

Increasing Enrollment of Underrepresented Populations in Cancer Clinical Trials:
Summary of Best Practices from a Literature Review
CHDI, September 2017

The Cancer Health Disparities Initiative conducted a literature review of best practices in increasing enrollment of underrepresented populations in cancer clinical trials. The following recommendations are those most supported by the current literature available.

1. Consider effects of inclusion/exclusion criteria on participation of underrepresented populations
2. Offer trials that most impact underrepresented populations
3. Provide bias training to investigation team
4. Provide community health clinics with resources to conduct clinical trials
5. Reduce geographic barriers to clinical trial site
6. Reduce perceptions of cost of participation in clinical trials
7. Increase community education around clinical trials
8. Engage racially concordant staffing

STUDY DESIGN

Consider inclusion and exclusion criteria

In designing a new study, it is crucial to consider the effects of including specific inclusion and exclusion criteria on the recruitment and enrollment process. Without specific attention to these criteria, large groups of populations, particularly underrepresented populations, may be excluded from participation in the studyⁱ. For example, many studies list certain comorbid diseases as exclusion criteria. Communities of color are disproportionately affected by hypertensionⁱⁱ, diabetesⁱⁱⁱ, obesity^{iv} and other comorbidities and exclusion of these comorbidities disproportionately limits the eligibility of these communities for clinical trials. Acknowledging that certain conditions are more prevalent among minority racial/ ethnic groups allows investigators to account for comorbidities that take away from the pool of participants.

Offer trials that most impact underserved populations

Lung, colorectal, breast, cervical, prostate and skin cancers rates are disproportionately higher in black patients when compared with white patients.^v Recruitment efforts of minority populations should be focused in studies that are most likely to affect their communities.

Provide bias training to investigation team

Unconscious bias and preconceived perceptions of patients from underrepresented populations have a significant effect on recruitment for clinical trials. A study in South Carolina identified physician misperceptions as a contributor to decreased enrollment from rural populations.^{vi} Physicians assumed ineligibility of rural patients based on certain physician biases which excluded large pools of rural participants who would have been eligible for participation.

Provide community health clinics with resources to conduct clinical trials

Partner with community health clinics and safety net hospitals that most often serve traditionally underserved patients. However, these clinics are often understaffed and under resourced. In order to increase capacity of these clinics to participate as clinical trial sites, it is necessary to provide staff, resources, and training to carry out clinical trial activities at health centers with access to underserved patients.

BARRIERS

Reduce geographic barriers

The National Cancer Institute identifies transportation as a barrier to participation in cancer clinical trials, especially among older, rural, and minority patients.^{vii} Examining the geographic limitations of clinical trials and implementing the necessary features to accommodate a provider/ patient's participation will encourage recruitment onto a project. Studies have shown improvement in

participation from underrepresented populations with providing bus fare, taxi vouchers, or transportation services.^{viii}

Reduce perceptions of cost of participation in clinical trials

A commonly cited reason for lower participation in clinical trials among minority patients is perceived cost of participation.^{ix} A series of focus groups conducted by researchers at Johns Hopkins School of Nursing identified concerns about clinical trial costs as a significant factor in the decision to participate in clinical trials.^x Assuring patients that the cost of participation in clinical trials is not an additional treatment cost for them is important. Other sources of financial burden such as child care and time off work should be considered as well. Clinical trial sites may benefit from offering child care services nearby.

Increase community education on clinical trials

In a survey conducted by researchers at Memorial Sloan-Kettering Cancer Center, African American and Latino patients identified fear of mistreatment, lack of trust in medicine, and lack of cultural/language literacy by clinical staff as barriers to health literacy.^{xi} Efforts to increase community education, account for varying levels of health literacy in educational programs, and develop health literate trial materials, should be implemented to reduce these barriers.

STAFFING

Engage racially concordant clinical trial support teams

Researchers have found that the use of community health advisors significantly increased both recruitment and retention of minority, low-income women in a multicenter, randomized clinical trial.^{xii} A different study found that the use of patient navigators increased participation of minority patients in a cancer clinical trial.^{xiii} These roles could be filled with racially concordant staff or community liaisons trained to serve as research partners.

ⁱ Brooks, S. E., Carter, R. L., Plaxe, S. C., Basen-Engquist, K. M., Rodriguez, M., Kauderer, J., . . . Brown, C. L. (2015). Patient and physician factors associated with participation in cervical and uterine cancer trials: an NRG/GOG247 study.

ⁱⁱ Guo F., He D., Zhang W., Walton R.G. (2012). Trends in prevalence, awareness, management, and control of hypertension among United States adults, 1999 to 2010.

ⁱⁱⁱ McBean A.M., Li, S., Gilbertson, D.T., Collins A.J. (2004). Differences in diabetes prevalence, incidence, and mortality among the elderly of four racial/ethnic groups: whites, blacks, Hispanics, and Asians.

^{iv} Flegal, K.M., Carroll, M.D., Ogden, C.L. (2010). Prevalence and Trends in Obesity Among US Adults, 1999-2008.

^v Banda, D. R., Germain, D. S., McCaskill-Stevens, W., Ford, J. G., & Swain, S. M. (2012). A critical review of the enrollment of black patients in cancer clinical trials.

^{vi} Bergeron, C. D., Foster, C., Friedman, D. B., Tanner, A., & Kim, S. H. (2013). Clinical trial recruitment in rural South Carolina: a comparison of investigators' perceptions and potential participant eligibility.

^{vii} Denicoff, A. M., McCaskill-Stevens, W., Grubbs, S. S., Bruinooge, S. S., Comis, R. L., Devine, P., . . . Meropol, N. J. (2013). The National Cancer Institute-American Society of Clinical Oncology Cancer Trial Accrual Symposium: summary and recommendations

^{viii} UyBico S.J., Pavel, S., Gross, C.P. (2007). Recruiting Vulnerable Populations in Research: A Systematic Review of Recruitment Interventions.

^{ix} Langford, A. T., Resnicow, K., Dimond, E. P., Denicoff, A. M., Germain, D. S., McCaskill-Stevens, W., . . . Go, R. S. (2014). Racial/ethnic differences in clinical trial enrollment, refusal rates, ineligibility, and reasons for decline among patients at sites in the National Cancer Institute's Community Cancer Centers Program.

^x Wenzel, J. A., Mbah, O., Xu, J., Moscou-Jackson, G., Saleem, H., Sakyi, K., & Ford, J. G. (2015). A Model of Cancer Clinical Trial Decision-making Informed by African-American Cancer Patients.

^{xi} Pelto, D. J., Sadler, G. R., Njoku, O., Rodriguez, M. C., Villagra, C., Malcarne, V. L., . . . Jandorf, L. (2016). Adaptation of a Cancer Clinical Trials Education Program for African American and Latina/o Community Members.

^{xii} Fouad, M. N., Acemgil, A., Bae, S., Forero, A., Lisovicz, N., Martin, M. Y., . . . Vickers, S. M. (2016). Patient Navigation As a Model to Increase Participation of African Americans in Cancer Clinical Trials.

^{xiii} Holmes, D. R., Major, J., Lyonga, D. E., Alleyne, R. S., & Clayton, S. M. (2012). Increasing minority patient participation in cancer clinical trials using oncology nurse navigation.