AWARD NUMBER: W81XWH-21-1-0098

TITLE: Addressing Health Literacy with a Tailored Survivorship Care Plan to Improve Access in Underserved African American Prostate Cancer Patients

PRINCIPAL INVESTIGATOR: Kerry Kilbridge, MD, MSc

CONTRACTING ORGANIZATION: Dana-Farber Cancer Institute

REPORT DATE: May 2023

TYPE OF REPORT: Annual Technical Report

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

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE	2. REPORT TYPE	3. DATES COVERED
May 2023	Annual Technical Report	15APR2022 - 14APR2023

4. TITLE AND SUBTITLE

Addressing Health Literacy with a Tailored Survivorship Care Plan to Improve Access in Underserved African American Prostate Cancer Patients

5a. CONTRACT NUMBER
W81XWH-21-1-0098

5b. GRANT NUMBER
PC200248

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)

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5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

Dana-Farber Cancer Institute, Inc.
450 Brookline Avenue
Boston, MA 02115-5418

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

In our previous work, we have documented that health literacy barriers impact the ability of many underserved African American prostate cancer patients to understand cancer treatment and its side effects. To address these barriers, the research team designed a scripted, low literacy educational supplement that demonstrated a statistically significant improvement in understanding of prostate cancer treatment side effects, and a statistically significant decrease in decisional conflict compared to usual care. Our project is a randomized comparative effectiveness study that is a direct extension of these findings. Our study randomizes 150 African American prostate cancer patients, in a 1:1 ratio, to a standard survivorship care plan (SCP) based on the American Society of Clinical Oncology (ASCO) template versus a tailored SCP combined with the low literacy educational supplement. The team has encountered multiple Covid-related delays in the project period including the co-principal investigators ongoing serious medical illness. The research team has been working on the first major milestone, multi-institutional IRB/HRPO approvals with the goal of completing major milestones 1-4 and initial data collection in the next annual reporting period.

15. SUBJECT TERMS

Health disparities, health literacy, survivorship, African American prostate cancer patients, survivorship care plan, access

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRDC
U	U	U	UU	13	19b. TELEPHONE NUMBER *(include area code)*

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1. INTRODUCTION:

In our previous work, we have documented that health literacy barriers that impact the ability of many underserved African American prostate cancer patients to understand cancer treatment and its side effects. To address these barriers, the research team designed a scripted, low literacy educational supplement that demonstrated a statistically significant improvement in understanding of prostate cancer treatment side effects, and a statistically significant decrease in decisional conflict compared to usual care. Our project is a randomized comparative effectiveness study that is a direct extension of these findings. Our study randomizes 150 African American prostate cancer patients, in a 1:1 ratio, to a standard survivorship care plan (SCP) based on the American Society of Clinical Oncology (ASCO) template versus a tailored SCP combined with the low literacy educational supplement. We compare 1) understanding of survivorship care and recommendations, 2) understanding of treatment side effects and their prevalence, 3) decisional conflict, 4) decision regret 5) access to survivorship care. Results will be immediately applicable for early-stage African American prostate cancer survivors with low literacy skills. Improving understanding of treatment side effects and cancer surveillance directly addresses the PCRP Overarching Challenge of "improving quality of life for survivors of prostate cancer".

2. KEYWORDS:

Health disparities, health literacy, survivorship, African American prostate cancer patients, survivorship care plan, access

3. ACCOMPLISHMENTS:

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

The major goals of the project as stated in the approved SOW during the most recent year of the project are listed in the chart below (Target completion dates were updated in the most recent Semi-annual Technical Report filed November 2022). Target completion date and completion or percent completion are shown in columns 2 and 3.

	Target Completion Date	Completion Date or % Completion
Milestone 1 – IRB & HRPO approvals Emory, DFCI, HRPO	Months 18-27	10% complete
• Subtask 1– subcontract between DFCI & Emory executed	Month 12	May 2022 (Month 12)
• Subtasks 2 to 6 – prepare regulatory documents and obtain IRB approvals	Months 18-26	8% complete
Milestone 2 – access database operational	Months 22-26	0% complete
Milestone 3 – research staff trained	Months 24-27	0% complete
Milestone 4 – initial accrual and data analysis	Months 28-30	0% complete

DFCI – Dana-Farber Cancer Institute
IRB – Institutional Review Board
HRPO – Human Research Protection Office

- **What was accomplished under these goals?**
  We are continuing to prepare the regulatory documents and the research protocols for Emory, Grady and Atlanta IRB approvals. The completion of Milestones 1-4 was not met. Additional delays were introduced due to the Co-Principal Investigator's ongoing serious illness.

- **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?**
  In the next reporting period (6m - from months 25-30 in the Quad Chart on page 8), we will:
  1. Initiate preparation of regulatory documents and research protocols for all 4 project sites.
  2. Obtain approval of consent forms and human subjects protocols at the Emory University IRB, Grady Memorial Hospital, and initiate review at the Atlanta VAMC. Grady and VAMC approvals are contingent on Emory IRB approval. The Dana-Farber Cancer Institute (DFCI) IRB approval of retrospective records review protocol (scheduled in months 31-32) is contingent on Emory, Grady and VAMC human subjects approvals
  3. If possible, we will initiate second level IRB review and approval by ORP/HRPO (scheduled months 31-33).
  4. Begin to program and possibly complete the Access database (scheduled months 28-32).

4. **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

5. **CHANGES/PROBLEMS:**

- **Changes in approach and reasons for change**
  Nothing to report - There have been no changes in objectives and scope of the project.

- **Actual or anticipated problems or delays and actions or plans to resolve them**
  We have encountered ongoing Covid-related delays since we submitted our semi-annual technical progress report. The principal investigator, Dr. Kilbridge, has continued to experience pandemic-related serious health issues. This has had a direct impact on expenditures and the

timeline. The project start has been delayed by nearly 24 months with significant delays in all subsequent milestones. Although we have initiated the project, we are in the early stages of activating our Emory personnel. Only Dr. Kilbridge's effort (less than projected due to illness) has been credited to the budget because other personnel are just beginning to onboard. We anticipate requesting at least a 24 month no cost extension. There are no changes to the project or its direction.

Over the last seven months Dr. Kilbridge has been able to incrementally increase her research activities. However, she is continuing to require intermittent medical leave to decrease her clinical activities and manage her research. To help address delays, Dr. Kilbridge and Dr. Master have been scheduling face-to-face site visits using institutional and discretionary funds in support of this important research investigation.

- **Changes that had a significant impact on expenditures**
  Due to the necessity of ongoing medical leave, Dr. Kilbridge's effort has been less than budgeted in the last reporting periods. There are no changes to the budget or budget justification. There is no change to the scope of work. We are offsetting the project timeline (SOW) by two years and anticipate requesting a no cost extension of two-three years. Because of this delay, no Emory University personnel have drawn on the budget.
- **Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents**
  Nothing to report
- **Significant changes in use or care of human subjects**
  Nothing to report
- **Significant changes in use or care of vertebrate animals**
  Nothing to report
- **Significant changes in use of biohazards and/or select agents**
  Nothing to report

6. **PRODUCTS:**
   - **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

7. **PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS**

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

Name:	*Kerry Kilbridge*
Project Role:	Co-Principal Investigator
Researcher Identifier (e.g. ORCID ID):	0000-0001-7460-6273
Nearest person month worked:	0 (0.18 Cal Months)
Contribution to Project:	*Dr. Kilbridge is coordinating the preparation of regulatory documents and IRB approvals. She is mapping the plan to operationalize the project at Emory University, Grady Memorial Hospital and the Atlanta VA Hospital with Dr Master, Co-Principal Investigator.*
Funding Support:	

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

Yes, please see below.

Kilbridge, Kerry
Newly active other support since last reporting period.

Title: A Pilot Study Addressing Health Literacy to Improve Access and Understanding of the INTREPID Clinical Trial for Intermediate Risk Prostate Cancer
Major Goals: 1) To partner with the Prostate Health Education Network (PHEN) to offer both print and 2-3 minute video patient summaries for the INTREPID clinical trial through the PHEN website. The video summary will provide a visual alternative for men who prefer this learning style and does not rely on health literacy to convey trial information; 2) To characterize health literacy among patients participating in the INTREPID clinical trial for intermediate risk prostate cancer; 3) To measure the improvement in understanding of the INTREPID trial among enrolled patients attributable to a longer 10-minute educational video that reviews the primary objective, trial structure, and treatment side effects. The video avoids medical jargon and provides an animated, graphic representation of the treatment arms to address health literacy.
Status of Support: Active
Project Number: FY21 MO Grant
Name of PD/PI: Kilbridge, Kerry
Source of Support: Dana-Farber Cancer Institute
Primary Place of Performance: Dana-Farber Cancer Institute, Boston MA
Project/Proposal Start and End Date: 09/2021 – 08/2023
Total Award Amount:
Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (#.#)
2. 2023	0.00 calendar

Overlap:
There is no budgetary or scientific overlap

Master, Viraj
Newly active other support since last reporting period.

Title: Gut Microbiome and Cancer Immunotherapy Outcomes in Advanced Renal Cell Carcinoma
Role: Co-Investigator
Time Commitment: 0.24 Calendar Months
Supporting Agency: MD Anderson
Name of Agency Contact: Wesley Harrott, AVP Research Administration
Address of Agency's Grants Office:
Performance Period: 3/1/2022 - 2/28/2027
Level of Funding:
Goals: The study results will contribute considerably to our understanding of the role of the gut microbiome in cancer immunotherapy response, efficacy, and adverse events, and will be relevant not only for advanced RCC patients, but also for a larger group of cancer patients treated with cancer immunotherapy
Specific Aims: 1) identify and validate pre-treatment gut microbiome profiles, specific bacterial species, and bacterial functional pathways associated with cancer immunotherapy response, systemic immune response to immunotherapy, adverse events, and progression-free survival among patients with advanced RCC; 2) identify and validate cancer immunotherapy-associated changes in the gut microbiome profiles and bacterial functional pathways, and their association with cancer immunotherapy response, systemic immune responseto immunotherapy, adverse events, and progression-free survival among patients with advanced RCC, 3) explore the role of bacterial metabolites and related biomarkers in cancer immunotherapy response, and 4) obtain preliminary data on the gut microbiome

Overlap: None
[Internal Reference #62864]

Title: Percutaneous Nephrostomy Catheters and Sets Study
Role: PI
Time Commitment: 0.12 Calendar Months
Supporting Agency: Cook Research Incorporated
Name of Agency Contact: Jennifer Kerr, President
Address of Agency's Grants Office: 1 Geddes Way, West Lafayette, IN 47906
Performance Period: 9/6/2022 - 9/5/2032
Level of Funding:
Goals: This is a post-market study agreement related to Universa Loop and Malecot Drainage Catheter Sets
Specific Aims: n/a
Overlap: None
[Internal Reference #69707]

Filson, Christopher
Newly active other support since last reporting period.

Title: Prostate Cancer Active Surveillance Study (PASS) Cohort: Infrastructure Support for Cancer Research
Role: Sub PI
Time Commitment: 0.12 Calendar Months
Supporting Agency: NIH (Fred Hutchinson Cancer Research Center)
Name of Agency Contact: Shannon Lysen
Address of Agency's Grants Office: 1100 Fairview Ave N, Mail Stop J6-500, Seattle, WA 98109
Performance Period: 9/1/2021 - 8/31/2023
Level of Funding:
Goals: missing
Specific Aims: n/a
Overlap: None
[Internal Reference #49108]

Previously active grants that are now closed since last reporting period

Title: Mentored Research Scholars Grant 18-015-CPHPS
Role: PI
Time Commitment: x Calendar Months
Supporting Agency: American Cancer Society
Name of Agency Contact: Extramural Grants Department
Address of Agency's Grants Office: 250 Williams St, NW, 6th Floor, Atlanta, GA, 30303
Performance Period: 7/1/2018 - 6/30/2022
Level of Funding:
Goals: MRI-guided Prostate Biopsy: Maximizing Value and Optimizing Utilization
Specific Aims: Aim 1: To evaluate population-level patterns of adoption of MRI-guided prostate biopsies and determine the patient and physician contributions to variations in their use.
Aim 2: To compare effectiveness associated with MRI-guided prostate biopsies versusTRUS-guided biopsies.
Overlap: None
[Internal Reference #n/a]
Status (delete): Ended

Title: Emory Prevention Research Center
Role: Co-Investigator
Time Commitment: 0.24 Calendar Months
Supporting Agency: CDC
Name of Agency Contact: Natalie Darling, CDC Project Officer
Address of Agency's Grants Office: 1600 Clifton Rd., Atlanta, GA, 30333
Performance Period: 9/30/2019 - 9/29/2024
Level of Funding:
Goals: The obesity epidemic continues to worsen, with low-income, rural and African American women

- **What other organizations were involved as partners?**
    - **Organization Name:** Emory University
    - **Location of Organization:** Atlanta, Georgia
    - **Partner's contribution to the projec**t
        - **Facilities** –Emory University (including Grady Memorial Hospital and the Atlanta Veteran's Administration Medical Center which are clinical research sites affiliated with Emory).
        - **Collaboration** – Emory personnel are active collaborators including the following. Dr. Master is Co-Principal Investigator. Dr. Filson is Co-Investigator. Dr. Patel is assisting with programming the Access database and will oversee data analysis. Sierra Williams is providing research coordination.

8. **SPECIAL REPORTING REQUIREMENTS**

- **COLLABORATIVE AWARDS:**
  A collaborative report will be submitted to ebrap.org
- **QUAD CHARTS:**

See next page

STATEMENT OF WORK – July 13, 2020
PROPOSED START DATE – December 1, 2020

Site 1:	Dana-Farber Cancer Institute		Site 2:	Emory University
	Boston, MA			Atlanta GA
	PI: Kerry L. Kilbridge			Co-PI: Viraj Master
Site 3:	Grady Memorial Hospital		Site 3	Atlanta Veteran's Admin Med Ctr
	Atlanta, GA			Decatur, GA
	Co-PI: Viraj Master			Site-PI: Christopher Filson

There is no change to the scope of work. The project timeline (SOW) is offset by 2 years in anticipation of requesting a no-cost extension due to the co-principal Investigator's ongoing serious illness.

Specific Aim 1: Characterize health literacy in a group of early stage, African American prostate cancer survivors across four empirical domains **Specific Aim 2:** Assess comprehension of survivorship care recommendations and prostate cancer treatment side effects in survivors after they receive a standard ASCO prostate cancer survivorship care plan (SCP)	**Timeline**	**DFCI**	**Emory**	**Grady**	**VAMC**
Major Task 1: Obtain IRB approvals	Months				
Subtask 1: Prepare and execute subcontract between DFCI & Emory	12	x	x		
Subtask 2: Prepare regulatory documents and research protocol for at all sites	Present to 28	x	x	x	x
Subtask 3: Perform multidisciplinary review of updated script by team members in urology, radiation oncology and medical oncology	26-28	x	x	x	x
Subtask 4: Approval of consent forms & human subjects protocol for Emory, Grady, Atlanta VAMC Grady & VAMC are contingent on Emory	28-30	x	x	x	x
Subtask 5: Approval of retrospective records review protocol by DFCI IRB contingent on Emory, Grady & VAMC approvals	31-32	x			
Subtask 6: 2nd level IRB review & approval by ORP/HRPO contingent on DFCI, Emory, Grady & VAMC approval	31-33	x	x		
Milestone Achieved: All IRB and HRPO approvals					
Major Task 2: Program Access database					
Major Task 3: Training of Study Staff and Operationalizing Subject Recruitment and Data Flow					
Subtask 1: Program Access database	28-32	x	x		
Subtask 2: Train research staff with database	33-34	x	x		
Subtask 3: Review data flow and operationalize subject recruitment, perform first interviews N=3-5	34-35	x	x	x	x

Milestone Achieved: Access database operational					
Milestone Achieved: Research staff trained					
Major Task 4: Initial Subject Recruitment and Data Collection					
Subtask 1: Initial target subject accrual: N=25-27 [cumulative total 30]	35-36	x	x	x	x
Subtask 2: Initial data analysis	36-37	x	x		
Milestone Achieved: Specific Aim 1: Characterize health literacy in a group of early stage, African American prostate cancer survivors across four empirical domains Specific Aim 2: Assess comprehension of survivorship care recommendations and prostate cancer treatment side effects in survivors after they receive a standard ASCO prostate cancer (SCP)					
Milestone Achieved: Dissemination of interim reports					
Specific Aim 3: Tailor content of the ASCO prostate cancer SCP by explicitly addressing each domain of health literacy and deliver a low literacy educational supplement to augment information that patients get from their providers					
Major Task 5: Interval Subject Recruitment and Data Collection					
Subtask 1: Interval target subject accrual: N=60 [cumulative total 90]	36-48	x	x	x	x
Subtask 2: Interval data analysis	36-48	x	x		
Milestone Achieved: Dissemination of interim reports					
Milestone Achieved: Specific Aim 3 Tailor content of the ASCO prostate cancer SCP by explicitly addressing each domain of health literacy and deliver a low literacy educational supplement to augment the information that patients receive from their providers					
Specific Aim 4 & 5 Compare outcomes after patients receive A standard ASCO SCP versus A standard ASCO SCP + Tailored SCP + Ed Supp Compare providers' assessment of patients' outcomes to measures obtained from patients					
Major Task 6: Final Subject Recruitment and Data Collection					
Subtask 1: Final target subject accrual: N=60 [cumulative total 150]	48-57	x	x	x	x

Subtask 2: Final data entry	56-57	x	x		
Subtask 3: Complete data library	57-58	x	x		
Subtask 4: Complete descriptive statistical analysis and statistical comparisons of interview data	58-60	x	x		
Subtask 5: Perform multivariable modeling on predictors of understanding of survivorship care recommendations and access to survivorship care	58-60	x	x		
Subtask 6: Share output and findings with all investigators	58-60	x	x	x	x
Subtask 7: Complete summary reports, manuscript preparation, and submission	58-60	x	x	x	x
Subtask 8: Disseminate study findings to ASCO, the National Medical Association and the American Urological Association	59-60	x	x	x	x
Milestone Achieved: Specific Aim 4 & 5 Compare outcomes after patients receive A standard ASCO SCP versus A standard ASCO SCP + Tailored SCP + Ed Supp Compare providers' assessment of patients' outcomes to measures obtained from patients					
Milestone Achieved: Report results from data analyses					

Projected Quarterly Enrollment

	Year 3				Year 4 (no cost extension)				Year 5 (no cost extension)			
Target Enrollment (per quarter)	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**
Grady				10	5	5	5	5	8	7	7	
Atlanta VAMC				20	10	10	10	10	12	14	12	
Target Enrollment (cumulative)				30	45	60	75	90	110	131	150	

Abbreviations List

ASCO	American Society of Clinical Oncology
DFCI	Dana-Farber Cancer Institute
IRB	Institutional Review Board
ORP/HRPO	Office of Research Protections/Human Research Protection Office
PI	Principal Investigator
SCP	Survivorship Care Plan
VAMC	Atlanta Veterans Administration Medical Center

9. APPENDICES

Nothing to report