

AWARD NUMBER: W81XWH-16-1-0782

TITLE: Influence of Prostate Cancer Treatment on Work Experiences with Focus on Race and Income

PRINCIPAL INVESTIGATOR: Joanne C. Sandberg, Ph.D.

CONTRACTING ORGANIZATION: Wake Forest University Health Sciences
Winston-Salem, NC

REPORT DATE: October 2020

TYPE OF REPORT: Annual Report

PREPARED FOR: U.S. Army Medical Research and Development Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;
Distribution Unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports (0704-0188), 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. **PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ADDRESS.**

1. REPORT DATE October 2020			2. REPORT TYPE Annual		3. DATES COVERED 30Sep2019-29Sep2020	
4. TITLE AND SUBTITLE Influence of Prostate Cancer Treatment on Work Experiences with Focus on Race and Income					5a. CONTRACT NUMBER W81XWH-16-1-0782	
					5b. GRANT NUMBER 0010831602-0001	
					5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) Joanne C. Sandberg Department of Family and Community Medicine E-Mail: jsandber@wakehealth.edu					5d. PROJECT NUMBER	
					5e. TASK NUMBER	
					5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Wake Forest University Health Sciences Medical Center Blvd. Winston-Salem, NC 27157-0001 Attn: Sara Stanley,					8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Development Command Fort Detrick, Maryland 21702-5012					10. SPONSOR/MONITOR'S ACRONYM(S)	
					11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited						
13. SUPPLEMENTARY NOTES						
14. ABSTRACT The objective of this study is to determine how a prostate cancer diagnosis, its treatment, and side-effects from treatment influence African American survivors' work ability and experiences. More specifically, the study will examine factors that influence desired and actual length of sick leave; work-related challenges following treatment; and changes in work ability and status following treatment, and compare how African American and white prostate cancer survivors experiences are similar or different. Questionnaire data and transcripts of in-depth interviews will be analyzed.						
15. SUBJECT TERMS African-American men, prostate cancer, urinary issues, men's health						
16. SECURITY CLASSIFICATION OF:				17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE	19b. TELEPHONE NUMBER (include area code)			
Unclassified	Unclassified	Unclassified	Unclassified	10	USAMRMC	

TABLE OF CONTENTS

	<u>Page</u>
1. Introduction	4
2. Keywords	4
3. Accomplishments	4
4. Impact	6
5. Changes/Problems	6
6. Products	7
7. Participants & Other Collaborating Organizations	8

INTRODUCTION:

The objective of this study is to determine *how* a prostate cancer diagnosis, its treatment, and side-effects from treatment influence African American survivors' work ability and experiences. More specifically, the study will examine factors that influence desired and actual length of sick leave; work-related challenges following treatment; and changes in work ability and status following treatment. The sample is stratified by race (African American and white) and income (low and moderate to high). Two-hundred and twenty men who were working prior to primary treatment for prostate cancer will be administered structured questionnaires prior to primary treatment initiation, and 3 and 6 months following primary treatment completion, with the expectation that 160 of these men will be retained through completion of the 6-month interview. A separate sample of 60 prostate cancer survivors, also stratified by race and income will complete one in-depth interview. Quantitative and qualitative analyses will be conducted to achieve project goals.

• KEYWORDS:

Prostate cancer; cancer survivorship; African American; men; men's health; employment; race; work ability; sick leave; medical leave; cancer treatment.

• ACCOMPLISHMENTS:

QUANTITATIVE PROJECT

• What were the major goals of the project?

During the Project Year 4 (first no cost extension) we moved toward our goal of recruiting 220 participants, administering a set of three interviews, and pulling data from their charts for protocol, WF_1802. As of September 29, 2020, 53 participants had completed the 6-month-post treatment questionnaire, 24 had completed the 3-month post-treatment questionnaire but not yet completed the 6-month questionnaire, and 10 participants had completed the baseline questionnaire only. National Cancer Institute Community Oncology Research Program (NCORP) sites are continuing to recruit and enroll participants.

Specific Aim 1b: Delineate and compare the factors identified by African American and white prostate cancer survivors that influence (a) desired and actual length of sick leave and (b) work status (e.g., full-time, part-time, unemployed) following treatment for prostate cancer. (Quantitative)

Major Task 1: Collect Quantitative Data

Major Task 2: Analyze Quantitative Data that Addresses Preferred & Actual Length of Sick Leave & Work Status

Specific Aim 3: Describe and compare changes in work ability by African American and white prostate cancer survivors before treatment, and at 3 and 6 months after treatment, including the effects of (a) prostate cancer treatment-related function, (b) work environment, and (c) type of treatment, accounting for individual factors such as age, race, education, income. (Quantitative)

Major Task 1: Analyze quantitative data that address revised Specific Aim 3.

- **What was accomplished under these goals?**

Data collection continued. During the year we advanced from having only 9 participants enrolled to having 53 participants had completed the 6-month-post treatment questionnaire, 24 had completed the 3-month post-treatment questionnaire but not yet completed the 6-month questionnaire, and 10 participants had completed the baseline questionnaire only. Our goal is to have 160 participants complete the 6-month questionnaire. We are approximately 1/3 of the way there.

The analyses will completed when data collection is complete. However, we have been addressing basic data cleaning issues throughout the process.

QUANTITATIVE PROJECT

- **What were the major goals of the project?**

Specific Aim 1a: Delineate and compare the factors identified by African American and white prostate cancer survivors that influence (a) desired and actual length of sick leave and (b) work status (e.g., full-time, part-time, unemployed) following treatment for prostate cancer. (Qualitative)

Major Task 1: Collect Data

Major Task 2: Conduct Qualitative Analyses that Address Preferred & Actual Length of Sick Leave & Work Status

Specific Aim 2a: Delineate and compare the work-related challenges experienced by African American and white prostate cancer survivors at different periods following completion of treatment, and formal and informal accommodations initiated by survivors, supervisors, or coworkers to address these challenges. (Qualitative only)

Major Task 1: Analyze transcripts as they relates to Specific Aim 2.

- **What was accomplished under these goals?**

An amendment was approved by the Wake Forest University IRB and HRPO that enabled us to expand our recruitment to South Carolina and expand recruitment options in North Carolina. A subcontract with the University of South Carolina enabled Dr. Otis Shaun Owens to recruit, consent, and interview participants in South Carolina. Twenty-one participants were enrolled and interviewed during Project Year 4, for a total of 22 participants. We still have 38 participants left to recruit, consent and interview. (An additional 9 participants have already been consented and interviewed in the first month of Project Year 5, i.e., the 2nd no cost extension). All of the 22 interviews have been transcribed and codes (tags that represent a concept or theme) have been attached to the each transcript as part of the process of analyzing the data. We anticipate having data collection completed in the first 6 months of Project Year 5. Interviews will continue to be transcribed shortly after interview completion and subsequently coded. We expect to submit one or more manuscript for publication by the end of Project Year 5 that address the Specific Aims.

-

- **What opportunities for training and professional development has the project provided?**

Nothing to Report

- **How were the results disseminated to communities of interest?**

Nothing to Report

- **What do you plan to do during the next reporting period to accomplish the goals?**

Quantitative Project:

We will continue to recruit participants and collect data with the assistance of the Wake Forest (WF) NCORP Research Base (RB), and NCORP sites across the country. We will present the protocol at the WF NCORP RB Annual Meeting in October to further advertise the study to NCORP sites and address any questions or concerns they might have. We will continue to have regularly meetings both with the WF NCORP RB team to oversee progress and address relevant issues and quarterly meetings designed for NCORP sites across the country to address questions and encourage participation.

Qualitative Project: *Influence of Prostate Cancer on Work Experience with Focus on Race and Income: A Qualitative Study.*

We will continue to recruit and conduct semi-structured in-depth interview with participants to achieve a sample size of 60. Recruitment will continue in NC and SC. We will continue to systematically analyze the transcripts, and prepare manuscripts to submit to one or more academic journals. As mentioned above, our rate of enrollment has increased at the end of Project Year 4. Furthermore, less than a full month into Project Year 5 we have already consented and interviewed 9 additional participants. This timeline is therefore feasible.

- **IMPACT:**

- **What was the impact on the development of the principal discipline(s) of the project?**

Nothing to report.

- **What was the impact on other disciplines?**

Nothing to report.

- **What was the impact on technology transfer?**

Nothing to Report

- **What was the impact on society beyond science and technology?**

Nothing to Report

- **CHANGES/PROBLEMS:**

- **Changes in approach and reasons for change**

- Nothing to report

- **Actual or anticipated problems or delays and actions or plans to resolve them**

- Recruitment for the quantitative projects slowed down substantially during March and subsequent months due to COVID-19 as medical centers and practices reduced non-emergency procedures as the COVID-19 epidemic, and then adjusted their processes and procedures to address the epidemic. At many NCORP sites energy was diverted from this project to optimize the care of patients in clinical trials.

Quantitative Project:

- Near the end of October 2020 the WF NCORP RB is holding its Annual Meeting which is attended by physicians and research staff from sites across the country. As part of that meeting, Dr. Sandberg will give a short presentation to provide updates about our study, encourage staff to continue to recruit participants for this study, and answer any questions they might have. In addition, the WF NCORP RB continues to hold quarterly webinars with sites to provide updates about this study, share strategies that different sites have used to recruit participants, and encourage sites to continue to recruit participants.
- The co-PI of the WF NCORP RB is committed to completing data collection, data cleaning, and data analysis even if we are unable to complete recruitment and data collection during Project Year 5.

Qualitative Project: *Influence of Prostate Cancer on Work Experience with Focus on Race and Income: A Qualitative Study.*

Recruitment for this study has increased substantially after several amendments that were designed to facilitate recruitment were approved by the WFUHS Institutional IRB and HRPO. (At least 8 additional interviews will be completed during the first month of the 5th project year.) We therefore do not anticipate problems during Year 5.

- **Changes that had a significant impact on expenditures**

- With the approval of the Grants Officer, an amended budget was approved to include the cost of a subcontract awarded to the University of South Carolina for Project Year 4.

- **Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents**

- **Significant changes in use or care of human subjects**

No significant changes in the use or care of human subject occurred, although the protocol was modified with approval from WFUHS IRB and HRPO regarding recruitment and consent processes.

- **Significant changes in use or care of vertebrate animals.** Not applicable

- **Significant changes in use of biohazards and/or select agents.** Not applicable.

- **PRODUCTS:**

- **Publications, conference papers, and presentations**

- **Journal publications.** Nothing to report.

- **Books or other non-periodical, one-time publications.** Nothing to report.
- **Other publications, conference papers, and presentations.** Nothing to report.
- **Website(s) or other Internet site(s)** Nothing to report.
- **Technologies or techniques.** Nothing to report.
- **Inventions, patent applications, and/or licenses.** Nothing to report.
- **Other Products** Nothing to report.

● **PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS**

● **What individuals have worked on the project?**

Name: Joanne C. Sandberg
Project Role: Principal Investigator
ORCID ID: 0000-0001-6056-6186
Nearest person month worked: 1.8 calendar months
Contribution to Project: No change.

Name: Emily Van Meter Dressler – No change
Project Role: Co-Investigator
ORCID ID: 0000-0002-6054-7839
Nearest person month worked: 0.6 calendar months
Contribution to Project: No change.

Name: Andrew Mayfield
Project Role: Project Manager
Nearest person month worked: 4.8 calendar months
Contribution to Project: No change.

Name: Guadalupe Hernandez
Project Role: Assistant Project Manager
Nearest person month worked: 5.0 calendar months
Contribution to Project: Ms. Hernandez checked transcripts against audio recording, coded transcripts for the qualitative project, engaged in recruitment activities, and assisted with literature review.
Funding support Her effort was funded by this grant.

Name: Tammy Vogler
Project Role: WF NCORP RB Clinical Studies RN
Nearest person month worked: 1.0 calendar month
Contribution to Project: Ms. Vogler has performed work in the area of site coordinator, site activation activities, training, and issues raised at individual sites for quantitative study.
Funding support Wake Forest NCORP Research Base which is funded by the National Cancer Institute National Cancer Institute

Name: Eden Gurganus – No change
Project Role: NCORP Assistant Project Manager
Nearest person month worked: 1.0 calendar months
Contribution to Project: No change

Name: Otis Shaun Owens
Project Role: PI of subcontract – University of South Carolina
ORCID ID: 0000-0002-1023-1449
Nearest person month worked: 2 calendar months

Contribution to Project:

Dr. Owens has overseen recruitment and data collection efforts in South Carolina; he has conducted research interviews and assisted in the qualitative coding of interviews.

- **Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?**

Dr. Emily Dressler's active other support has changed since the last Annual Report. She is currently at 1.20 calendar months for NCI P50 CA244693, *IDAPT: Implementation and Informatics-Developing Adaptable Processes and Technologies for Cancer Control – Research Program*, 0.60 calendar months for NCI UG1 CA189824S1, *Internet-delivered Management of Pain Among Cancer Survivors (IMPACTS)*, 4.86 calendar months for NCI UG1 CA189824, *Wake Forest NCORP Research Base*, 0.12 calendar months for NHLBI U24 HL141732, *2/2 PROMote weight loss in obese PAD patients to preVEnt mobility loss: The PROVE Trial—DCC*, and 0.30 calendar months for NCI ATLAS: *Alleviating Lung Cancer disparities Through Cancer Control*. She continues to contribute 1.14 calendar months for NCI R01 CA226078, *Assessing Efficacy and Implementation of an EHR tool to Assess Heart Health among Survivors*, and 1.20 calendar months for NCI R01 CA207158, *Implementation of Smoking Cessation Services within NCI NCORP Community Sites with Organized Lung Cancer*.

Dr. Sandberg effort's on *An Informal STEM Learning Model: Genetics, Genomics, and Adult Bilingual Learners* changed to 2.4 calendar months per year. Her funding remains at 1.7 calendar months per year for the project, *The Effect of Pesticide Exposure on Cognitive and Brain Development in Latino Children: PACE5*. Her effort on *Hired Youth Farmworkers: Work Organization, Safety, Hazards, and Health* was 1.0 months per calendar year. She continues to contribute 0.8 calendar months effort on a new project, *A Direct-to-Patient Alert for Glycated Hemoglobin Screening Using Prediction Modeling and Mobile Health (mHealth)*. She has neither added nor ended participation on any grants she had been on in Project Year 3.

Dr. Otis Shaun Owens at the University of South Carolina was not involved in the study during Project Year 3. His support for the grant "Advancing Quality Lung Cancer Survivorship in South Carolina 2.0 has ended.

- **What other organizations were involved as partners?**

- **Quantitative Project**

- **Organization Name:** Wake Forest National Cancer Institute Community Oncology Program Research Base (WF NCORP RB). The WF NCORP RB
- **Location of Organization:** Winston-Salem, NC
- **Partner's contribution to the project** (*identify one or more*)
 - **Collaboration** Multiple team members from the WF NCORP RB are assisting with the project so that staff at NCORP sites across the country can enroll and consent participants and collect data.

Qualitative Project: *Influence of Prostate Cancer on Work Experience with Focus on Race and Income: A Qualitative Study.*

- **Organization Name:** University of South Carolina.

- **Location of Organization:** Columbia, SC
- **Collaboration.** WFUHS subcontracted with the University of South Carolina to have Dr. Otis Shaun Owens recruit, consent, enroll and interview participants as well as contribute to the analysis of qualitative data.
- **Organization Name:** Gibbs Cancer Center & Research Institute
 - **Location of Organization:** Greer, SC
 - **Collaboration.** Research staff conducted initial screening to identify patients who might be potentially eligible to participate in this qualitative research study. With patient approval, contact information for potentially eligible participant was provided to Dr. Otis Shaun Owens.

Quantitative and Qualitative Projects

- **Organization Name:** Tulane University
 - **Location of Organization:** New Orleans, LA
 - **Collaboration.** Dr. Krane, M.D. is a co-investigator on both the qualitative and quantitative project. He is an Assistant Professor of Urology at Tulane University. He provides expertise in prostate cancer treatment, particularly in respect to prostatectomies.