding of how MCEDs operate in practice.

Investigator-level considerations

Investigators often assume patients are not able or willing to participate in research studies. This bias stems from investigators assuming patients will fail to comply with scheduled assessments or medication regimens due to patient visit and medication adherence histories. Investigators also assume that if a patient is already managing an existing treatment regimen well, then they would not be interested in participating in a research study. Patients from underrepresented communities are also

[1] Kenny, N., McDonough, K., & Keith, S. (2022, July 21). *6 ways to bolster FDA's guidance for diversifying participation in clinical trials*. Retrieved from STAT: https://www.statnews.com/2022/07/21/6-ways-to-bolster-fdas-guidance-for-diversifying-participation-in-clinical-trials/

[2] Younossi, A., Sanahi, W., Shah, S., Chang, C., & Overman, J. (2021, November 11). *Enhancing clinical trial diversity*. Retrieved from Deloitte: https://www2.deloitte.com/us/en/insights/industry/life-sciences/lack-of-diversity-clinical-trials.html/

more disproportionately impacted[3] in terms of social determinants of health (SDOH) which could impede patient research study participation. Investigators cite concerns over patients' ability to reach research study sites and lack of medical and health literacy.

Investigators' preconceptions on patient willingness to participate in research studies have a self-fulfilling effect, where even though 75 percent of patients are likely to consider a research study if recommended by a doctor, investigators do not make patients aware of research study participation opportunities.[4] Decentralized trials and wearable technologies have helped address some SDOH issues, where travel distance may be less of a burden on participants, but they do not address investigators' underlying biases regarding patient willingness.[5]

Patient-level considerations

Personal benefits are the strongest motivators for patient research study participation. The most prominent motivators include the opportunity to be treated by experts in their disease(s), to receive free treatment (in the context of an insurer-based healthcare system), to receive additional care and attention from research staff, and to learn more about individual health. Research study participants also report highest satisfaction scores when research studies deliver in both experience and outcome. When research study staff treat patients with empathy and professionalism, patients report feeling more supported, more educated, and satisfied with research study results.

While patient demographics are important to consider, trust and relationship strength are ultimately the strongest factors in patient research study participation. When their own doctor versus a recruiting specialist recommends a research study, patients are 15 percent more likely to follow through on the recommendations.

Underrepresented groups considerations and implications

Personal benefits remain the strongest motivator across racial and ethnic groups, and the statistic that 75 percent of patients are more willing to consider a research study if recommended by a doctor is consistent across racial and ethnic groups.

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[3] Hamel, L. M., Penner, L. A., Albrecht, T. L., Heath, E., Gwede, C. K., & Eggly, S. (2016, December 1). Barriers to Clinical Trial Enrollment in Racial and Ethnic Minority Patients With Cancer. Cancer control: journal of the Moffitt Cancer Center, 23(4), 327–337. https://doi.org/10.1177/107327481602300404

[4] U.S. Department of Health and Human Services. (2016, March 16). The need for awareness of clinical research. National Institutes of Health. Retrieved February 17, 2023, from https://www.nih.gov/health-information/nih-clinical-research-trials-you/need-awareness-clinical-research

[5] Adams, D. V., Long, S., & Fleury, M. E. (2022). Association of Remote Technology use and other decentralization tools with patient likelihood to enroll in cancer clinical trials. JAMA Network Open, 5(7). doi:10.1001/jamanetworkopen.2022.20053

Personal benefits that are high-value and consistent across demographics

- Free treatment
- Opportunity for additional care and attention
- Opportunity for treatment from disease expert(s)
- Opportunity to learn more about individual health
- Paid travel and time off work
- Opportunity to improve the lives of others

Key factors for underrepresented groups' participation in research studies relative to white individuals

Principal Investigator (PI) is :

- A doctor they see regularly (55 percent of underrepresented surveyed vs. 56 percent of white individuals)
- Someone that their regular doctor knows well (47 percent of underrepresented surveyed vs. 53 percent white individuals)
- Has the same condition as the patient (40 percent of underrepresented surveyed vs. 34 percent white individuals)
- The same race/ethnic background (29 percent of underrepresented surveyed vs. 8 percent white individuals)
- The same gender (27 percent of underrepresented surveyed vs. 8 percent white individuals)

Regardless of patient background, research studies need to leverage patient-provider relationships. However, these ties are even more important for involving underrepresented patients, as public health institutions have historically pushed them away from adequate care through discrimination, medical experimentation, and historical trauma.[6]Patients with negative medical experiences are less likely to participate in research, which can explain some of the gaps in research study diversity.[7]

Implications

At the investigator level, PIs and research staff can collaborate to raise awareness and encourage study participation across investigators' patients. Research studies of different styles can increase the rigor and access of potentially life-changing research studies by partnering with physicians, investigators, and community organizations that serve low income, Black, Brown, or Asian populations. While randomized clinical trials are essential to understanding MCED's effects on different patient populations, PIs and

[6] Racism and discrimination in health care: Providers and patients. (2017, January 16). Retrieved from Harvard Medical School: https://www.health.harvard.edu/blog/racism-discrimination-health-care-providers-patients-2017011611015

[7] Devlin, A., Gonzalez, E., Ramsey, F., Esnaola, N., & Fisher, S. (2020). The Effect of Discrimination on Likelihood of Participation in a Clinical Trial. Journal of racial and ethnic health disparities, 7(6), 1124–1129. https://doi.org/10.1007/s40615-020-00735-5

researchers can better understand sources of patient hesitation, discomfort, and patient experience from focus group discussions, key personnel interviews, and mixed-methods research methodologies. By leveraging their trust and cultural competency, physicians and organizations can bring these underrepresented patients into research studies. Investigators can also collaborate with underrepresented populations in research study design, data collection, and public education.[8]

Physicians and investigators also need to actively address their own biases and inform patients about the potential costs and benefits of study participation rather than assume patients are unwilling or unmotivated. Moreover, investigators need to understand how patient motivators differ from theirs, as patients are motivated by the study's personal benefits while investigators are motivated by potential contributions to medicine, belief in the study's medical efficacy, and lack of existing treatments for patient populations. On top of ensuring study criteria and trial materials are developed inclusively, research studies can use coordinators and recruiters that specialize in sourcing study participants and are culturally competent. Cultural competency training for all staff can minimize bias towards different ethnic groups, clarify consent depending on cultural setting, and identify respectful cultural mannerisms.[9]

At the community level, research studies with broader recruiting strategies tend to be more successful in recruiting diverse populations. More nontraditional forms of outreach, such as print or digital media, community organization partnerships, and advocacy group collaborations, are better at engaging underrepresented populations. At a systematic level, research study sponsors can work with academic or commercial research sites to set broad enrollment areas or targets in contractual agreements. For example, sponsors can require site selection enrollment to reflect the populations' disease burden, and researchers can work with faith-based or local educational organizations to understand a wider array of patient expectations and experiences. These outreach and recruitment methods actively prioritize research study diversity from the beginning as opposed to relying on PI direct outreach.

While studies center around the patient, they also begin with research staff. Patient recruitment and referral is a competitive space, with 50 percent of trial sites studied only finding one patient and another 20 percent failing to recruit any. By supplying them with much-needed training and resources, study staff can automate much of the recruitment processes and direct their efforts towards building trust with community organizations to increase the size and diversity of potential study populations. PIs also benefit from increased training and education, as they can better understand patient-level motivators and how influential they are in encouraging research study participation.

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[8] UK standards for Public Involvement. (n.d.). Retrieved February 17, 2023, from https://sites.google.com/nihr.ac.uk/pi-standards/home

[9] Dawson, S., Banister, K., Biggs, K. et al. Trial Forge Guidance 3: randomised trials and how to recruit and retain individuals from ethnic minority groups—practical guidance to support better practice. Trials 23, 672 (2022). https://doi.org/10.1186/s13063-022-06553-w

Recommendations

Investigator and PI measures	• Address their own biases about patient willingness and expectations • Invite and collaborate with their own patients • Represent and involve researchers that are part of target populations
Participant-level measures	• Identify patient motivators early on, separate from investigators' motives • Communicate potential participant benefits upfront • Include opportunities to be treated by disease experts • Compensate participants for involvement
Underrepresented participants measures	• Identify historical or community barriers for underrepresented populations • Leverage institutional connections with communities of color (advocacy group collaborations, community partnerships) • Advertise and collaborate with physicians that regularly work with underrepresented communities • Utilize nontraditional forms of outreach (print, digital media, community organizations) • Partake in cultural competency training and respectful mannerisms
Study measures	• Diversify research methodologies to include clinical trials, surveys, focus group discussions, and ethnographies • Develop research study communication and materials to be understandable for targeted communities (given health literacy levels, English comprehension, preferred communication styles) • Establish formal academic or commercial research partnerships • Set broad enrollment areas or targets in contractual agreements • Dedicate or hire specific staff for participant recruitment