

Establishing a Primary Care Alliance for Conducting Cancer Prevention Clinical Research at Community Sites



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ABSTRACT

In September 2020, the National Cancer Institute convened the first PARTNRS Workshop as an initiative to forge partnerships between oncologists, primary care professionals, and non-oncology specialists for promoting patient accrual into cancer prevention trials. This effort is aimed at bringing about more effective accrual methods to generate decisive outcomes in cancer prevention research. The workshop convened to inspire solutions to challenges encountered during the development and implementation of cancer prevention trials. Ultimately, strategies suggested for protocol development might enhance integration of these trials into community settings where a diversity of patients might be accrued. Research Bases (cancer research organizations that develop protocols) could encourage more involvement

of primary care professionals, relevant prevention specialists, and patient representatives with protocol development beginning at the concept level to improve adoptability of the trials within community facilities, and consider various incentives to primary care professionals (i.e., remuneration). Principal investigators serving as liaisons for the NCORP affiliates and sub-affiliates, might produce and maintain “Prevention Research Champions” lists of PCPs and non-oncology specialists relevant in prevention research who can attract health professionals to consider incorporating prevention research into their practices. Finally, patient advocates and community health providers might convince patients of the benefits of trial-participation and encourage “shared-decision making.”

Rationale for a Primary Care Alliance in Cancer Prevention Studies

Clinical detection of both cancer and premalignant conditions exists within the domain of primary care professionals, who in this respect are the “first responders” and medical “gate-keepers” of the healthcare system (1). Traditionally, they comprise family physicians, internists, pediatricians, obstetrician–gynecologists, nurse practitioners, and physician assistants (2). Yet, the subsequent active consultation and management of frank disease and pre-cancer that has been detected early necessitates involvement by medical oncologists, general surgery or surgical subspecialists (e.g., colorectal surgeons, urologists, gynecologists), radiologists

(e.g., diagnostic and interventional), and other specialists (e.g., dermatologists, geneticists, etc.) (3). As such, accruing participants to cancer prevention trials is highly dependent on primary care professionals and the numerous specialists engaged in prevention, detection, and management of premalignant conditions, as well as on the people themselves who are at risk for cancer (4). However, the recognized gulf in professional communication and coordination between primary care professionals and oncologists of multiple specialties—surgical, radiological, and pharmacological—indicates the overdue need for relational change in these clinical practice settings (5). Moreover, the chasm between the groups can impede clinical oncology research, although primary care professionals, particularly Black and Latino physicians, have indicated they are interested in learning more about cancer clinical trials (6). Experiences conducting cancer prevention studies through the National Cancer Institute Community Oncology Research Program (NCORP) are affected by the accrual challenges within this cancer care delivery system, and thus led to the concept and inaugural workshop called “PARTNRS: The Primary Care Alliance in Research Trials Involving NCORP Sites.”

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Purpose of the PARTNRS Workshop

The PARTNRS workshop, convened on September 18, 2020, was developed to improve participant accrual to NCORP-

supported cancer prevention trials by forging effective partnerships between oncologists, primary care professionals, and medical specialists. The immediate goal was to establish a platform for generating strategies to overcome barriers to accrual. The long-term goal is the establishment of highly effective accrual methods that support rigorously developed cancer prevention clinical trials.

Workshop attendees included family physicians, general internists, nurse practitioners, and specialists in medical, pediatric, surgical and radiation oncology, academicians, NCORP community oncologists, and clinical administrators. To facilitate a robust discussion, the following organizations were invited: General medical organizations, including the American Medical Association (AMA), the National Medical Association (NMA), and the National Hispanic Medical Association (NHMA); internal medicine organizations, such as the American College of Physicians (ACP) and the Society of General Internal Medicine (SGIM); and advanced practice organizations, such as the American Association of Nurse Practitioners (AANP). Also participating were the principal investigator and staff from the NCORP Minority/Underserved Baptist Memorial Health Care/Mid-South. The workshop chairs were the past presidents of the AMA and the NMA.

NCORP is a national network that brings cancer clinical trials and care delivery studies to people in their own communities. The network designs and conducts clinical trials in cancer prevention, screening, surveillance, supportive care and symptom management, along with health-related quality of life and cancer care delivery studies. NCORP investigators also enroll patients onto cancer treatment trials. NCORP is committed to integrating health equity research questions across all studies. By bringing cancer clinical research to individuals in their own communities, NCORP clinical trials reflect national diversity so the evidence generated contributes to improved patient outcomes and a reduction in cancer disparities for all people. The network is comprised of seven Research Bases and 46 Community Sites, 14 of which are designated as Minority/Underserved Community Sites, collaborating with more than 9,000 physicians, nurses, and research staff across the United States. See Fig. 1.

NCORP Research Bases develop the study concepts and protocols with input from Community and Minority/Underserved Sites. Sponsored meetings and conferences provide opportunities to discuss experiences in patient accrual to cancer prevention trials. Community investigators often describe protocols as having insufficient input from primary care providers or non-oncology specialists, a situation that leads to suboptimal opportunities for engaging these groups as research partners. In addition, primary care professionals have suggested that integration of research protocols into their practice must meet the following requisites without cumbersome administrative or regulatory procedures: The protocols must be convenient, not time-consuming, and without additional costs for interventions; and favorable such that the benefits exceed the perceived risks.

The PARTNRS Workshop tackled the challenges of enrollment into cancer prevention studies by analyzing the roles and interactions of five pertinent stakeholders: Research Bases that produce the protocols; the NCORP Site principal investigators, who are liaisons between Research Bases and their affiliated community oncologists; the affiliated community oncologists; the community non-oncologists (e.g., primary care professionals and specialists); and the patients/participants.

A vital area of discussion was the protocol-production to protocol-implementation trajectory, from the perspective of the NCORP Community Sites, which has been characterized as a “trickle-down” directive process and siloed with lines of demarcation between each stakeholder instead of an exchange. See Fig. 2.

Principal investigators also suggested that the Research Bases were not fully aware of the complexities encountered when integrating new prevention protocols within the sphere of routine primary care, where protocols should be aligned with quality metrics required in the primary care setting. Quality metrics and maintenance of clinical credentials, such as clinical medical education credits, and specialty certification and recertification boards, are important priorities for primary care providers.

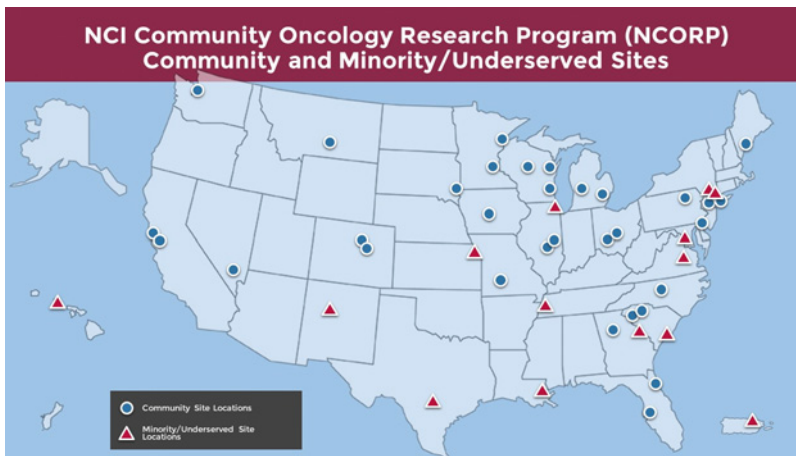


Figure 1. NCORP Community Oncology Research Program locations of Community and Minority/Underserved Sites throughout the United States.



Figure 2.
Interactions among stakeholders during the participant accrual process.

Recommendations for the Protocol Process

Research Bases

Typically, protocol development is a multi-tiered, labor-intensive process requiring time commitments that may not be feasible for primary care professionals, community practitioners, and patient-advocates. There is substantial remodeling in protocol-development, beginning with conceptualizing a protocol, until the protocol is deemed acceptable by the Research Base to release for review and final approval by the NCI and the Central Institutional Review Board. Upon receipt of the protocol, the NCORP Community Site principal investigator typically collaborates with an interested community provider who manages the target population within a facility. Despite initial efforts to integrate the trial within the community, requirements can emerge that are cumbersome for implementation within the clinic. Recommendations are as follows:

1. Develop strategies to promote greater involvement of primary care professionals, non-oncology specialists, and patient representatives within the Research Base's Prevention Committee. For a target patient population, the committee can seek representation by primary care professionals, specialists, and patients during concept and protocol development, and the NCORP principal investigator can identify appropriate individuals to inform the Research Base about the feasibility of integrating the trial into the community setting without disrupting the clinic's daily operations.
2. Promote ways to stimulate the interest of primary care professionals and non-oncology specialists in participating in prevention trials. This may come through financial remuneration through partial or full funding for travel for annual meetings, as well as

enhancing professional development in the area of clinical research. In addition, "Relative Value Units" may be the principal subsidy for most primary care professionals (7). This was discussed during the session of a successful non-federal oncology network—the National Cancer Care Alliance (8)—where financial challenges faced by oncology-primary care partnerships in research were described. Also, professional enhancement can be stimulated through continuing medical education credits from the AMA or American Academy of Family Physicians related to the roles for primary care professionals in research; this may also potentially provide co-authorship opportunities.

3. Consider cancer prevention research presentations at specialty meetings as opportunities for recruiting those specialists who are pertinent for accruing patients. Research Base study chairs may consider presenting their proposals and/or results at meetings conducted by general medical organization or specialties pertinent to the area being investigated. For example, prostate prevention protocols can be presented at urology meetings; cancer prevention studies investigating cervical screening can be presented at gynecological meetings. In addition, in quality improvement sessions, prevention committee attendees may advocate incorporating cancer prevention research as a metric within the Merit-based Incentive Payment System, the payment system in the Medicare Access and CHIP Reauthorization Act (9).
4. Incentivize participation of community facilities. Incorporating incentives into the protocol deemed as relevant and desirable for the participating NCORP clinics may attract other providers, clinic administrators, and their patients. This amplifies the need for greater participation from primary care professionals and non-oncology specialists at earlier stages of protocol development, with anticipation that these participating providers may identify incentives deemed germane to various other clinics and practices.
5. Consider incentives based on current metrics recognized by administrative management at healthcare facilities. Petitions to administrative management for cancer prevention protocols should appeal to administrative interests by magnifying the merits of research in community practice settings from a business perspective. These requests may be buttressed by obtaining additional funding from industry, the Patient-Centered Outcomes Research Institute, or others, to offset potential unanticipated budgetary challenges.
6. Promote the role of research as an extension of standard-of-care that may serve as a vehicle to improved patient care and longitudinal improvement in patient morbidity and mortality outcomes. This suggestion during a workshop session by an NCORP principal investigator and primary care professional from the Baptist Memorial Health Care/Mid-South Minority Underserved NCORP presented an

eloquent lung screening study designed by and executed at the site. The site created an amalgam of pragmatic (e-mails) and innovative (Epic Medical Software) tools integrated into their practice's electronic lung cancer early detection system. Within a few years of the study, a significant impact in lung cancer early detection was achieved within their predominantly rural community. This unique model can be extrapolated for use in preventing other types of cancer with recognizable risk factors.

7. Promote the community's involvement in innovative prevention research as a way to contribute to cancer research advances (10). Introducing novel cancer prevention approaches, such as immunoprevention, allows Community Sites to broadly explore new areas while contributing to the scientific efforts of the national cancer program.
8. Explore ways to expand recruitment sites beyond NCORP. Propose ideas to include the partnering of NCORP investigators with Primary Care Practice-based Research Networks, who represent a combination of community-based practices with academic centers (11). Another partnership to consider is the Patient-Centered Outcomes Research Institute, which funds "research that can help patients and those who care for them make better-informed decisions about the healthcare choices they face every day, guided by those who will use that information" (12). Research Bases may consider inviting sources for target-patient accrual, such as clinical representatives from Federally Qualified Health Centers and other safety net facilities. Such facilities would enhance enrollment of underserved patients who may be under-represented in cancer prevention research.

NCORP principal investigators

Recommendations include the following:

1. Develop a "Research Champions" database of primary care professionals and non-oncology specialists with sustained interests in participating in prevention research. This group would serve to encourage other community providers to consider integrating prevention research into their practices. The list can also serve as a roster to help Research Bases identify pertinent individuals to participate in concept and protocol development.
2. Create supplementary educational modules for providers who participate in NCORP cancer prevention research. Some studies suggest that community providers may not be as familiar with designing and conducting research studies and could benefit from learning fundamentals of clinical research.
3. Engage with the practices' administrative management in identifying pertinent and desirable incentives for the

affiliated clinical sites. This action serves to follow-up three earlier recommendations mentioned for Research Bases (in bullets #1, #2, and #4) to facilitate further integration of the protocol into the practice. The NCORP principal investigator must be aware of feasibility concerns in primary care professionals' clinical practice routines and convince them that the protocol is compellingly beneficial for integration within the providers' practices with minimal additional infrastructures and complexities.

NCORP affiliate providers

Recommendations are as follows:

1. Enlist patient advocates and community health workers. Patient advocates are recognized as profoundly influential in cancer research, and community health workers are influential among healthy volunteers. These advocates may also play a role in protocol-development at the level of the Research Base and Prevention Committees. The advocates should be educated with the fundamentals of research but also be able to engage within community settings. Those who live within local communities, or at least share or are familiar with the customs of community members, are particularly influential.
2. Encourage "shared-decision making." Shared-decision making has been suggested as a model of patient-centered care, where patients' goals and preferences are central to final decision-making in both medical care and clinical trial participation. Patients can be informed through evidence-based tools known as patient-decision aids (13). In this context, partnership with the Patient-Centered Outcomes Research Institute may prove beneficial.

Actionable items

Recommendations include the following.

1. Research Bases can consider greater primary care professional/relevant specialist input/involvement with protocol development in the Prevention Committee for the Research Base, providing incentives such as co-authorships and financial remuneration, obtaining a roster of PCP/Specialists for selecting participation in protocol development, and Research Base activities such as CME-awarding educational sessions teaching the fundamentals of research. In addition, patient representation, such as community- and/or patient-advocates, is desirable at this level as well.
2. Research Base principal investigators and study chairs can attend and participate in primary care professionals-affiliated meetings and relevant specialists' conferences. Attendees can consider presenting on cancer prevention sessions. These meetings might also provide the opportunity to recruit other clinical representatives such

as Federally Qualified Health Centers and other safety net facilities, where enrollment of underserved and underrepresented patients can be achieved.

- Clinical and administrative management should be included as stakeholders to promote cancer prevention research and its importance in improving long-term patient outcomes. Cancer prevention research can be endorsed as beneficial to community health by identifying and investigating risk factors in patients that lead to early detection of cancer, less-aggressive therapy and better cancer outcomes. Finally, extolling the merits of participating in precision prevention and immunoprevention trials at the Community Sites can bring national recognition for the NCOPR site's contribution in the advancement of oncology science.

Conclusions

The recommendations provided during the inaugural PARTNRS Workshop, which address the problems derived from the distinctive perspectives provided during the collaborations sessions, may convert the perception of the “Trickle-Down-Directives” on protocol development into a more collaborative, transactional approach for NCORP-funded protocol development and implementation. Future workshops will seek greater representation from national family-physician organizations (i.e., the American Academy of Family Physicians) and other non-oncology specialist organizations, such as from obstetrics-gynecology, to enhance understanding of the challenges and opportunities facing community providers who are interested in participating in cancer prevention trials. More robust involvement of official representatives from various national non-oncology organizations could result in discussion of unanticipated problems such as infrastructural hindrances (i.e., need for clinical informatics that are compatible for identifying and recruiting potentially eligible participants). Such representation could also provide alternative approaches to improve patient enrollment, such as patient-stakeholder

engagement type of analysis used by the Patient-Centered Outcomes Research Institute.

This is the first of several PARTNRS Workshops aimed at bringing about more fruitful partnerships between all groups within the cancer care delivery system and the oncology research realm. It is our fervent hope that these gatherings will lead to more rapid fulfillment of accrual goals for community patients and all participants into cancer prevention studies, and thereby improve and enhance public health.

Authors' Disclosures

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