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Meharry-Johns Hopkins Center for Prostate Cancer Research

PRINCIPAL INVESTIGATOR: Flora A. M. Ukoli, M.D., M.P.H.

CONTRACTING ORGANIZATION: Meharry Medical College
Nashville, TN 37208

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Meharry Medical College
Flora A. M. Ukoli
LaMonica Stewart, M. Sanderson
A. Pasipanodya, & Carlton Adams
email: fukoli@mmc.edu

John Hopkins University
Thomas A. LaVeist

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Meharry Medical College
1005 Dr. D. B. Todd, Jr. Blvd.
Nashville, TN 37208

John Hopkins University
615 N. Wolfe Street
Baltimore, MD 21205

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14. ABSTRACT

This project seeks to add to research knowledge that impacts racial disparities in prostate cancer by examining how prostate cancer experience of fathers influence the prostate health preventive patterns of their adult sons. The study will combine qualitative and quantitative research techniques to assess the knowledge, attitudes, preventive health practices, and prostate cancer related informed decision making of adult sons of prostate cancer survivors and how these factors relate to the diagnostic pathways, treatment experience, and quality of life of their fathers.
1. Investigate the effects of race, economic status, and psychosocial factors, on the quality of life of men diagnosed with prostate cancer. 2. Investigate psychosocial factors that influence help seeking behavior among men who are diagnosed with prostate cancer. 3. Examine the effects of informed decision making and knowledge on prostate cancer treatment decision making. Adult sons of prostate cancer survivors will complete a structure questionnaire to assess their prostate cancer health seeking behavior.

15. SUBJECT TERMS

Prostate cancer, Dietary risk factors, Lycopene, Genetic predisposition, African-Americans, Cancer research training, Quality of life, Community outreach, Recruiting study participants, Cell line inhibition, Animal studies, Prostate cancer screening.

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INTRODUCTION:

[Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.]

Research Question:

This project seeks to add to available research on racial disparities in prostate cancer by examining health patterns among sons of fathers with the disease. The study will combine qualitative and quantitative research techniques to: assess the knowledge, attitudes, and preventive practices of adult sons of men with prostate cancer and how these relate to the diagnostic pathways, treatment experiences, and quality of life of their fathers who participated in the study, Disparities in Prostate Cancer Treatment and Quality of Life, A.K.A. "The Fathers Study," which was conducted at Johns Hopkins University where Thomas LaVeist, Ph.D. served as principal investigator and Daniel L. Howard, Ph.D. was the subcontract PI. In doing so, the
"Sons Study" will examine the following hypotheses: (1) Among adult sons of prostate cancer patients, those who have more knowledge of prostate cancer risks and consequences will be more likely to regularly utilize prostate cancer screening. (2) Sons who report close relationships with their fathers will be more likely to regularly utilize prostate cancer screening. (3) Sons whose fathers report a high disease burden will be less likely to regularly utilize prostate cancer screening.

Rationale:

The burden associated with prostate cancer fall disproportionately on African American men. The prostate cancer incidence rate among African American (AA) men is 55% greater than that of Caucasian (CA) men and, according to the National Cancer Institute (NCI) state cancer profiles, the mortality rate is almost three times that of CA men (73.9 per 100,000 AA / 25.6 per 100,000 C). Genetic and dietary factors have been identified in explaining a portion of the excess burden experienced by AA men, yet we have been unable to identify risk factors that are both of substantial magnitude and amenable to preventive intervention. AA men are less likely to be enrolled in clinical trials and there are indications that supportive services may not be as readily available to them. While AAs have a substantially worse profile with regard to prostate cancer, differential use of preventive health behaviors such as prostate cancer screening may attenuate the racial disparities in prostate cancer outcomes, yet, research examining the factors associated with such behaviors is underdeveloped. Family history is one of few predictors of elevated prostate cancer risk. Accordingly, the proposed study will focus on the sons of men with prostate cancer, and will examine the roles of informed decision-making, knowledge on utilization of prostate cancer screening procedures, individual socioeconomic characteristics, characteristics of the father-son relationship, and characteristics of the father's prostate cancer experience as they may be associated with sons' consequent use of prostate cancer preventive/early detection behaviors.

The study will combine qualitative and quantitative research techniques to assess the knowledge, attitudes, and preventive practices of adult sons ("sons") of men with prostate cancer ("fathers"). It will be conducted in parallel with an examination of men with prostate cancer ("The Fathers Study"), the goals of which are (1) to investigate the effects of race, economic status, and psycho-social factors on the quality of life of men diagnosed with prostate cancer; (2) to investigate psycho-social factors that influence help seeking behavior among men who were diagnosed with prostate

cancer; and (3) to examine the effects of informed decision-making and knowledge on prostate cancer treatment decisions-making. Correspondingly, the participants in this study ("The Sons Study") will be the adult sons of men with prostate cancer. Equal numbers of African American and white males with prostate cancer will be identified for The Fathers Study. These men, in turn, will be asked to identify their sons, who will be contacted for participation in this, The Sons Study. The study consists of a telephone interview.

For the parent study ("The Father's Study"), Dr. Thomas LaVeist is the principal investigator and Dr. Daniel L. Howard is the subcontract PI, while Dr. Daniel L. Howard is the PI and Dr. Thomas LaVeist is the subcontract PI for the companion study ("The Sons Study). Dr. Howard was formerly at the Institute for Health, Social, and Community Research (IHSCR) Center for Survey Research (CSR) at Shaw University in Raleigh, NC. Because there was a two-year delay in getting the grant transferred from Shaw University to Meharry, Johns Hopkins took over the administration of the Sons Study in an effort to keep datasets from both The Fathers Study and The Sons Study together. Dr. Daniel Howard has recently resigned from Meharry Medical College and is no longer the PI of The Sons Study. Dr. Flora Ukoli has agreed to replace Dr. Howard as PI on this project. Dr. Ukoli is an established investigator, a prostate cancer epidemiologist with over twenty years of experience in the field of cancer prevention. She has served as principal investigator on numerous DOD and NIH prostate cancer and cancer prevention studies. Dr. Ukoli has numerous publications in the prostate field. Her appointment as PI will enhance the project, and ensure the project goals and objectives are met. As with The Fathers Study, the Sons survey will be conducted at CSR which is now located at Johns Hopkins Bloomberg School of Public Health (JHBSPH) located in Raleigh, NC. The Sons Study dataset used for analyses will be housed at the JHBSPH located at 624 N. Broadway, Hampton House Suite 441, Baltimore, MD site under the supervision of Dr. LaVeist, which is also the location of the parent study dataset.

The purpose of the study is to identify factors that influence prostate cancer prevention/early detection behaviors among sons of men with prostate cancer. We will prospectively recruit 315 white and 315 African American sons of men who enter the North Carolina Central Cancer Registry (NCCCR) by obtaining contact information for the sons from the fathers that participate in the Fathers Study. To date, we have been able to recruit 891 fathers to participate in the Fathers Study; therefore, the 630 sons will be recruited from this pool.

We will employ appropriate statistical procedures to analyze data obtained from survey responses and address the study's major hypotheses. Descriptive statistics including means and percentages will be examined. Regular use of prostate cancer screening will be assessed using logistic regression and generalized estimating equations to assess trends over time. Model selection procedures will be employed to determine optimal set of predictors for our outcome. All tests will be two-sided with and significance will be determined by a p-value less than 0.05. All analyses will be conducted using SAS version 9.1 (SAS Institute, Cary, NC).

BODY:

*[This section of the report shall describe the research accomplishments associated with each task outlined in the **approved** Statement Of Work. Data presentation shall be comprehensive in providing a complete record of the research findings for the period of the report. Appended publications and/or presentations **may** be substituted for detailed descriptions but **must** be referenced in the body of the report. If applicable, for each task outlined in the Statement of Work, reference appended publications and/or presentations for details of result findings and tables and/or figures. The report shall include negative as well as positive findings. Include problems in accomplishing any of the tasks. Statistical tests of significance shall be applied to all data whenever possible. Figures and graphs referenced in the text may be embedded in the text or appended. Figures and graphs can also be referenced in the text and appended to a publication. Recommended changes or future work to better address the research topic may also be included, although changes to the original Statement of Work **must** be approved by the Grants Officer. This approval must be obtained prior to initiating any change to the original Statement of Work.]*

Statement of Work:

Task 1: **Start-Up Phase and Plan Development** **(Month 1 – 4)**

Complete a sub-contract with Johns Hopkins University.

Secure IRB approval at Meharry Medical College and at Johns Hopkins University.

Interview, hire and train student research interviewers (Ms. Carol Burt) to recruit, consent, and conduct the study interviews.

Deliverables: Sub-Contract to JHU
IRB Approvals from both institutions
Trained interviewers.

Task 2: **Data Collection** **(Month 5 – 18)**

Recruiting and interviewing study participants.
-After low recruitment success in year 1, Ms. Burt had to contact 'The Fathers' from the first study to update contact information of their sons.
-Ms. Burt also utilized free 'people search' websites and public record websites to locate participants by cross-referencing the information she had for the potential participants (the sons) and their fathers with some success.
-Ms. Burt also mailed study invitation letters addressed to 'the sons' to their father's address on file. This was the strategy to contact sons for whom she had no address or phone number. It was hoped that the father will notify the son to contact the study.

Complete data entry of all interview information collected. (Ms. Carol Burt).
-Information for all study participants interviewed was entered into the database.

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Deliverables: Recruitment brochure
Complete data collection program, 240 participants.
Complete data file of study participants.

Task 3: **Report and Presentation of Program Outcome** **(Month 9 – 24)**

Data analysis, result interpretations, and manuscript development.

Deliverables:
Annual Reports & Annual DOD Report
Poster & Manuscript

KEY RESEARCH ACCOMPLISHMENTS:
[Bulleted list of key research accomplishments emanating from this research.]

The program was able to meet most of its research goals in the second year. The first year was a challenge because of the sudden departure of the original PI, Daniel Howard, Ph.D., and the long time that its took for the new P, Flora A. Ukoli, M.D., MPH., to be appointed by the the Department of Defense following the recommendations of the Director of Research at Meharry, Mr. G. Ballard. The following processes were completed:

1 Dr. Ukoli met with the PI from JHU, T. LaVeist, Ph.D., they agreed on a working plan, and they went ahead to start recruiting study participants.
2 This became possible after they secured a Non-Cost extension approval from DOD.
3 Dr. Ukoli obtained IRB approval at Meharry.
4 Dr. LaVeist secured definitive IRB approval at JHU.
5 Working budgets were developed and sub-contract with JHU was signed by both parties.
6 Both PIs scheduled the 1st study site visit for August 13, 2014.
The PI (Ukoli, F) and Co-PI (LaVeist, P) visited the study coordinator, Ms. Carol Burt, and her student research interviewers at Shaw University.

REPORTABLE OUTCOMES:
[Provide a list of reportable outcomes that have resulted from this research to include:]

Non-Cost Extension request letter
IRB approval: MMC
IRB approval: JHU
Revised study brochure

Trained study interviewers	3
Participants enrolled:	77
Interviews completed:	24

CHALLENGES:

1) The administrative process to establish a sub-contract with JHU was protracted such that JHU delayed signing the sub-contract until May 30, 2014. This led to a delay in project initiation by the coordinator (C. Burt). Research interviewers were trained and they started data collection in July.

2) The PI (LaVeist) has obtained IRB approval to contact the participants in his previous research project to obtain the most current contact information of their sons. We should be able to reach more potential participants and improve the number of participants recruited into the study within the next 6 months.

3) Over 50% of the contact information of potential participants was no longer valid. This may be due to the lapse in years since the contact information was collected from their fathers in a previous study (PI: LaVeist). In the second year participants in the first study were contacted again by Ms. Burt to update the contact information of their sons where possible.

a) Challenges with participants:

Some of the participants refused to participate for two main reasons:

i. Do not want to participate in research
ii. Do not want to talk about prostate cancer

Some of them requested that their names be removed from the call list.

b) Challenges with fathers of participants:

i. Phone numbers were invalid, disconnected, wrong numbers, no answers, hang ups and redirected to voice mail
ii. Some fathers were able to provide only little or no information for the sons.
iii. Some fathers promised to ask their son to call the study if they were interested.
iv. Some contacts information they gave were incorrect.

CONCLUSIONS:

[Summarize the results to include the Importance and/or implications of the completed research and when necessary, recommend changes on future work to better address the problem. A "so what section" which evaluates the knowledge as a scientific or medical product shall also be included in the conclusion of the report.]

Participant recruitment and data collection has been completed. The study will no longer require funding from the Department of Defense to complete both data analysis and manuscript development.

REFERENCES: *[List all references pertinent to the report using a standard journal format (i.e. format used in Science, Military Medicine, etc.).]*

Prostate Cancer

Prostate cancer is the most common cancer and the second leading cause of cancer death among men.

Risk Factors

Family History

- If a man has one close relative with prostate cancer, his risk is twice as high as the general population to develop this condition.
- If he has two close relatives, his risk increases by five-fold.
- If he has three or more, it is increased by eleven-fold.

Race

- African-American men have the highest prostate cancer incidence in the world.
- African-American men are 2.4 times more likely to die from prostate cancer than Caucasian men.

Increasing Age

For all men the risk of prostate cancer increases with age, especially after age 50. However, prostate cancer may occur earlier and be more aggressive among African-American men.

Other possible risk factors include obesity, lifestyle and environmental exposure.

JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH

Robert Wood Johnson Foundation | Center for Health Policy at Meharry Medical College

Hopkins Center for Health Disparities Solutions

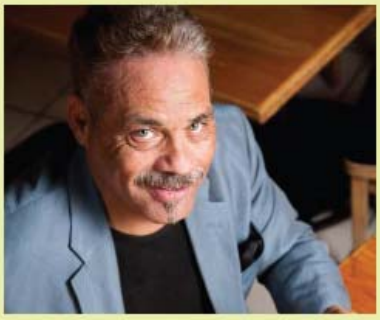
MEHARRY MEDICAL COLLEGE

1005 Dr. D.B. Todd Jr. Blvd.
Nashville, TN 37208
Phone: 615-327-5503
Fax: 615-327-6331
Email: meharryhealthpolicy@mmc.edu

The Meharry-Johns Hopkins Center for Prostate Cancer Research

Screening, Prevention Behavior & Risk Perception Among Adult Men

A multi-generational study



About the Study

The RWJF Center for Health Policy at Meharry Medical College, the Hopkins Center for Health Disparities Solutions and the Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins University have teamed up to form the Meharry-Johns Hopkins Center for Prostate Cancer Research.

We want to better understand how personal experience and risk perception impact lifestyle choices and screening behaviors of adult men. We believe that, by working together, we can find ways to reduce the impact of prostate cancer in men and their families for current and future generations.

This study is not a clinical trial. It is a survey asking for men's responses to questions. We will not ask participants to take medicine or drugs, give blood or other such medical specimens and, we will not give any kind of medical treatment.

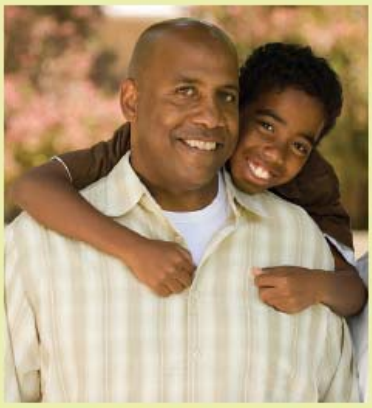
Study Participants

The Meharry-Johns Hopkins Center for Prostate Cancer Research is working with the North Carolina Central Cancer Registry to identify men who might be willing and able to participate in this study. All of their personal information will be kept confidential and secure.

We want to better understand how personal experience and risk perception impact lifestyle choices and screening behaviors of adult men.

- Participants include men over the age of 34 who have not been diagnosed with prostate cancer.
- Each participant will receive a call from a trained interviewer who will ask questions about his health, health care, diet, beliefs and interpersonal communication with friends and relatives about prostate cancer.

By working together, we can find new and better ways to minimize the impact of prostate cancer on future generations and improve the lives of men.



This research is supported by the United States Department of Defense Prostate Cancer Research Program Grant# PC060224 (Contract# W81XWH-07-1-0350) and Grant# PC060396 (Contract# W81XWH-07-1-0452).

Visit www.meharryhealthpolicy.org for more information.

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Demographic Characteristics of 24 Participants Who Completed Interviews

Race	*Freq.*	*Percent*
White	*18*	*75.00*
Black	*6*	*25.00*
Total	*24*	*100.00*

Age	*Freq.*	*Percent*
37	*1*	*4.17*
39	*1*	*4.17*
41	*3*	*12.50*
42	*5*	*20.83*
43	*1*	*4.17*
44	*1*	*4.17*
45	*5*	*20.83*
48	*2*	*8.33*
50	*1*	*4.17*
51	*1*	*4.17*
54	*1*	*4.17*
55	*2*	*8.33*
Total	*24*	*100.00*

Annual income	*Freq.*	*Percent*
< $25,000	*1*	*4.17*
$50,000-$75,000	*3*	*12.50*
$75,000-$100,000	*5*	*20.83*
>$100,000	*8*	*33.33*
Refused	*7*	*29.17*
Total	*24*	*100.00*