

COMMENTARY: CLINICIAN AND RESEARCHER CONTRIBUTIONS TO DISPARITIES IN RACIAL AND ETHNIC MINORITY PARTICIPATION IN HUMAN SUBJECTS RESEARCH

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Despite efforts focused on outreach to minority populations, the literature reveals that the problem of disparities in minority involvement in clinical research persists. Thus, the objective of this article was to present an overview of the barriers to engage minorities in human subject research and the identification of promising strategies for their recruitment and retention. I identified a need for an innovative approach, which would focus recruitment efforts primarily on clinicians and researchers who contribute their own barriers to the process of recruitment and retention. In this way, the most common outreach efforts, which specifically focus on targeted minority groups, would be replaced. The inclusion of minorities in clinical research is an important bioethical issue, particularly when considering drug pharmacokinetics and pharmacodynamics, which may vary widely among different racial and ethnic populations.

In conclusion, patient barriers to participation in clinical research are well-documented and remain of great importance; however, clinician and researcher barriers, equally as important, continue to be overlooked. Focusing on clinicians and researchers is needed to help increase their awareness about the barriers to minority participation that they may present. Continued research and efforts are needed to understand how best to identify, address, and overcome these barriers. (*Ethn Dis.* 2014;24[3]:298–301)

Key Words: Health Disparities, Clinical Research, Human Subject Research, Minorities Recruitment, Cultural Competency

INTRODUCTION

Human subjects research, particularly clinical research studies, has led to a proliferation of innovative biotechnologies and promising therapeutics, as well as models for effective intervention

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strategies. However, human subjects research has been plagued by the problem of low rates of participation from minority populations.^{1–3} This lack of sufficient inclusion of minorities presents a number of concerns, which could relate to health inequities and the persistence of health disparities.^{2,4} For example, African Americans are disproportionately affected by numerous diseases and conditions, such as hypertension, diabetes, and obesity, which require research to formulate effective interventions, including therapeutics to respond to these health disparities. Yet, African Americans continue to be underrepresented in research.^{3,5–6} Also, when considering pharmacokinetics, as well as racial differences in genetics and physiology, reasonable concerns exist regarding issues of safety and efficacy for these underrepresented populations.^{7–9}

BARRIERS TO MINORITIES' PARTICIPATION IN RESEARCH STUDIES

The psychosocial, cultural, and economic factors that act as common barriers to minority participation in clinical trials include, but are not limited to: distrust, access to care, language and literacy issues, financial matters, lack of cultural competency, provider bias, clinician perceptions, and the resultant lower rates of referral of minority patients.^{10–12} However, much of the effort to increase the participation of minority populations in human subjects research overlooks or does not address the barriers and roles that clinicians and researchers have or play in this persisting problem.¹³ Furthermore, minorities are less likely than Whites to have health insurance, which is often a prerequisite for gaining access to some phase III clinical trials.¹⁴

THE BARRIER OF PERCEPTIONS AND BIAS

Clinicians' and researchers' perceptions, biases, and actions may act as barriers to minorities' possible participation in human subjects research. An additional part of this barrier is that many clinicians and researchers may not be aware of prevalent health disparities.¹⁵ For example, African Americans have higher rates of Alzheimer's disease compared with the general population^{16–18}; yet, they continue to be greatly underrepresented in Alzheimer's disease and dementia research studies.¹⁹ Another aspect of this barrier is that physician bias, false perceptions, and personal prejudices affect their decision-making process and this can affect referral of minority patients to research studies.^{4,20} Provider bias has been identified as an important contributor to disparities in health care,⁹ and this problem has been found to be carried into human subjects research recruitment and retention.^{21–22} Bias is defined as the negative evaluation of one group and its members in relation to another; provider bias is a form of implicit bias, which may involve the use of negative nonverbal behavior.²⁰ Thus, provider bias, although operating in an unintentional and unconscious manner,^{23–24} and based on series of situational cues, may cause clinicians and researchers to automatically and unknowingly perceive specific patients in a certain way. Minority patients, who often pick up on these nonverbal cues^{25–27} may be less likely to participate in clinical trials.

THE ROLE OF CLINICIANS

The literature shows that physicians are less likely to prescribe certain treatments to their minority patients

and that their reluctance to refer minorities to clinical studies is often based once again on biases, including the belief that racial and ethnic minorities are less interested in participation, concerns about minority participants willingness or ability to adhere to medication schedules, insufficient health literacy to understand the trial, language proficiency, and the issue of access to reliable transportation.^{4-5,28}

Due to clinical uncertainty, clinicians tend to make decisions based on prior beliefs or experiences, and these beliefs and experiences will differ depending on the age, sex, socioeconomic status, race, and ethnicity of the patient.²⁹ Consequently, diagnosis based on clinical uncertainty, results in a greater likelihood of the needs of a minority patient being unmet and a lesser likelihood that clinicians will bother with referring them to a clinical study.^{13,30} In other words, although clinician referrals are among the most effective and essential means of recruiting patients for research studies, evidence suggests that clinicians sometimes refer their minority patients to clinical trials less frequently than their Caucasian patients.²⁸ Thus, the perceptions, attitudes, decisions and actions of clinicians play a significant role in the enrollment of underrepresented minorities in human subjects research, in that they act as gatekeepers who influence patient decision-making through the dissemination of information about available studies.

EXISTING POLICIES

Past abuses and unethical research on minorities and the current disparity in recruitment has led to policies that require biomedical studies investigators to ensure that only scientific rationales, rather than costs, convenience, or any other form of bias, dictate the recruitment and enrollment of minorities. For example, it would be deemed scientifically acceptable to have a lower minority

enrollment in a study involving cystic fibrosis research, being that it occurs most frequently in Caucasian populations. Under the 1994 Revitalization Act, the National Institutes of Health (NIH) has a guideline which urges researchers to develop "appropriate and culturally sensitive outreach programs" as a means to "actively recruit the most diverse study population consistent with the purposes of the research project."³¹ Researchers are required to declare their intent to recruit a study cohort with appropriate sex and minority representation.

These plans should rightfully extend beyond the Planned/Targeted enrollment tables currently required by the National Institutes of Health and should include a provision and discussion of epidemiological data. Having this information could help to justify the exclusion of certain groups, or support the need for the full inclusion of specific minority groups. In other words, the appropriate level of inclusion depends on the prevalence of the condition or disease studied in the overall population. In terms of research programs focused on diseases such as sickle cell anemia, which is highly prevalent in African Americans, or diabetes being highly prevalent in Hispanics and Native Americans, being aware of and having an understanding of these higher rates of prevalence in specific populations will prove useful in the development of research study protocols and the completion of stated recruitment quotas. That is, these detailed research diversity plans or enrollment tables will help to ensure that study enrollment would actually include higher percentages of those most affected by a particular disease or condition.

RELEVANCE OF RACE TO HEALTH RESEARCH

Race and ethnicity, and thus the inclusion of ethnic minorities in human subjects research is of great importance

due to the possibility of noticeable variations in the pharmacokinetic and pharmacodynamic effects of drugs in different racial and ethnic populations. The research has revealed clinical increases or decreases in both the intensity and duration of an expected drug effect, and has shown that substantial dosage adjustments may be necessary for individuals from different populations.³² These studies reveal an area of concern that requires further explanation, and simply conducting research trials with homologous groups of non-minority subjects will not reveal any information about the safety and effectiveness of therapies in the excluded minority populations. In other words, it may prove to be risky to distribute therapeutics to populations who were underrepresented in clinical studies. In addition, the applicability of the resulting data to the entire patient population who would be expected to utilize the product would be a significant measure of success of a clinical study.

Furthermore, health disparities persist, in part, because the exclusion and the lack of active recruitment of ethnic and racial minorities for human subjects research, which deprives these groups from opportunities to benefit more directly from developmental therapeutics or gain access to routine health care provided in the course of clinical studies.

ETHICAL CONSIDERATIONS

Since the limited inclusion of minority populations in research studies has great consequences, a number of considerations can be drawn when taking into account the role of clinicians and researchers in ensuring diversity in human subjects research recruitment strategies. Concerted efforts, including health communications, policy change, and other interventions directed at clinicians, researchers, and their staff are needed to assist them in becoming

aware of the possibility that they may exercise bias, intentional or unintentional, in their interactions with patients. In terms of adopting strategies to increase minority participation in human subjects research, increasing awareness and removing biases, would allow researchers to better advise patients about research participation and conscientiously expand their recruitment plans.⁴ In order to effectively assist in the reduction of disparities in human subjects research, researchers and clinicians should receive appropriate training in minority recruitment and retention, particularly culturally competent training.^{22,33-34} Cross-cultural education may assist clinicians and researchers in learning how to communicate effectively with patients and research subjects (including minorities as well as women, children and the elderly), and may help to avoid stereotypes, bias, and clinical uncertainty.³⁵

CLINICIANS AND STAKEHOLDERS INCENTIVES

Incentives provided to clinicians and other stakeholders to assist with recruitment strategies may include some form of compensation for time spent recruiting and educating participants, which would demonstrate gratitude and acknowledgment of their value to the research study. However, in some cases monetary compensation may be seen as a means for unethical coercion; thus, alternatives should be utilized when possible. The following incentives may be offered:

- Professional development, in the form of donated books, annual journal subscriptions, screening/assessment tools, as well as reprints of articles on study-related topics³⁶;
- Certificates of appreciation, along with small tokens of appreciation;
- Certification or continuing education units (CEUs) for completion of cultural competency training;
- Issuing a Request for Information (RFI) during the initial development of

the study protocol to provide clinicians and stakeholders with a chance to contribute input;

- A quarterly newsletter, featuring a recognizable study logo, which provides continued updates about the progress of the study³⁶; and,
- An opportunity for shared authorship on any resultant study-related publications.

DISCUSSION

The persisting health disparity involving the recruitment, enrollment, and retention of minorities for human subjects research involves a number of factors.³⁷⁻³⁸ Although much of the focus has been on interpersonal barriers to health and outreach efforts targeting those in minority populations,³⁹ there is a need and ethical responsibility of public health professionals to focus efforts on clinicians and researchers, as well as to explore and advocate for needed modification of existing policies. The inclusion of minority populations in human subjects research may be a complex and challenging task; however, the consequences brought about by the gaps in data and information about the effects of therapeutics and other interventions on these groups are dire and of ethical importance.

This survey of the literature revealed that there are a limited number of interventions focused on the increased engagement of clinicians and researchers in the inclusion of minorities in clinical research.⁴⁰⁻⁴¹ However, a priority should be made to ensure that professionals who are directly involved in the efforts to recruit and conduct these studies are well educated about any existing disparities in the study population and should be required to include detailed plans that consider this in their research protocols and grant proposals. Formoso et al found three key areas that would require improvements, in order to carry out communication efforts to clinicians and researchers; these areas

include: the availability of valid and relevant information, the comprehensibility of the information, and the readers' attitude.⁴²

CONCLUSION

A greater understanding of patient-provider interactions and their influence on clinical trial referrals, decision-making, and retention is needed; this information may serve as the basis for the development and implementation of interventions that do not focus on patients,¹⁰ but on clinicians and researchers. Thus, this research will also need to assist in the identification of the most effective channels of communication, whether medical websites, journals, professional newsletters, webinars, or conferences that can be utilized to educate providers. In addition, there is a need to streamline the message and application of culturally competent and unbiased recruitment and retention strategies for minorities in human subjects research. In terms of policy, there is a clear need for ensuring that NIH and FDA human subjects requirements for inclusion are met. Overall, increasing participation of minorities in clinical research is imperative, in terms of the conduct of good science, as well as a continued commitment to the reduction of health disparities.

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