

January 2006

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Recommended Citation

Mokwunye, N. O. (2006). African Americans' Trust and the Medical Research Community. *Journal of Health Ethics*, 3(1). <http://dx.doi.org/10.18785/ojhe.0301.03>

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African Americans' Trust and the Medical Research Community

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Abstract

African Americans have been victims in many of the medical atrocities involving human subject research. It is well established that African Americans are less likely to enroll in research protocols and have more distrust of the medical field than any other ethnic group due to the Tuskegee Syphilis Study. Researchers must be responsible for creating a trustworthy environment. The creation of a cultural competency curriculum designed specifically for training researchers is warranted and will help open the communication barrier between researcher and participant. Trust must be created before the distrust of the medical research community will be resolved. This paper describes successful recruitment strategies that help foster a trusting environment and increase enrollment. Enrollment increase will help lead to understanding disparities and creating solutions.

Keywords:

African-Americans, Distrust, Clinical Research, Medical Community, Trust

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INTRODUCTION

African Americans have been victims in many of the medical atrocities involving human subject research. Experimentations on African Americans have been documented from the early days of slavery to the present day (Byrd & Clayton, 2000). Gamble (1993) notes that African Americans are less likely to enroll in research protocols and have more distrust of the medical field than other ethnic groups. One reason for this distrust, which is reiterated throughout the literature, is the Tuskegee Syphilis Study (Reverby, 2000). What has not been discussed, however, is the true concept of trust and how trust really works. Trust is the basis for a solid relationship and is necessary to understand the mechanisms of gaining, and most importantly, keeping it (Gambette, 1990).

In order to establish trust between the African American and the medical research communities, the author submits that a trustworthy environment has to be created. Within this trustworthy environment, both parties need to be educated on the sensitivities of each party's background and objectives. Further, there is an immediate need for solving the mistrust issue because of the increasing health disparities faced by African Americans as illustrated in the Department of Health and Human Services (DHHS) Healthy People 2010 report[1] (Goal 2). Hence, the author proposes that the creation of a trusting environment begins with the education of both parties on the sensitivity and urgency of this dilemma with the medical research community assuming the responsibility for finding solutions. Corbie-Smith, Thomas, Williams, & Moody-Ayers (1999) have shown that researchers feel the lack of recruitment is due to a lack of high-quality enrollment strategies and the distrust from the fallout of Tuskegee. The author submits that in addition to the aforementioned recruitment barriers, it is imperative that multiple approaches combined with some sort of mandatory cultural competency curriculum for all researchers should become best practice in efforts to have African-Americans more involved in clinical research.

THEORETICAL AND SOCIETAL UNDERPINNINGS OF TRUST

Valuable human relationships and interactions all have a component of trust associated with them. Trust is an important part of the decision making process. People tend to associate themselves with other persons whom they consider trustworthy. This is exemplified in ones choices from spouses and partners to doctors and stock brokers. Often time, decision-making rights are relinquished to another simply based on trust. Phrases like I trust your judgment, or even, I trust you with my life, are used to transfer the power and responsibility from one party to another. By trusting, vulnerability is increased. It is done by placing a level of confidence in someone who will not take advantage of you, exploit, or render a negative repercussion. I contend this is the premise for why African Americans distrust the medical research community.

Societal repercussions for atrocities against African Americans have been limited and, in some instances, this limitedness may persist today (Dula, 1994). The criminal justice system and its unfairness towards African Americans are often cited as evident and confirmatory of this practice (Dula). It stands to reason, from my perspective, that African Americans may not feel sufficiently protected from abusers of trust within a system that many believe to be inherently untrustworthy. The same rule may also apply to the relationship built between a patient and his or her physician or a researcher and his or her subject. I submit that trust must be the foundation of this relationship and that it cannot be established without the comfort of knowing the system will provide protection. History suggests this assurance might not be plausible for African Americans.

The physician-patient relationship is recognized as an important feature in the delivery of good healthcare. This relationship has long been assumed to be a straightforward encounter between an expert in medicine and a person in need of medical care (Chin, 2001). Traditional views on the relationship between physicians and their patients have been of a paternalistic nature. The physician-patient relationship is a classic example of how trusting relationships are formulated. The fear of death can be compared to the fear of repercussion. If a person dies as a result of their doctor's conduct, there are consequences this physician must face. Patients therefore trust in the fact that those consequences are severe enough to deter negative actions by physicians. Today, there are more options for choosing a physician from a particular expertise than in the past. However, these options are not open to everyone; only those who have the luxury of a health insurance provider that offers the option to choose a physician. Insurance providers with these benefits are not generally accessible to socioeconomically disadvantaged populations; thereby, creating the potential for minimal health care involvement by the patient. Benefits like physician interviewing and increased access to specialists may not be offered. According to the U.S. Census Bureau, in 2004, African Americans made up one of the largest portions of this population: 9 million in poverty and 7.4 million uninsured (U.S. Census Bureau, 8/30/05; Table 3 and Table C-1). Trust between a researcher and a subject is somewhat different. With the exception of select clinical trials, research is meant for increasing knowledge and not as therapy; hence, researchers may not be seen as potential curers to subjects. Researchers may thus be perceived as developers of potential future cures.

In general, the population believes that there is some good that comes from medical research (Ohmann, 2004). In the public's view, medical research is valuable for finding cures for illnesses, thereby, giving an otherwise hopeless person some hope of a cure. This belief is called therapeutic misconception (Miller & Brody, 2003). In treatment settings, physicians owe primary allegiance to their patients' wellbeing. Typically, patients can expect that this allegiance translates into personal care designed specifically to treat their own disorder in a manner that is consistent with their own needs. In the research setting, I submit that this allegiance is not specific to the participant, but more to the scientific value of the outcome.

REVIEW OF LITERATURE

African American Enrollment in Research

An American Cancer Society study (2000) states:

“The underrepresentation of African Americans among medical research participants is receiving considerable attention because of recent government mandates for the inclusion of all racial/ethnic groups in human subject research. Although several investigators have offered reasons for the relative absence of African Americans among medical research participants, to our knowledge, few are based on empirical research. Thus, there is a need to determine firsthand those factors that influence the willingness of African American individuals to participate in medical research studies. “

In the study, *Factors That Influence African Americans Willingness to Participate in Medical Research Studies* (Shavers, Lynch, & Burmiester, 2001), researchers randomly surveyed 198 eligible households through the Detroit Primary Metropolitan Statistical Area between 1998-1999 to determine self-reported barriers to medical research participation. Results indicated that out of the 198 respondents, 46% were African American with 62% being female. The mean age was 41.9 years; approximately 73% of the respondents had attended college, and 44% had a total household income of at least \$50,000. Researchers report that fifty-six percent of respondents indicated that they would be willing to participate in a medical research study if asked in the future. Study participants did not significantly differ in their willingness to participate when stratified by gender, educational attainment, age group, or income.

It is unclear from the above study what factors influence African Americans willingness to participate in clinical research. In all fairness to the designers of this study (Detroit), the researchers did report that the ethnicity of the physician might influence research participation, but there were no other specific factors described. Suggestions given by researchers in the study to increase enrollment of ethnic minorities included the following:

- Giving people money and other incentives, e.g. free transportation.
- Increase the trustworthiness of the researchers by using doctors from the community.
- Use information received from the community members points of view.
- Have patients receive copies of all signed documents to increase trustworthiness in the study.
- Have educational programs held in elementary schools within the community.

These points, although appropriate suggestions, are not in the authors opinion satisfactory for establishing a solution; nor do they seem to be directly correlated with the proposed purpose of the study.

The few studies (Robinson, Ashley, Haines, 1996; Gorelick, 2000, Ohmann, 2000) that have been done in effort to focus more on the main problem with African Americans and their reluctance to enroll in clinical research seem to have all been focused on understanding the mindset of the people, and, thereby, appear to be severely lacking when it comes to a solution. They have addressed the same issues of concern, but it is the author's opinion that they fail to propose realistic options for eradicating the problem.

Another study, *The Recruitment Triangle: Reasons Why African Americans Enroll, Refuse to Enroll, or Voluntarily Withdraw from a Clinical Trial* (Gorelick, Harris, Burnett, & Bonecutter, 2000) attempted the same task of understanding the reasons for non-participation or withdrawal. The results were just as referential as the study mentioned above, and just as vague with regards to a solution. However, it should be mentioned that income level was reported as playing a major part in recruitment and retention statistics; higher income increased the likelihood of study completion.

Finally, a community-based study held in Tuskegee, Alabama (Fouad, Partridge, Wynn, Green, Kohler, & Nagy, 2001), as a symbolic attempt to right the wrongs of history, is also deemed in the opinion of the author as falling short in providing empirical evidence as to why ethnic minorities are reluctant to participate in clinical trials. This program, *Statewide Tuskegee Alliance for Clinical Trials* (Fouad, 2001) was based on a focus group design. The object was to use community leaders, i.e. doctors, teachers, ministers, etc., and community venues, i.e. elementary schools and local meeting places, as a means of gaining community trust. The researchers held informative workshops to educate community leaders on the study so that they, in return, could do the participant recruitment. This study concluded that the community leaders believe honesty, incentives like free meals, transportation, childcare, and adequate information on the clinical trial should increase recruitment of African Americans, but were not able to demonstrate this potential from this study since the researchers did not test these conclusions for generalizability.

Several studies (Robinson 1996; Gorelick, 2000; Ohmann, 2000; & Shavers, 2001) done under the umbrella of understanding African Americans reasons, beliefs, ideas, etc. towards medical research have been conducted through various methodologies and study designs, yet, it appears in the authors opinion that none have really contributed new, useful information to help alleviate this problem. There is significant understanding within the research community that distrust is the main problem associated with African Americans recruitment and retention. There are some studies (Gorelick, 2000; Shavers, 2001, Wolinsky, 1997) that incorporate the influencing factors as an attempt to find the best strategy. I submit that the only way to understand the

influencing factors associated with the distrust are by taking the time to understand the community and population.

Few researchers have reported successful recruitment of minority participants without specifically designing the study or recruitment practices to enhance minority participation (McDougall, Holston, & Wilks, 2001; USDHHS, 1992). Some of these minority-specific practices include matching the ethnicity of the investigator with the target populations, forming community advisory boards, and using lay health advisors (Derose et. al, 2001). There are only a handful of researchers that have tried trial and error studies to see which strategies worked for which study and for what demographics. For example, in a school-based study, Berman, Grosser, and Gritz (1998) found that recruitment activities (e.g. letters, phone calls) designed specifically for a Latino and African American adult smoking cessation class were more effective than publicizing the program through established community and school events. Researchers have also found that proactive strategies, like investigators contacting potential subjects personally have helped to increase enrollment. While some studies have had success through personal contact, others do well with reactive strategies where participants have to contact the investigators on their own. These studies make general announcements of clinical trials and then leave it up to the potential participants to contact the researchers. Not many studies have had success stories with this technique, however (Vollmer et. al, 1998).

Kick It at Swope (Harris, Ahlywalia, Catley, Okuyemi, Mayoo, Resnicow, 2003) was a double blind, randomized trial that evaluated bupropion for smoking cessation among African American adults who smoked 10 or more cigarettes a day. Researchers used both the proactive approach and reactive strategies over a 16-month period. Researchers report that the study was a success story because of the dual method approach. Table 1 outlines strategies researchers used in recruitment. Note the inclusion of several cultural specific strategies. It is therefore the opinion of the author that the Kick it Swope study was successful because they used a number of strategies in various combinations, and not just based on the two proactive-reactive approaches elucidated by the researchers.

TABLE 1

STUDY FEATURES DESIGNED TO INCREASE PATIENT PARTICIPATION

Staff Characteristics

Staff members were trained, stable, friendly, and enthusiastic.

Staff members were all African American.

Staff members responded quickly to questions or problems (message machine, calls returned within the day, 24-hr on-call number). The study setting health center was trusted by the African American community (mostly African American staff).

Transportation was easy (on a major bus line; parking always available).

Study Operations

Phone or postcard reminders were provided for enrollment appointments.

Appointments were scheduled based on participants' preferences.

Evening and weekend appointments were available.

Participants had no or little waiting for enrollment appointment.

Walk-ins were accepted.

Some counseling sessions (n~3) and assessments (n~2) were conducted via the telephone.

Incentives and Reimbursement

Attractive incentives displaying project logo were offered at each visit (e.g., tote bag, water bottle, T-shirt).

Three personalized certificates of accomplishments were offered.

Participants were offered US \$100 in cash over three visits (week 1, week 6, and month 6).

Source: Kick It at Swope Harris, Ahlywalia; Catley, Okuyemi; Mayoo; & Resnicow (2003)

By incorporating various strategies in combination with the proactive and reactive approaches, researchers were able to successfully recruit 600 participants. This study is the closest example in the opinion of the author of a successful strategy, which established trust with the African American community.

Lastly, in October 2003, the National Institute of Allergy and Infectious Diseases sponsored a symposium on Health Disparities. The focus of this conference was on increasing diversity in clinical trials and explores best practices. Several researchers, public health officials, and community leaders gathered in order to gain insight on how far the community has come towards reaching this goal. At the end of the day, the conclusion was the same as it was when the symposium started that morning: there still is a lot of work to do and a long way to go.

CONCLUSION AND RECOMMENDATIONS

A society in which a significant number of persons believe that they are being treated unjustly will be unstable according to Philosopher John Rawls (Rawls, 1971). Society,

therefore, has an ethical obligation to demonstrate that it is indeed just in order to achieve reasonable citizens' cooperation with its rules and procedures. Many African Americans believe the health care system in the United States is not designed in accordance with principles that are publicly recognized as fair and just. It is the opinion of the author and is alluded to in the Institute of Medicine report: *Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care* (1999) [2] that Institutional racism is an inherent element of the infrastructure and functional ability of the healthcare institution. With regards to the medical community, this form of racism may be a major explanatory reason why African Americans are less likely to receive good medical care, have access to care, and subsequently have a higher mortality rate from the major illnesses like Cardiovascular Disease and Cancer.

In efforts to understand how influential racism and distrust are to African Americans with respect to enrollment and retention in clinical trials, researchers (Robinson, 1996; Gorelick, 2000, Ohmann, 2000, & Shavers, 2001) have tried to pinpoint reasons. The results reveal that those willing to remain and complete the study did so for possible preventative and curative reasons. They stated that their decisions to remain were based on their families and primary physician encouragement. Those who chose to voluntarily withdraw cited concerns about being experimented on and because their families did not trust the research environment. Finally, those who chose to not participate at all claimed their reasons were based on not wanting to be a guinea pig, not trusting the researcher community, and because their families were concerned with being used (Goerlick et. al, 2000). Addressing the aforementioned issues is very important if there is any hope for success. The main problem, as perceived by the author, is that of establishing an entity that is responsible for considering the bigger picture as it relates to recruitment of African Americans in research. I believe that the responsibility should lie with the research community. For dealing with issues regarding insurance, it's the responsibility of the insurance companies. For dealing with issues surrounding prevention methods and early screenings, it is the responsibilities of the public health workers. If research is the main focus, the research community should assume responsibility. If studying African Americans for the purpose of understanding the many disparities and, hopefully, finding a cure for them is a goal, then it is their responsibility to ensure the beneficence of their participants. I submit that this can only be done through the education of researchers on the sensitivity surrounding African Americans and clinical research and the use of multiple recruitment strategies. We have to move beyond just Tuskegee to look at the whole area of building institutional trust.

It is this limited thinking the belief that there once was trust, it was lost with Tuskegee, and now trusts needs to be rebuilt - that researchers have to be re-educated on. Principle Investigators are trained in the basics of clinical research on human subjects, but anything more, like cultural competency training, depends on the institution that the researcher is a part of. The National Institutes of Health has a certification test that can be taken online in order to be able to conduct human subject research. The reality is that there is no government mandatory research-training module that all prospective

investigators who will engage in human subject research are required to attend. In 2000, the National Institute of Health (NIH) and the Department of Health and Human Services (DHHS) mandated that all investigators and other key staff members had to show evidence of human subject training when applying for a federal grant (Zimmerman, 2000). The mandate, however, does not mention anything with regards to cultural competency or any other cultural sensitivity training. The fact that there exists the option that investigators not receiving federal funds could possibly receive little to no investigatory training is problematic. Not only should there be mandatory basic research and ethics training for all investigators, federal funding or not, I submit that a cultural sensitivity module should also be included. This requirement should be mandatory for all research Principle Investigators. The American Medical Association (AMA) understood the need to educate physicians to be more culturally competent. The AMA published a 447-page manual called Cultural Competence Compendium [3]. This document is designed for physicians to educate themselves on being more culturally competent. It is also designed to be a quick reference guide to help with cultural situations that physicians may encounter. The same level of education is imperative in order to begin the creation of a trusting environment and lead to trusting relationships in research. With the initiation of building a foundation of trust, society can start taking on the responsibility to fix unjust situations for its citizens. If the research community understands that trust is a process with multiple levels, and that trust is necessary in order to perform good research, then the creation of trust between African Americans and the research community will occur. With trust established, even in some infancy format, I am convinced that this represents a first step in improving the recruitment and retention in clinical studies. Even though society is more understanding of cultural issues, there are still many racial incidents occurring which continue to support the distrust. There is no way to resolve the issue of racism within this society, but there are ways to deal with them. Society has to recognize that racism still exists and society as a whole is responsible for regulation.

There is no better time like the present to help change the future. By understanding that trust needs to be established before there is change, the research community can begin to cause change. This is not to say that it is only in the hands of the research community. On the contrary, the public must also be educated to be more receptive and open to change. It is a definite two way street, but I contend that beginning with the medical research community is a better starting point. There are many studies that substantiate the existence distrust, but few provide viable solutions. My belief is that studies that only outline incentives and community leader participation as factors to increase enrollment are missing the point. Yes, there is a need to know that these options may work, but there is also the need to know what options do work. If there continues to be a shift in study designs like in the Kick It at Swope project, the future will be more promising. Multiple strategies, incorporating the education of researchers, with an emphasis on African American culture, can combine to create trust between the African American community and the medical research community. Without these, the potential for progress will be weak and health disparities will continue. Also, researchers

will continue to walk out of the hopeful symposiums and conferences with the same conclusion that there is still a lot of work be done.

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