

AWARD NUMBER: W81XWH-20-1-0110

TITLE: Genetic Testing in the Safety Net: Improving Equity in Prostate Cancer Treatment

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REPORT DATE: May 2021

TYPE OF REPORT: Annual

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

DISTRIBUTION STATEMENT: Approved for Public Release;  
Distribution Unlimited

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# REPORT DOCUMENTATION PAGE

*Form Approved*  
*OMB No. 0704-0188*

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<b>1. REPORT DATE</b> May 2021			<b>2. REPORT TYPE</b> ANNUAL		<b>3. DATES COVERED</b> 01Apr2020-31Mar2021	
<b>4. TITLE AND SUBTITLE</b> Genetic Testing in the Safety Net: Improving Equity in Prostate Cancer Treatment					<b>5a. CONTRACT NUMBER</b>	
					<b>5b. GRANT NUMBER</b> W81XWH-20-1-0110	
					<b>5c. PROGRAM ELEMENT NUMBER</b>	
<b>6. AUTHOR(S)</b> Christine Gunn  E-Mail: Christine.Gunn@bmc.org					<b>5d. PROJECT NUMBER</b> 0011433661	
					<b>5e. TASK NUMBER</b>	
					<b>5f. WORK UNIT NUMBER</b>	
<b>7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)</b> Boston Medical Center Corporation BMC 1 Boston Medical Center Pl Ste. 1 Boston, MA 02118-2908					<b>8. PERFORMING ORGANIZATION REPORT NUMBER</b>	
<b>9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)</b>  U.S. Army Medical Research and Development Command Fort Detrick, Maryland 21702-5012					<b>10. SPONSOR/MONITOR'S ACRONYM(S)</b>	
					<b>11. SPONSOR/MONITOR'S REPORT NUMBER(S)</b>	
<b>12. DISTRIBUTION / AVAILABILITY STATEMENT</b>  Approved for Public Release; Distribution Unlimited						
<b>13. SUPPLEMENTARY NOTES</b>						
<b>14. ABSTRACT</b> Prostate cancer treatment advances and associated mortality benefits have left behind substantial segments of the US population. African American men have a higher incidence of prostate cancer (203.5 vs. 121.9 per 100,000) and are 2-3 times more likely to die of prostate cancer relative to white men.1-3 These disparities are due in large part to the receipt of less effective treatment. Socioeconomic status is a major independent contributor to survival: ten years post-diagnosis, those in the highest socioeconomic strata have a 15% higher survival rate compared to those in the lowest strata.4 Genetic testing to guide treatment decision making is now recommended for certain prostate cancer patients following diagnosis of localized disease and all patients with metastatic disease. Treatment-based disparity gaps may continue to be exacerbated by the underutilization of genetic testing in racial/ethnic minorities and those with low socioeconomic status. The complex underlying reasons for a lack of uptake of genetic testing in vulnerable patient populations remain largely unexplored. Thus, there is a critical need to elucidate the multi-dimensional reasons for disparities in treatment utilization for minority and low-income men with prostate cancer that reside at the system, provider, and patient levels.						
<b>15. SUBJECT TERMS</b> None listed.						
<b>16. SECURITY CLASSIFICATION OF:</b>				<b>17. LIMITATION OF ABSTRACT</b>	<b>18. NUMBER OF PAGES</b>	<b>19a. NAME OF RESPONSIBLE PERSON</b>
<b>a. REPORT</b>	<b>b. ABSTRACT</b>	<b>c. THIS PAGE</b>	<b>USAMRMC</b>			
Unclassified	Unclassified	Unclassified	Unclassified	12	<b>19b. TELEPHONE NUMBER (include area code)</b>	

**Standard Form 298 (Rev. 8-98)**  
Prescribed by ANSI Std. Z39.18

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## 1. INTRODUCTION:

Most of what is known about implementing new cancer care procedures comes from large health care delivery settings, like comprehensive cancer centers and Veterans Affairs (VA), but most men do not get their cancer care in these settings. Many factors may contribute to a failure to receive genetic testing, including cost, a lack of available genetic counselors, mistrust of how results might be used, or lack of recommendation by a doctor. The goal of this proposal is to identify opportunities for health care delivery interventions that improve access to prostate cancer genetic testing to guide appropriate treatment and improve patient quality of life among a racially and socioeconomically diverse patient population treated at an urban safety-net hospital, Boston Medical Center (BMC). This project aims to: 1) Characterize the use of germline genetic testing in patients diagnosed with prostate cancer in a safety-net setting using electronic medical record data from 2011 – 2021; and 2) Use qualitative key informant interviews to identify patient, provider, and clinical factors that influence the decision to pursue genetic testing and the impact of this testing on prostate cancer management.

## 2. KEYWORDS:

Genetic testing; prostatic neoplasms; health care disparities; health services research; qualitative research; retrospective studies; safety-net providers

## 3. ACCOMPLISHMENTS:

### What were the major goals of the project?

Our first project aim was to characterize the use of germline genetic testing in patients diagnosed with prostate cancer in a safety-net setting using electronic medical record data from 2011 – 2021. The major goals of the aim for this year were to create a prostate cancer cohort at Boston Medical Center and prepare data for cohort and interrupted time series analyses (both to be completed within Months 14-16). Milestone 1, which was to obtain local IRB approval within Months 1-2 was completed on schedule. Milestone 2, the completion of cohort-based descriptive analysis is slated to be completed as planned in Month 14. As of February 2021, we are on track to meet this milestone, with approximately 80% of the associated tasks completed to date.

Our second project aim was to use qualitative key informant interviews to identify patient, provider, and clinical factors that influence the decision to pursue genetic testing and the impact of this testing on prostate cancer management. In this reporting period (Year 1), we aimed to identify a range of stakeholders, and conduct “Connecting Community to Research” training with interested stakeholders. We have completed a landscape review of stakeholders, and engaged with our prostate cancer support group community, leaders in the Massachusetts Prostate Cancer Coalition, and the Prostate Health Education Network. We were delayed in conducting the trainings for two reasons. First, the Boston University Community Engagement Core are currently re-vamping this curriculum. Second, the COVID-19 pandemic has disrupted the typical engagement platforms, and we are exploring new ways to engage with prostate cancer survivors, especially those with less access to technology. We do have plans in place to attend a virtual cancer support group meeting in April 2021, have put a communication plan in place with the cancer support services team, and expect to complete engagement activities and conduct the training this spring.

Because of delays in engagement, we did make the decision to proceed with submitting an IRB for Aim 2 (approved December 2020). We also proceeded to interview clinician participants about the delivery of genetics services. As of February 2021, we have completed the planned 15 clinician interviews, had them transcribed, and are beginning qualitative coding. These tasks were slated to be completed in Months 28-30.

## What was accomplished under these goals?

- 1) In the first year of the project, we aimed to complete the following major tasks as defined in the proposed scope of work:

### AIM 1 MAJOR TASKS:

1. Assemble a cohort of prostate cancer patients treated at Boston Medical Center.

**STATUS:** This has been completed. We obtained IRB approval, obtained electronic medical records from our Clinical Data Warehouse, and assembled a prostate cancer cohort for Aim 1. This step was completed as of December 2020.

2. Clean data and complete quality verification.

**STATUS:** In the process of cleaning data, we consulted with Co-Investigator Claire Hacking and identified discrepancies between our own data pull and genetics data held by the Cancer Genetics Program at the institution. This prompted us to go through an additional iteration of data extraction with the clinical data warehouse to ensure the completeness of our outcome data (referrals to genetics, completion of genetic testing, and receipt of genetic counseling). After some brief delays in acquiring the additional data, this was obtained, and all data has been verified as of January 2021. The source data obtained from the clinical data warehouse has been cleaned and manipulated programmatically into an analytic dataset by excluding non-salient variables from the source data, combining similar variables across several source datasets into a single variable for analysis, collapsing variables into meaningful categories for analysis, and fixing structural errors like typos or invalid data formats.

Below are the descriptive statistics of our current cohort displayed in tabular format.

Individual Characteristics of Cohort, 2011-2021 (n = 1,656)

	Total
Age M (SD)	64.76 (8.89)
<b>Year of Diagnosis % (n)</b>	
2018	10.9% (182)
2017	16.4% (271)
2016	16.1% (267)
2015	11.6% (192)
2014	10.0% (166)
2013	10.5% (173)
2012	12.4% (205)
2011	12.1% (200)
<b>Race % (n)</b>	
Black or African American	43.5% (720)
White	33.3% (551)
Asian	2.2% (36)
American Indian/Alaska Native	0.2% (3)
Native Hawaiian or Other Pacific Islander	0.1% (1)
Other	4.2% (71)
Unknown/Missing	16.6% (274)
<b>Ethnicity % (n)</b>	
Not Hispanic or Latino	80.4% (1331)
Hispanic or Latino	16.4% (271)
Unknown/Missing	3.3% (54)
<b>Marital Status % (n)</b>	
Married	48.9% (809)
Single	34.1% (564)
Divorced or Legally Separated	9.9% (164)
Widowed	2.9% (48)
Other or Unknown	4.3% (71)
<b>Country of Birth % (n)</b>	
Foreign born	45.4% (751)
US born	39.0% (646)
Unknown/Missing	15.6% (259)
<b>Language % (n)</b>	
English	67.3% (1112)
Spanish	15.1% (250)
Haitian Creole	8.9% (147)
Other or Unknown	8.9% (147)
<b>Insurance % (n)</b>	
Medicaid	32.8% (543)
Private	25.9% (428)
Medicare	24.2% (401)
Self-Pay	0.3% (5)
Other <sup>1</sup>	6.5% (108)
Unknown/Missing	10.3% (171)

<sup>1</sup> Includes Free Care & Other, Charity, Government-Assisted Healthcare, Workers Compensation, Auto Insurance

3. Conduct Cohort Analysis and manuscript preparation.  
STATUS: Within the first 11 months, on which this report is based, the goals for the analysis were to produce descriptive statistics (completed and partially displayed above), identify associations between demographic and clinical characteristics and primary outcome (75% completed), and identify associations with secondary outcomes (50% completed).
4. Interrupted Time Series Analysis and Manuscript Preparation.  
STATUS: For this task, we planned to visualize and describe baseline trend-line and identify time-varying covariates and complete the interrupted time series with segmented linear regression. This is approximately 50% completed, having produced baseline time trends. The subsequent regressions are being planned and finalized after receiving more complete outcome data through the beginning of 2021. These activities are planned to be completed in Summer 2021, per the proposed scope of work, and we are on target to achieve this deliverable.

**AIM 2 MAJOR TASKS:**

1. Engage Stakeholders.  
STATUS: We were able to meet initially with a series of stakeholders and continue to have conversations about how to best engage our planned partners for the qualitative research (Aim 2). We met with the Community Engagement Program Manager in August 2020 and January 2021 to plan training activities. While training has not taken place, we plan on conducting trainings in Spring and Summer 2021. We are currently not permitted by our institution to conduct in person research activities, like this training, so are planning for virtual options and later in person trainings, as the COVID-19 pandemic associated distancing guidelines evolve. In February 2021, we conducted a planning meeting with the Cancer Support Services team and will begin engagement, training, and further outreach in April 2021. This task is approximately 60% complete.

**TASKS COMPLETED BUT INTENDED FOR LATER REPORTING PERIODS:**

1. Prepare for field work.  
STATUS: We have completed the IRB submission for Aim 2 qualitative interviews with clinicians. Because these are conducted by research staff, we were able to create the interview guide, train staff to conduct telephone interviews, and create outreach and enrollment protocols for the qualitative interview portion of the study. These tasks were planned for Months 13 -17, but are now complete.
2. Conduct Interviews.  
STATUS: We had originally planned for clinician and staff interviews in Month 23, concluding enrollment by Month 28. We were able to recruit and complete all of these interviews in December – February of this year. In addition, we have transcribed, verified, and de-identified all transcripts associated with this group of interviews.

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

While not intended by the grant, involvement did facilitate attendance at the Prostate Health Education Network's 16th Annual African American Prostate Cancer Disparity Summit on October 1, 2020.

**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 coming reporting period, we will complete the cohort analysis and plan on submitting a manuscript for peer review (Months 12- 15). We further plan on completing the time series analysis and reporting those results with the cohort analysis. The results of these Aim 1 activities will be disseminated to our stakeholder partners.

In Months 13-14, we will refine our research protocol for Aim 2, informed by results of the cohort and time series analyses. An IRB is expected to be approved by our local IRB and CDRMP in Month 17. Training of stakeholders for their involvement in Aim 2 interviews will begin in Month 14 and continue through Month 18.

By the second half of the next reporting period (September 2021), recruitment of prostate cancer patients for qualitative interviews will begin. After a short start up time, we will expand to family member recruitment (Month 20). Enrollment and data collection will continue into the next reporting period.

#### **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?

While the impact of engagement with prostate cancer survivors on this project is in its early stage, there is great potential for our activities with our partners to improve knowledge about genetic testing across communities. In conducting trainings, we are also building the capacity of our partners to engage in the research process and are planning to ensure there are ongoing opportunities for those who engage with us to connect to other advisory boards or groups seeking patient input into the research process. We anticipate that the impact of these activities will manifest in later reporting periods.

## 5. CHANGES/PROBLEMS:

### Changes in approach and reasons for change

There have been no changes in scope of the proposed aims. We did accelerate clinician interviews due to availability of a graduate student with an interest in this topic area, and due to anticipated delaying in stakeholder engagement due to the COVID-19 pandemic and restrictions on in-person research activities. Our overall approach and activities remain consistent with the original proposal.

### Actual or anticipated problems or delays and actions or plans to resolve them

We had some delays in acquiring all of our data, including complete outcomes. This has slightly, but not significantly, delayed our analyses. In order to resolve any delays that have occurred as a result of data acquisition delays, we have devoted additional personnel resources to ensure analyses can be completed on time. This includes engaging our Biostatistics and Data Analytics Center to help with coding of the cohort and time series data.

The delays with patient engagement due to the COVID-19 pandemic will have an expected minor impact on our ability to complete the project. While training was delayed, we are actively working with our cancer support services team to leverage the lessons they have learned in working with cancer support groups during the pandemic to inform our training and engagement in the coming months. We are prepared to move quickly when the training is ready to deliver it and begin patient engagement in the interview process. If we are unable to engage sufficient numbers of men to act as interviewers, we will be prepared to elicit interviewer qualities that men value in identifying and hiring an interviewer to help support the conduct of interviews for Aim 2.

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

Because of the COVID-19 pandemic, we have not spent conference travel funds. We plan to increase engagement at conferences in the next year in presenting our findings from the cohort analysis, whether conferences be virtual or in-person.

Training materials for the CTSI and advocate stipends for training were also not spent in Year 1. They will be spent in the coming year, and some later costs for clinician interviews were spent this year instead. We had further budgeted for support for the cohort analysis development, but Clinical Data Warehouse costs were low such that we were instead able to direct these costs to analytic services at the Biostatistics and Epidemiology Data Analytic Center to make up for a lag in data acquisition. These activities still came below budget. No other major impacts on budget were identified.

**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**

*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**

**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.*

## 7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

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

Name: Christine Gunn  
Project Role: PI (No change)

Name: Catharine Wang  
Project Role: Co-I  
Researcher Identifier (e.g. ORCID ID): [0000-0001-8584-2781](https://orcid.org/0000-0001-8584-2781)  
Nearest person month worked: 2

Contribution to Project: Dr. Wang has supported the EMR data extraction and guidance of analysis. She has also supervised a graduate student conducting activities for Aim 2.

Name: Gretchen Gignac  
Project Role: Co-I (No change)

Name: Magda Pankowska  
Project Role: Data Analyst  
Researcher Identifier (e.g. ORCID ID): 0000-0003-4194-7017  
Nearest person month worked: 9

Contribution to Project: Ms. Pankowska has performed data cleaning and coding, as well as providing administrative support to the project.

Name: Emma Li  
Project Role: Graduate Student  
Researcher Identifier (e.g. ORCID ID): n/a  
Nearest person month worked: 2

Contribution to Project: Ms. Li has developed the qualitative interview guide for clinician and staff interviews, conducted the interviews, and is involved in qualitative analysis.

**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. Rider (Co-I) left the project, and her role was assumed by Dr. Wang. Claire Hacking (Co-I) also left the project and was replaced by Kim Zayhowski in January 2021 (0.6 CM effort). Otherwise, there have been no changes in support for senior or key personnel since last reporting.

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

None to report.

**8. SPECIAL REPORTING REQUIREMENTS**

**COLLABORATIVE AWARDS:**

**QUAD CHARTS:**

**9. APPENDICES:**