Abstract Title: Minority Participation in Clinical Trials: A Multifaceted Approach to Increase Enrollment

Author(s): Jessica Thein, MPH, MSW; Nick Fisher, MBA; Amanda DeMoss, MS, CCRP

Cancer Center Name: Siteman Cancer Center

Describe the background of the problem: Public Law 103 mandates adequate representation of minorities in NCI-funded clinical trials (CTs); however enforcement of the law proves to be difficult. Beyond the legal obligation, lack of inclusion of minorities in clinical research poses two primary issues: one of scientific inquiry and the other of equity. Thus, the responsibility of providing equitable care falls to the medical community. Care provided in a CT setting results in better clinical outcomes and may expose a patient to a novel agent, but African Americans (AA) and other minorities are not proportionally enrolled to CTs. Consequently, AAs are not receiving cutting edge treatments to the same degree as Caucasians. This is clearly exemplified in the case of triple negative breast cancer (TNBC), widely considered to be the most aggressive subtype with the poorest prognosis. A contributory factor to the paucity of scientific knowledge regarding TNBC treatment is the lack of inclusion of AA women in breast cancer CTs. Enrollment to these trials skews heavily towards Caucasian women with conspicuous underrepresentation of AA women (despite respective TNBC prevalence rates of 10% and 25%). This is the result of a complex array of barriers that Ford et al. conceptualized through three principle domains: Awareness, Acceptance, and Opportunity. Using this framework, Siteman Cancer Center (SCC) surveyed 250 patients to evaluate barriers and attitudes towards CT participation.

Provide metrics or goals hoped to be achieved with the solutions to address the problem: Our goal is to use existing literature and insights gained from SCC patient responses to develop a comprehensive program that will address barriers to participation, thereby increasing minority enrollment to CTs at rates that mirror SCC’s catchment area.

Describe the solutions or methods implemented: Survey results indicated that enrollment barriers specific to minorities fell in the Acceptance domain (mistrust and conflict with religious beliefs). These barriers develop long before patients are seen at SCC and must be addressed in a multi-pronged approach, including community outreach initiatives, CT education, and supportive services. Outreach will focus on partnerships with local churches, advocacy organizations, news outlets, and federally qualified health centers; such institutions have established relationships with patients and will act as conduits to deliver CT education as well as address mistrust and religious conflict. Community-based partnerships can assist in the dissemination of information and use existing relationships to present the option of CT participation in a relatable way. SCC will also provide services to clinic teams by developing learning modules to reinforce best practices when discussing CTs with minority patients and provide a basis for understanding and addressing barriers to participation. Additionally, a patient navigator identifies potential obstacles and coordinates with social services to ensure appropriate resources are obtained. The navigator also provides general CT education to address misconceptions regarding research.

Describe the outcome of the solutions implemented or show data representing a change whether positive or negative. Success will be measured by the number of minority patients reached by the navigator and the percent change in minority enrollment at 1 and 5 years.
Show lessons learned, others to involve in the future, changes to the methods to achieve a better outcome. Increased minority representation in CTs will not only provide more equitable care but also increase the scientific rigor of our investigations. It is our hope that this will prove to be an effective model in overcoming minority patients’ barriers to participation.