

**The Effect of Racial Discrimination on the Underrepresentation of Minority Groups in  
Clinical Trials**

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On my honor as a University Student, I have neither given nor received  
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### **Importance of Diversity in Clinical Trials**

Underrepresentation of minorities in clinical trials is a challenge that is currently a huge problem in the field of medicine and biomedical sciences. Studies have shown that various groups respond very differently to the same treatment and sometimes result in worse outcomes for minority patients (Burroughs et al., 2002). Albuterol, the most commonly prescribed asthma medication, is a drug that relaxes muscles in the airway which increases airflow to the lungs, allowing children suffering from an asthma attack to breathe again. Taking albuterol has helped millions of children suffering asthma. However, a study showed that 47% of African American children and 67% of Puerto Rican children with moderate to severe asthma do not respond to the drug (Naqvi et al., 2007). Another study showed that although minority groups make up 40% of the population, they only consist of 6% of clinical trial participants (EDT, 2015). Increasing racial and ethnic diversity in clinical trials is extremely important for screening the effectiveness of drugs since different racial groups often respond differently to drugs and treatments (Bustamante et al., 2011). The following STS research project focuses on understanding how social factors such as racial discrimination lead to the underrepresentation of minorities in clinical trials. The underlying causes behind the underrepresentation of minorities in clinical trials are explored using the social construction of technology (SCOT) framework to evaluate how racial discrimination and mistreatment of minority groups in the field of medicine throughout history have influenced the general mistrust of medical research institutions among minority groups. In addition, actor network theory (ANT) is used to assess the different factors that are currently influencing the underrepresentation of minorities in clinical trials.

## **Analysis of Underrepresentation in Clinical Trials using SCOT and ANT Theories**

The research question asks, what factors lead to the under enrollment and thus underrepresentation of minority groups in clinical trials? In order to answer this question, documentary research methods are used to conduct the analysis for this research project. Journal articles that discuss historical events of medical research misconduct towards African Americans are used to understand the effect of such studies on the perception that minorities have towards research institutions. Additionally, research studies that interview minority groups across different ages, socioeconomic class, location, etc. are used to provide evidence of the mistrust among minority groups toward research institutions and investigators and to reveal the different barriers preventing minorities from participating in clinical trials. The journal articles are found by searching through databases such as PubMed and Web of Science, and journals, such as the American Journal of Clinical Research, the American Journal of Public Health, and the Journal of General Internal Medicine. The goal of the literature review is to identify the barriers to the low participation of minorities in clinical trials and provide evidence for how these barriers play a role in their underrepresentation in clinical research. In addition, historical case studies are used to evaluate how previous cases of mistreatment and victimization of minority groups in clinical research shaped their perceptions on medical research institutions and how these cases have influenced the way these institutions recruit and treat minorities. Network analysis is used to identify and connect different actors involved in the underrepresentation of minorities in clinical trials. Each barrier and its effect on the instability of the medical research institution due to racial disparities is evaluated separately.

## **Challenges in Clinical Trial Enrollment**

Clinical trials are a critical part of the drug development process as it provides researchers and clinicians information on the effectiveness and potential side effects of the medication or treatment plan. Ensuring that the results from clinical trials accurately represents how patients will respond to the treatment is important for making sure that all patients benefit from the drug or treatment plan and for reducing the number of cases where patients experience severe side effects including death (Unger et al., 2016). One of the major challenges in medical research is figuring out a way to address low clinical trial participation among adult patients (Brody, 2015). An insufficient number of participants in a trial may result in the discontinuation of a certain drug or treatment in development that could have the potential to benefit a lot of patients. Additionally, repeated cancellations of clinical trials impede the advancement of medical research by obstructing the ability to use clinical trial results to discover better ways to diagnose, detect, and treat diseases.

Ethnic and racial groups such as African American, Hispanics, or Asian American/Pacific Islanders are even less likely to participate, making them extremely underrepresented in clinical trials (EDT, 2015). Since these ethnic and racial groups are underrepresented in clinical trials, these groups tend to respond worse to treatments than Caucasian patients (Bustamante et al., 2011). A major reason for the low enrollment of minority groups is the general mistrust of medical research institutions which can be traced back to a long history of racial discrimination in the medical research field (George et al., 2014). Minority groups such as African Americans, Native Americans, and Asian Americans have a history of being victimized, abused in unethical clinical trials, and being excluded from trials that aim to identify risk factors for disease (EDT, 2015). The Tuskegee Syphilis study, is a primary example

of how African Americans have been mistreated in medical research and how these past cases influence the mistrust that certain ethnic and racial groups feel towards the medical research institution (Harris et al., 1996). The study was conducted in Macon County, Alabama with the purpose of understanding the natural course of syphilis in a group of untreated African American men. The effects of the study are still relevant today and the racial implications of the study are also studied among researchers interested in understanding how racial discrimination affects the relationship minorities have with the medical research institution. Mistrust towards physicians is common among African Americans. Since patient-physician relationships are important for improving the enrollment of patients in clinical trials, understanding how patient-physician relationships differ in certain racial and ethnic groups is useful for developing solutions to improve those relationships and increase clinical trial enrollment rates (George et al., 2014; Russo et al., 2019; Swanson & Ward, 1995)

Other factors, such as socioeconomic status, availability of clinical trials, and knowledge gaps with regard to clinical trials have also been shown to influence the underrepresentation of certain ethnic and racial groups. It has been shown that the barriers to enrolling certain ethnic and racial groups in clinical trials span across several institutional levels and are categorized into three main levels: the systems level, the individual level, and the interpersonal level (Hamel et al., 2016). Systems level barriers include availability of clinical trials and strict eligibility criteria. Individual level barriers include awareness of clinical trials, and the race, religion, and ethnicity of patients. Interpersonal level barriers include patient-physician relationships and perceptions of medical institutions (Hamel et al., 2016). The complex interactions between these barriers and factors makes it difficult to come up with effective solutions that address the problem of low enrollment and underrepresentation of certain minority groups in clinical trials.

However, understanding how these barriers and factors interact with each other can be useful for designing more effective solutions to increase enrollment of minority groups.

### **Social Construction of Technology and Actor Network Theory**

Underrepresentation of minority groups in clinical trials is a major issue surrounding the field of medical research. Racial discrimination is embedded into the current healthcare system in many different ways. Understanding how racial discrimination affects individual patients on the interpersonal level is important for understanding how social constructs of clinical trials and the medical field developed among certain racial groups. The social construction of technology (SCOT) framework is applicable when studying how society shapes technological development (Klein & Kleinman, 2002). The original idea for SCOT was first conceived by two STS researchers, Trevor Pinch and Weibe Bijker, and has been used by many science and technology (STS) scholars since then. Using SCOT as a framework for STS analysis is useful for many different cases, including the evaluation of how perceptions of clinical trials and medical research developed throughout history. Mistrust in the medical field stems from historical cases, such as the Tuskegee Syphilis Study, and some authors suggest that the mistrust in medicine started with slavery (Corbie-Smith et al., 2002). The mistrust in medicine and clinical research is a major reason for the challenges in convincing and recruiting racial groups such as African Americans for clinical trials.

One of the components of SCOT addresses and identifies relevant social groups, which can be useful for evaluating the differing perceptions of medical institutions among the minority groups that are commonly underrepresented in clinical trials. The initial framework proposed by Pinch and Bijker states that all members of these social groups have the same perception of the technological artifact. A major critique of this component is that it treats all groups as equals and

lacks distribution of power among social groups (Klein & Kleinman, 2002). Although, not all perceptions among individuals associated with a particular social group are the same, it is still beneficial to look at the general population to identify major factors that influence participation of social groups in clinical trials. There are other limitations of SCOT, which are outlined by Langdon Winner (*Upon Opening the Black Box and Finding It Empty: Social Constructivism and the Philosophy of Technology—Langdon Winner, 1993, n.d.*). He states that SCOT explains how technologies arise but does not address the long-term consequences of the technologies after they are created. He also states that SCOT only focuses on the immediate needs and problems of the social groups of interest but disregards deep cultural or economic origins of the creation of socially constructed technologies. To address the limitations, ANT will be used as another framework to assess the consequences of racial discrimination and other factors that are involved in the underrepresentation of minorities.

Low enrollment of minority groups in clinical trials is due to a number of different barriers including socioeconomic status, knowledge of clinical trials, and patient-physician relationships. The complex interactions between various barriers make it difficult to identify the specific role of individual actors on the underrepresentation of minorities in clinical trials and to come up with solutions that will increase participation of minorities. Actor network theory is a useful STS framework to use for this study because it addresses how different barriers are involved in the underrepresentation of minorities in clinical trials and how the interactions between these different barriers causes instability in the network. The actor network theory analysis is useful for investigating on how these different factors influence the decisions of certain racial groups to enroll in clinical trials (Callon, 2001). Some scholars do have concerns with ANT, stating that ANT assigns non-human properties equal importance in the development

and organization of a network even though those properties are fundamentally different from human actors (*Criticism of Actor-Network Theory*, n.d.). Despite the limitations with ANT, it still provides a good framework for analyzing the organization and complexity of actor networks such as the roles of various barriers in the underrepresentation of minorities in clinical trials.

### **Development of Mistrust in the Medical Research Institution among African Americans**

Despite creating policies that require participation of underrepresented groups in clinical trials, there is still a lack of enrollment among minority groups in clinical trials. Minority groups such as African Americans have been underrepresented in clinical studies for cancer, HIV/AIDS, cardiovascular disease, Alzheimer's disease, and many other diseases (Hamel et al., 2016; Scharff et al., 2010). Although there are many factors for the lack participation of minorities in clinical trials, mistrust of academic and medical research institutions, clinicians, and investigators stands out as the primary barrier to the lack of enrollment of African Americans in clinical trials. The mistrust that African Americans have towards research institutions developed from historical roots and is further intensified by other factors such as discrimination in the health care system, socioeconomic statuses, lack of education and informational resources (Scharff et al., 2010). How the perceptions of medical research institutions among African Americans developed over time and can be evaluated using the social construction of technology (SCOT) framework. Since the mistrust of medical research institutions among African American is primarily due to social factors, SCOT is an ideal framework to use for evaluating how the mistrust of medical research ultimately developed among the African American populations. ANT is used to assess the various factors involved in the underrepresentation of minority groups and how it adds systemic complexity and instability leading to the underrepresentation of minority groups in clinical trials.



Historically, African Americans have been subjected to numerous accounts of unethical medical experimentation and mistreatment. The most notable and widely cited reason for the mistrust of the medical research institution among African Americans is the Tuskegee Syphilis Study (Brandon et al., 2005). The Tuskegee study was conducted by United States Public Health Services and lasted for over 40 years between 1932 and 1972. African American men who had syphilis and men who did not have syphilis were recruited for the study. The study was advertised as a way for African Americans to get special treatment for bad blood. However, the true purpose of the study was so investigators and scientists could see the long term effect of syphilis in the participants. They did so by keeping participants diagnosed with syphilis, untreated for the entire duration of the study. In addition, the participants were also told that the study would last for only 6 months, but the study ended up lasting 40 years (Brandon et al., 2005). The true purposes of the study and the way the researchers were conducting the study were eventually revealed to the public, destroying trust of medical research institutions among African Americans.

Although, there have been many regulations implemented since the Tuskegee study to protect subjects in clinical trials against unethical behavior and mistreatment, the impact of the Tuskegee study still affects African American perceptions of the medical research institution. Any knowledge of the Tuskegee Syphilis study increases the skepticism and mistrust African Americans have towards the medical research institution to this day. A study showed that two-fifths of African Americans who were interviewed knew about the Tuskegee study and 87.1% of those who knew about the study believed that a similar study could happen again. This was contrasted with only 37.8% of white people who knew of the Tuskegee study believed that a similar study could happen again (Brandon et al., 2005).

The Tuskegee study serves as a primary example and symbol for racial mistreatment and research misconduct on African Americans. However, the negative perceptions and mistrust among African Americans for the medical research institution have long predated the Tuskegee Study (Gamble, 1997). Therefore, it is important to look at how the mistrust and perceptions of medical research institutions developed in a broader historical and social context. Racial discrimination of African Americans is rooted in American history and continues to affect the perceptions African Americans have towards the medical research institution. It also serves as the basis of how race developed as a construct within the medical field. An early example of abuse was an experiment lead by Dr. Marion Sims who performed gynecology studies on African American slaves (Studies et al., 1999). Three women were subjected to 30 operations that were described by Sims himself as being extremely painful and gruesome. Mistreatment of African Americans continued even after emancipation of slavery. Medical research institutions have dug graves in order to use African American bodies for dissections and they would also give the poorest care to African American patients (Gamble, 1997). In addition, there have been accounts of African Americans being skeptical and also fearful of being exploited by medical research institutions. These fears are still evident in the African American community today, despite socioeconomic status or educational background (Gamble 1997). These historical events and studies where African Americans were oppressed by medical researchers have influenced the development of social constructs of race within the medical research institution. A study that laid out the development of mistrust among African Americans towards medical research institutions reveal that African Americans are not likely to enroll in clinical trials because they do not want to feel like “guinea pigs” (Gamble, 1997).

Racial discrimination is evident in many current studies and can explain different reasons for how certain barriers against the participation of African Americans in clinical trials came to be and how racial constructs can influence the perception of the medical research institution among African Americans. For example, one study showed that African American patients are less likely to be recommended for and receive coronary bypass graft than white patients, even after correcting for income and socioeconomic status (LaVeist et al., 2016). The poor quality and differential treatment of African American patients further exacerbates mistrust among African Americans towards the medical research institution. Another study also points out differences in treatment between African American patients and white patients who suffer from cardiac disease (LaVeist et al., 2016). The study looked at patient satisfaction with regards to several predisposing factors that include gender, age, medical mistrust, and perception of racism. The authors reported that African American patients were more likely to report lower satisfaction in patient care, perceived racism, and medical mistrust than white patients. Perceived racism and medical mistrust lead to lower satisfaction of patient care and after controlling for these factors, there was no association between race and patient satisfaction, demonstrating that perceived racism and medical mistrust play a major role in patient satisfaction.

In addition, African Americans are very underrepresented among clinicians and medical researchers making it difficult for researchers to assess cultural differences and relate to the patients they are trying to study. For example, in one study, an African American male volunteer revealed that he dropped out of the study because the clinicians and researchers he was working with did not understand his razor cutting technique as it is primarily used by African Americans (Scharff et al., 2010). Lack of culturally appropriate information can also influence awareness of clinical trial studies and mistrust of physicians and researchers. Inadequate information has been

reported as factor that can lead African Americans to not be able to trust clinical trials and physicians (Scharff et al., 2010). Among 18 studies that focused on understanding how clinical trial awareness acts as a barrier to cancer clinical trial enrollment among minorities, lack of education and educational resources was the most frequently reported barrier to clinical trial enrollment (Ford et al., 2008). Other studies have reported that African American patients do not see how these trials benefit them and tend to think that their participation in clinical trials only benefits the white patient population, leading them to feel used (Ford et al., 2008; Scharff et al., 2010).

Differences in patient-physician relationships among racial groups is another factor that has been shown to influence the lack of enrollment of minority groups in clinical trials (Fisher & Kalbaugh, 2011). Another study used video analysis to assess interactions of oncologists with African American versus white patients (Eggly et al., 2015). They reported that African Americans talked to oncologists for significantly less time than white patients and they also reported that African Americans asked less questions about studies. The reduced time that African Americans spend with their oncologists means that they are not receiving the same amount of information about their health and also clinical trials. Thus, exacerbating the unstable relationship African Americans have with physicians and medical researchers.

Lack of clinical trial awareness may also be influenced by socioeconomic status. Patients who are from a lower socioeconomic class are less likely to participate in clinical trials due to a number of factors. One of the major factors is that patients from lower socioeconomic classes tend to live further away from large medical institutions (Ambroggi et al., 2015). This means that they are less likely to have access to specialty clinics and quality of care (Hamel et al., 2016). Since African Americans are more likely to come from lower socioeconomic backgrounds they

are more likely to experience difficulties to access healthcare services and a receive a lower quality of care (Anderson et al., 2004; *Ethnic and Racial Minorities & Socioeconomic Status*, n.d.). However, many studies have shown that general mistrust and perceived patient-physician relationships are similar among African Americans despite prior experience and socioeconomic status (Scharff et al., 2010).

In addition to individual and interpersonal barriers, there are also systems-level barriers that influence lower enrollment of minorities in clinical trials. These barriers include availability of clinical trials, amount of supporting infrastructure in place to sustain clinical trials, and strict eligibility criteria. These barriers in addition to the individual level barriers such as awareness of clinical trials and previous experience with clinical trials and interpersonal level barriers such as the perception of medical research institutions, are all related in a complex manner. The relationships between these barriers constitute a complex actor network revolving around the underrepresentation of minorities in clinical trials (Hamel et al., 2016). The human and social interactions involved in the underrepresentation of minorities in clinical trials are largely due to the development of racial constructs in healthcare and these relationships are further strained by other barriers affecting the participation of African Americans in clinical trials. The combination of social constructs of race explained by SCOT, and the barriers and actors involved in the underrepresentation of African Americans makes the entire actor network very unstable. The instability of the actor network by the various actors and barriers explains why it is has been so hard to address the problem of racial discrimination in the healthcare system and how it leads to the underrepresentation of African Americans in clinical trials.

## **Limitations and Addressing Underrepresentation of Minorities in Clinical Trials**

This study has several limitations. It primarily focuses on African Americans and their perceptions of the medical research institution. Other minority groups such as Hispanics, Native Americans, and Asian groups are also strongly underrepresented in clinical trials (Hussain-Gambles et al., 2004). It is not clear whether or not the social construct of clinical trials developed the same way in these minority groups as compared to African Americans. Therefore, the results of this study cannot be directly translated to other minority groups. An interesting analysis for the future could be looking at whether or not the same pattern of mistrust and factors causing underrepresentation of African Americans exists for other minority groups. Another limitation of the study is that it focuses on minority groups based on race. Other groups that are underrepresented in clinical trials include women and older patients. Future analysis would include factors such as gender or age discrimination and how they impact the lack of enrollment of women and older patients in clinical trials.

Identifying the factors and barriers that increase the difficulty of recruiting underrepresented groups in clinical trials is the first step to creating effective solutions for the problem. The current study focuses primarily on how mistrust of medical research institutions lead to the underrepresentation of minorities in clinical trials and how the mistrust developed throughout history. In order to develop and improve solutions to address the problem, a further analysis of the success and failures of current intervention strategies to recruit patients from these minority groups is needed.

The underrepresentation of African Americans in clinical trials is a result of multiple historical and social factors. The primary factor contributing to the lack of willingness of African Americans to participate in clinical trials is mistrust of medical research institutions. Changing

perceptions about the medical research institution is challenging since the mistrust has deep roots which results from a history of oppression and racial discrimination felt by African Americans. Analyzing how race developed as a social construct throughout history is important for understanding the way African American patients feel about medical research institutions and how to improve recruitment strategies to overcome these negative perceptions. Clinical trials are an extremely important step in the development of drugs and treatments. Results from clinical trials inform researchers on how to improve the diagnosis, detection, and prevention of diseases. Therefore, it is extremely important for minorities to participate to ensure that results from these trials accurately reflect the patient population. There is no way to change the past but moving forward research institutions should address disparities in racial groups among their staff and their patients so that intervention strategies to improve recruitment of minorities can be developed and improved.

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