Improving the Recruitment of Minority Populations in Clinical Trials:
Advocating for a Strategic Shift Toward Community-Based Recruitment

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INTRODUCTION

As the healthcare industry shifts to a population health approach that focuses more on the prevention of diseases and conditions, healthcare and the delivery of healthcare continues to change rapidly. In addition to the rapidly changing healthcare environment, the demographic composition of the U.S. population continues to diversify. According to the U.S. Census Bureau (2015), minorities represented 37.9% of the U.S. population as of 2014. This number is expected to continue to increase, especially when looking at the representation of minorities within younger generations. For example, in 2014, those younger than five years old became the majority-minority for the first time, representing a whopping 50.2% of the U.S. population (U.S. Census Bureau, 2015). In addition, statistics have shown that the fastest growing population in the U.S. is Asian Americans (Ma et al., 2014_b). However, despite this, they are the least represented U.S. ethnic group in clinical trials (Ma et al., 2014_b).

Clinical trials must not only keep up with the current trends in U.S. healthcare, but they must also produce evidence that is representative and generalizable to the current population, especially since the need for current trials will continue to increase and expand. As of May 2015, Clinicaltrials.gov noted having an outstanding 191,938 studies listed across 190 countries (Clinicaltrials.gov, 2015). Although they may be different in their disease-focus and study design, similar issues are generally experienced. One set of challenges researchers face are those related to participant recruitment. Participant enrollment has proven to be difficult in all disease areas and especially difficult when it comes to the inclusion of minority populations. Researchers have acknowledged this as an ongoing problem with effects seen throughout the clinical trial process and beyond. For example, without sufficient representation of minorities in clinical trials, the effectiveness of those treatments is questioned as it is known that racial and ethnic factors play a role in efficacy (Akhtar, Israel, & D'Abundo, 2015). Furthermore, as clinical trials continue to fail recruitment targets, researchers agree that a change with recruitment methods is needed. As noted by Tanner, Kim, Friedman, Foster, and Bergeron (2015), current strategies for recruitment in clinical trials involve primary investigators recruiting patients personally, by utilizing patient databases, and through printed materials. These strategies continue to be used because primary investigators are familiar and comfortable with them (Tanner et al., 2015). However, these strategies do not include all individuals such as those who live in underserved areas, highlighting the need for a strategic shift that will help address these issues.

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Before delving further into the issues surrounding minority recruitment, it is first important to describe clinical trials along with those who are involved. A clinical study is research that evaluates ways to prevent, detect, or treat disease, and involves humans who have chosen to volunteer to participate (National Institutes of Health, 2015). These individuals are often referred to as subjects or participants; however, for the purposes of this chapter, the term participants will be used. In the simplest form, clinical trials are differentiated according to their phase. More specifically, they are categorized by Phases I-IV depending on the study's characteristics such as its' objectives and the number of participants that are expected to be enrolled (Akhtar et al., 2015). Additionally, every clinical trial has a design known as the protocol that maps out the role that each contributor will play during the conduct of the trial. For example, "The study is typically carried out by investigative sites, teams of healthcare professionals, and led by principal investigators" (Akhtar et al., 2015, p. 235). Principal investigators are the lead researchers who play a key role in treating the patients according to the protocol and ensuring their safety. Their role is crucial because they are the main point of contact with the patients. This also means they are at the forefront of identifying eligible patients for inclusion in trials and introducing them to these trials. They, along with the other investigative site personnel, need to spend the time and make the effort to identify the patients who would be the most appropriate in participating in each trial. In doing so, they are able to meet the recruitment targets set forth by the sponsors who have the overall responsibility to conduct and manage the studies. This means that the investigators and their investigative site personnel must enroll a certain number of patients in a certain period of time to not only achieve enrolling the necessary number of participants as per the protocol, but to also minimize the consequences of not achieving this goal (i.e., additional time, increased costs, delays in obtaining the study results) (Akhtar et al., 2015).

Problem Statement for Insufficient Recruitment

A clinical trial is designed with the purpose of enrolling a certain number of participants who are to receive a certain treatment (Akhtar et al., 2015). However, if there are not enough participants included in the clinical trial, then the clinical trial may be delayed or even cancelled. This fact is supported by a review that was done on Clinical Trials Cooperative Groups. Clinical Trials Cooperative Groups are funded by the National Cancer Institute and conduct pivotal late stage oncology trials. The review found that almost half of the Phase III oncology trials in one Clinical Trials Cooperative Group were discontinued due to insufficient patient accrual (Schroen et al., 2010). More specifically, research has shown that there is an insufficient enrollment of minorities in clinical trials that is a large contributing factor to the success of a trial and specifically the success of enrollment. For example, one review found that although minority groups are as willing as White individuals to participate in clinical research, they are less likely to be invited to participate (Wendler et al., 2005). The literature has shown that there are various reasons for why this occurs such as the investigative site personnel's view that minorities will not make "good" study participants. On the contrast, the literature has also shown that researchers who make an effort to recruit minorities find it difficult to do so for various reasons such as their lack of cultural knowledge. Therefore, the complex problem of increasing enrollment of minorities in clinical trials needs to be evaluated from the perspective of investigators and their investigative site personnel. The purpose of this chapter is to review how the recruitment of minority populations can be improved by creating a strategic shift toward community-based recruitment.