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## Involving disparate populations in clinical trials and biobanking protocols: Experiences from the Community Network Program Centers (CNPCs)

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### Introduction

Underserved groups tend not to participate in a wide array of cancer research ranging from primary prevention to screening and treatment trials (1-5). With intensified focus on personalized medicine to target therapeutic recommendations, those groups who choose not to participate are left out of research aimed at developing exciting and potentially life-saving innovations (6-8). Further, lack of participation in research limits the advances that occur as a result of clinical therapeutic and prevention trials (9, 10). To make significant progress in cancer prevention and control, it is necessary to engage members of high-risk groups, such as those affected by health disparities, in cancer research. This will require methods to increase participation in an array of prevention and treatment trials; perhaps with the explicit goal of improving designs so that trials are more appealing to underserved groups (11). For personalized medicine, this requires providing biospecimens to understand gene-environment interactions that allows for some of the variability between populations in cancer incidence and mortality (12, 13).

Research aimed at methods of cancer prevention and treatment requires at least two basic levels of commitment on the part of potential study participants. First, individuals must be willing to provide biospecimens to help answer important questions about the biological causes of cancer (as well as other diseases). Second, individuals need to participate in prevention and therapeutic clinical trials designed to identify and quantify basic differences in biological susceptibility and to assess the efficacy of medicines and devices that are developed. In both activities, there are disparities in participation; with individuals from many racial/ethnic minority, as well as other underserved, groups being less likely to participate in either biospecimen donation and prevention or therapeutic trials. In this *Focus* issue, we discuss efforts made to better understand why members of underserved populations do not participate in biospecimen donation or in clinical trials, and strategies that have successfully engaged such groups in participating in biospecimen collection and in prevention, screening, and therapeutic trials.

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## Biospecimen collection

With the advent of personalized medicine in cancer, it is increasingly important to use the science of biospecimen collection and banking to improve understanding of how cancer is managed and treated (7-10, 12, 14). Biobanks that serve as repositories for large collections of biospecimens have the potential to advance rapid scientific discovery and to advance novel therapeutic interventions (9, 12). It is the nature of the science that researchers studying the molecular basis of cancer need many, often thousands, of biospecimens in order to find answers to questions relating environmental exposures (which people can change) to genetic predispositions (which are typically beyond the control of individuals to change) (15, 16). Moreover, genetic materials differ according to a number of variables (e.g., gender), including variables that describe race/ethnicity. Thus, a diverse collection of participants, with relevant information on potential effect modifiers, is necessary to identify genetic and biological markers for cancer (17). To provide data on relevant risk groups, biobanks need to have biospecimens from people who represent all races / ethnicities and SES groups, and who are willing to provide additional personal information on variables that can alter disease risk according to genetic susceptibility. Unfortunately, participation by large numbers of racial/ethnic populations is lacking (3, 18). Furthermore, among many underserved populations, there is a tradition of reluctance to participate fully in research and provide personal information (e.g. on diet, physical activity, smoking, sexual behavior) that would enable researchers to identify practical means for reducing cancer-related disparities.

Data indicate that members of underrepresented groups do not provide biospecimens at the same rate as their White counterparts (19-21). For example, 76 percent of the breast tumor samples in the National Cancer Institute's "The Cancer Genome Atlas" (TCGA) biorepository are from White donors and 6 percent are from Asians; while only 7 percent of breast tumor samples are from African Americans and the American Indian/Alaska Native population has not donated any breast tumor tissue to TCGA (22).

It is well-established that people of minority race/ethnic status are less likely to contribute biospecimens compared to non-Hispanic Whites (NHW). The reasons people of minority race/ethnic status are less likely to contribute biospecimens compared to non-Hispanic Whites (NHW) are many: common barriers include fear or distrust of research; personal obstacles; cost problems; lack of access to interventions that may be necessary; unawareness of such studies; and practical barriers, such as distance from biospecimen collection sites. A series of twelve focus groups conducted by the NCI-funded Tampa Bay Community Cancer Network identified a variety of barriers to biobanking participation among diverse populations; for example, the perception by underrepresented group members that research only benefits the NHW population, that people feel as though they are being used as "lab rats", basic mistrust of researchers, and privacy concerns. (3, 4, 18). Although some of these barriers may seem intractable, one strategy to recruit minority group members to participate in such studies is community-based participatory research (CBPR). By involving group members in helping to define the problem, as well as finding potential solutions, researchers are increasingly drawing minority group members into both providing biospecimens and participating in research studies.

CBPR is the primary methodology of the Cancer Network Program Centers (CNPC). Based on the principles of CBPR (ref-Israel), the CNPCs work with disparate communities around cancer issues. The 23 CNPCs around the country are committed to working with under-represented groups in their regions. Each CNPC includes a Research Core with a randomized controlled research project and a pilot project, a Community Outreach Core that works with under-represented community members to provide cancer awareness and education, a Training Core that seeks to instruct early-career investigators in health disparities research, and an Administrative Core. These Centers also work to increase the community's capacity to conduct cancer education and, via community outreach and training activities, to enhance the probability of research success.

By having established organizations with credibility in the community bring the topic of biospecimen donation to the forefront of community participation, there is greater potential that we will begin to develop a deeper understanding of the barriers to and perceptions of biospecimen donation within various populations.

### Prevention and Treatment Trials

Prevention and therapeutic trials are other methods through which advances in cancer treatment can be made. Such trials are designed to decrease the likelihood of getting cancer or to improve long-term survival and/or reduce side effects of cancer treatment. Clinical therapeutic trials are a critical component in the advancement of cancer research; however, participation in research studies remains low, especially among minority populations. Only approximately 3 to 5 percent of adults with cancer in the U.S. participate in such trials and historically, clinical therapeutic trial participation among NHWs far exceeds that of minority populations (15, 23). For example, Hispanics make up 16 percent of the U.S. population but only 1 percent of trial participants (24). From 2003 to 2005, African Americans made up only 8 percent of participants in Phase I-III treatment studies that were publicly funded by the National Cancer Institute. Asian/Pacific Islanders made up 2.8 percent while Native American/Alaska Natives made up only 0.5 percent of participants (23).

There are a number of factors that contribute to this discrepancy, including fear and apprehension as a result of past abuses, cultural and ethnic views of Western medicine, language barriers, and lack of invitation (15, 24, 25). It is imperative that these and other factors be addressed in order to increase minority participation in clinical trials. Without comparable representation of racial and ethnic groups, researchers are unable to generalize trial results and underrepresented populations may not experience the benefits of pioneering cancer research.

Although much attention is focused on therapeutic clinical trials, there is great untapped potential for prevention trials and for trials that are conducted outside of clinical settings. An important focus of the CNPCs is on community-based trials. Not only are the results potentially important, but they may make the community more comfortable with lower-risk trials that may produce a very immediate benefit in terms of screening successes and improvements in diet or physical activity. Conducting such studies in underserved populations also may lessen community anxiety about being involved in more intensive,

potentially riskier research ventures in the future. In this issue, we present a variety of community and clinical trials oriented to under-represented populations.

### Papers Included in this Issue

Seven papers are included in this **Focus** issue. They span the areas of biospecimen contribution and clinical and community trials, all organized through principles of CBPR. The first paper, “Development and validation of the biobanking attitudes and knowledge survey (BANKS),” describes the creation of a survey instrument that assesses attitudes toward biospecimen donation, an area that has been under-researched. Further, it gives some psychometric properties of scales developed in the questionnaire. Consequently, an instrument to evaluate attitudes and knowledge was developed.

The next set of papers deals with interventions to promote biospecimen donation. The Gao et al. paper describes the development and implementation of a culturally appropriate intervention to change knowledge and attitudes about biospecimen donation, and sought to increase participation in donating blood as part of the project. It is followed by a randomized community trial by Tong et al., in which Chinese Americans received a biospecimen seminar or a general cancer seminar and then were asked to donate blood. The success rate of specimen donation was significantly higher after the biospecimen seminar than the specimen donation rate following the general cancer education seminar.

Lopez et al. noted that acculturation was likely to be important in the decision to donate biospecimens. The authors found that those who were bicultural were more likely to contribute biospecimens than those who were highly acculturated. They noted that the engagement with the community was a key approach when dealing with participants of Mexican descent.

A study of Native Americans and Alaskan Natives by Kaur et al, is the first report of American Indian and Alaskan Native cancer patients and their participation in biobanking. The cases came from the Phoenix area and the Alaska Native Medical Center. The paper goes on to lament the very small numbers of American Indians and Alaskan Natives in clinical trials.

Two papers focus on clinical trials. The Greiner et al. paper reviews clinical trial recruitment activities in three CNPC sites: Moffitt Cancer Center in Tampa, Florida; University of South Carolina; and the University of Kansas Cancer Center. They provide evidence to support the effectiveness of CBPR techniques to enhance recruitment of minorities into clinical trials. The Ma et al. paper notes that a culturally appropriate educational intervention among Chinese Americans delivered effective messages and increased intention to participate in clinical trials.

In sum, these papers resonate with the positive impact of CBPR—working with communities that are underserved can greatly increase participation in two of the most vexing problems facing the challenge of identifying the underlying causes of disparities in cancer incidence and the promise of personalized medicine for those faced with a diagnosis of cancer. Accumulating biospecimens and recruiting individuals of diverse groups to

prevention and treatment trials will help allow the contribution of personalized medicine to all, regardless of status.

Very disjointed. Why the large paragraph on biospecimen collection, then a review of the papers. I would like the review of papers to provide more of a discussion of the findings rather than just the findings. What does this mean?

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