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Meharry-Johns Hopkins Center for Prostate Cancer Research

PRINCIPAL INVESTIGATOR:

Flora A. M. Ukoli

CONTRACTING ORGANIZATION:

Meharry Medical College
Nashville, TN 37208

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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-
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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 – 8)**

Recruiting and interviewing study participants.

Complete data entry of all interview information collected. (Ms. Carol Burt).

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

Task 3: **Report and Presentation of Program Outcome** **(Month 9 – 12)**

Data analysis, result interpretations, and manuscript development.

Deliverables: Poster & Manuscript and Annual Reports & Annual DOD Report

10/08/2013

Status Report
Meharry-Johns Hopkins Center for Prostate Cancer Research

12/21/2011: DoD transfers the prostate center grant to Meharry from Shaw University. The amount of the award by the U.S. Army Medical Research Acquisition Activity to Meharry was $136,533.50. The period of performance was 01/01/2012 – 08/31/2012 (Research ends 07/31/2012) The transfer award notice also indicates that Research under this award involving the use of human subjects, to include the use of human anatomical substances or identifiable private information, shall not begin until the USAMRMC's Office of Research Protections (ORP) provides authorization that the research may proceed. Written approval to begin research will be issued from the USAMRMC ORP, under separate notification to the recipient. Written approval from the USAMRMC ORP is also required for any subrecipient that will use funds from this award to conduct research involving human subjects.

Research involving human subjects shall be conducted in accordance with the protocol submitted to and approved by the USAMRMC ORP. Complete study records shall be maintained for each human research study and shall be made available for review by representatives of the USAMRMC. Research records shall be stored in a confidential manner so as to protect the confidentiality of subject information

02/21/2012: Meharry issues a subcontract to Johns Hopkins that is fully executed on 02/21/2012 for the performance period of 01/01/2012-12/31/2012.

04/05/2012: The project receives IRB approval from Meharry's IRB but has not received IRB approval from Johns Hopkins.

07/17/2012: Maria A. Drayton from the DoD Human Research Protection Office writes to Jarrod Lockhart to say "Since the Hopkins site is engaged in the research, we will need a copy of their IRB approval letter and initial submission form and if applicable consent that is used."

08/21/2012: Dr. Daniel Howard wrote Peggy Lesnow, DoD Grants Manager, to request a one year no cost extension of the project for 08/31/2012- 07/31/2013. Dr. Howard also indicated in his letter to Ms. Lesnow receipt of IRB approval from Meharry but no IRB approval from Johns Hopkins. Dr. Howard was instructed by the DoD through Maria Drayton the expectation of receiving approval from Johns Hopkins's IRB.

08/31/2012: DoD grants approval of Meharry's no cost extension request for the period of 08/31/2012-07/31/2013.

10/10/2012: Dr. Howard emails Dr. Thomas LaVeist to ask him about Johns Hopkins approval of the Son's study. Dr. LaVeist replies the same day; "It is in the process. Unfortunately it has to be reviewed first by the cancer center. That process will begin tomorrow. After the cancer center it goes to the IRB."

01/31/ 2013: Dr. Daniel Howard resigned from Meharry and PI of the Meharry Johns Hopkins Prostate study.

02/12/2013: Before Dr. Howard left he approved the payment to a consultant at Johns Hopkins for $5,520 for WIN/CATI Computer Program work that was not linked to human subjects use. Meharry paid the consultant on 02/12/2013.

04/03/2013: Dr. LaVeist received notice from Johns Hopkins' IRB bestowing approval on the planning phase of the Son's study.

06/21/2013: Drs. F. Ukoli, T. LaVeist, J. Lockhart, and G. Ballard met in the President's Conference Office at Meharry. The parties agreed to request a second no cost extension along with appointing Dr. Ukoli the PI and setting the period of performance to start in April 2013 to coincide with receipt of the initial IRB approval from Johns Hopkins for planning the Son's project.

07/03/2013: Meharry; Drs. L. Dent, R. Poland, and Mr. G. Ballard write to Ms. Peggy Lesnow and Dr. Theresa Miller requesting approval to appoint Dr. Flora Ukoli as PI of the study along with a no cost extension for the 04/91/13-03/31/2014 project period.

09/26/2013: G. Ballard received an email from Peggy Lesnow requesting.

1. Salary verifications on each personnel on both the prime and subawards;
2. Biosketch on Dr. LaVeist;
3. Negotiated Rate Agreement for both institutions to include the fringe benefit rates;
4. A revised Request for No-Cost Extension with the requested dates 1 SEP 2013-31 AUG 2014 (one year).
5. The SF425 showing the unobligated balance of $130,571.

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

This program did not meet any of its research goals because of the sudden departure of the original PI, Daniel Howard, Ph.D. However, before he left the sub-contract with JHU was established.

IRB at Meharry was obtained and so was IRB approval at JHU to begin developing the study protocol.

The program research administrator, Mr. Jarod Lockhart, prepared IRB continuing review and worked with Dr. Flora Ukoli (the new PI) and Mr. G. Ballard, Director of Grants Management, to prepare a Status Report as shown below. Mr. Lockhart has since left Meharry Medical College.

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

Developed a computer program for data collection and storage. (Consultant)

CHALLENGES:

Resignation of Key personnel

The resignation of Daniel Howard (PI) from Meharry Medical College was a major setback for this study. This has been overcome by the appointment of a new PI, Flora A. M. Ukoli, MD, MPH

Report Preparation

A status report was submitted by Mr. J. Lockhart. ters and final reports.

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.]

It is highly encouraging that the Department of Defense approved a non-cost extension and allowed the study to continue in view of the administrative challenges.

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

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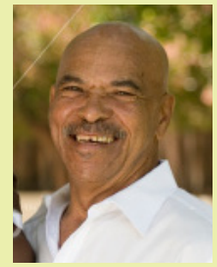
The
Meharry-Johns Hopkins Center
for
Prostate Cancer Research

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.