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ABSTRACT

Ethical Considerations for Conducting Cancer Medical Studies: The Tuskegee Study Aftermath

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The recruitment and retention of African-Americans, particularly males, in clinical and prevention studies has not been successful and remains a major challenge. This paper examines the impact of the Tuskegee Study on research in the 21st century and its effect on the recruitment of African-Americans into medical studies. A total of 6 focus groups were conducted among male participants diagnosed with prostate cancer to elicit responses regarding factors influencing participation in prospective studies and trials. Sessions were transcribed and analyzed using content analysis. Echoes of the Tuskegee Public Health Study legacy were a major concern voiced by participants throughout the focus group process. Participants recognized the importance and benefit of research; however, the potential for unethical practices continues to linger in their minds. Attitudes and beliefs toward research and the stigma associated with the Tuskegee Public Health Study also must be addressed to increase enrollment of African-Americans in medical studies. Ten recommendations are given which researchers believe may enhance the participation of this group in medical studies.

Keywords: Medical studies, cancer, ethics, recruitment, African-American

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Introduction

Historically, researchers have faced difficulties recruiting and sustaining African-Americans in clinical trials and other types of medical studies (Harris, Gorelick, Samuels, Bempong, 1996). Mistrust has been documented as the common factor for the lack of participation (Robinson, Ashley & Haynes, 1996; Fouad, Partridge, Green, Kohler, Wynn, Nagy, et. al, 2000; Million-Underwood, Sanders, & Davis, 1993).

Prostate cancer, the most common cancer in men, occurs disproportionately in African American men and is thought to be detected later in this population group. In a vast majority of cases, once detected, the cancer has spread beyond the prostate. Decreased participation in prostate cancer screening, clinical studies and prospective cohort studies by African-Americans greatly impact the disease morbidity and mortality. Hence, efforts are needed to enhance earlier detection among this group (Green, Partridge, Fouad, Kohler, Crayton, & Alexander, 2000).

While the recruitment, enrollment and retention of participants in medical trials are important factors in disease detection and prevention, participation in medical trials and screenings for prostate cancer remains low among African-American males. The recruitment and retention of African-Americans in general and African-American males in particular in clinical and prevention studies has not been successful (Bates & Harris, 2004; Connolly, Schneider & Hill, 2004). In this study, researchers explore possible reasons for the reluctance of African-Americans to participate in medical trials and screening for disease processes.

Background

From 1932-1972, the Tuskegee Public Health Study was conducted by the U.S. Public Health Service to observe 400 sharecroppers with untreated syphilis to document the course of the disease in African-Americans and the racial differences in the clinical manifestation of the disease. These men were not informed of their disease status nor given counseling to avoid the spread of the disease (Corbie-Smith, 1999). In 1972, the study was disclosed to the public, leaving a lasting negative impression in the minds of African-Americans regarding unethical research (Shavers, Lynch, & Burmeister, 2000; Shavers, Lynch, & Burmeister, 2001; Reverby, 2001). A modern day result of the Tuskegee study legacy appears to be feelings of mistrust for researchers among African Americans. Many continue to believe that researchers will not fully disclose the risks of participation, nor will they inform them of any potential for harm. As a result, participation among African-Americans in medical studies has been low. Further, The Tuskegee study legacy is believed to continue to influence African-American attitudes, beliefs and perceptions toward the entire scientific and medical establishment (Patsdaugther,

Christensen, Kelly, Masters, & Ndiwane, 2001; Brown & Topcu, 2003; Whitfield, 1997). This fear of exploitation and ethical concerns have led to apprehension in medical research participation and in some instances, medical practice. In the current study, researchers used focus group discussions among African-American males diagnosed with prostate cancer to explore possible barriers to participation in medical studies.

Methods

A qualitative exploratory research design was used to enhance the understanding of African-American male involvement in medical research. The original study used a series of 10 focus groups (54 male and 37 female participants) in homogenous groupings (six male and four female) to investigate perceived barriers to participation, perceptions of cancer and cancer research, factors that may increase the probability of sustained participation, health awareness, social support, and coping strategies. The research methodology and findings related to the initial study have been published (Hughes, Sellers, Fraser, Knight, & Areghan, 2003). This paper focuses on the 6 focus groups conducted among male participants recruited from a urology clinic and a prostate cancer support group and those recruited by referral of others (snowballing technique). A list of eligible participants was generated based on the following criteria 1) African-American; 2) between the ages of 40 -75; 3) a patient at a urology clinic; and 4) diagnosed with prostate cancer (ICD-9 code 185) within the past 10 years.

Each selected person was first contacted by telephone and informed about the study. A participation letter was mailed and then a follow-up telephone call was to place schedule potential participants for the focus group. The groups were in convenient locations and lasted one-and-a-half hours. All sessions were tape recorded and transcribed.

Analysis

Two researchers analyzed data independently. Content analysis was guided by the objectives of the research and themes were generated. Transcribed interviews were read and word codes were assigned to the text. Data were then categorized into headings that arose from coding. The categories were reexamined for relevance to the purpose of the research. To enhance the validity of the categories and to prevent researcher bias, two researchers were asked to generate categories independently. Then the list of categories was adjudicated. Information sought in the focus groups included: perceived barriers to participation, view of cancer and cancer research, and facilitators for participation in screening and medical studies. The main themes that emerged have been summarized and illustrated in prior publications (Hughes, et al., 2003). As noted, the findings of the original study have been published already; therefore only the results related to the ethical consideration and the Tuskegee Public Health study are mentioned. The study was reviewed and approved by the institution's IRB (Institutional Review Board).

Findings

Topics about prostate cancer treatment, awareness and participation in medical studies were discussed. The following themes were expressed by participants:

Tuskegee Study Legacy

“I think if your fore parents have been burned and they told you about it (Tuskegee) then you will be hesitant to participate. In other words, it sticks with you - you’ll be hesitant to talk or do anything about it. The thing about it is, that’s a scar and if you cut your hand, that scar is never going to leave you. I think that is something in the back of people’s minds, that scar is still there.”

Echoes of the Tuskegee study legacy were a major concern. Although not addressed in the focus group script, the participants’ apprehension towards medical studies radiated from this event. Fear of unethical treatment (having something “done” to them) made many participants cautious in their involvement in research. Older participants who vividly remember the Tuskegee study were more hesitant than their younger counterparts. As a result, many only would agree to participate if they received adequate information and were thoroughly informed.

Importance of Trust

Participants expressed dissatisfaction with past medical encounters when receiving health care and information about their condition. Healthcare providers that were prostate cancer survivors were trusted more, since it was felt they could relate from personal experience.

The participants desired an open dialogue and implored researchers to develop relationships and trust with communities prior to the study inception. In addition, the credibility of the institution conducting/sponsoring the research was a major component in establishing this trust. Institutions that had an unfavorable past with the community were viewed with skepticism. They were perceived as engaging the community only when they “wanted” something.

“I think as more of us (African-American researchers) control studies like this, fear will disappear, but it’s a matter of whose controlling it- a matter of trust.”

Perceived Role and Value of Cancer Research (understanding medical studies)

Even though most participants were aware of the importance of research and its potential benefit, they were still apprehensive about the research process. They felt researchers had an obligation to make sure participants understood the nature of the research being conducted and its potential benefit. Research information targeting African-Americans should be culturally appropriate including regionalism (acknowledging rural/urban differences) and the literacy level should reflect laypersons’ understanding.

Participation in Medical Studies

Participants stated they would be involved in medical studies if they knew it would benefit them directly. They also expressed interest in participating in medical studies unselfishly to learn more about [prostate] cancer and how to prevent other African-Americans from developing the condition.

Several incentives and barriers to participation were noted among participants. Incentives such as free medical services, monetary compensation and refreshments were indicated as ways to increase the likelihood of participation. In addition, participants said study visits conducted at times that were more convenient for them (evenings and weekends) or providing transportation to and from study sites were helpful.

“Well for me and others, participating in a study is time. You have to set aside time to do this (participate). I’m always saying ‘I have this to do’ or wearing a monitor for 24 or 48 hours, I don’t have time to do that because I have other stuff that I need to do.”

Discussion

This paper provides some insight into the reluctance among African -Americans to participate in medical studies. Many of the participants recognized the benefits of research but were still apprehensive about enrolling in medical studies (Outlaw, Bourjolly & Barg, 2000; Comis, Miller, Aldige, Krebs, & Stoval, 2003). When mentioning the Tuskegee Public Health Study, participants used the study to illustrate how, in their opinions; researchers may hide information regarding the true nature of their work. As a result, many participants had a distrust of research, researchers, and the research process. To address the issue of distrust regarding research in the African-American community, there must be a vested interest in the community other than as research participants.

Participants must be fully knowledgeable about the research process in order to make an informed decision to participate in medical studies (Kennedy & Burnett, 2002).

In addition, researchers must ensure participants understand the Institutional Review Board process established by institutions assuring ethical research (Marshall & Rotimi, 2001; Richards & Schwartz, 2001). Having members of the research team reflective of the community and enlisting community leaders is also a way to establish trust. Also, enlisting respected community leaders to serve as continuous gatekeepers is beneficial in gaining trust of potential participants. Finally, the acknowledgement of diversity within the African-American community (i.e. socioeconomic status and geographic locale) is important to recruitment efforts in medical studies.

Recommendations

Below are recommendations that can be used to increase participation in medical studies:

- Establish trusting relationships built on service and respect prior to the onset of a research agenda.
- State researchers' commitment to ethical research and describe provisions to protect participants.
- Educate children to develop early preventive habits, so they will be accustomed to accessing health services and increase their familiarity with health care systems as adults.
- Encourage spousal/partner involvement for recruitment and retention.
- Target support groups as ways to encourage recruitment.
- Use Informed Decision Making (IDM) and decision aides.
- Obtain adequate community involvement and support prior to the initiation of the study.
- Target existing organizations (i.e. community organizations, churches and civic/social groups), support groups and gatekeepers for outreach and recruitment and use qualitative research techniques to aid in this process (town hall meetings, in-depth interviews and focus groups).
- Acknowledge that racial/ethnic populations are heterogeneous and develop strategies based on regionalism, age, education, and economic status.
- Be aware of and recognize the lasting legacy of the Tuskegee Public Health Study.

Conclusion

Dialogue with African-American men regarding (prostate) cancer is needed to increase awareness about the importance of participation in long-term medical studies. Attitudes and beliefs toward research and the research process must also be addressed. Both the researcher and the institution conducting the research must be viewed as trustworthy and competent and the organization conducting the research must be a credible source. Establishment of duality of trust between the participant and the doctor/researcher is essential for recruitment and retention in medical studies.

The Tuskegee Public Health Study is not a recent event; the legacy affects the perception of research and the willingness and trust to participate in these studies. Until an open and honest dialogue between research participants and the scientific community takes place, the mistrust

will continue to exist and impact the communities and individuals' motivation to participate in medical research studies.

It is imperative to fully understand the continued legacy of the Tuskegee Public Health Study on participant involvement in medical studies. Successful interventions are contingent on the strategic incorporation of culturally sensitive methodologies into scientific endeavors.

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