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Integrating primary care, shared decision making, and community engagement to facilitate equitable access to multi-cancer early detection clinical trials

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Effective implementation of cancer screening programs can reduce disease-specific incidence and mortality. Screening is currently recommended for breast, cervical, colorectal and lung cancer. However, initial and repeat adherence to screening tests in accordance with current guidelines is sub-optimal, with the lowest rates observed in historically underserved groups. If used in concert with recommended cancer screening tests, new biospecimen-based multi-cancer early detection (MCED) tests could help to identify more cancers that may be amendable to effective treatment. Clinical trials designed to assess the safety and efficacy of MCED tests to assess their potential for reducing cancer mortality are needed and many are underway. In the conduct of MCED test trials, it is crucial that participant recruitment efforts successfully engage participants from diverse populations experiencing cancer disparities. Strategic partnerships involving health systems, clinical practices, and communities can increase the reach of MCED trial recruitment efforts among populations experiencing disparities. This goal can be achieved by developing health system-based learning communities that build understanding of and trust in biomedical research; and by applying innovative methods for identifying eligible trial patients, educating potential participants about research trials, and engaging eligible individuals in shared decision making (SDM) about trial participation. This article describes how a developing consortium of health systems has used this approach to encourage the uptake of cancer screening in a wide range of populations and how such a strategy can facilitate the enrollment of persons from diverse patient and community populations in MCED trials.

KEYWORDS

multi-cancer detection assays, primary care, shared decision making, community engagement, cancer, screening, clinical trials

1 Introduction

When effectively implemented, standard of care (SOC) cancer screening tests reduce disease-related morbidity and mortality (1–5). Unfortunately, observed reductions in mortality have not been distributed evenly across cancer types and diverse patient populations (6). Importantly, SOC cancer screening via periodic mammography, Pap testing, stool testing/colonoscopy, and low-dose CT scans is recommended for only four cancer types in the U.S. – breast, cervical, colorectal and lung. This leaves eight of the twelve most common cancer types without a recommended screening test. More than 60% of cancer deaths in 2022 are expected to have occurred for cancer types with no recommended screening test (7–9). Importantly, even for those cancers with a recommended screening test, adherence to screening is sub-optimal for all types, especially lung cancer (10). Furthermore, there are disparities in screening among medically underserved groups, with lower rates of screening and poorer outcomes in African American and Hispanic populations, as well as in populations residing in rural areas (6). Incomplete diagnostic follow-up of positive screening tests also limits the overall impact of SOC cancer screening (11).

Many populations with disparities in cancer screening also are underrepresented in clinical trials, including racial and ethnic minority groups, individuals of low socioeconomic status and rural residents (12, 13). Disparities are noted at eligibility, interest in participation and actual enrollment (14). There are many established reasons for lower enrollment of these groups, including transportation, cost, trust in medical system, and patient knowledge or comprehension of the research (15), and multi-level interventions are needed to increase enrollment of underrepresented populations (16).

Blood-based multi-cancer early detection (MCED) tests, alone or in concert with existing SOC screening modalities, have the potential to increase the detection of early, curable cancers and reduce disparities in screening. MCED tests, which analyze cell-free DNA and other biomarkers for the presence of cancer, have been shown in early trials to be capable of detecting cancers for which there is no SOC screening (17, 18). The collection of biospecimens, such as a simple blood test, that requires no preparation could improve adherence to cancer screening and, if distributed equitably, could reduce disparities in screening (11, 19). Further, MCED tests, by nature of being blood based, may be easier and cheaper to distribute across communities compared to large imaging equipment, such as mammography machines or CT scanners.

MCED tests are not currently part of routine cancer screening. They have not been approved by any of the regulatory bodies involved in evaluation of cancer screening tests. However, trials demonstrating clinical efficacy are underway around the world (20). Determining how to best implement broad use of these tests in diverse populations will require specific effort different than simply proving efficacy in selected populations. In this regard, initiatives like the National Cancer Institute's Cancer Screening Research Network (CSRN) and The White House's Cancer Moonshot programs are essential. It is crucial to develop new technology for screening and early detection in ways that do not increase, and preferably decrease, gaps in access and efficacy between

populations. This involves ensuring that trials are conducted in diverse populations and settings with representation from communities that have traditionally been underrepresented in screening and other trials (21–24). For example, Jefferson Health (JH) has experience in using a theory-based model to guide the creation of a “health system learning community infrastructure” that can organize and adapt strategies for implementing interventions in primary care that can increase cancer screening and reduce disparities in screening use (25, 26). This learning community brings together health system leaders, healthcare providers, patients, insurance carriers, community stakeholders, and disease-specific advocacy groups. Evidence-based screening information and screening intervention implementation strategies and outcomes data are shared. Research project coordination (e.g., enrollment, longitudinal participant engagement and follow-up, data collection) is a key component of the learning community. The development of the CSRN for running large scale MCED trials presents an opportunity to establish this learning community on a broader scale. Here we describe examples of engaging with diverse community and clinician stakeholders in MCED trials and other cancer screening studies in hopes that these experiences will inform equitable MCED trial design.

2 Use of shared decision making in cancer screening and MCED trials

Shared decision making (SDM) and bidirectional communication between clinicians and potential research study participants can build trust in biomedical research. Mistrust in the health care system is disproportionately prevalent among racial and ethnic minority groups and members of underserved communities (27, 28). However, SDM can be challenging to implement well. The learning community model can be helpful for improving SDM for large scale trials with large numbers of providers involved in patient recruitment. SDM-based decision counseling has been used successfully in different health systems to advance colorectal cancer screening and prostate cancer screening research by guiding the recruitment of primary care practices and providers, delivery of decision counseling to patients, and engagement of diverse populations (29, 30). In a recent study on lung cancer screening, JH primary care physicians were encouraged to identify and refer patients who were eligible for lung cancer screening. Patients were randomized to one of three study groups: Outreach Contact plus Decision Counseling (OC-DC), Outreach Contact alone (OC), or usual care control group (UC). The research team found that screening was significantly higher in the combined OC/OC-DC group versus UC controls (5.5% vs. 1.8%, $p = 0.001$), where the UC group's very low rates are similar to what is observed nationally (31). Screening was not statistically significantly higher in the OC-DC group than in the OC group (7% vs. 4%, respectively, $p = 0.123$). Screening referral and scheduling was also significantly higher in the OC/OC-DC group compared to controls (11% v. 5%, $p = 0.001$).

To examine the use of decision counseling related to MCED trial participation, a JH research team recently completed a prospective observational study with primary care patients at a large, urban healthcare system. Patients 50 to 80 years of age

received mailed information about a planned MCED trial. After receiving this mailing, a research coordinator contacted patients by telephone, obtained consent, administered a survey, and completed a decision counseling interview to elicit factors affecting interest in the trial. The research coordinator also completed an endpoint telephone survey at one month to assess participant interest in and decisional conflict related to joining the trial. Of 1,000 eligible patients, we contacted 690 (69%). Of those contacted, 246 (36%) consented and completed the baseline survey; 217 (88%) completed decision counseling, and 219 completed the endpoint survey. On the endpoint survey, 177 (81%) respondents expressed interest in joining the MCED trial, and 162 (74%) reported low decisional conflict. Among 485 decision factors identified during decision counseling, 396 (82%) favored trial participation.

In concert with this effort, JH also completed a pilot study to assess primary care provider support for patient participation in a planned MCED test clinical trial. Information provided to primary care providers in an infographic explained that in a multi-year trial, health system research coordinators would be responsible for recruiting and following patients in the MCED trial. In addition, the infographic noted that study participants would undergo serial blood draws for MCED testing and would be randomly assigned to either a control group or an intervention group. The control group would receive usual care, with retrospective MCED test analysis; the intervention group would receive usual care, with immediate MCED test analysis and follow-up, as needed. Furthermore, it was explained that costs associated with testing and follow-up would be covered for both study groups. Providers who agreed to complete the survey (N=27) were asked if they intended to support patient participation in the MCED trial; 25 (93%) reported that they would support participation.

3 Use of community engagement in cancer screening and MCED trials

Community engagement is another important way to increase the reach of MCED trial participation, particularly for underrepresented individuals. Partnerships with community organizations and engagement with members and key stakeholders from underserved areas can help us identify eligible patients and communicate effectively with them, thereby diversifying representation in the trials. Earlier studies have shown that community-based participatory research can result in very high recruitment rates and very low refusal rates (32).

Over the past 20 years Fox Chase Cancer Center/Temple University has developed a research infrastructure linking over 400 community- and faith-based organizations with clinical partners across the PA-NJ region directed towards cancer screening within diverse Asian American populations (notably Chinese, Korean, and Vietnamese). Several community advisory boards inform collaboration and facilitate linkages among researchers, community members and clinical partners. These

collaborations have resulted in successful completion of projects ranging from efforts intended to curb tobacco use, improve cervical cancer education or increase hepatitis B vaccination to broader questions like factors influencing clinical trials participation or willingness to contribute to biorepositories (33–37).

Numerous other examples of community engagement that improves cancer screening trial recruitment in underserved populations can be cited, including many studies aiming to account for cultural differences in a trial (38). For example, Wood et al. partnered with a members of a First Nations tribe to successfully enroll participants into a cervical cancer screening trial (39). These examples demonstrate that the positive impact of partnering closely with the communities from an early stage in the research development, empowering the community partners to help direct the research activities and doing so in a culturally sensitive manner.

Partnerships with federally qualified health centers (FQHCs) and other community hospitals represent another opportunity to enhance trial participation, particularly from underrepresented populations that are missed when recruitment is limited to academic medical centers. FQHCs serve patients regardless of their insurance status and ability to pay and can be an important source of primary and specialty care for many people, including 1/3 of people living in poverty (40).

4 Strategies for trial recruitment in rural communities in MCED trials

Members of rural communities are traditionally underrepresented in clinical trials as well. While this is influenced by much research happening in academic medical centers that are more commonly found in urban areas, other barriers to participation among rural residents, including concerns about access and knowledge of trials (41). In addition, researchers should consider ways of meeting community members where they are and bringing the trials to them instead of relying on under resourced individuals to come to academic medical centers.

Geisinger, which serves a largely rural area across 46 counties in central and northeastern Pennsylvania, has established a Multi-Cancer Screening Research Program to identify participants from the largely rural population it serves. An existing mobile team improves access to trials by traveling throughout the Geisinger service area and meeting potential participants in their communities. The team, which is responsible for conducting ongoing and upcoming MCED trials, includes a program manager, project managers responsible for recruitment, data collection, data transfer, and regulatory functions, as well as research assistants and phlebotomists. As demonstrated in the DETECT-A study (42), the Multi-Cancer Screening Research Program successfully enrolled 10,000 females in less than two years. The team's approach included distributing study teams of research assistants and phlebotomists to 22 clinical and community sites across Geisinger's geographic service area (43).

5 Discussion

Population-level cancer screening trials, specifically MCED trials, will require large consortia of multiple recruitment sites. Enrolling sufficient numbers of diverse participants is critical for their success. The strategies described above, including Learning Communities, community engagement, and efforts to improve access to trials in rural communities, represent promise for engaging diverse groups in large-scale MCED trials.

Community health workers (CHWs) represent another promising strategy that has not yet been applied to MCED trial recruitment. CHWs are trusted community members that understand the community that they live in and are advocates for better health in their community. CHWs represent a unique opportunity for researchers to engage with communities for trial enrollment as well. CHWs have repeatedly shown to enhance access to and quality of care in various settings, including primary care (44). However, few empirical trials have been done to test their effectiveness for increasing accrual to cancer screening trials. This represents a research opportunity specifically for MCED trials as well.

Although some trials of MCEDs are underway and others are planned, there are examples of successful studies that describe strategies for engaging primary care, facilitating SDM, and engaging communities that can increase the equitable representation of persons from diverse populations and underserved communities in cancer research. These studies and approaches suggest novel ways in which trial design and implementation strategies can be operationalized. Furthermore, using proven approaches in the context of health system learning communities could serve to amplify their effectiveness. Additional studies that explore these models and their use in addressing the recruitment of participants to MCED trials are needed. Using such evidence-based strategies will help us be more deliberate in our inclusion of individuals from underrepresented groups in trials, thereby making it possible to discern the effects of different MCED tests in diverse populations and set the stage for the equitable implementation of safe and effective tests in clinical practice.

Data availability statement

The original contributions presented in the study are included in the article/supplementary material. Further inquiries can be directed to the corresponding author.

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Author contributions

CT: Conceptualization, Writing – original draft, Writing – review & editing. AB: Conceptualization, Writing – original draft, Writing – review & editing. RM: Conceptualization, Writing – original draft, Writing – review & editing. DW: Conceptualization, Writing – original draft, Writing – review & editing.

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Conflict of interest

AB holds equity stake in MeTree and You, Inc.

The remaining authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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