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The underrepresentation of African Americans in clinical trials

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ABSTRACT

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This thesis examined the representation of African Americans in the clinical trials of antihypertensive and antiviral drugs. Race can be an important variable in clinical drug trials. Studies have shown that racial differences in drug response and metabolism are important determinants in the design of therapeutic regimens. Research has also indicated that African Americans are underrepresented in clinical trials.

Thirteen antihypertensive and antiviral drugs that were researched by eight pharmacology companies were analyzed over a ten-year period. Research revealed that in the majority of the studies providing racial data, the proportion of African American subjects was less than their proportion in the national population. It was also found that recruitment efforts and subjects' reactions may be a factor in their representation. This research and racial data have revealed that there is an underrepresentation of African Americans in clinical trials of antihypertensive and antiviral drugs.

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Introduction

Freedom from disease is a universal cultural value that has existed throughout history. The United States has attained a high level of medical technology. Yet, the benefits of this technology have not been shared equally by all of its citizens, particularly African Americans. Historically, in comparison to other groups, African Americans have shared unequally in the availability of health care. For example, it was not until 1964, following the passage of the Civil Rights Act, that African Americans were allowed to receive medical care in most hospitals (private or public) on a non-segregated basis. Throughout most of the history in the United States, it was common for some African Americans to be denied medical care, frequently resulting in preventable deaths.

In 1984, the Secretary's Task Force on Black and Minority Health in the Department of Health and Human Services (HHS) was formed to examine the ethnic disparity in the health status of its citizens. In 1985, the task force found six health problem areas that cause more than 80 % of excess deaths (those that would not have occurred had mortality rates for non-Whites been as low as for Whites). The areas were cardiovascular disease and stroke; diabetes; cancer; infant mortality; chemical dependency; and suicide, homicide, and unintentional injuries. Acquired Immune Deficiency Syndrome (AIDS) was later added because non-Whites represented over 40 % of the AIDS cases in the United States.

In January 1990, Congress passed the Disadvantaged Minority Health Improvement Act of 1990. At that time, Congress found that the health status of African Americans was significantly lower than the health status of the general population and

that they suffered disproportionately higher rates of stroke, AIDS, cancer, heart disease, substance abuse, diabetes, and other diseases and disorders. Congress also found that the infant mortality rate for African Americans was twice as high than for the general population.[1]

Several studies have been conducted on preventable deaths (those preventable through medical intervention) among the African American population. One study that gained national attention found that due to "excess mortality" in Harlem in the late 1970's and early 1980's, African American men were less likely to reach the age of 65 than men living in Bangladesh, one of the poorest countries in the world.[2] Furthermore, the death rate from all causes in Harlem was more than double that for Whites in the United States. The overall cause of discrepancy was a lack of basic health care and widespread poverty.

In a nationwide study of 8,806 adults, African Americans had higher rates of mortality than Whites, varying from 149 % for those individuals between 35 and 44 years old to 97 % for persons between 45 and 55 years old.[3] While controlling for risk factors such as smoking, diabetes, alcohol intake, and cholesterol level, it was found that low income accounts for at least 54 % of the excess mortality of African Americans.

In 1990, the council on Ethical and Judicial Affairs of the American Medical Association issued a report on disparities in health care between African Americans and Whites.[4] The report noted that African American men under 45 years of age had 10 times the likelihood of dying from hypertension and a 45 % higher rate of lung cancer than White men in the same age category. Although African Americans have greater health care needs, they are less likely than Whites to be recipients of health care services.

Even when differences in severity of disease and income were considered, surgery was recommended for Whites more often than for African Americans. African Americans patients with kidney disease were less likely than Whites to receive long term dialysis or kidney transplants. African American patients who received dialysis were less likely than White dialysis patients to receive kidney transplants. The report suggested that these disparities were due to inconsistent decisions enacted in the medical care system with regards to race.

Racial disparities have been known to exist in treatment decisions in internal medicine. In a study conducted of patients hospitalized for pneumonia, African Americans, regardless of income, were less likely than Whites to receive medical services, especially intensive care.[5] A study of hospital admissions from the emergency department found that African Americans were more likely to be classified as ward patients and Whites as private patients, even when the ability to pay was comparable. African American ward patients were less likely to be admitted to the hospital than White private patients, even when clinical characteristics were similar.[6]

Variations in metabolism and drug response are important determinants in the design of therapeutic regimens. Factors such as diet, age, underlying disease, and drugs can have a strong influence on drug response. Another less understood variable is race. Earlier studies were conducted involving the examination of racial differences in drug response.[7-9] These studies found that differences may be related to variations in the rate of pharmacological response, drug metabolism or mechanisms of the disease (i.e., pathophysiological differences in hypertensive African Americans and Whites).

A preliminary report noted that the antihypertensive effects of the serotonin receptor antagonist ketanserin may differ between African Americans and Whites.[10] Research has shown that African American hypertensive patients do not respond as well to the antihypertensive effects of beta-blockers as do White hypertensive patients.[11] These studies underscore the significance of race as a variable in research data.

The purpose of this study was to examine the representation of African Americans in the clinical trials of antiviral and antihypertensive drugs and analyze some of the reasons that may influence their participation rate. These particular types of drugs were chosen because AIDS and hypertension are two major debilitating health problems affecting the African American community. This study is important because clinical trials can provide important research data for the rationale use of new drugs. If a group of the population is underrepresented or excluded from these trials, essential information on the proper use of drugs for that particular group will not be available. Therefore, it is vital that African Americans be adequately represented in clinical trials to ensure that sufficient data exist to accurately assess the efficacy and safety of new drugs when prescribed for them.

Method

To examine the representation of African Americans in clinical trials, all published studies that were listed in the journal of *Clinical Pharmacology and Therapeutics* involving antiviral and antihypertensive agents were reviewed within a ten-year period (1990-2000). Only those studies conducted within the United States were examined. This journal was chosen because it is an authoritative source of one of the major clinical pharmacology organizations in the United States. Statistical analysis was done via measurement of the mean scores and percentages of each group. The percentage of African Americans in each clinical trial was compared to the percentage of African Americans in the city where the trial was conducted. The frequency of the racial composition of the study population was measured as well. The racial composition of the area was estimated utilizing year 2000 census data.

Results

Thirteen studies examining antihypertensive and antiviral drugs were analyzed. The percentage of African Americans in the studies ranged from 15% to 57% (Table 1, p.7). Angiotensin II, sodium nitroprusside, and delavirdine were the only drugs that provided racial data about their subjects. Almotriptan, delavirdine, angiotensin II, and sodium nitroprusside included African American participants in their studies. Angiotensin II, sodium nitroprusside, and almotriptan exhibited a slightly lower percentage of African Americans in the study population than was present in the city where the drug trial was conducted. Angiotensin II and sodium nitroprusside exhibited the highest percentage of African Americans in their studies. Delavirdine exhibited a greater percentage of African Americans than was present in the population at the study site.

In the past, African American participation in clinical trials in the United States have been low.[12] Clinical trials noting the racial differences in drug metabolism between African Americans and Whites have been documented.[13-14] Only one study utilizing angiotensin II and sodium nitroprusside made an attempt to determine if there was a difference in response between African Americans and Whites. The frequency with which researchers noted the racial composition of the study population was higher in the antihypertensive drugs studied, angiotensin II, sodium nitroprusside, and almotriptan, (60%) than with the antiviral drug, delavirdine (13%).

Table 1. Racial Distribution of Participants in Clinical Trials

Drug Name	Drug Class	Object of Study	Number of African Americans of Total Participants and (%) of African Americans in Study	Volume: Page*	% of African Americans in Population @ Study Site[b]
Angiotensin II	Antihypertensive	Efficacy	16/28 (57.1)	65:408	60.0
Sodium Nitroprusside	Antihypertensive	Efficacy	16/28 (57.1)	65:408	60.0
Nicardipine	Antihypertensive	Efficacy	0/22 (0)[a]	60:461	25.3 & 60.0[c]
Ramipril	Antihypertensive	Efficacy	0/15 (0)[a]	65:420	8.8
Almotriptan	Antihypertensive	Efficacy	3/20 (15)	71:169	20.6
Ritonavir	Antiviral	Kinetics	0/58 (0)[a]	63:453	6.9
Saquinavir	Antiviral	Kinetics	0/58 (0)[a]	63:453	6.9
Interleukin-2	Antiviral	Kinetics	0/68 (0)[a]	64:492	2.76, 6.4, & 13.0[d]
Zidovudine	Antiviral	Kinetics	0/11 (0)[a]	48:161	64.3
2',3'-dideoxyinosine	Antiviral	Kinetics	0/25 (0)[a]	50:278	2.7
Ribavirin	Antiviral	Kinetics	0/7 (0)[a]	50:442	67.3
Oligodeoxynucleotide phosphorothiate	Antiviral	Kinetics	0/6 (0)[a]	58:44	73.5 & 2.7[c]
Delavirdine	Antiviral	Kinetics	3/12 (25)	61:531	11.6 & 9.7[c]

*The volume and page number refer to the study of the drug which can be found in Clinical Pharmacology and Therapeutics.

[a]Number of African Americans in study not reported.

[b]Data was obtained from U.S. Bureau of the Census, Profile of General Demographic Characteristics: 2000, Washington, D.C., 2000.

[c]Study was conducted at two sites.

[d]Study was conducted at three sites.

Source: Clinical Pharmacology and Therapeutics, 1990-2002.

Discussion

Acquired Immune Deficiency Syndrome

Acquired immune deficiency syndrome (AIDS) is a disease caused by the human immunodeficiency virus (HIV) which is transmitted via semen, vaginal secretions, and the blood of infected persons. AIDS weakens the victim's immune system, thus enabling it to be susceptible to opportunistic infections that do not normally attack a healthy body.

Some opportunistic infections resulting from HIV are Pneumocystis carinii pneumonia, the most prevalent infection in AIDS victims; mycobacterium avium complex, a gastrointestinal tract infection; cytomegalovirus, which can cause colon and brain infections and blindness; cryptococcal meningitis, which affects both lungs and brain; and Kaposi's sarcoma, a form of cancer.[15]

The incubation period (the time between initial transmission and the development of disease symptoms) for AIDS is from 3 to 10 years or more.[16] When the symptoms develop, the victim has acquired full-blown AIDS which eventually leads to death. The disease has become a public health problem of major proportions in the United States.

Hypertension

In the United States, hypertension is one of the major causes of death in African Americans.[17] African Americans suffer excess mortality from hypertension in comparison to whites. The primary cause of stroke in African Americans is hypertension. Research has estimated that the rate of mortality from strokes among African Americans is approximately 66 % higher than among Whites.

It is estimated that sixty million people with hypertension live in the United States. Approximately 28 % are African American.[18] This is disproportionately higher than their percentage in the population. Hypertension in African Americans tends to appear at an earlier age than in Whites and usually is not treated either early or aggressively enough. Consequently, this may lead to a higher prevalence of more severe hypertension among African American patients. Hypertension in African Americans is often accompanied by target organ damage. Furthermore, effective treatment of hypertension in African Americans is hampered by limited medical care, expensive treatment costs, and lack of knowledge about the disease.

Physiological and hormonal differences may be associated with the racial disparity in prevalence of hypertension. A study found that in children between the ages of five and thirteen (63 %White), the renin levels were higher in Whites and lower in African Americans.[19] The low renin levels could be the result of primary volume expansion due to other intrarenal factors promoting water and sodium retention or prohibiting sodium excretion. These factors could lead to differences in response to drug treatment.

A significant purpose of clinical pharmacology research is the establishment of factors that could result in substantial differences in drug response.[20] An understanding of such factors is important in rendering clinical decisions regarding drug choice and dosage. Studies have shown that certain racial groups within the population display different responses to certain drugs in comparison to the "average" population.[21-22] Observations from these studies demonstrate that race can be an important variable in

drug response. However, some clinical researchers may view it as an insignificant variable. This lack of consideration for the variability of race in drug response may contribute to an underrepresentation of African Americans in clinical trials.

Hall conducted a study to examine the representation of African Americans, women, and the very elderly (aged 80 or more years) as participants in 28 past or ongoing randomized clinical trials.[23] The study found that most of the completed clinical trials exhibited an underrepresentation of African American participants (0% to 8%). Four of the 5 trials reported a small percentage of African Americans (4.6%). The study concluded by noting that African Americans, women, and the very elderly were underrepresented in many past randomized clinical trials and that the rate of accrual for African Americans was low.

McCaskill-Stevens et al. examined the African American accrual rate in clinical trials.[24] The study conducted 15 workshops utilizing discussions and open-ended, self-administered questionnaires. Seventy-percent of the National Medical Association (NMA) members, a group of approximately 22,000 African American physicians, cited fear of losing patients, mistrust of the research centers, and a lack of respect from the Eastern Cooperative Oncology Group (ECOG) institutions as the main barriers to referring African Americans onto cancer clinical trials. Sixty-nine percent of NMA and 43% of ECOG physicians noted a lack of information about trials. Nearly half of the NMA physicians (47%) reported a lack of minority researchers as a barrier compared to 4% of ECOG physicians. The study concluded that if adequate representation is to

occur, an equitable partnership must be formed with the NMA to enhance African American representation.

Svensson conducted a study to examine the representation of African Americans in the clinical trials of new drugs.[25] Fifty clinical trials were conducted over a three-year period. The study found that only 35 trials provided full racial data. Fifty-seven percent included African American participants. Twenty-three of the 35 trials exhibited a lower percentage of African Americans in the study population than was present in the city where the study was conducted. Twenty studies exhibited a lower percentage of African Americans than the average percent of African Americans in the United States. The racial composition of the study population was higher in the trials involving antihypertensive agents (47%) in comparison to the remaining studies (9%). The study concluded that the data seem to suggest that African Americans are underrepresented in clinical trials of new drugs.

Some studies have suggested that the underrepresentation of African Americans in clinical trials may be attributed to their participation rate.[26-28] This could be due to their reactions and beliefs of clinical trials as well as recruitment efforts. Some African Americans may feel apprehensive and distrustful of the medical establishment . Therefore, they may be unwilling to participate in clinical trials of new drugs.

A study was conducted by Sengupta to examine the willingness of African Americans to participate in AIDS clinical trials.[29] The study revealed that although African Americans comprised almost 12.3 % of the United States population, participation in both therapeutic and preventive research trials was lower than the

national prevalence rate (47%) for African Americans diagnosed with AIDS. Their underrepresentation was attributed to their distrust of the medical establishment which could affect their willingness to engage in clinical trials.

Millon-Underwood, Sanders, and Davis conducted a study to analyze the factors affecting the willingness of African Americans to participate in clinical trials.[30] A regional survey of 220 African American men and women was assessed. Qualitative data were analyzed via percent, frequency, and chi-square. The study found that beliefs and perceptions have an impact on African Americans willingness to participate in clinical trials.

There is a widespread belief among African Americans that the HIV was invented in a laboratory by racist conspirators. A growing number of African Americans believe that some of the problems affecting their community can be attributed to racist government conspiracies. In 1990, a New York Times/CBS-TV News poll revealed that such conspiracies are prevalent among African Americans.[31] When polled with the question whether the virus that causes AIDS was deliberately created to infect African Americans, 10 % of African Americans responded that it was true and another 19 percent responded that it could possibly be true.[32] Altogether, 29 % did not reject the theory. For Whites, 5 % accepted the theory. African Americans distrust of the government seems to stem from the notorious 1932 Tuskegee Experiment. The experiment was perpetuated by the United States Public Health Service who gathered up hundreds of poor African American sharecroppers who were suffering from syphilis for an experiment in Tuskegee, Alabama. For 40 years, the truth of their disease was withheld from them

while physicians observed the destructiveness of the disease, ranging from blindness to paralysis, dementia, and death.[33]

Even after penicillin was introduced as an effective treatment for syphilis, the men were never told of the medicine or treated. They were utilized as subjects in one of history's most sinister, racist, and inhumane experiments. Therefore, it would seem obvious that some African Americans are suspicious of the Unites States government and the medical establishment that committed this act of racist victimization.

Harris et al. examined the victimization of African Americans in clinical research throughout history.[34] A questionnaire was utilized and data were analyzed via the mean, standard deviation, and percent. A historical review found evidence of past medical experimentation on African Americans that were unethical and often brutal. The study also found that communication issues, lack of awareness about trials, mistrust, and economic factors may act as barriers to participation in clinical trials.

Corbie-Smith et al. conducted a study to examine the attitudes of African American patients that may act as barriers toward participation in medical research.[35] The study utilized focus groups and analyzed the data via grounded theory. The study found that the patients reported distrust of the medical community as a major barrier toward participation in research. The study noted that understanding the importance of interpersonal trust may prove to be a significant factor in enhancing the participation of African Americans in medical research.

Stone et al. examined the participation rate among racial ethnicities (not including Whites), women, and drug users in medical research.[36] A cross-sectional survey of 260

HIV patients was utilized. The study found that 22.3% of patients had been noted as having participated in a clinical trial. Racial ethnicities and women reported less knowledge of clinical trials and were less likely to have been informed about those of which they were eligible. Racial ethnicities were half as likely as Whites to note ineligibility as their primary reason for non-participation (10.4% vs. 40.5%). The study concluded by noting that when AIDS clinical trials are available on-site, racial ethnicities, women, and drug users are less likely to participate.

There has been some concern about the participation rate of American Americans in clinical trials. Levine believed that they could be overrepresented.[37] He believed that many inner city locations of university hospitals were problematic because they increased the likelihood of a disproportionate use of African Americans as research subjects. Thus, possibly leading to their overrepresentation in clinical trials. This overrepresentation could result in African Americans bearing an unfair burden of the risks involved in clinical trials. A balance should be achieved in the representation of African Americans. The representation needs to be sufficient in order to detect important differences. In other words, there should be proper representation and not exploitation.

Past research has found that African Americans have been underrepresented in clinical trials.[38] The data from this study seems to suggest that although researchers may be noting the racial composition of their study population more often, there still exists an underrepresentation of African Americans in clinical trials of antiviral and antihypertensive drugs.

It should be noted that only a single biomedical research journal was utilized for this study and only two classes of drugs were examined. Therefore, the results may be viewed as preliminary due to the limited sampling size. More research is needed to specifically analyze the influence of race on drug response and prescription drugs. Yet, the reviewed studies and the data underscore the importance of race as a variable when planning, conducting, and analyzing clinical drug trials. The need for proper representation of African Americans is vital to ensure that information on drug response and disposition for new agents is accurate and available. The data from this study can be utilized as a model to provide insight to clinicians and others when prescribing drugs to African Americans patients. This can help to enhance their safety and health benefits.

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