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Introduction

Clinical trials are used as the basis to evaluate the safety and efficacy of new therapeutic drugs and preventative vaccines (Pocock, 2013). Clinical trials generally utilize a limited sample of patients to make inferences about how treatment should be conducted in the general population of patients who will require treatment in the future (Pocock, 2013). Because clinical trials are used as the basis to inform clinical and therapeutic decision-making across all populations, representation from diverse segments of the population is essential. Diverse participation in clinical trials is also crucial to assure generalizability of findings, assess the safety and efficacy of new treatments across all population groups, and foster an equitable distribution of the burdens and benefits of clinical trials participation (Gifford et. al, 2002). In recognition of the importance of diverse representation in clinical trials, several federal mandates have emerged. The National Institutes of Health (NIH) Revitalization Act of 1993 is one example of a federal regulation that mandated all NIH-funded studies to include participation of women and minorities (Heller et. al, 2014).

Despite such federal mandates, racial and ethnic minorities continue to be underrepresented in several clinical trials initiatives (Heller et. al, 2014; George, Duran and Norris, 2014). The inadequate representation is clearly seen in the participation of African Americans in HIV/AIDS clinical trials. Between 1985 and 2002, African Americans accounted for 51% of cumulative AIDS cases (Cargill and Stone, 2005). In 2010, African Americans represented approximately 12% of the United States population, but accounted for approximately for 44% of new HIV infections (CDC, 2015). Despite being the racial/ethnic group that is most affected by HIV/AIDS, African Americans remain inadequately represented in HIV/AIDS clinical trials (Cargill and Stone, 2005; Sengupta et. al, 2000). In 2011, African Americans comprised 23% of the Center for Drug Evaluation and Research’s (CDER) HIV trials whereas Whites comprised 61%; the racial composition of clinical trials is inconsistent with the disease prevalence of HIV/AIDS (FDA
The persistent lack of representation of African Americans in HIV/AIDS clinical trials suggests that mandates and policies alone are not going to translate to changes in the demographics of clinical trials; new strategies and paradigms are perhaps necessary to improve the representation of African Americans in HIV/AIDS clinical trials.

By examining African American’s participation in HIV/AIDS clinical trials as a case study example, this paper aims to contextualize a larger critique of the clinical trials research approach; in the context of this paper, the clinical trials research approach is specific to biomedical clinical research. Participation in clinical trials is a confluence of individual, investigator, study-related, and structural factors, all of which are shaped by larger social, economic, and political forces. In addition to attitudes and beliefs, African Americans continue to experience a disproportionate share of economic, health care-related, and social burdens that create barriers to their research participation. The clinical trials research approach does not address these barriers comprehensively, which is perhaps why African American’s underrepresentation in HIV/AIDS clinical trials continues to persist. This paper argues that clinical trials need to locate individuals and their decision to participate within the larger social, economic, political, cultural, historical, and structural context in which they and their decision to participate exist; this larger context is referred to as the sociostructural context throughout this paper. After providing a brief literature review concerning the factors that affect the participation of African Americans in HIV/AIDS clinical trials, this paper discusses why the clinical trials research approach is limited and proposes potential steps clinical trials researchers can take to address the multidimensional needs that affect participation.

Equitable participation of African Americans and other minority groups in clinical trials is essential to achieving systemic equity in the provision of health care. This paper serves as a call for biomedical researchers to take into account the sociostructural context in which the multidimensional factors that impede African American and other minority group’s participation in
clinical trials are embedded. By failing to take the larger sociostructural factors into account, the disparity in clinical trials participation may continue to persist.

**Literature Review**

**Factors Influencing African American’s Participation in HIV/AIDS Clinical Trials**

Several factors can pose as barriers or facilitators for participation of African Americans’ participation in HIV/AIDS clinical trials. The barriers and facilitators are categorized as participant, investigator, study-related, or structural in order to demonstrate the multiple factors and forces that influence the participation of African American’s in HIV/AIDS clinical trials (Table 1). Participant-related refer to barriers and facilitators perceived by or related to the participants in clinical trials. Investigator-related refer to those perceived by or related to the researchers that conduct the clinical trials. Study-related barriers and facilitators refer to those related to the research process, investigational drug, and vaccine. Structural barriers and facilitators refer to the broader social, economic, policy, and environmental forces that contribute to participation in clinical trials (Sumartojo, 2000). The separation of the barriers and facilitators into these categories is for organizational clarity only; the barriers and facilitators are interrelated and are not mutually exclusive.
Table 1: Barriers and Facilitators of African Americans’ Participation in HIV/AIDS Clinical Trials

<table>
<thead>
<tr>
<th>Category</th>
<th>Barriers</th>
<th>Facilitators</th>
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<tr>
<td>Individual</td>
<td>• Distrust</td>
<td>• Altruism</td>
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<td>• Benefits to Participation</td>
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<td>Investigator</td>
<td>• Biases and Pre-existing notions</td>
<td>• Increase in Minority Researchers and Training</td>
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<td>• Costs</td>
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<td>Study-Related</td>
<td>• Study Demands</td>
<td>• Communication</td>
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<td>• Fear of Vaccine Induced Infection</td>
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<td>• Misinformation about the Research Process</td>
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<tr>
<td>Structural</td>
<td>• Power and Racism</td>
<td>• Community Involvement</td>
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<td>• Poverty, Socioeconomic Status, and Access</td>
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<td></td>
<td>• Stigma</td>
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Barriers to Participation.

**Participant Barriers**

*Distrust.* African Americans’ distrust of the medical establishment traces back to slavery, legalized racial discrimination, and the overt racism that followed the passage of the Civil Rights Act in 1964, which still pervades society today (Shavers-Hornaday et. al, 1997). Historically, African Americans have been misused by the medical establishment (Shavers-Hornaday et. al, 1997; Huang and Coker, 2010). Medical theories that perpetuated the racial inferiority of African Americans were used to justify their enslavement and misuse in medical research (Shavers-Hornaday et. al, 1997; Gamble, 1993). Several examples of research abuse and unethical conduct are found in the literature, one of most notable being the Tuskegee Syphilis Study (Shavers-Hornaday et. al, 1997; Corbie-Smith et. al, 1999; Huang and Coker, 2010). The Tuskegee Syphilis Study was a government-sponsored study initiated by the United States Public Health Service to observe and document the natural course of syphilis and occurred over the course of forty years (Huang and Coker, 2010). The researchers knowingly withheld treatment to the study participants even after penicillin was
discovered to be effective against syphilis (Shavers-Hornaday et al., 1997; Thomas and Quinn, 1991).
The history of the Tuskegee Syphilis Study with its failure to adequately educate or treat the
participants helped lay the foundation for African Americans’ distrust in medical research as well as
their suspicion of the motives of researchers (Thomas and Quinn, 1999; Shavers-Hornaday et al.,
1997). This distrust can be seen in present day medical contexts as well. Concerning HIV/AIDS research, the distrust resulting from historical medical abuses and institutional racism contributes to
the underrepresentation of African Americans in HIV/AIDS clinical trials (Corbie-Smith, 1999;
Gamble, 1993; Sengupta et al., 2000). Thomas and Quinn (1999) discuss how African Americans’
perception of HIV/AIDS as a “manmade weapon of racial warfare” (p. 1498) or a form of genocide
is partly predicated upon the distrust, which may contribute to African American’s hesitancy and
reluctance to participate in HIV/AIDS clinical trials. The legacy of the Tuskegee Syphilis Study and
other past abuses continues to influence African Americans attitudes and deepen the racial suspicion
that African Americans may have towards the medical and research establishment (Shavers-
Hornaday et al., 1997; Huang and Coker, 2010).

Investigator Barriers.

Biases and Pre-Existing Notions. Researchers’ beliefs about the difficulty in recruiting and
retaining African Americans may contribute to the underrepresentation of African Americans in
HIV/AIDS clinical trials (Shavers-Hornaday et al., 1997). Howerton et al. (2007) found that
clinician-researchers’ perceptions of their patients’ ability to adhere to study protocol affected their
likelihood of referring patients to clinical trials. In addition, Swanson and Ward (1995) define
researchers’ biases as reflections of their own prejudices against the individuals and populations to
be recruited for clinical trials, which in turn influence who they reach out to. Shavers-Hornaday et al
(1997) describe how some researchers suggest that the inclusion of minority groups in clinical trials
introduces confounding variables, which complicates the interpretation of results. Further,
Howerton et. al (2007) found that clinician-researcher perceptions of patient costs influence their choices to discuss clinical trials with their patients; researchers may think that the recruitment and retaining of African American participants is more costly and thus may extend research opportunities to more accessible and convenient populations. Wendler et. al (2006) found that ethnic minorities were as willing as non-Hispanic whites to consent for participation in clinical studies, but one of the main barriers of participation is the likelihood of being asked to participate. Improving minority participation requires increased access to research opportunities for all individuals (Wendler et. al, 2006).

**Study-Related Barriers.**

*Study Demands.* Participation in clinical trials often requires time and money and can interfere with an individual’s daily schedule, often making research participation difficult. Poverty further complicates African Americans’ ability to participate in HIV/AIDS clinical trials, due to their inability to pay for childcare, transportation, and other costs related to participation (Shavers-Hornaday et. al, 1997). Newman et. al (2006) found that for the African American and gay men in their study, the more participation required of the HIV vaccine trial, the less likely individuals were to enroll. The time and financial investment often required of participation in clinical trials, coupled with poverty, affects the ability of African American to participate in HIV/AIDS clinical trials.

*Fear of Vaccine-Induced Infection.* Safety concerns and negative side effects of the drug or vaccine impede participation in clinical trials. More specifically, the fear of contracting HIV through a clinical trial poses a barrier to African American’s participation (Corbie-Smith et. al, 1999; Newman et. al, 2006). A survey conducted by Allen et. al (2005) found that 78% of African Americans believed that the HIV vaccine could cause HIV infection. Vaccine-induced seropositivity can damage the professional and personal life of a clinical trial participant. The ambiguous nature of clinical trial participation as a result of blinding and unknown efficacy perhaps further contributes to
fear of the drug or vaccine (Ma et. al, 2014). Newman et.al (2006) found that the perception of the risk of vaccine-induced HIV seropositivity, even in the absence of actual risk, had the greatest impact on willingness to participate in HIV trials among 123 vulnerable, low-income, and largely ethnic minority participants in Los Angeles. Trial-related risks and side effects can negatively influence the participation of African Americans in HIV/AIDS clinical trials.

*Misinformation and the Process of Informed Consent.* Misinformation can result from a multitude of factors including trust and communication. Lack of understanding of the definitions, purpose, and procedures of a clinical trial can dissuade individuals from participating and complicate a patient’s ability to provide informed consent (Freimuth et. al, 2001). Corbie-Smith et. al (1999) found that participants had a limited understanding of the informed consent process and generally believed that its purpose was to protect researchers and doctors from legal responsibility. None of the participants knew of any legal protection for participants of medical research, which perhaps speaks to the broader issues of the underlying power dynamics in research structures (Corbie-Smith et. al, 1999). Mason (2005) described how the technical and legal language of consent documents and protocol are difficult to understand and might further deter individuals who already may not trust the research institution. The lack of trust between researchers and participants that undermines the informed consent process coupled with a lack of understanding of the research process can deter African Americans from participating in HIV/AIDS clinical trials.

*Structural Barriers.*

*Power and Racism.* Power structures inherent to clinical research are multidimensional, often operating between a researcher and participant as well as between different racial groups. In traditional clinical research approaches, the researcher has power over the entire research process from defining the research question to obtaining results (Horowitz, Robinson, and Seifer, 2009). Thomas and Quinn (1991) describe how research collaborations need to be cognizant of the power
structure in research as it relates to the broader context of historical racism in the United States. Historically, the discipline of medicine has been influenced by racism and has perpetuated the idea of racial inferiority of African Americans (Shavers-Hornaday et. al, 1997; Gamble, 1993). Medical theories of antebellum physicians about the anatomical and physiological distinctiveness of African Americans were used to justify their enslavement (Gamble, 1993). Dr. J Marion Sims, who has been called the father of modern gynecology, used three black slaves to develop and perfect an operation to repair vesico-vaginal fistulas, all without anesthesia (Gamble, 1993). The Tuskegee Syphilis Study was also influenced by racist thought: white physicians pointed to “intrinsic racial characteristics such as excessive sexual desire, immorality, and overindulgence” to explain the high rates of syphilis in African Americans (Gamble, 1993, p. 36). Coupled with their desire to study the natural course of disease, white physicians withheld treatment because they thought that syphilis in African Americans was difficult to treat because of both the difficulty of convincing African Americans to come in for treatment and because African Americans did not adhere to treatment regimens (Gamble, 1993). African Americans’ distrust in the medical establishment is partially predicated on these dimensions of power, which historically allowed researchers to take advantage of their positionality. The historical abuse of power underpins the context in which barriers for African Americans’ participation in HIV/AIDS clinical trials become manifest.

Poverty, Socioeconomic Status, and Access. The burden of HIV amongst African American is perhaps exacerbated by the presence of social and economic forces in access to care. From 2007 to 2011, the poverty rate of Blacks or African Americans averaged 25.8% compared 11.6% for Whites (Macartney, Bishaw, and Fontenot, 2013). The high prevalence of poverty in African American communities may complicate access to health care and consequently access to information about opportunities to participate HIV/AIDS clinical trials (Shavers-Hornaday et. al, 1997). Additionally, Corbie-Smith et. al (1999) found a lack of perceived benefit from advancements of medical research
among African Americans because of poverty and racial discrimination, which perhaps contributes to their low-level of participation in HIV/AIDS clinical trials. Moreover, low socioeconomic status is related to insurance status; individuals of low socioeconomic status are more likely to rely on Medicare or Medicaid, and the coverage of their costs associated with clinical trial participation is often denied or unreliable (Giuliano et. al, 2000). The issues of access, perceived benefit, and insurance are shaped by poverty and influence African American’s participation in HIV/AIDS clinical trials.

**Stigma.** Stigma can be understood as the co-occurrence of labeling, stereotyping, separation, status loss, and discrimination in the context of unequal power structures (Link and Phelan, 2001). The fear of stigmatization related to HIV/AIDS in the African American community perhaps contributes to African Americans’ underrepresentation in HIV/AIDS clinical trials (Shavers-Hornaday et. al, 1997). Strauss et. al (2001) found that when asked about their willingness to participate in a HIV vaccination trial, African Americans expressed concern over the social consequences of trial participation, such as being ostracized from the community. Additionally, homosexuality is stigmatized within the African American community, further complicating African Americans’ participation in HIV/AIDS clinical trials (Fullilove and Fullilove, 1999; Brooks et. al, 2006).

**Facilitators to Participation**

*Participant Facilitators.*

*Altruism.* The desire to advance medical knowledge and help individuals and communities can motivate individuals to participate in clinical trials. The perceived benefit of contributing to the welfare of a community and/or family improves African American’s willingness to participate in research studies (Corbie-Smith et. al, 1999; Huang and Coker, 2010). Ma et. al (2014) found that
altruism was the most prominent factor related to willingness to participate in their study of the predictors of the participation of African Americans in HIV vaccine trials.

**Benefits to Participation.** Benefits to participation can include both monetary and nonmonetary forms of compensation. Newman et. al (2006) found protection against HIV infection, free insurance and medical care, and payment as reasons for ethnic minority communities to participate in HIV vaccine trials. George, Duran, and Norris (2014) found that modest monetary incentives, free health examinations, free lunch, and access to healthcare resources and services may positively impact minority research participation. Incentives that address factors related to the logistical inconveniences of clinical trial participation, such as transportation and childcare may facilitate participation in clinical trials (Shavers-Hornaday et. al, 1997; George, Duran and Norris, 2014). While monetary and nonmonetary benefits to participation can motivate African American’s participation in HIV/AIDS clinical trials, such benefits can be unintentionally coercive and thus should be used with caution (Freimuth et. al, 2001).

**Investigator Facilitators.**

**Increase of Minority Researchers and Training.** An increased representation of African American researchers on clinical trial teams may help increase trust between researchers and participants, which in turn might facilitate African American participation in HIV/AIDS clinical trials (Huang and Coker, 2010). Shavers-Hornaday et. al (1997) describe the inclusion of African Americans as members of the research team as well as the use of African American role models as successful recruitment strategies for addressing the underrepresentation of African Americans in medical research. African American researchers are perhaps more likely to understand the historical, social, and economic contexts in which some of the hesitations and fears of African American participants are embedded. Freimuth et. al (2001) discuss how increasing African American investigators and research staff alone is not enough to improve African American participation, as disparities in class
and education still exist and the use of African American researchers in Tuskegee did not prevent misconduct from occurring. Researchers should be trained in the cultural, historical, and social aspects of conducting research so that they can more effectively address issues of culture, race, and class (Freimuth et. al, 2001). Increasing training as well as African American representation in research can help make researchers and participants more comfortable working together in a research setting, which in turn, may improve the participation of African Americans in HIV/AIDS clinical trials.

**Study-Related Facilitators.**

*Communication.* Open and honest communication between researchers and participants that provides comprehensive information about the risks and benefits of research may improve African American participation in clinical trials (Corbie-Smith et. al, 1999). Harris et. al (1996) suggest that a communications system that is centered around the community and involves community organizations and individuals is essential to conducting a clinical trial in the African American community. Freimuth et. al (2001) discuss the importance of enhancing the understanding of informed consent and research procedures for prospective participants to improve African Americans’ participation in research and suggest the development of a comprehensive communication campaign about research that includes definitions, purposes, terms, and procedures among other aspects. Crawley (2001) explains the importance of verbal and non-verbal communication that is culturally competent in developing and maintaining trust between researchers and African American participants. Honest and open communication throughout the research process can positively influence African American's participation in HIV/AIDS clinical trials.

*Structural Facilitators.*

*Community Involvement.* Engaging community members and organizations in the research process can facilitate African Americans’ participation in clinical trials (Thomas and Quinn, 1991;
Huang and Coker, 2010). Meaningful community involvement has the potential to address power dynamics, enhance trust, and improve access to research information and opportunity through partnerships. Community involvement can embody multiple forms such as the use of outreach workers and partnerships with existing individuals, community organizations, and churches (Yancey, Ortega, Kumanyika, 2006). The extent of community involvement in a clinical trial can vary from planning and development of intervention to analysis of data and dissemination of results. Yancey, Ortega, Kumanyika (2006) describe how community involvement can build trust and alleviate attitudinal barriers. Shavers, Lynch, and Burmeister (2002) explain how community involvement can help design appropriate studies and improve the understanding of the research project. Smith et. al (2007) found that community involvement on the research team and use of existing community networks for recruitment were emphasized by the participants in their study of the perceptions of African American women towards clinical research. Blankenship et. al (2006) describes community mobilization as one type of structural intervention in public health, which promotes health by altering the context within which health is produced and reproduced. Community involvement in research can help participants feel ownership of the project and results, which can aid in increasing the participation rates of minorities in research (Giuliano et. al, 2000).

**Statement of the Problem**

The participation of African Americans in HIV/AIDS clinical trials is shaped by multidimensional factors that are influenced by larger sociostructural forces and operate at the individual, investigator-related, study-related, and structural level. For example, issues of trust are shaped by historical racism. Investigator biases and pre-existing notions can be shaped by dominant social stereotypes about racial groups. Study demands are further complicated by issues of poverty and low socio-economic status. Thus, when approaching African Americans to participate in HIV/AIDS clinical trials, researchers need to understand and address the sociostructural context in
which the factors that influence the participation of African Americans are embedded. This research paper aims to explain why the clinical trials research approach need to be improved to address the underrepresentation of African Americans in HIV/AIDS clinical trials by demonstrating that the approach does not adequately situate individuals and their decision to participate within larger sociostructural contexts. In order to achieve this aim, this paper will provide a history of the development of the clinical trials research approach, describe the characteristics and components of the approach, and discuss the challenges and limitations of the approach in addressing the barriers and facilitators that affect the recruitment of African Americans in HIV/AIDS clinical trials. Additionally, this research paper aims to demonstrate how the clinical trials research approach can be improved to begin to address the larger sociostructural forces that shape African Americans’ participation in HIV/AIDS clinical trials. In order to achieve this aim, this paper will discuss potential recommendations on how to modify clinical trials research approach so that the approach can begin to understand sociostructural influences in the participation of African Americans in HIV/AIDS clinical trials. The clinical trials research approach needs to encompass not only the individual, but also the broader social, economic, and political structures in which the individual exists, as it is these structures that co-shape an individual’s decision to participate. Thus, the clinical trials research approach should locate individuals within their sociostructural context. Addressing the sociostructural context that influence participation may help researchers attend to the racial disparity in HIV/AIDS clinical trials participation, as this context underpins the barriers and facilitators of African American’s participation in HIV/AIDS clinical trials and thus co-influences an individual’s decision to participate in a clinical trial.

**Methods**

The primary research method for this paper is an interdisciplinary review of peer-reviewed literature and books spanning medicine, sociology, public health, and psychology; the rationale for
using different disciplines is to comprehensively capture the perspectives of the different research frameworks to both critique and substantiate the research aims. The electronic databases that were searched include PubMed, Social Services Abstract, Sociological Abstracts, Anthropology Plus, and PsycINFO. Free-text searches using the terms “African American”, “clinical trials”, “critique” and “research design” were also conducted. Studies were restricted to original articles published in the United States because this paper seeks to address disparities within the United States. The references sections were examined for additional articles. The following specific search terms were used individually and in combination with one another:

- PubMed: Medical Subject Heading (MeSH) terms - “African American”, “blacks”, “attitudes of health personnel”, “attitude to health”, “minority groups”, “biomedical research”, “ethnic groups”, “HIV infection”, “acquired immunodeficiency syndrome”, “research design”, “United States” and “clinical trials as topics”
- Social Services Abstract: “HIV”, “clinical trials”, “research methods”, “biomedical research”, “blacks” and “African Americans”
- PsycINFO: “clinical trial participation”, “blacks”, “research methods”, “biomedical research”, “African Americans”, and “HIV”

The literature was synthesized and organized into the following categories based on relevance:

- History of Clinical Trials
- Characteristics Clinical Trials Research Approach
• Limitations of the Clinical Trials Research Approach

The literature was analyzed and related to the barriers and facilitators of African Americans’ participation in HIV/AIDS clinical trials. The use of the broader search term of “clinical trials” rather than the specific phases of clinical trials reflects the inconclusive nature of data specific to particular phases.

Results

The Clinical Trials Research Approach

History of Clinical Trials. The history of clinical trials has spanned over 250 years (Jenkins and Hubbard, 1991). One of the first controlled clinical trials was conducted by the physician James Lind, who in 1747, evaluated twelve patients with scurvy and studied their response to different interventions (Jenkins and Hubbard, 1991). Comparative clinical trials with various drugs and vaccines continued throughout the 1800s (Jenkins and Hubbard, 1991). The first placebo-controlled randomized controlled trial was conducted by the British Medical Research Council and evaluated Streptomycin for pulmonary tuberculosis (Jenkins and Hubbard, 1991). This trial laid the foundation for the basic principles of clinical trials research methodology, as the trial utilized randomization, blinding, and considered ethics prior to initiating the clinical trial (Jenkins and Hubbard, 1991).

Social and political influences have also shaped the history of clinical trials. Single, white males were considered to be the prototype and standard of comparison for human subjects research (Dresser, 1992). The rationale for the exclusion of women and racial and ethnic minorities was based on ideas of normality and abnormality, statistical analysis of randomized controlled trials, and structures of power (Dresser, 1992). Whether consciously or unconsciously, researchers defined the single, white male as representative of all human beings and thus believed advancing human health and welfare would be achieved by examining the white, male body (Dresser, 1992). The exclusion of women and people of color perhaps reflected the racial composition of researchers who were also
predominantly white, males as well as dominant racial and gender ideologies of the time on who should get access to the health benefits of biomedical research (Dresser, 1992).

The social and political impacts on clinical trials are also demonstrated by the influence of racism on unjust human experimentation of African Americans within the broader context of medicine and clinical research. Clinical researchers utilized physiological and biological differences between black slaves and the presumed standard norm of white, males to warrant their enslavement and racial inferiority (Gambles, 1993; Duster, 2006). In the 1800s, hundreds of slaves were inoculated with the small-pox virus to assess the safety of a new vaccine (Dula, 1994). Dr. Walter F. Jones tested a remedy for typhoid pneumonia by pouring five gallons on boiling water down the spines of slaves (Randall, 2006). More recently, in the 1970s, blood samples from 7000 black children were collected by the government (Randall, 2006). The parents were told that the purpose was to test the blood for anemia, but instead the blood samples were used to looks for markers that the black children were genetically predisposed to criminal activity (Randall, 2006). A number of radiation experiments were conducted on predominantly black populations, including 15 studies conducted by Tulane University and Charity Hospital in New Orleans where 300 black, mostly women, swallowed radioactive capsules and were injected with radioactive mercury that resulted in blisters that were then intentionally cut open and exposed to up to 188 degrees heat (Randall, 2006). The stated purpose of the study was to determine the effect of mercury on people with congestive heart failure, but the patients in the study did not have that disease (Randall, 2006).

Several ethical safeguards emerged in response to various medical abuses that had taken place both in the United States as well as around the world. Ethical principles for the protection of human subjects in clinical trials were first formulated with the Nuremberg Code in 1947, a series of 10 principles that established the basic moral, legal, and ethical concepts for human experimentation (Jenkins and Hubbard, 1991; Shuster, 1997). In 1964, the Helsinki Declaration offered
recommendations to guide physicians and researchers on conducting biomedical research with human subjects (Jenkins and Hubbard, 1991). Specific to the United States, the Department of Health and Human Services and the Food and Drug Administration have created formal regulations for all clinical trials conducted in the United States that require certain ethical standards (Jenkins and Hubbard, 1991). In 1974, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was created after the passage of the National Research Act and basic ethical principles to protect human subjects in biomedical and behavioral research, which included four principles: analyzing boundaries between biomedical and behavioral research and the routine practice of medicine, assessing risk and benefit in determining the appropriateness of the research, defining guidelines for the selection of human subjects, and defining informed consent in the context of different settings (Jenkins and Hubbard, 1991; Department of Health, Education, 2014). This commission also developed the Belmont Report in 1979, which established ethical principles and guidelines for the protection of human subjects in behavioral and biomedical research related to respect for persons, beneficence, and justice (Jenkins and Hubbard, 1991).

In an effort to address the issue of justice outlined in the Belmont Report, the National Institutes of Health mandated inclusion of women and minorities in clinical research in order to address the potential harms created by their omission or exclusion (Taylor, 2009). Yet, minorities continue to remain underrepresented in clinical trials (George, Duran and Norris, 2014). In fact, most physicians and scientists are still informed by research that is inferred from a largely homogenous population of usually white males, perhaps suggesting that mandates and policies alone are not going to translate to changes in the demographics of clinical trials (Oh et. al, 2015).

Specific to HIV/AIDS, the history of HIV/AIDS clinical research is unique in that activists from the HIV/AIDS community mobilized and drove HIV/AIDS clinical research in the late 1980s (Epstein, 1996). Clinical trials were the focus of the movement against AIDS between 1986 and
The advent of HIV/AIDS coupled with the mobilization of the HIV/AIDS community activists profoundly changed the drug development process by expediting the pace of drug development and access to investigational drugs (Sepkowitz, 2001). Activists radically altered the decision-making process of biomedical research; Epstein (1996) explains how activists “challenged the formal procedures by which clinical drug trials are designed, conducted, and interpreted; confronted the vested interests of the pharmaceutical companies and the research establishment; demanded rapid access to scientific data; insisted on their right to assign priorities in AIDS research; and even organized research on their own, with the cooperation of allied professionals” (p. 32). Despite this unique history, however, HIV/AIDS clinical trials research approach today is largely driven by researchers and disparities exist in the access to research participation as well as rates of participation in HIV/AIDS clinical trials.

**Characteristics of the Clinical Trials Research Approach.** The clinical trials research process consists of several stages: the planning and formative stage, study selection and design, funding stage, implementation, analysis, and interpretation of data, dissemination of findings, translation of research into practice and policy, and sustaining of the research team and resources (Horowitz, Robinson, and Seifer, 2009). All of these stages are largely driven by the researcher and their academic discipline. The researchers plan the research project and form the research team in the formative stage (Horowitz, Robinson, and Seifer, 2009). The researchers also choose the topic, variables, and subjects and design the study based on existing literature and scientific theory, academic interests, and feasibility (Horowitz, Robinson, and Seifer, 2009). The grant to fund the study is written by researchers with the funds going to the researchers and the needs of their project (Horowitz, Robinson, and Seifer, 2009). Researchers are also solely responsible for the analysis and interpretation of data (Horowitz, Robinson, and Seifer, 2009). The results are disseminated by the research team primarily to academic audiences such as publications in academic journals (Horowitz,
Robinson, and Seifer, 2009). Once the results are published, the research project is usually
completed, and researchers will typically move onto a new research question and project (Horowitz,
Robinson, and Seifer, 2009). The purpose of the research is often to further the knowledge of the
academic discipline of the researcher and is generally not perceived as a mechanism for social change
(Nyden, 2003).

The clinical trials research methodology consists of four phases. Phase I trials are primarily
concerned with drug safety and are usually performed on human volunteers (Pocock, 2013). Phase I
trials often aim to determine the appropriate single drug dosage (Pocock, 2013). Phase II trials are
smaller in scale and are concerned with the preliminary efficacy and safety of a drug (Pocock, 2013).
Phase III clinical trials are the most rigorous and extensive type of clinical trial investigation and are
concerned with a full-scale evaluation of treatment among the targeted population and a comparison
to other available drugs (Pocock, 2013). Phase IV clinical trials focus on monitoring the
investigational drug for adverse effects, side effects, and longer-term studies of morbidity and
mortality (Pocock, 2013).

The randomized control trial is generally accepted to be the most reliable method to conduct
clinical research (Pocock, 2013). Randomized controlled trials utilize probability to randomly assign
patients to different study treatments (Rosenberger and Lachin, 2016). Blinding is often used in
clinical trials. Double-blind procedures have been considered to be salient design features in clinical
trials, often used to prevent certain biases of both subjects and researchers (Bang, Ni, and Davis,
2004). Double-blinding refers to “keeping study participants, investigators and data assessors
unaware of the allocated treatment or therapy, so that they are not influenced psychologically or
physically by that knowledge” (Bang, Ni, and Davis, 2004, p. 143).

Limitations of the Clinical Trials Research Approach. The clinical trials research
approach is limited in its capacity to address barriers and facilitators of African Americans’
participation HIV/AIDS clinical trials. Specific to the barriers, the unequal balance of power in the hierarchal nature of the research approach that results from racial, class, gender, and educational differences may not be conducive to building trust between the researcher and participant. The clinical trials research approach is often hierarchal in nature, creating unequal power differentials between the researcher and the researched. The positivist tradition often privileges expert technical knowledge, objectivity, and universal claims to characterize the world (Minkler and Wallerstein, 2008). Power structures in a typical clinical trials research approach are hierarchal, and academic positions are disproportionately held by individuals who are already privileged in terms of race, class, and gender (Minkler and Wallerstein, 2008). The clinical trials research approach often maintains hierarchies of power by disproportionately favoring the researcher concerning the allocation of power (Minkler and Wallerstein, 2008). This power differential may not be conducive to maintaining trust between the researcher and participant.

Additionally, clinical trial research approaches and interventions have not been effective in addressing the complex social, economic, and structural forces that influence health disparities (Horowitz, Robinson, and Seifer, 2009). Increased recognition of health inequities associated with social, economic, political, and structural factors has necessitated the development of new orientations of research that understand that individuals and their decision to participation in research are embedded in social, economic, and political systems that influence behavior and access to resources (Israel et. al, 1998). Given the multidimensional factors that affect the participation of African Americans in HIV/AIDS clinical trials, the clinical trials research approach needs to understand how social, economic, and structural forces manifest in the factors that influence participation. The lack of focus on the social and structural context that influences an individual’s decision to participate makes it difficult to address the structural barriers of stigma, poverty, and racism within the confines of the dominant clinical trials research approach. However, given how
sociostructural forces influence all levels of the barriers of African Americans’ participation in HIV/AIDS clinical trials, the lack of consideration of these forces may contribute to the persistence of the racial disparity in clinical trials participation.

Moreover, the fact that the research process is largely driven and defined by the researcher may complicate its ability to address researcher biases as well as the socioeconomic barriers that may impede an individual from participating in a clinical trial such as the study demands. Similarly, the researcher-driven approach may not be aware of the educational needs and knowledge base of those that are participating. Although the processes of blinding and randomization and the various phases of clinical trials have scientific merit and specific meaning within the confines of research, these concepts are not necessarily conveyed effectively to the participants of research. Ard et. al (2005) explain how these research terms may suggest secretive or covert tactics for the layperson. Freimuth et. al (2001) stated that the level of knowledge about research terms and procedures was not very high in their study of African American views on research and the Tuskegee Syphilis Study. The misunderstanding and lack of knowledge of research terms can support distrust in biomedical research (Ard et. al, 2005). The terminology associated with clinical trials and the way it is presented in the clinical trials research approach often aligns with the educational knowledge of the researcher; the terminology in the consent form as well as the processes of blinding and randomization may be framed in a way that is not understandable and clear to the participants.

Specific to the facilitators, the clinical trials research approach generally does not involve the community in the development and conceptualization of the research study idea, materials, and processes. Since the researcher drives the clinical trial, culturally competent communication may be difficult if the researcher is not trained on the cultural and social context of the participants. The shortage of minority physicians can further complicate the relationship between the researcher and minority participants, and coupled with power structures inherent to the researcher-researched
relationship in the research process, adds a racial dimension of power that may contribute to the underrepresentation of African Americans participation in HIV/AIDS clinical trials.

**Discussion**

Accommodating the specific barriers and facilitators of the participation of African Americans in HIV/AIDS clinical trials will require a multipronged approach that recognizes the social, economic, and cultural needs of a participant in addition to the biological and clinical needs. The clinical trials research approach can begin to be both more inclusive of the multidimensional factors that influence African Americans’ participation in HIV/AIDS clinical trials by improving the training of researchers, increasing the involvement of the community, and diversifying clinical trials research teams. The following section provides recommendations to help clinical researchers learn how to situate individuals within broader sociostructural contexts so that researchers can learn how to navigate the multidimensional factors that influence African Americans’ decision to participate in HIV/AIDS clinical trials. The recommendations, while derived from existing literature, are theorized to the application of African Americans and HIV/AIDS clinical trials participation (Table 2).
Table 2: Recommendations to Address the Factors Influencing the Participation of African Americans in HIV/AIDS Clinical trials

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>Potential Implications</th>
</tr>
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| Training: Intersectionality, Cultural Competency, and Structural Competency | - Training can provide researchers with the skills, tools, frameworks, and knowledge to navigate the sociostructural context in which individuals exist.  
- Potential barriers addressed: distrust, biases and pre-existing notions, misinformation, and stigma  
- Facilitators emphasized: increase in training of researchers and communication |
| Community Involvement | - Community involvement can help researchers tailor research projects to the needs of the participants.  
- Potential barriers addressed: distrust, study demands, and misinformation  
- Facilitators emphasized: community involvement |
| Increase in Minority Researchers | - Increasing the diversity of researchers can help develop racial and ethnic concordance with diverse participants.  
- Potential barriers addressed: distrust, misinformation, and access  
- Facilitators emphasized: increase in minority researchers and communication |

Recommendations to Improve the Clinical Trials Research Approach

More Comprehensive and Interdisciplinary Training of Researchers:

Intersectionality, Cultural Competency, and Structural Competency. Social, cultural, and structural forces largely shape an individual’s participation in a clinical trial. The extent of cultural adaptations of a research study can impact outcomes (Yancey, Ortega, Kumanyika, 2006). Research materials, programs, and interventions that are culturally appropriate to the populations they serve can be more effective that those that are not (Kreuter et. al., 2003). Research studies that take into account the structural impediments of participation often related to poverty and access may be more
effective in recruiting minority populations than those who do not (Shavers-Hornaday et. al, 1997; George, Duran and Norris, 2014; Wendler et. al, 2006). Yet, the training of clinical researchers is largely focused on research methodology and research-related skills and knowledge, often stressing the biomedical and hard sciences more than social and soft sciences. Broadening the training of the clinical researchers to encompass the social, economic, structural and cultural factors that contribute to the participation of minorities in clinical trials may help them be able to better address the multifaceted barriers and facilitators that influence an individual’s decision to participate. In order to do so, the training of clinical researchers may need to extend beyond the biomedical sciences and into other disciplines such as anthropology, sociology, and psychology; thus improving the training of clinical researchers may require diverse disciplinary representation on the faculty of training institutions.

**Intersectionality.** Intersectionality can be a useful framework for researchers to begin to tease apart the multiple factors that impact the underrepresentation of racial minority groups in research (Fryer et. al, 2015). Bowleg (2012) defines intersectionality as “a theoretical framework that posits that multiple social categories (e.g., race, ethnicity, gender, sexual orientation, socioeconomic status) intersect at the micro level of individual experience to reflect multiple interlocking systems of privilege and oppression at the macro, social-structural level (e.g., racism, sexism, heterosexism)” (p.1267).

Given the multiple, interrelated dimensions of African Americans and their participation in HIV/AIDS clinical trial (individual, investigator-related, study-related, and structural), intersectionality can provide a useful framework through which researchers can begin to understand the nuances and complexities of an individual’s decision to participate. An intersectional framework recognizes that no social group is homogenous, people must be located in terms of social structures that capture power relations implied by those structures, and that there are unique multiplicative
effects of identifying with more than one social group (Kelly, 2009, p.43). African Americans are not a homogenous population and the diversity amongst African Americans within communities needs to be addressed when conducting research (Huang and Coker, 2010). An intersectionality framework may help researchers understand the diversity amongst African Americans when approaching them for HIV/AIDS clinical trials participation. Intersectionality might also help researchers begin to recognize and be cognizant of the power structures that are inherent to the research process because of its focus on power differentials and structural inequalities within society. Moreover, an intersectional framework would recognize that race is only one identity at play in an African American’s decision to participate in HIV/AIDS clinical trials; gender, age, education, ability, and class among other factors may also be at play. Thus, an intersectional framework can be used to examine the multiple sociostructural factors that contribute to an African American individual’s decision to participate in an HIV/AIDS clinical trial.

**Cultural Competency.** Culture can be conceptualized as “integrated patterns of human behavior that include the language, thoughts, communications, actions, customs, beliefs, values, and institutions of racial, ethnic, religious, or social groups” (Anderson et. al, 2003, p. 68). Culture contributes to conceptualizations of health and illness, methods of communication, and perceptions of institutions (Anderson et. al, 2003). Cultural factors are often entangled with social factors such as socioeconomic status (Betancourt et. al, 2003). Sociocultural factors contribute to an individual’s participation in clinical trials. Attitudes towards healthcare providers, cultural perceptions of disease, linguistic and communication preferences, and the conceptualizations and understanding of the research process are examples of cultural barriers to participation of minorities in clinical trials (George, Duran and Norris, 2014; Corbie-Smith et. al, 1999).

Specific to African Americans and HIV/AIDS, cultural expectations of masculinity and heterosexuality as well as gender expectations of the role of men can contribute to HIV-related risk
behaviors (Wyatt, 2009). The distrust in the medical establishment of many African Americans and belief of AIDS as a form of genocide are also examples of sociocultural influences of their participation in HIV/AIDS clinical trials (Freimuth et. al, 2001). Sociocultural factors can also contribute to a researcher’s attitudes and beliefs towards African Americans, which play a role in the participation of African Americans in HIV/AIDS clinical trials (Swanson and Ward, 2005).

Individuals are embedded in a dynamic sociocultural context that shapes their decision to participate in HIV/AIDS clinical trials; thus, researchers should be trained on understanding this context in which an individual’s participation is embedded to move towards reducing the disparity in clinical trials representation.

Cultural competence training curricula have emerged to help reduce health disparities and improve the quality of health care. Betancourt et. al (2003) explain that cultural competence in healthcare “entails: understanding the importance of social and cultural influences on patients’ health beliefs and behaviors; considering how these factors interact at multiple levels of the health care delivery system (e.g., at the level of structural processes of care or clinical decision-making); and, finally, devising interventions that take these issues into account to assure quality health care delivery to diverse patient populations” (p. 297). When training researchers and providers on culture, it is important to remember that nuances exist both within and between the cultural groups and their constituencies. Thus, cultural competence aims to equip providers with the skills and tools needed to implement patient-centered care, which include empathy and responsiveness to a patients’ values, needs, beliefs, and preferences (Betancourt, 2004).

Cultural competency offers one potential mechanism through which researchers can begin to learn how to encompass the sociocultural factors that affect an individual’s participation in a clinical trial. Specific to the barriers and facilitators of African Americans and HIV/AIDS clinical trials, cultural competence training can impact provider knowledge, skills, and attitudes, which can
help address the researcher’s biases and pre-existing notions (Beach, et. al, 2005). Additionally, lack of cultural understanding and sensitivity can contribute to communication problems and the establishment of trust and satisfaction (Cook, Kosoko-Lasaki, O’Brien, 2005). Cultural competence training perhaps then can help with communication between a provider and patient, which can help address the barrier of misinformation. Moreover, the lack of cultural competence is one of the factors that relates to the distrust of African Americans towards the health care system (Kennedy, Mathis, and Woods, 2007). Therefore, cultural competency training may be one component for addressing the distrust that impedes the participation of many African Americans in HIV/AIDS clinical trials. Huang and Coker (2010) explain how cultural competence and sensitivity are essential to tailoring research interventions to the context of the participants to help reduce the suspicion and fear of stereotyping that may influence distrust.

**Structural Competency.** Sociocultural factors that influence participation are also shaped by larger structural factors such as racism, power structures, poverty, and access. Historical racism stemming from slavery and continuing into the present day plays a role in the distrust of African Americans in the medical establishment, which in turn may contribute to their underrepresentation in HIV/AIDS clinical trials (Gamble, 1993). Power structures inherent to the research process tend to privilege the knowledge and needs of the researcher, and coupled with the racial dimension of power between a white researcher and black participant, may play a role in the participation of African Americans in HIV/AIDS clinical trials. Poverty can also serve as a structural barrier to access to clinical trials research opportunities (Swanson and Ward, 1995). The structural context in which an individual exists influences their decision to participate in clinical trials; thus, in addition to training on sociocultural forces, researchers should be trained on how to conceptualize and traverse these broader structural forces.
Structural competency can be defined as “the trained ability to discern how a host of issues defined clinically as symptoms, attitudes, or diseases (e.g., depression, hypertension, obesity, smoking, medication “non-compliance,” trauma, psychosis) also represent the downstream implications of a number of upstream decisions about such matters as health care and food delivery systems, zoning laws, urban and rural infrastructures, medicalization, or even about the very definitions of illness and health” (Metzl and Hansen, 2014, p. 128). Structural competency offers a promising mechanism to situate individual experiences of health care and clinical research within the confines of broader social, economic, and political structures. The five-step conceptual model of structural competency, which consists of recognizing the structures that shape clinical interactions, developing an extra-clinical language of structure, rearticulating “cultural” presentations in structural terms, observing and imagining structural intervention, and developing structural humility, sheds light on the forces that shape health outcomes at levels above individual interactions (Metzl and Hansen, 2014). Overall, structural competency conceptualizes health inequities in relation to the institutions and social conditions that determine health-related resources (Metzl and Hansen, 2014).

While structural competency has been theorized as an approach for medical education, the conceptual model is also relevant to addressing the barriers that shape African Americans participation in HIV/AIDS clinical trials; similar to how clinical presentations are shaped by cultural, social, and economic variables, African American’s participation in HIV/AIDS clinical trials is also shaped by larger social and economic forces. Structural competency may offer a mechanism through which the barriers of stigma, distrust, and poverty can begin to be addressed. HIV/AIDS-related stigma is largely shaped by power structures and is tied to broader issues of social hierarchies and inequality (Parker and Aggleton, 2003). Thus, addressing stigma will require researchers to understand the broader structural forces that enable stigma. Structural competency offers a prospective paradigm through which researchers can situate the individual enactments of stigma.
within the broader structural confines in which the stigma was produced. Additionally, Gamble (1993) explains how African American’s distrust in the medical establishment is predicated on the historical pervasiveness of racist thought throughout institutions such as medicine. Epstein (2008) explains how distrust cannot be addressed without considering the broader historical and political issues that affect racial and ethnic minority groups. Utilizing a structural competency paradigm may be able to situate the issue of distrust within the broader sociohistorical context in which it is embedded. Moreover, because structural competency aims to shed light onto how individuals are influenced and constrained by larger structural forces, this paradigm might be able help to researchers learn about the influence of poverty on research participation of African Americans in HIV/AIDS clinical trials. Overall, African American’s participation in HIV/AIDS clinical trials is largely shaped by social, economic, and political structures; structural competency can help researchers navigate the sociostructural context in which an individual and their decision to participate are embedded. While these training approaches have been theorized and applied to the physician-patient relationship, intersectionality, cultural competency, and structural competency can also be extended to the researcher-participant relationship; improving the training of clinical researchers to encompass intersectionality, cultural competency, and structural competency is promising to address the multidimensional factors that influence an individual’s participation.

More Grassroots: Community Involvement in the Research Process. Community involvement in the research process has been recommended as a strategy to address the individual as well as the broader social, economic and environmental factors that contribute to disparities in clinical trials participation (George, Duran and Norris, 2014; De las Nueces et. al, 2012; Yancey, Ortega, Kumanyika, 2006; Minkler and Wallerstein, 2008). Community involvement develops relationships between individuals, communities, organizations and academic institutions that improve access to research opportunities, offer different perspectives, and foster trust, all of which
are important to improve minority research participation (Wendler et al., 2006; Shavers-Hornaday et al., 1997; Horowitz, Robinson and Seifer, 2009). Community engagement has been also recommended as a strategy to enhance the relevance of research (Israel et al., 1998).

Community-based participatory research (CBPR) is a predominant paradigm towards community engagement in research that fosters an equitable relationship of all involved in the research process, challenging researchers to share responsibility, power, and information (Israel et al., 1998; Horowitz, Robinson and Seifer, 2009). CBPR has been defined as “a collaborative process that equitably involves all partners in the research process and recognizes the unique strengths that each brings. CBPR begins with a research topic of importance to the community with the aim of combining knowledge and action for social change to improve community health and eliminate health disparities” (Minkler and Wallerstein, 2003, p. 4). However, many aspects of the CBPR paradigm such as power sharing, the time and financial demands of spending time in a community, and an action research methodology pose a challenge to clinical trials researchers given their time constraints in a clinical research setting, the power hierarchy in academic medicine, and the focus on controlled trials as a standard for evidence in medicine (Jones and Wells, 2007). While the translation of the theory of CBPR to the practice of clinical research poses challenges, blending various degrees of community engagement with the clinical trials research approach is promising to address the disparities in clinical trials participation.

Community involvement in the research process can take a variety of forms. Scharff et al (2010) describe how research centers such as Harvard University, the University of Pittsburg, and the Mayo Clinic utilize Community Research Advisory Boards (CRABs) to review the research project design, materials, and procedures and provide advice to investigators conducting clinical trials; community involvement can help researchers consider the knowledge and skills of the participants rather than solely designing the study based on the knowledge of the participant. In a
recent systematic review, Yancey, Ortega, Kumanyika (2006) found that working through community-based organizations, such as churches, as well as the use of community members as outreach workers from the targeted population have been used as strategies to involve community members in the research process. Additionally, community involvement can occur to various extents in the different stages of the research process from the planning stage through the analysis stage. The extent of community involvement may vary depending on a number of factors including the nature of the research question, time, financial, and resource constraints, and the skills and knowledge of both the researcher and community partner.

Specific to African Americans and HIV/AIDS clinical trials, community involvement may help address the barriers of distrust, study demands, and misinformation. Concerning distrust, community involvement can help address the distrust that African American’s have towards research through open and honest communication and active engagement in the research study planning and implementation (Ammerman et. al, 2003). Increased concordance between the researcher’s goals and those of the community through open communication and community involvement throughout the research process may also be effective in addressing the distrust of African Americans towards the medical establishment (Yancey, Ortega, Kumanyika, 2006). Moreover, Shavers, Lynch, and Burmeister (2002) explain how community involvement can help design appropriate studies and improve the understanding of the research project, which may be able to help with the issue of study demands; involving the community can help researchers learn about the ways in which they can make research participation more convenient for the participants. Furthermore, community engagement in research process may help address misinformation of the research process because community members can give researchers feedback on their research materials and study design, which can help researchers adapt their materials and information in a way that is more understandable and tailored to the knowledge of the participants. Strauss et. al
describe how community advisory boards offer a space for researchers and community members to discuss the risks, benefits, intent and implications of research projects, emphasizing how communities can play a vital role in the ethical conduct of research and the process of informed consent.

**More Diversity: Improving Minority Representation on Research Teams.** Most racial and ethnic minority groups including African Americans, Hispanics, and Native Americans, are not adequately represented in health professions compared to their proportions in the overall United States population (Evans et al., 2001). Racial and ethnic minorities are more likely to serve in and study minority and underserved communities as well as organize health care delivery systems to meet the demands of minority populations (Evans et al., 2001; Betancourt et al., 2003). Because of their likely social and cultural understanding of the communities and broader cross-cultural experiences, minority researchers are more likely to be able to address issues of distrust and help improve the communication between the scientific and participant community (Evans et al., 2001; Betancourt et al., 2003).

Improving the racial and ethnic diversity of researchers may be able to help address the underrepresentation of minorities in clinical research (Cohen, Gabriel, Terrel, 2002). In their study of increasing the participation of minorities in cancer-related clinical trials, Stark et al. (2002) found that having health care providers and researchers who "looked like them" was an important factor in an individual’s willingness to participate in a clinical trial (p. 34). Specific to the barriers of African Americans and HIV/AIDS clinical trials, increase in the representation of racial and ethnic minorities on research teams can help address distrust, access, and misinformation. Racial concordance between researchers and participants can help promote a greater understanding of the social, economic, and structural factors that influence participants, which in turn can help foster trust and communication (Spevick, 2003). Mouton et al. (1997) suggest that increasing minority
researchers in research role can help address issues of mistrust. Because minority researchers are more likely to serve in minority communities, increasing their representation on research teams may be able to increase minority access to research opportunities (Evans et. al, 2001).

However, it is important to note that while, important, racial and ethnic concordance between researcher and participant is only one component of the complex and nuanced relationship between researcher and participation; discordances in gender, age, class, and education level among other factors may also be at play (Freimuth et. al 2001; Fryer et. al, 2015). Researchers need to understand the converging impact of these factors in order to comprehensively understand the researcher-participant relationship. Intersectionality may offer a framework for researchers to begin to recognize and navigate the multiple factors that contribute to the researcher-participant relationship. Improving the diversity of research teams can help develop some concordance in the sociostructural context between researchers and participants, which in turn, may help researchers address this larger context in which participants exist.

In summary, the recommendations of broadening the training of researchers, involving the community in the research process, and diversifying clinical trials research teams, while not exhaustive, can provide researchers with the knowledge and skills to navigate sociostructural context that underpin the barriers and facilitators of HIV/AIDS clinical trials participation among African Americans.

Limitations

This research paper was limited to peer-reviewed literature and inherently excluded gray literature, meaning that it may not encompass the full and complete perspective of African American’s participation in HIV/AIDS clinical trials. Additionally, this research paper was limited to studies conducted in the United States and papers published in English, which does not cover all of the literature related to African Americans and HIV/AIDS clinical trial participation.
Despite these limitations, this paper presented both a critique of and theorized on an opportunity to improve the clinical trials research approach that was based on the factors that affect African Americans’ participation in HIV/AIDS clinical trials. However, given the persistence of the underrepresentation of other minorities in other types of clinical research, the critique and recommendations perhaps extend beyond this specific subset of individuals; researchers should consider the sociostructural context in which the individuals they aim to recruit for research are located when designing and implementing research projects across the board.

**Conclusion and Implications**

This paper demonstrated the need to integrate sociostructural context into the recruitment methodology of the clinical trials research approach by providing a case study of the participation of African Americans in HIV/AIDS clinical trials as a basis to both critique and offer recommendations to improve the clinical trials research approach. The findings of this paper also have practical implications. Locating individuals and their decision to participate within a larger sociocultural context is essential to comprehensively addressing the multidimensional factors that affect participation in clinical trials. This paper offers recommendations on how researchers can begin moving towards a more contextualized approach when recruiting African Americans into HIV/AIDS clinical trials.

There are many opportunities for future research. Empirical research is needed to examine the theory proposed in this paper of situating people in their sociostructural context to improve the diversity of clinical trials participation. Additionally, future research can examine the within group differences in factors affecting participation among African Americans across different identities (gender, class, etc.). Finally, further research analyzing the factors that affect other minority groups in clinical trials is needed to examine the generalizability of findings.
Participation in clinical trials is a function of both individual autonomy and larger sociostructural forces; an individual and their decision to participate in clinical trials do not exist in a vacuum, but rather are embedded in a sociostructural context that constrains or facilitates their ability to participate in clinical trials. The clinical trials research approach has historically tended to decontextualize an individual from the larger sociostructural context in which they exist; yet, as evidenced by the multidimensional factors that affect African Americans’ participation in HIV/AIDS clinical trials, an individual’s decision to participate is often a product of social structures. Thus, to fundamentally address the disparity in HIV/AIDS clinical trials participation, the clinical trials research approach needs to embed African Americans in the larger framework of the social, economic, historical, cultural, and political structures that co-shape their decisions to participate.
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