English 7701
Project 2: Developing an Appropriate Research Treatment, Methodology, and Analysis
Topic: African American Participation in Medical Research Studies

Introduction
The lack of participation of minority populations in medical research studies continues to be a significant problem for researchers who strive to recruit a diverse group of participants. While physicians and scientists have sufficient data to prove that minority participation is minimal in most research studies, few can offer comprehensive reasons for and effective solutions to this problem. The need for minority participation is underscored by the fact that the health disparities between minority populations and the majority continue to exist despite the availability of state-of-the-art diagnostic procedures, treatment regimens, and pharmaceutical medications. Minorities, particularly African Americans, still present with more advanced disease and exhibit poorer outcomes for all the major health conditions facing Americans such as diabetes, heart disease and cancer. Thus, it is imperative that researchers enroll minorities into research studies to ascertain the reasons for and to develop strategies to counteract these disparities.

The motivation for increasing minority enrollment in research studies extends beyond the need to improve their overall health condition. By law, researchers are required to include minorities in their studies in order to determine how preventive and treatment therapies affect them. The National Institutes of Health (NIH) enacted the NIH Revitalization Act of 1993 to help encourage and ensure minority participation in research. A portion of the Act is quoted below:

It is the policy of NIH that women and members of minority groups and their subpopulations must be included in all NIH-funded clinical research, unless a clear and compelling rationale and justification establishes to the satisfaction of the relevant Institute/Center Director that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. The inclusion of women and members of minority groups and their subpopulations must be addressed in developing a research design or contract proposal appropriate to the scientific objectives of the study/contract. (NIH)
Despite the mandate from the federal government to enroll more minorities into research studies, researchers have found it difficult to meet their goals for minority recruitment. Studies examining the major killers of African Americans—cancer, heart disease and diabetes—still lack a representative number of African American participants. The medical community has discussed at length the problems with recruitment and has been unable to identify one single cause for the difficulty in enrolling minorities in research. Many doctors and researchers cite distrust of African Americans towards the medical establishment and clinical trials due to the injustices of the Tuskegee syphilis study. Yet, few, if any, have examined the possibility that merely being unfamiliar with the nature and purpose of research studies and how they are conducted may prove to be a major factor in the lack of participation.

**Background**

The problem of recruitment of African Americans into research studies has been discussed in detail among the medical community. Numerous articles and papers have been written about the barriers to enrollment. These barriers have been identified—some more than others. The most cited barrier is fear and mistrust of the medical establishment. In a newsletter published by the Office of Minority Health, the idea of being used as “guinea pigs” still pervades the minds of many African Americans (“Cancer Clinical Trials…”). The article suggested that change in the way this population is treated by the medical establishment is needed in order to gain their trust.

The effect of the medical establishment on the perception of research is reiterated in an article published by the American Cancer Society (ACS). The organization cited that some researchers actually avoid recruiting African Americans because they believe that this population would be less likely to remain in the study once enrolled, thus adversely affecting the study’s retention rate (“African Americans Urged…”). ACS also noted that many African Americans receive healthcare in clinics or emergency rooms where physicians are either not aware of research studies or do not take the time to offer them as an option.
The Tuskegee Syphilis study is often cited as the most damaging event that created a barrier to minority recruitment. Yet, in their study “Willingness to Participate in Clinical Treatment Research Among Older African Americans and Whites,” Diane Brown and Meral Topcu found that income levels and ages of potential participants served as more of a barrier than knowledge of the Tuskegee study. They found that younger persons of higher income levels were more likely to participate in research and suggested that future studies relating to age and income level need to be conducted.

A few researchers have acknowledged that a significant but ill-pursued barrier to enrollment is the lack of general education about research studies. Betty Kennedy examined the perceptions that African Americans have towards research in her article “Clinical Research Trials: A Comparison of African Americans Who Have and Have Not Participated.” Dr. Kennedy proposed that members in the target population may not even understand research results when they are published, and therefore, do not receive full knowledge of the benefits of research. She suggested publishing results in culturally sensitive, lay terminology and disseminating these results through outlets that reach the African American community. Cheryl Munson of the Atlanta Research Center also noted that “a general lack of awareness” and an “overall misunderstanding of the entire clinical process” significantly hinder the recruitment of African Americans into research studies, particularly clinical trials that test investigational drugs (Munson).

Perhaps the most convincing need for patient awareness and education comes from the mouths of African Americans themselves. In a study that featured focus group responses from African Americans regarding participation in medical research, Dr. Giselle Corbie-Smith found that the majority of participants desired to receive broader education about the importance of research studies as well as the opportunities to participate in them. According to Dr. Smith, “The suggestion to increase awareness of research may be taken as a call for a more open and frank dialogue about medical research with the African American community” (544).
This study proposal focuses on exploring the barrier of the lack of education and knowledge about research studies in general and how that hinders the recruitment of African Americans into disease-specific studies. By further exploring the desire for more education as expressed by the target population, we hope to learn how to better recruit them into research studies.

Problem

Because of the lack of participation of African Americans in research studies, this population is underrepresented, and therefore, may not receive the benefits of the results of research studies.

Research Question

Would modifying recruitment public relations techniques to gradually introduce the subject of research in general increase the enrollment of African Americans in disease-specific research studies?

Hypothesis

Gradually introducing the topic of research studies in general prior to inviting African Americans to participate in a specific, disease-related study will increase enrollment in such studies.

Variables

Selection of participants

African Americans who have been diagnosed with any type of cancer will be selected from the medical records database of a major university’s hospital which will be called Hospital “A”. This database contains demographic information about every patient who has been seen in any department of the hospital.
Participants will fill out questionnaires, complete a telephone interview and participate in a focus group.

Data will be gathered using written questionnaires, oral surveys and discussion questions.

African Americans, regardless of education level, socioeconomic level and age, will be more likely to participate in specific, disease-related studies once they have been introduced to the general purpose of research and its benefits for themselves and for future generations of African Americans.

Definition of Terms

Gradually: Over a period of 6 months

More likely: More favorable view will result

Increase: Will improve enrollment rates by at least 20%

Methods and Design

Phase 1

Participants will be selected from the health information system (HIS) of Hospital “A”. All patients who are seen in any Hospital “A” department have their medical records contained in the Hospital “A” database. This database includes demographic information. Cancer patients who have had a medical office visit in any department in the hospital within the past six months will be mailed an introductory letter and a questionnaire about research studies. (See Appendices A and B) The initial sampling size is approximated to be 300 (N=300). The questionnaire will use a Likert rating scale to collect their responses. If the written questionnaire has not been returned to us two weeks after mailing, recipients will be called and asked if they
received the questionnaire and if they had any questions about it. They will be encouraged to return the completed questionnaire.

Phase 2
Of the participants who return the completed questionnaire, 50% will be mailed general information about research studies. The information will detail the purpose of research studies, the overall process of conducting research studies, the process of informed consent, the right to withdraw consent, and the possible benefits of participating. One week after the mailing, the participants will be contacted by phone and asked to complete a telephone survey about research studies. (See Appendix C)

Phase 3
Twenty percent of those who complete the telephone interview will be invited to participate in a focus group about research. The invitation will be printed in the form of a letter and flyer. (See Appendix D) The flyer will contain the date, time, and location of the focus groups. Each focus group will be asked the same set of questions. (See Appendix E)

Phase 4
After analyzing the responses of the focus groups, Phase 4 will implement the recruitment strategies suggested by participants. Then, all Phase 1 participants will be invited to join a research study related to their specific cancer.

Future Research
No literature currently exists regarding gradually introducing this population to research before inviting them to join a specific study. Future studies need to be conducted to control for education level, age and gender. Future studies regarding increasing the enrollment of African Americans into disease-specific studies also need to be conducted.
Appendix A: Introductory letter

Dear [Study Participant]:

We are writing to invite you to take part in a research study to learn more about how patients feel about participating in medical research studies. You were selected because you were recently seen at Hospital “A” for an appointment.

As you may know, medical research studies are conducted to find better ways to prevent and diagnose diseases and disorders. In order to do this, researchers ask patients to volunteer to participate in research studies. We would like to learn more about our patients’ attitudes, beliefs and feelings about participating in research studies.

If you decide to participate, you may be asked to
a) Fill out a questionnaire about how you feel about research studies
b) Receive and review information about research studies
c) Complete a telephone interview
d) Attend a focus group meeting
e) Join a specific research study.

You will be paid $20 for each item listed above that you complete.

Your participation is voluntary. You can refuse to participate, and you can stop your participation at any time for any reason without jeopardizing your future healthcare at Hospital “A” or your relationship with your doctor.

If you have any questions, or for more information, please call us toll-free at 1-888-888-8888. If you do not have any questions and would like to participate, please return the bottom portion of this page in the enclosed, postage-paid envelope.

Thank you for considering participating in this study.

Sincerely,

Terri Goode
Study Coordinator

___ I agree to participate in the study. Please contact me with more information.

___ I do NOT agree to participate in this study. Please do not contact me further regarding this study.

________________________________________
Signature of Research Participant

________________________________________
Date
Appendix B: Mailed Questionnaire

Please read each question carefully. Circle the number that best matches how strongly you agree or disagree with the following statements. The higher the number you circle, the more you agree with a statement. The lower the number you circle, the more you disagree with the statement.

1. I know a lot about medical research studies.
   Disagree 1 2 3 4 5 6 7 Agree

2. I have participated in a medical research study.
   Disagree 1 2 3 4 5 6 7 Agree

3. Medical research studies benefit all people.
   Disagree 1 2 3 4 5 6 7 Agree

4. Medical research studies always help the person participating.
   Disagree 1 2 3 4 5 6 7 Agree

5. I know someone who has participated in a medical research study.
   Disagree 1 2 3 4 5 6 7 Agree

6. All research studies compensate participants for participating.
   Disagree 1 2 3 4 5 6 7 Agree

7. I am afraid to participate in a medical research study.
   Disagree 1 2 3 4 5 6 7 Agree

8. The purpose of research is to spend taxpayer’s dollars.
   Disagree 1 2 3 4 5 6 7 Agree

9. Most researchers are trustworthy.
   Disagree 1 2 3 4 5 6 7 Agree

10. My family disapproves of me participating in a research study.
    Disagree 1 2 3 4 5 6 7 Agree

11. Doctors use patients as “guinea pigs” without their knowledge.
    Disagree 1 2 3 4 5 6 7 Agree

12. I am aware of the research studies that Hospital “A” offers.
    Disagree 1 2 3 4 5 6 7 Agree

13. My doctor has discussed participating in research studies as an option.
    Disagree 1 2 3 4 5 6 7 Agree

14. I trust my doctor to ensure my safety while participating in a research study.
    Disagree 1 2 3 4 5 6 7 Agree

15. I have personal beliefs that keep me from participating in research.
    Disagree 1 2 3 4 5 6 7 Agree
Appendix C: Telephone Survey & Script

“Hello Mr./Ms. __________. My name is ______________, and I’m calling from __________. Thank you for returning the questionnaire we mailed you. We would like to ask you a few more questions. This will take about 10 minutes. Would you happen to have time now? Great. Let’s get started.”

1. Before participating in this research study, I had a good understanding of research studies.
   - Strongly disagree
   - Disagree
   - Agree
   - Strongly agree

2. I would participate in a research study as long as it does NOT involve taking medication.
   - Strongly disagree
   - Disagree
   - Agree
   - Strongly agree

3. I would participate in a research study if my doctor recommended it.
   - Strongly disagree
   - Disagree
   - Agree
   - Strongly agree

4. I can withdraw from a research study at any time without penalty.
   - Strongly disagree
   - Disagree
   - Agree
   - Strongly agree

5. Compensation is my greatest motivation for participating in a research study.
   - Strongly disagree
   - Disagree
   - Agree
   - Strongly agree

6. I am concerned about confidentiality.
   - Strongly disagree
   - Disagree
   - Agree
   - Strongly agree

7. Research studies testing investigational drugs are tested on animals first.
   - Strongly disagree
   - Disagree
   - Agree
   - Strongly agree

8. Research studies need the participation of minorities to improve minority healthcare.
   - Strongly disagree
   - Disagree
   - Agree
   - Strongly agree

9. I feel medical research is important.
   - Strongly disagree
   - Disagree
   - Agree
   - Strongly agree

10. It is convenient for me to participate in research studies.
    - Strongly disagree
    - Disagree
    - Agree
    - Strongly agree

11. I am concerned about out-of-pocket expenses related to participating in a research study.
    - Strongly disagree
    - Disagree
    - Agree
    - Strongly agree

12. I would like to learn more about participating in a research study.
    - Strongly disagree
    - Disagree
    - Agree
    - Strongly agree

Comment [E10]: Do you need to indicate that they will receive $20 for this phone interview?

Comment [E11]: Use with noun
Appendix D: Invitational Letter and Flyer Mailed to Focus Group Participants

Dear [Study Participant],

Thank you for completing the questionnaire and the telephone interview for our research study. We appreciate your willingness to help us learn more about how patients feel about participating in research.

We are inviting you to participate in the next phase of this study. We are asking patients to come and share their ideas about research studies with other patients and with the research team. We call this meeting and sharing of ideas a focus group. The focus group will meet on three separate days for your convenience. The entire group will be asked questions about how they feel about participating in research studies. You are encouraged to answer the questions openly and honestly.

You will be paid $20 for participating in the focus group.

Your participation is voluntary. You can refuse to participate, and you can stop your participation at any time for any reason without jeopardizing your future healthcare at Hospital “A” or your relationship with your doctor.

Please note the dates, times and locations of the focus group meetings below. If you have any questions, or for more information, please call us toll-free at 1-888-888-8888.

<table>
<thead>
<tr>
<th>Focus Group Meeting Dates and Times</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jan 4, 2006 at 7:00pm</td>
</tr>
<tr>
<td>Ground Floor Lounge</td>
</tr>
<tr>
<td>Hospital “A”</td>
</tr>
<tr>
<td>Noville, NC</td>
</tr>
<tr>
<td>Jan 6, 2006 at 10:00am</td>
</tr>
<tr>
<td>Community Health Center</td>
</tr>
<tr>
<td>101 Jones Street</td>
</tr>
<tr>
<td>Noville, NC</td>
</tr>
<tr>
<td>Jan 21, 2006 at 4pm</td>
</tr>
<tr>
<td>YMCA</td>
</tr>
<tr>
<td>52 York Drive</td>
</tr>
<tr>
<td>Noville, NC</td>
</tr>
</tbody>
</table>

Refreshments will be served at each meeting.

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Appendix E: Questions for Focus Group

1. How long have you been receiving your healthcare at Hospital “A”?
2. How would you rate the quality of your medical care?
3. What do you think of when you hear the term “medical research?”
4. What does the term “medical research” mean to you?
5. Have you ever been asked to participate in a medical research study?
6. If so, how many of you participated?
7. Why did you decide to participate?
8. Did you complete all the requirements of the study? Why or why not?
9. If no, why did you decide not to participate?
10. Have any of you known anyone who has participated in a medical research study?
11. What are the reasons that would most influence you to participate in a research study?
12. What are the reasons you would be most likely to NOT participate in a research study?
13. Are you familiar with the Tuskegee Syphilis Study?
14. Tell me what you know about the Tuskegee study.
15. Do you know what changes the government enacted as a result of the Tuskegee study?
16. What does informed consent mean?
17. What recommendations would you give researchers who are trying to recruit more African Americans into research studies?


