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Award Number: DAMD17-01-1-0073

TITLE: Motivators and Barriers to Seeking Prostate Cancer Screening and Treatment of Urban African-American Men

PRINCIPAL INVESTIGATOR: Keith O. Plowden, Ph.D., R.N.
Leonard Derogatis, Ph.D.

CONTRACTING ORGANIZATION: University of Maryland
Baltimore, Maryland 21201

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13. ABSTRACT ***(Maximum 200 Words)***

African American men are disproportionately affected by prostate cancer. In order to positively impact this disease, early interventions that encourage early detection and treatment are essential. The overall objective of this study is to explore motivators and barriers to seeking prostate cancer screening and treatment among urban African-American men. The proposed study has 2 phases. During phase 1, ethnographic interviews will be conducted with African-American men and other individuals who have insight into their culture. These other individuals could include health care providers and significant others of African-American men. Twenty-two informants were interviewed. After analysis of the qualitative data, the Plowden/Young Prostate Cancer Belief Instrument was refined. Psychometric properties of the instrument will be established, and data collection will begin. The findings will be utilized to design a culturally appropriate intervention that will motivate urban African-American men to seek early prostate cancer screening, participate in clinical trials, and seek effective treatment.

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Introduction

The overall aim of this 2-phase study was to explore motivators and barriers to seeking prostate cancer screening and treatment among urban African-American men. Ethnographic interviews were conducted with African-American men and other individuals who have insight into their culture. An estimated 22 informants were interviewed. After analysis of the qualitative data, the Plowden/Young Prostate Cancer Belief Instrument will be refined and tested. An additional 115 men will be recruited to complete the instrument. After establishing the psychometric properties of the instrument, results will be analyzed. The results will be used design a culturally appropriate intervention that will motivate urban African-American men to seek early prostate cancer screening, participate in clinical trials, and seek effective treatment. Urban African American men will be recruited for the project. Inclusion criteria was urban African-American men above the age of 40. The participants had to understand and speak English. Exclusion criteria will be any man unable to participate in an interview. These men will be recruited from community-based organizations in the Baltimore City and surrounding counties.

Body

Based on the recommendations of the Human Subjects Protection Specialist, the project was divided into 2 distinct phases. A separate proposal was submitted for each phase. Approval for recruitment of informants for phase I was not received until January 2002. Based on the timeline, this phase ended June, 2002, and I am awaiting approval of phase II protocol before I begin recruitment of men to complete the instrument. This report will reflect work completed during phase I.

Research Accomplishment:

In this section, I will outline each task and accomplishments

Task I: Project startup and program development. (Months 1-3)

Approval to hire a research assistant and purchase research equipment was obtained in September, 2001. However, permission to recruit human subjects was not obtained until January, 2002. During the initial period of this grant, consultation was done with Dr. Derogatis to discuss interview process and recruitment strategies. An intial meeting was done with the School of Nursing's biostatistician to discuss the project. Additionally, Dr. Plowden was accepted as a Post-Doctoral Fellow at Johns Hopkins University School of Public Health and completed several classes as part of this fellowship. During this time, he completed the following classes:

1. Principles of Epidemiology
2. Sociological Perspectives of Health
3. Principles of Health Behavior
4. Statistical Methods I and II

5. Principals of Behavior Change.

These classes were instrumental in further developing his research skills and recruitment strategies. Dr. Plowden also participated in the Baltimore City Prostate Cancer Demonstration Project. This project is a multidisciplinary initiative at Johns Hopkins School of Public Health as a part of the Cigarette Restitution Fund to decrease prostate cancer disparity among African American men in Baltimore City. This allowed increase interaction with epidemiologist, statisticians, and community groups. As a member of this group, Dr. Plowden presented his project as well as recruitment strategies for feedback.

A Graduate Student was hired as a Research Assistant. During this phase, Dr. Plowden was responsible for training the Research Assistant in qualitative methods. While awaiting approval to recruit informants, the Research Assistant participated in Dr. Plowden's National Institute of Health study in order to gain practical experience with qualitative methods.

Equipment needed for phase I was purchased during this time. This included a laptop for data entry, Atlas.Ti software for data analysis, and a transcription machine. All transcriptions were completed by Dr. Plowden and the Research Assistant.

Task II: Assess prostate cancer beliefs, motivators, and barriers beliefs of urban African-American men in Baltimore, MD and surrounding counties. (Months 3-9)

Final Institutional Review Board (IRB) approval was obtained on November 16, 2001. However, Human Subjects Protection Permission to recruit informants was obtained in January, 2002. The first interview took place on February 20, 2002. A total of 10 Key Informants and 12 General Informants were recruited and interviewed before information redundancy was reached.
The Plowden/Young instrument was revised based on the qualitative interviews and literature. The revised instrument is now 23 items. A new protocol and instrument was submitted on July 5, 2002 to the Human Protection Specialist for approval. Approval has not been obtained yet.

Data analysis for phase I is currently being done. Level 1 analysis has been completed and theme development is underway. The data is being grouped according to identified motivators and barriers to prostate cancer screening and treatment. Psychometric properties have not been established to date. However, construct validity has been completed.

Task III. Formulation of Research questions for further evaluation-Idea Award proposal.

Based on phase I data, a proposal was submitted entitled, "Baltimore City Faith-Based Prostate Cancer Prevention and Control Coalition" to the Health Disparity

Research- Prostate Scholar Project. Initial review and revisions have been completed. The overall objective of this 3-year project is to create a sustainable faith-based prostate cancer prevention program that will result in an increase in knowledge about prostate cancer screening; increase perceived benefits of screening, decreased perceived barriers to screening, and increase in screening behaviors among Black men in Baltimore City.

Reportable Outcomes

Manuscripts are being written from phase I data, and an abstract is being submitted to the National Black Nurses' Association for presentation at their annual conference.

Preliminary qualitative data analysis have shown a strong relationship between social factors and prostate cancer behaviors among urban African American men. The critical social factors are economics, education, social support (kinship), and cultural beliefs. Although free screening and treatment are available in Baltimore City, many men perceived cost as a major barrier to seeking care. Many informants were not aware of the free screening and the need for primary and secondary prevention. Although outreach is a major component of the Prostate Cancer Demonstration, many informants were not aware of basic prostate cancer information. Informants who had participated in screening were influenced by their significant others or men in the community who had prostate cancer. Finally, beliefs about health behaviors and health systems influenced screening behaviors. Mistrust of health systems was a major barrier to seeking screening and treatment. Many informants did not believe the information regarding prostate cancer and was reluctant to participate in treatment because of mistrust. These social factors will be explored further as the research team continues with in depth data analysis.

Conclusion

This study has significant implications. Critical social factors influencing screening and treatment behaviors were identified. These factors will be crucial in the development of a culturally appropriate intervention that will influence men to seek screening and participate in treatment. From this preliminary data, a faith based prostate cancer initiative was developed.

Appendices:

1. Statement of Work
2. Revised protocol
3. Assistance Agreement
4. Phase I review letter

Statement of Work

The overall aim of this 2-phase study is to explore motivators and barriers to seeking prostate cancer screening and treatment among urban African-American men. Ethnographic interviews will be conducted with African-American men and other individuals who have insight into their culture. An estimated 24 individuals will be interviewed. After analysis of the qualitative data, the Plowden/Young Prostate Cancer Belief Instrument will be refined and tested. An additional 350 men will be recruited to complete the instrument. After establishing the psychometric properties of the instrument, results will be analyzed. The results will be used design a culturally appropriate intervention that will motivate urban African-American men to seek early prostate cancer screening, participate in clinical trials, and seek effective treatment. Urban African American men will be recruited for the project. Inclusion criteria will include urban African-American men above the age of 40. The participants must be able to complete a study instrument and participate in a focus group. Exclusion criteria will be any man unable to complete the instrument or participate in an interview. These men will be recruited from community-based organizations in the Baltimore City and surrounding counties.

Motivators and Barriers to Seeking Prostate Cancer Screening and Treatment of Urban African-American Men.

Task 1. Project startup and program development. (Months 1-3)

a. Meeting with collaborating investigator to discuss interviews. A minimum of weekly meetings will be held between Principle Investigator and collaborator.
b. Consult with urologists, oncologists, and other health care practitioners to discuss strategies for recruitment of clients for interview and instrument completion.
c. Consult with community organizations to discuss recruitment of clients.
d. Purchase laptop computer for data collection.
e. Hire research staff- research assistant and transcriptionist.
f. Consult with biostatistician
g. Estimate content validity of instrument

Task 2. Assess prostate cancer beliefs, motivators, and barriers beliefs of urban African-American men in Baltimore, MD and surrounding counties. (Months 3-9)

a. Obtain Institutional Review Board approval from University of Maryland, Baltimore.
b. Recruit African-American men and others for the ethnographic interviews and instrument evaluation.
c. Conduct interviews to explore motivators and barriers and assess face validity of instrument. Interviews will continue until saturation has been reached (approximately 24 individuals).
d. Assess psychometric properties of instrument.

e. Data analysis- qualitative and quantitative
f. Continue to meet with collaborating investigator to discuss progress, item refinement, and instrument testing.

Task 3. Formulation of Research questions for further evaluation-Idea Award proposal (Months 9-12)

a. Analyze data gathered from interviews and instrument.
b. Formulate research question from data.
c. Submit final report summarizing project to DOD.
d. Summarize findings for presentation at research conference and scholarly journal.
e. Begin draft of manuscript and publication.
f. Design intervention for implementation.

Protocol Title: "Motivators and Barriers to Seeking Prostate Cancer Screening and Treatment of Urban African American Men"

2. Phase: II- Quantitative Analysis

3. Principal Investigator: Keith O Plowden, Ph.D., RN
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1. Location of Study: Baltimore City community and University of Maryland School of Nursing.
2. Time required to complete: This phase 2 of the original study. The study is expected to start approximately 1 August 2002 and complete 30 December 2002.
3. Objectives: Phase II

The overall objective of this study is to explore motivators and barriers to participating in prostate cancer screening and treatment among urban African American men. Specific aims are:

1. Identify potential barriers and facilitator to seeking prostate cancer screening.
2. Identify perceived severity of illness in the community.
3. Explore perceived susceptibility to prostate cancer.
4. Explore their intent to seek prostate cancer screening, participate in clinical trials, and receive prostate cancer treatment.

Instrument Refinement and Testing

Under the guidance of Dr. Derogatis, the data from the qualitative interviews will serve as a guide for item refinement and validation of the Plowden/Young Prostate Cancer Belief Instrument. This instrument will be used to quantitatively explore motivators and barriers to seeking prostate cancer screening and participation in treatment. The items of for this instrument were developed during phase 1 of this study, qualitative interviews.

Background and significance

Baltimore City Black men are disproportionately affected by prostate cancer as demonstrated by available statistics. For the period between 1994-1998, age-adjusted incidence for prostate cancer was 211.8 per 100,000 for Black men and 173.9 for White men in Baltimore City (Maryland Department of Health and Mental Hygiene [DHMH], 2001). This disparity is also seen in the mortality rate associated with prostate cancer. Age-adjusted mortality associated with prostate cancer for Black men is estimated at 77.5 per 100,000 compared to 37.4 for White men (DHMH, 2001). These incidence and mortality for prostate cancer rates are statistically significantly higher than 1998 U.S. and overall rates in the state of Maryland. Maryland has the 10th highest mortality rate for prostate cancer among the states and the District of Columbia (Surviellance,

Epidemiology, and End Results [SEER], 2000. Black men are more likely to develop prostate cancer at an earlier age and present with advanced (invasive) disease (Optenberg et al., 1995; Powell, Schwartz, & Hussain, 1995; Moul, 1998; Stanford et al., 1998). Survival is strongly dependent on early detection and treatment (Greenlee, Hill-Harmon, Murray, Thun, 2001). However, Black men are less likely to participate in prostate cancer screening activities.

Several factors (biological and social) influence the prostate cancer disparity among Black men (Airhihenbuwa, 1995; Morris, 1998; Cohen, Scribner, & Farley, 2000). It has been estimated that 80% of all chronic illnesses, such as cancer, are influenced by behavior and sociostructural factors (Roderick, 1992). Sociostructural factors are defined as barriers to, or facilitators of, preventive behaviors among at risk individuals (Sumartojo, 2000). The factors include social, cultural, organizational, community, economic, legal or policy (Sumartojo, Doll, Holtgrave, Gayle, and Merson, 2000). In looking at the current prostate cancer disparity, it is important to explore social factors that influence behavior and those that act as barriers to accessing and utilizing prevention services.

Social structure affects health within three contextual factors: availability, acceptability, and accessibility (Facion, 1999; Blakenship, Bray, & Merson, 2000), and functions at individual, organizational, and environmental levels to influence risk for exposure. Availability assumes that necessary preventive prostate cancer resources are available for at risk individuals (Facion, 1999; Blakenship, Bray, & Merson, 2000). Acceptability focuses on changing the norms of a social system. The system accepts and respects individuality. Studies show that changing the norms, attitudes, and beliefs can significantly influence behaviors (Rotheram-Borus, Rosario, Reid, & Koopman, 1995; Stokes & Peterson, 1998). When individuals feel less accepted, they are less likely to participate in health related behaviors, such as primary prevention (Plowden & Miller, 2000; Plowden 2001a, 2001b). Accessibility focuses on equal distribution of resources throughout communities and includes the ability to utilize services within the community. Studies have shown individuals who are poor are less likely to have access to needed services (Ayanina, Cleary, Weissman, & Epstein, 1999; Bach, Cramer, Warren, & Begg 1999; and O'Malley et al., 2001).

Several studies have shown how social structure factors influence prostate cancer disparity among Black men. Bradely, Given, and Roberts (2001) found that low income played a role in explaining why ethnic minorities and individuals in the lower socioeconomic status group had reduced cancer survival rates. Their study suggests that being diagnosed at a later stage was more likely related to income than race. In this country, a higher percentage of Blacks are poor, which may explain the disparity (US Census Bureau, 2002). Tingen, Weinrich, Heydt, Boyd, and Weinrich (1998) found poor men (annual income of $4800) were less likely to participate in screening as compared to men in higher income categories. This reduces the health care system's ability for early detection and treatment of prostate cancer, which could decrease the mortality. Plowden and Miller (2000) found Black men were less likely to participate in health related behaviors, such as screening, because of lack of resource in their community and

neighborhoods. Tingen et al (1998) observed that men who are less educated were less likely to participate in free prostate cancer screening. Likewise, Weinrich, Weinrich, Boyd, and Atkinson (1998) found that men who had more knowledge of prostate cancer were more likely to participate in a free prostate cancer screening. Agho and Lewis (2001) also found that men who demonstrated a poor knowledge of prostate cancer were less likely to report having a prostate exam as a part of their annual physical. Other studies have shown similar relationships among social factors and health related behaviors (Watts, 1994; Powe & Johnson, 1995; Weinrich et al.,1998; Weinrich, Boyd, Bradford, Mossa, Weinrich, M.,1998; Bennett, Ferreria, Davis, &, 1998; Kalichman, Ramachandra, & Catz, 1999; Powe & Weinrich, 1999; Facion, 1999, Plowden & Miller, 2000).

7. Study Population

African-American men, 40 and over, will be recruited from community based organizations to complete the instrument. The current instrument is a 23- item questionnaire focusing on identified motivators and barriers to participating in prostate cancer screening and treatment programs among urban African-American men. Therefore, an estimated 161 African-American men will be recruited to complete the survey (approximately 7 participants per items). This number is needed to reliably evaluate the dimensional structures of the instrument through factor analysis (Jacobson, 1997; Tasbschnick & Fidell1996). A sample instrument is attached. Through the Office of Research, a Biostatistician will be hired to assist with data analysis. Each participant will receive $10.00 for completing the instrument. The anticipated time range for the session is 1 to 1.5 hours. Instrument completion will take an estimated 20 minutes and the educational session is estimated at 1 hour.

8. Protocol Design

Before any intervention can be successful, a link between health care providers and African American men must be developed. Weinrich, Boyd, Bradford, Mossa, & Weinrich (1998) suggest a consumer-oriented program within the community. Educational programs that are consumer-oriented programs take place within the target community where it is a safe and familiar environment for the participants. The proposed project will use this approach in reaching African American men in Baltimore City and surrounding counties.

a. Subject Identification

All information collected from participants will be kept confidential to the fullest extent permitted by law. All participants will be identified by a code. The code will be assigned by the PI. Only the research team will be aware of the assigned code. The data will be reported in a group format; no names will be used. The Institutional Review Board and U.S Army Medical Research and Material Command may review the records.

b. Recruitment Process

For this study, African American men will be recruited from community agencies such as, clinics, community-based organizations, and churches in the Baltimore City and surrounding counties. As Principal Investigator during phase I of this study, Dr. Plowden

is currently working with many community-based organizations throughout the city. Therefore, a relationship has already been established. Organizations and other community individuals will be contacted by Dr. Plowden. A meeting will be set up in order to provide a complete explanation of the study to include goals and methodology. The organization will be asked to identify potential participants. The PI will ask the organization to contact the potential participants in order to gain initial consent. .

Informed Process
If individuals agree to participate in the study, a date and time for completion of the instrument will be established. Completion of the survey will be conducted by the PI and research assistant. At the time of the meeting, the informed consent will be reviewed with the men by the team. Participation in this study is voluntary and the informant may terminate completing the instrument at any time without fear of retaliation. Instrument completion will not take place until the participants have signed the consent form and all questions answered. Based on the inclusion criteria, the informant must be able to speak and understand English. If the informant is unable to sign the consent form, an adult will be present to witness the consent. The witness will be required to be present during the informed consent. Two copies of the consent form will be completed so that the informant gets an original copy and a copy can be kept for the PI's study records. See attached consent form.

Evaluation prior to entry:
All informants must meet the inclusion criteria. Eligibility will be determined before scheduling an interview.

Clinical Assessment
Completion of the instruments will be done at a location convenient and comfortable for the participants. After review of the procedure, the participants will sign the consent. Completion of the instrument will begin after the consent has been signed and all questions answered. Each participant will complete a demographic forms.

Each participant will receive $10.00 for completing the instrument. This is a nominal amount and is not viewed as coercive.

Preliminary analyses will be done with the first group of data to assess the initial reliability of the instrument. Descriptive statistics will be computed for all demographic variables to describe the sample and to consider whether variables demonstrate sufficient variability for inclusion in multiple regression. Internal consistency of the instrument will be assessed using Cronbach's alpha for the overall scale and for motivators and barriers.

Confirmatory factor analysis (CFA) will be used to assess the construct validity of instrument. This permits the researcher to specify which items (i.e., indicators) reflect which dimensions correlate and whether error variances are permitted to correlate. Also, the measurement structure of each dimension as well as combinations of dimensions can be assessed. Multiple regression approaches will be used to examine the relationships

between demographic characteristics (IVs) and motivators of health seeking behavior (DVs). The final instrument will contain between 20-25 items.

Research activity
A member of the research team will verify meeting time and place with the organizational leader or individual completing the instrument. On the day of meeting, the PI or member of the team will meet the participants at the agreed upon site. The study will be explained to the participants, and the participants will be asked to sign the informed consent that will describe the study, benefits, and contact information. After the participants sign the consent form, completion of the instrument will begin.

Risk and Benefits
This project involves no physical risk or discomfort. The participant might experience some psychological distress with this study. If a participant should become psychologically distressed as a result of this interview, he will be given an opportunity to discuss it with the PI and a referral will be made to an appropriate mental health professional. There is also a loss of personal time for the study.

The participants might benefit from the information given. However, there is no guarantee that you will benefit from participating in this study. The study will help better understand motivators and barriers to seeking prostate cancer screening and treatment of urban African American men. This information will better help design prostate cancer prevention and control programs that may help decrease the number of African American men with this disease and the deaths associated with this disease.

10. **Reporting of serious or unexpected adverse events.**
    a. The IRB has classified this study as minimal risk. This does not mean that the research is risk-free, however, generally speaking there are some the risks associated with research participation. These risk are outlined in the consent form.
    b. An adverse event includes intercurrent illnesses and injuries and exacerbations of preexisting conditions.
    c. Adverse experiences will be reported immediately by telephone to the USARMC Deputy for Regulatory Compliance and Quality, and information will be sent by facsimile. A written report will follow the initial telephone call within 3 working days. Adverse experience will also be reported to the IRB within 24 hours. But, if the informant is harmed as a result of the negligence of a research, he/she can make a claim for compensation. If the participant believes he has been harmed through participation in this research study as a result of researcher negligence, they can contact the IRB for more information about claims procedures. This information will be provided to the participants at the time of the interview.

11. Disposition of Data
Data will be collected and entered into a data base for analysis. All data will be entered by the Research Assistant. Completed instruments will be kept in a locked file cabinet until destroyed. Only members of the research team will have access to the file cabinet.

Entered data will be verified by the PI. Each individual participant will be assigned a code as an identifier in the analysis. These codes will be known only to the research team. After accuracy has been determined, the principal investigator will transfer the data to SPSS for analysis.

12. Modification of Protocol.
The outlined procedure is no anticipated to be modified. If the protocol is modified, amended, or terminated before scheduled completion, a new protocol will be submitted to the local IRB and HSRRB for review and approval before initiated. Modifications to the protocol will be highlighted along with an explanation of the rational for modification. If modifications are made, data collection will not continue until full approval has been obtained.

13. Departure from Protocol.
Deviation from the protocol will be made only for safety reasons. If deviation from the approved protocol is made, a new protocol will be submitted to the local IRB and HSRRB for approval.

14. Roles and Responsibilities of Study Personnel
Dr. Keith O. Plowden will be responsible for the overall scientific responsibility and direction for this study. He will be responsible for recruiting, training, and supervising of the research assistant. He will take overall responsibility for directing the study including recruitment of participants, survey completion, reviewing files, and assuring that the protocol is implemented as planned. He will meet with all organizational individuals and take responsibility for orienting the research assistant to the organization. He will provide ongoing data collection, entry, and analysis in collaboration with a biostatistician and Dr. Derogatis.

Dr. Plowden and the research assistant will be responsible for administering the instrument and data entry of quantitative data. Following each session, Dr. Plowden will be responsible for debriefing with the research assistant and any follow-up needed with the organization.

Dr. Plowden will be responsible for ensuring that the research assistant is familiar with data entry procedure. Dr. Plowden will be responsible for the administration of the budget and for preparation of progress and final reports. Dr. Plowden, the research assistant, and biostatistician, will collaborate in writing research articles and research presentations. Dr. Plowden will devote 35% of his time to the project.

Dr. Leonard R. Derogatis will act as the measurement and instrument development mentor for this study. Dr. Derogatis is a senior scientist internationally recognized for his research and development of psychological measuring instrument. He will participant in the design and conduct of the study, the design and testing of instrument, data analysis and interpretation, annual reports, and papers for presentation and publication.

The research assistant will be under the supervision of Dr. Plowden. The research assistant will check all incoming data for completeness, collating and coding appropriately for computer entry, scoring, and analysis. The research assistant will assist with the administration of the instrument during each session. One hundred percent effort will be required for these duties.

The biostatistician will be responsible for establishing the overall plan for handling the quantitative data from the study site. This will include specifying the procedures for data preparation and processing and procedures for collating the quantitative data. The biostatistican will participate in the design and implementation of the instrument, annual reports, and papers for presentation and publication. This individual will oversee quantitative data analysis. The biostatistician will have expertise in measurement, data analysis, and quality assurance. This individual will be recruited through the Office of Research and will devote 8% of their time to this study.

Date _____

Plowden/Young Prostate Cancer Screening Instrument

Thank you for participating in this prostate cancer project. .
The purpose of this research study is to learn more about things that make a difference in whether or not African American men seek prostate cancer screening and treatment. Your answers will be kept confidential; no one will ever see your answers. The information we get will help us know how to develop cancer prevention and control programs aimed at helping African American men in the community. Please answer all questions honestly. If you have any comments or questions, feel free to write them in.

Motivators and Barriers to Seeking Prostate Cancer Screening and Treatment

Demographic Information
Please answer each question below. You may refuse to answer any question without repercussions

Please answer or check the following information that best describes you.

What is your marital status?

- ❑ Single
- ❑ Widowed
- ❑ Married
- ❑ Separated
- ❑ Divorced
- ❑ Partnered

What is your race?

- ❑ African American
- ❑ African
- ❑ Caribbean American
- ❑ Biracial
- ❑ Other

If other, please explain _____

What is your religion?_____

Highest education completed

- ❑ Finished Grade 1-8
- ❑ Finished some High School
- ❑ High School
- ❑ Some trade school
- ❑ Finished trade school
- ❑ Received Associate Degree
- ❑ Received Bachelors Degree
- ❑ Received Masters Degree
- ❑ Received Doctorate

What is your employment status?

- ❑ Employed full-time
- ❑ On disability/Social Security
- ❑ Employed Part-time
- ❑ Retired
- ❑ Unemployed

What type of health coverage do you have?

- ❑ Private Insurance
- ❑ Veteran
- ❑ Medicaid
- ❑ Medicare
- ❑ None

What is your household income?

- o Less than $10,000
- o $10,000-$19,999
- o $20,000-$29,999
- o $30,000-39,999
- o $40,000-$49,999
- o Greater than $50,000

How many people live in your household?_____

Are any other people dependent on you for financial support? 1. Yes or 2. No (Please circle one)

Do you know anyone with cancer?

- ❑ Yes
- ❑ No

Do you know anyone with Prostate Cancer?

- ❑ Yes
- ❑ No

If yes, who? (ie father, brother, cousin, friend, etc.). Please write in **(Please do not give names)**

_____

In the past 6 months, have you received any information about prostate cancer?

- ❑ Yes
- ❑ No

If yes, where did you receive the information?

_____

In the past 12 months, have you ever been tested for prostate cancer?

- ❑ Yes
- ❑ No

If yes, check all of the test you received

- ❑ Blood test
- ❑ Rectal Exam

Are you aware of any prostate cancer clinical trials (research)

- ❑ Yes
- ❑ No

Item	Strongly Agree	Agree	Disagree	Strongly Disagree
1. There is nothing I can do to stop prostate cancer.				
2. I would want to be checked for prostate cancer if I knew someone with it.				
3. Getting checked for prostate cancer could save my life.				
4. If I get prostate cancer, I will receive the best treatment available				
5. Treatment for prostate cancer is worst than having the disease.				
6. If I developed prostate cancer, I would rather not be treated for it.				
7. Having prostate cancer means death.				
8. There is a cure for prostate cancer				
9. Prostate cancer is an old man's disease.				
10. If I get prostate cancer, getting treated will make it worse.				
11. I do not want to know if I had prostate cancer.				
12. A digital rectal exam is embarrassing.				
13. If I had trouble urinating, I would see help.				
14. I know where to get tested for prostate cancer.				
15. I can afford to get tested for prostate cancer.				
16. Having a rectal exam would stop me from getting tested for prostate cancer.				
17. I have received information about prostate cancer.				
18. If treatment for prostate cancer caused me not to have an erection, I would not get treated for it.				
19. I am happy with the information I have about prostate cancer.				
20. My friends talk about prostate cancer.				
21. My doctor has talked about prostate cancer with me.				
22. Wetting myself after being treated for prostate cancer would stop me from getting treated.				

Research Consent Form

Name: _____

Project: Motivators and Barriers to Seeking Prostate Cancer Screening and Treatment of Urban African-American Men.

Investigator:

Keith O. Plowden, Ph.D., R.N. (410) 706-5868

Purpose of Study:

The purpose of this research study is to learn more about things that make a difference in whether or not African American men seek prostate cancer screening and treatment. This study involves surveying African American men about their thoughts about prostate cance. We are doing this study because African American men are at high risk for developing prostate cancer and dying from it. The information we get will help us know how to develop cancer prevention and control programs aimed at helping African American men in the community. We are asking you to participate in this study because we understand that you know about the issues that are important for this study.

Procedures:

If you agree to participate in this study, you will be asked your beliefs about prostate cancer, the kind of things that make you want to seek screening or early treatment if you need it and the things that make you want to avoid screening and treatment. This will take about 1 hour. You will complete a survey. The information will be entered into a computer for analysis. Your name will not be recorded on the information.

After completing the survey, you will be given information about prostate cancer. There is no cost to you for this information.

Risks/Discomfort:

This project involves no physical risk or discomfort to you. We will not be asking any questions that should embarrass or upset you. However, some people do get emotionally upset or psychologically distressed when they think or talk about cancer. If you become upset or worried during the interview and would like to stop, you can stop at any time. If you should become upset or worried as a result of completing this survey or afterwards, you can talk about your feeling with Keith Plowden, the Principal Investigator for this study. **You can reach him at (410) 706-5868 Monday thru Friday 8:30 am-4:30 pm. You can also page him at (410) 471-1211 after office hours.** If you would like additional help, or if you seem to need it, he can assist you to get a referral to an appropriate mental health professional. If you feel very upset and those feelings are getting out of control, you should call or go to the nearest emergency room. You may also feel that one or more questions invade your privacy. You can refuse to answer any questions that you don not want to answer. Your name will not appear on any of the information you give to us. The only other risk might be a loss of personal time and

inconvenience. We will try to minimize this by scheduling your interview at a time and place that is convenient for you and for the person who will be interviewing you.

Benefits:
There is no guarantee that you will benefit directly from participating in this study. This study will help us better understand how to help African American men to ask for prostate cancer screening and treatment. This information also will help us to design prostate cancer prevention and control programs that may help decrease the number of African American men with this disease and to decrease the number of men who die from prostate cancer. You will be given health information that you may find helpful.

Alternative:
This is not a treatment study. You do not have to participate in it. Your decision will not affect your health care in any way. We will give you information about prostate cancer whatever you decide about participating.

Cost/Compensation:
You will not be charged for participating in this study or for any of the information you receive. After the interview, you will receive $10.00 for your time and travel.

Confidentiality:
If you agree to participate, the consent form that has your name will be separate from any other information about you. Any information you give us will be identified by a code. Only the research team will know your code. All information collected from you will be kept confidential to the fullest extent permitted by law. The signed consent form and survey will be kept in a locked file in a secured area that only that only a member of research team can access. Neither your name or any information that can identify you will appear in any report. All data will be reported for groups of participants. The Institutional Review Board (IRB) (that is, a group of scientists, physicians, and other experts) and representatives of the U.S. Army Medical Research and Material Command that is funding this study are eligible to review research records as a part of their responsibility to protect human subjects in research.

Right to Withdraw:
Participation in this project is voluntary. You have the right to decline to participate in this study or to withdraw at anytime. If you feel uncomfortable, you may refuse to answer any questions. Your refusal or withdrawal will in no way affect your current or future medical care at the University of Maryland, Baltimore or University of Maryland Medical System. You will be told of any significant new findings that develop during the project that may affect your willingness to participate.

The Principal Investigator has the right to withdraw you from participation in this study if your health and/or safety are in jeopardy or there is a deviation from the approved protocol.

UNIVERSITY STATEMENT (Minimal Risk Studies)
The University is committed to providing subjects of its research all rights due them under State and federal law. You give up none of your legal rights by signing this consent form or by participating in the research project. Please call the Institutional Review Board (IRB) if you have questions about your rights as a research subject (see below for phone number).

The University of Maryland Institutional Review Board (IRB), a group of scientists, physicians, and other experts have classified the research described in this consent form as minimal risk. The Board's membership includes persons who are not affiliated with the University and persons who do not conduct research projects. The Board's decision that the research is minimal risk does not mean that the research is risk-free, however, generally speaking, you are assuming the risks of research participation, as discussed in the consent form. But, if you are harmed as a result of the negligence of a research, you can make a claim for compensation. If you believe you have been harmed through participation in this research study as a result of researcher negligence, you can contact the IRB for more information about claims procedures.

Institutional Review Board
University of Maryland
655 West Baltimore Street, #BRB-14-016
Baltimore, Maryland 21201
(410) 706-5037

If you have questions about this study, you should contact Dr. Keith Plowden, Principal Investigator at:

The University of Maryland School of Nursing
655 W. Lombard Street #355-D
Baltimore, MD 21201
(410) 706-5868

If you agree to participate in this study, please sign your name below

NOT VALID WITHOUT THE IRB STAMP OF CERTIFICATION

_____

_____
Subject's signature

___ I have read and understand the information on this form (please initial)
___ I have had the information on this form explained to me (please initial).

Date:_____

_____
Printed Name

Permanent Address

_____

_____

_____
Signature of Parent/Guardian
(When Applicable)

Date:_____

_____
Signature of Child (13-18 years old)
(For Child Assent)

Date:_____

VALID FROM_____TO_____

_____
*Witness to Consent procedures

_____
Please Print your Name

RPN NO._____

_____
Signature of Investigator

Date:_____

*Optional unless subject is illiterate, or unable to sign.
NOTE: Copies of this Consent Form with original signatures **must** be a) retained on file by the Principal Investigator; and b) given to the subject. A copy must also be deposited in the patient's medical record (if any).

A-10313
PI: Plowden

MCMR-RCQ (70-1n) 27 June 2001

MEMORANDUM FOR RECORD

SUBJECT: Protocol Entitled "Motivators and barriers to seeking prostate cancer screening and treatment of urban African-American men," -- Phase I, Qualitative Analysis, Submitted by Keith O. Plowden, PhD, RN, HSRRB Log No. A-10313, Proposal # PC001384

1. Background.

a. This is the initial review of the protocol for the qualitative phase of a one-year project with two distinct phases: a qualitative study to describe African-American men's attitudes and beliefs about PC screening, and a quantitative study to refine and test the internal consistency and validity of a questionnaire to discern African-American men's attitudes and beliefs about PC screening. It is anticipated that the resulting conceptualization and, subsequently, the information gained through the use of this questionnaire will enable developing and testing culturally appropriate health education interventions designed to increase early screening and, thereby ultimately improve treatment outcomes.

b. This proposal was awarded under the CDMRP-PCRP-Minority Population Focused Collaborative Training Award. The purpose of the MPFCTA is to "support the planning and development of a program of research, not necessarily the completion of the proposed program (PCRP Program Announcement, February 23, 2000, pVI-1).

c. Verbal communication with the Investigator indicated he would like to conduct this phase during the summer months.

2. Scientific Review. The proposal received PCRP Peer Review, 6-8 July 2000 and received a score of 1.5. The proposal was approved with no recommendations.

3. Review by IRB of Record. The University of Maryland, Baltimore, IRB (MPA # M-1174) reviewed and approved this project on 27 February 2001. The continuing review date was not specified; however, the letter of approval states, "...the enclosed stamped consent form expires on the anniversary date of this protocol. The expiration date can be found on the last page of the consent form." The date stamp states "valid from 02/27/01 to 02/26/02. Neither the risk level nor full board versus expedited review was noted in the approval letter. However, the approved consent form contains the University of Maryland

statement labeled, "minimal risk studies" (see p 2 of the consent form).

4. Level of Risk Assessment. This reviewer assesses this project as no greater than minimal risk.

a. It uses a semi-structured interview to obtain qualitative data that will be used to develop a conceptual framework to guide future interventions and studies and to refine the items that will be included in a structured questionnaire (under development).

b. A structured, demographic questionnaire will be used; it does not include any identifying information, sensitive, or self-incriminating questions that would affect the respondent's employability, insurability, social stigmatization, or criminal liability.

5. Research Design. This protocol is developed under a training award that proposes to develop and implement two phases (a qualitative and a quantitative phase) of a research program.

a. The first phase (protocol under review) is an ethnographic, qualitative study to "flesh out" a conceptual model of health-seeking behavior pertinent to prostate cancer and to provide additional information for developing the content of a qualitative questionnaire. It uses ethnographic methods and two groups of subjects: key informants and general informants (described below).

b. Subjects will be involved for approximately one-and-a-half to two hours for the interview process. The protocol states that each informant will be asked to verify the transcribed interview (protocol, p. 10) but this is not included in the time estimates and is not included in the consent form (see recommendation).

6. Research Objectives. The overall objective of this study is to explore motivators and barriers to seeking prostate cancer screening and treatment among urban African American men. There are three aims for this protocol: to explore beliefs and perceptions, perceived benefits, and barriers and facilitators to participating in clinical trials and seeking early prostate cancer screening and/or treatment. This protocol is a theory-building study designed to expand the Leininger Culture Care Diversity and Universality theory as it applies to African-American men and to identify questions and hypotheses for future testing.

7. Population. The target population consists of urban-dwelling, African-American men. The accessible population from which the two samples (key informants and general informants) will be drawn consists of African-American men and others (such as spouses, healthcare providers, clergy), living in the greater-Baltimore area, who are knowledgeable about the culturally-defined beliefs and behaviors of this population. The study population is appropriate for the objectives.

8. Inclusion/Exclusion Criteria. Criteria are specified for two types of subjects/informants: key informants and general informants. Both sets of informants must be able to speak and understand English (p 6). Key informants must be urban African American men, >40 years of age, who may or may not have been treated for prostate cancer. General informants might be significant others of African American men, health care providers, and other individuals who would have knowledge about the motivators and barriers for African American men. Criteria are presented on pages 6 and are appropriate for the study objectives.

9. Informed Consent Process. The investigator will use a snowball recruitment strategy that has been modified to protect potential subject's privacy rights as described below.

a. He will meet with key organizations and community leaders and will explain the study to them. These organizations/individuals will be asked to contact persons they know who might meet the study criteria and ask them if they might be willing to participate. After obtaining initial agreement from potential informants, the organizations/individuals will provide the investigator with the name(s) of the potential informant. The protocol does not state whether or not these recruitment resource persons will be given any flyers or other printed information about the study (see recommendations).

b. The investigator will contact that person to establish eligibility and willingness to participate. A follow-up letter will be sent to the potential respondent to confirm the time and place of the interview (sample letter included in protocol).

c. Upon meeting in person at the previously scheduled time and place, the investigator will again explain the nature of the project and obtain written consent.

(1) If the potential respondent would like additional time to discuss the study with anyone before making a decision, another appointment will be made to complete the consent process and conduct the interview.

(2) If the potential informant is willing to participate, the investigator will conduct the interview at the time of this initial meeting.

d. The investigator states that a witness will be present for the consent process if the potential respondent is unable to sign the consent form. This needs to be clarified -- under the still currently valid AR policy, the witness must be present for the entire consent process for all potential study volunteers, not just those unable to sign [(AR 70-25 3-2(d) (see recommendations)].

10. Population and Sample Size. For the qualitative protocol under review, a total of 24 informants will be recruited (12 key informants

and 12 general informants). Recruitment will continue until no new information is forthcoming ("cells" are saturated). Although this is a small N, it is consistent with accepted practice in ethnography and other, established qualitative methodologies and is appropriate for this stage of conceptualization and instrument-development. The rationale for the anticipated sample size is presented on page 16. Modified snowball sampling strategies are proposed as described above. The proposed modification is consistent with this accepted method for sample accrual in a study of this nature, while protecting an individual's privacy rights.

11. Data Collection Plan. Informants will be interviewed in a mutually agreed upon, convenient location at a mutually agreed upon time.

a. Semi-structured interviews will be conducted (see page 9 for a sample of probe questions), will be audio taped, and transcribed verbatim.

b. The researcher will maintain field notes and a summary of individual interviews in a (hard copy) journal.

c. Informants will complete a brief, investigator-developed, structured questionnaire to obtain descriptive, demographic data. The questionnaire has face validity and does not contain sensitive or potentially harmful questions.

d. Neither the protocol nor the consent form states whether the informant's name or other identifying information will be recorded in the field notes or on the audiotape (see recommendations).

e. The consent form does not specifically request permission to audiotape the interview (see recommendations).

f. Procedures for securing the data are described (pp. 9 and 10) and appear to be adequate.

12. Data Analysis Plan.

a. Data processing:

(1) Interviews will be audio taped and transcribed verbatim; field notes will be recorded in a journal and individual's interviews will be summarized.

(2) After the audio taped interview is transcribed, the investigator AND the informant will verify the accuracy of the transcriptions. The protocol does not state what type of identifiers will be on the tape or transcription (see recommendations).

(3) The verified, transcribed data will be transferred to QRS NUD*IST computer software program for analysis. This is a well-known, established program for qualitative analysis.

b. Although the investigator states that this type of inquiry is aimed at generating questions and hypotheses, he did not describe the steps he will use to analyze the data to identify and validate conceptual themes. For example, he did not define what a "data bit" will consist of, how the data bits will be grouped, labeled, defined, checked for consistency, and the labeling and conceptual themes validated. Articulation of these steps is an important aspect of being able to produce rigorous qualitative research. It can be assumed, reading this investigator's CV, that he is familiar with the steps because he has produced publishable reports using this methodology. Further, because this is a training award and the investigator has a credible mentor, it does not seem to be necessary to require that the investigator spell out these steps in detail (see "Other Observations," below).

13. Risks to Subjects. There are no known risks to the informants other than a loss of personal time, an invasion of privacy or break in confidentiality, and the possibility of psychological distress. The interview will be held at a mutually agreeable time and place, the probe questions are relatively benign, the investigator has adequately identified the risks in the protocol and consent form, and appears to have established procedures to manage them. However, it would be helpful to have more information about the researcher's (investigator and the research assistant who will be doing the interviewing) ability to identify psychological problems, to address the immediate reactions/concerns, and to make the appropriate referral(s) (see recommendations). Documentation of the availability of mental health support services is also needed (see recommendations).

14. Benefits to Subjects. There are no direct benefits to the informants or subjects for participating in the data collection. This is not a 10 USC 980 issue because informants and subjects will be of legal age of consent and must be able to actively participate.

a. Indirect benefit: The original proposal stated the investigator will provide informants with printed educational materials (from the ACS or other legitimate source) and will provide subjects who complete the questionnaire with a one-hour instructional session on PC. The consent form states that the informant "...may benefit from the health information we will provide you during the project." However, the protocol does not state that health information will be provided. This needs to be clarified and discrepancies between the protocol and consent form need to be resolved (see recommendations).

b. Compensation: Study participants will be provided compensation in the amount of $20 at the end of the interview. This is a nominal amount of compensation in this geographical area and is not viewed as coercive.

15. Recommendations for Approval. The following documents must be submitted prior to approval.

a. Required documents/information.

(1) Revised protocol that addresses the issues listed below.

(2) Revised consent form that is in compliance with all HSP regulations and resolves the issues listed below.

(3) Revised Demographic Questionnaire (see below).

(4) Documentation of the interviewer's (PI and Research Assistant) training and/or experience in mental health counseling and crisis intervention.

(5) Documentation of the agreement (from either an individual qualified therapist or a mental health facility) to provide back-up mental health services for subjects who need assistance.

(6) A copy of any flyers, posters, or other recruitment or advertisement materials that will be used (21 CFR 312.7; FDA Information Sheets, September 1998).

b. Revisions to be made to the protocol.

(1) Describe the information that will be given to the resource persons (and organizations) who will be aiding in the recruitment of informants. If any flyers or other materials will be used, submit a copy.

(2) Clarify the informant's time commitment in relation to the follow up contacts for verifying the transcripts and gathering other information. For how long will the informant need to stay available?

(3) Correct the description of the consent process in relation to the witness. The consent process must be witnessed for all subjects, not just those who are unable to sign the consent. [AR 70-25 3-2(d)]

(4) Clarify what identifying information will be included in the field notes and transcripts.

(5) Clarify the "indirect" benefits and resolve inconsistencies between the protocol and the consent form. If the informants will be given educational materials or have an opportunity to be instructed regarding prostate cancer screening/treatment, list the materials to be distributed (if published) or provide a description and copy of the materials to be used (including an outline of, or lesson plan for, the instructional session).

(6) In the section, "Deviations from Protocol," Include a statement that any changes or unanticipated problems in a research activity that require a deviation from the protocol will be promptly reported to the University of Maryland IRB and the HSRRB. Normally, changes may not be initiated without TSG approval, except where necessary to eliminate apparent immediate hazards to the human subject

or others. Any other changes would be submitted as an addendum or modification of the protocol as the investigator described in this section and in the preceding section of the protocol.

c. Revisions to be made to the consent form.

(1) Include a separate consent for audio taping the interview. Or, include this as an explicit paragraph within the consent document with space for the informant to initial or sign acknowledging awareness of the taping and willingness to be taped.

(2) Clarify the statement about "further contact." Clarify why you may contact the informant, i.e. specify that the informant will be asked to review and verify the transcript of the interview. If the informant may be contacted for other reasons, this needs to be specified. Also, add a statement about the duration of involvement (availability), i.e., a week, a month, or six months after the initial interview.

(3) In the section about risks, reword the second sentence about making a referral to a mental health professional. As written, it implies that if the informant becomes distressed and talks with the investigator a referral automatically will be made. It should allow for the informant to make the choice and should also make a provision that emergency mental health intervention is available and will be consulted if clinically indicated.

(4) In the paragraph about confidentiality, add the statement that representatives of the USAMRMC may review the files as described in the approved clauses (below)

Review of Research Records
It should be noted that representatives of the U.S. Army Medical Research and Materiel Command are eligible to review research records as a part of their responsibility to protect human subjects in research.

(5) Include the name(s) and contact information if the informant has questions or believes he (she) has been harmed as a result of participating in this study. [32 CFR 219.116(a)(7); AR 70-25, E-8]

(6) Add lines for the printed name and permanent address of the subject (informant) on the last page of the consent form.

(7) Add a line for the printed name of the witness on the last page of the consent form. Delete the line that says "Optional unless subject is illiterate, or unable to sign." The DOD regulations require having a witness for all volunteers.

(8) Add a section concerning the conditions under which the investigator may withdraw a subject from participation. [32 CFR 219.116(b)(2); AR 70-25, App. E-11]

(9) Add a statement about the anticipated number of people who will participate in this protocol.

d. Revisions to be made to the Demographic Questionnaire.

(1) Add the title of the study.

e. Sample donation form. Not needed for this study.

16. Other Observations. This is a well-written qualitative protocol. It could be strengthened with the addition of information about how the data will be analyzed. For example, what will constitute a "data bit" or unit of analysis? How will the data labeling be accomplished? Validated? Checked for consistent application of the labels? This information would facilitate the evaluation of the risk/benefit ratio but does not appear to be essential for the human subjects review of the current protocol. If, however, the proposed topic were more sensitive or the population more vulnerable, it would be essential for the HS review. It will be important for the investigator to include this information in the report of the outcomes of this phase of study when submitting the protocol for the quantitative phase of the study. It speaks directly to the issue of the validity of the questionnaire that will be developed from the information obtained in this phase. There are no other observations at this time.

Maryann F. Pranulis, RN, DNSc
Human Subjects Protection Specialist
AMDEX Corporation