Minority Recruitment and Participation in Health Research

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Since 1993, all investigators funded by the National Institutes of Health (NIH) to conduct clinical research have been expected to demonstrate appropriate inclusion of racial and ethnic minorities and women in their research or clearly demonstrate why they should be excluded in order to pursue a specific research objective. This mandate, the NIH Revitalization Act, was a response to the realization that women and minorities were underrepresented in clinical research. These guidelines have mandated the inclusion of minorities in clinical research in an effort to better understand disparities in health and to improve the generalizability of research findings. While few would argue with the goals of this mandate, investigators have been challenged in its implementation. This article gives an overview of some of the challenges raised by minority participation in research and describes some of the consequences of a lack of minority involvement in research.

Challenges Raised by Mandated Inclusion of Minorities

Most of the scientific literature on minority participation in research has focused on the barriers to minority participation. The factors that impede the participation of minorities in research can be specific to the participant, the investigator, or the study. For example, since African Americans are over-represented in lower socio-economic strata; race, as a commonly measured variable, may be a proxy for other socio-demographic factors. Socio-economic status can influence the decision to participate in a number of other ways. For example, access to transportation and the location of study sites significantly impact the recruitment and retention of patients in clinical trials. Educational level, age, and marital status all have been shown to be associated with various aspects of decision making. Among the economically disadvantaged, competing subsistence needs may outweigh any anticipated benefits of participation. Psychosocial factors such as perceived stress, community involvement, and social isolation may be powerful factors in a patient's decision to participate in a clinical trial and ability to maintain adherence to a research protocol, particularly in an older population.

In addition, trust or lack of trust is an important factor when deciding to participate in research. Fear, mistrust, and lack of knowledge were cited by minority respondents as the main reasons they didn't participate in oncology research. The history of clinical experimentation on blacks during slavery laid the foundation of distrust among blacks toward medical research. Yet, it is the Tuskegee Syphilis Study (1932-1972) that has become the contemporary metaphor of research that violates human rights of vulnerable groups. Several medical historians have asserted that this study, where 400 poor black men with syphilis were left untreated for 40 years, validated suspicions about ethical treatment in the context of research. Awareness of the Tuskegee Syphilis Study among minority and other underserved groups contributes to pervasive distrust of physicians and the medical research establishment. The dissemination of oral histories about the Tuskegee Study and fictional dramas may reinforce distortions in the historical record and provide moral justification for refusal to participate in any clinical research.

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another important influence on minority participation as research subjects. Health-seeking behavior influences where, when, and how one accesses the healthcare system. Bailey describes six culturally-based steps in health seeking behavior among African Americans. He noted that patients are active participants in their health, from the perception of symptoms to eventually seeking formal medical care (whether or not their actions are considered appropriate to the biomedical model of disease). Other authors have demonstrated that the combination of socio-economic factors and culture can account for racial differences in the stage of presentation of disease. Cultural differences in how the healthcare system is accessed and utilized can impact the availability and opportunities to participate in medical research. In addition, expectations of medical roles and responsibilities, explanatory models of disease, and verbal and non-verbal communication patterns are all influenced by the culture framework of patients. Investigators’ cultural competency, not just their ability to speak another language or dialect, but their desire to respectfully address the patient’s needs within the framework of that person’s health beliefs, religious background, cultural philosophy, and social customs will ease the transition in recruiting individuals that may hold beliefs and attitudes toward health that are discordant with those of clinical researchers.

However, empirical data are lacking on how well investigators understand and are able to negotiate these cultural differences. There have been no studies of investigators’ knowledge of the barriers to minority participation in clinical trials or how these recommendations have been translated into successful recruitment strategies. At the introduction of the NIH mandate, researchers were quite vocal about their concerns. Editorialists likened the mandate to include minorities and women in clinical research trials to affirmative action and quota systems. Investigators raised concerns about the potential added costs to recruiting more diverse study samples. Investigators also described the ethical consideration of mandating the inclusion of women and minorities. Some authors described the potential to give minorities the “hard-sell” and therefore not fully respecting an autonomous decision not to participate in a trial.

In the research community there is a general belief that minority groups may be more difficult to recruit into clinical trials, less likely to adhere to study protocols, and more difficult to retain in clinical studies. While there is some evidence that race alone is not a predictor of recruitment success, the belief that minority groups are hard to reach may affect some investigator’s willingness to recruit minority participants.

In fact, when investigators take more innovative approaches to recruitment, these efforts have been more successful. Community-based strategies can elicit and address differing cultural beliefs while informing the design of recruitment strategies that lead to successful minority enrollment and improved investigator-participant relationships.

Consequences of Lack of Minority Involvement in Research

While investigators have been conducting clinical research for a decade under this mandate, minorities are still under-represented in areas of known disparities in health research relative to the prevalence of disease in minority communities. Underrepresentation of minorities as subjects in research and lack of minority involvement in research partnerships may adversely affect minority communities in a number of ways.

Clinical research is the basis of advances in all areas of medical knowledge and clinical care. The lack of minority participation in research limits the generalizability of study results to those groups that are included in research. More diverse research populations allow the generation and testing of research hypotheses that may enhance our understanding of disparities in health by race and ethnicity and the development of interventions to address these disparities.

Minority participation in research also increases the likelihood that research results are more relevant to the needs of minority communities. If minority communities are not involved in the process of research, as participants, staff, or as community advisors, interventions are less likely to be culturally-relevant and therefore less likely to be sustainable once the study has ended. Research that actively engages target communities leads to interventions that are more likely to be successful and sustained and, more likely to lead to program institutionalization. In addition, involvement of the target communities also enhances the relevance and usefulness of the data, as well as data quality and validity. Finally, community involvement in research can also strengthen the research and program development capacity of the individuals and organizations in undeserved communities. The lack of active engagement of minority communities in research severely limits the potential of improving the health and well-being of minority communities, either directly through examining and addressing disparities in health, or indirectly through increasing the power and influence of minorities over the research process affecting the health and healthcare they receive.

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