AWARD NUMBER: W81XWH-20-1-0110

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

PRINCIPAL INVESTIGATOR: Christine Gunn, PhD

CONTRACTING ORGANIZATION: Boston Medical Center

REPORT DATE: MAY 2022

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

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	2. REPORT TYPE	3. DATES COVERED
MAY 2022	ANNUAL	4/1/2021 – 3/31/2022

4. TITLE AND SUBTITLE

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

5a. CONTRACT NUMBER

5b. GRANT NUMBER
W81XWH-20-1-0110

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
Christine Gunn

E-Mail: Christine.Gunn@bmc.org

5d. PROJECT NUMBER
0011433661

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
Boston Medical Center Corporation
BMC
1 Boston Medical Center Pl
Ste. 1
Boston, MA 02118-2908

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: 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.

15. SUBJECT TERMS

NONE LISTED

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
Unclassified	Unclassified	Unclassified	Unclassified	60	19b. TELEPHONE NUMBER *(include area code)*

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

TABLE OF CONTENTS

1. INTRODUCTION: *Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.*

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: *Provide a brief list of keywords (limit to 20 words).*

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

3. ACCOMPLISHMENTS: *The PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction.*

What were the major goals of the project?
List the major goals of the project as stated in the approved SOW. If the application listed milestones/target dates for important activities or phases of the project, identify these dates and show actual completion dates or the percentage of completion.

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 finalize a prostate cancer cohort at Boston Medical Center and conduct an interrupted time series analysis. Milestone 2, the completion of cohort-based descriptive analysis is completed as planned in with a slight delay from Month 14 to Month 20 due to the re-location of the PI from one institution to another, and the departure of analyst personnel. As of March 2022, we are on track to submit a full manuscript reporting on the descriptive cohort and interrupted time series design in May 2022.

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 2), we aimed to finalize our Aim 2 protocol, train survivor-interviewers and research staff on interviewing, and obtain IRB approval for interviews (Milestone 5, achieved in December 2020). In Year 2 we have hired a survivor-interviewer and two Spanish-speaking research assistants. They have translated all study materials to Spanish so that we can conduct the full scope of activities in Spanish, from outreach to compensating participants for interviews. This group has undergone extensive qualitative research interviewing training and practice to prepare them to collect data. We have developed a protocol (Milestone 4) and it has been tested and used successfully by the research team to conduct interviews.

In the latter half of the year, we planned to identify potential participants within the medical record and through the distribution of study information cards to both patients and family members. Interviews are slated to continue through Month 26 for patients (May 2022), Month 27 for families (June 2022), and Month 28 for providers (July 2022). Of note, we have already completed the provider interviews, and are on track to complete the patient interviews. Recruitment in both English and Spanish is active, with 12 interviews completed to date and several more scheduled.

What was accomplished under these goals?

For this reporting period describe: 1) major activities; 2) specific objectives; 3) significant results or key outcomes, including major findings, developments, or conclusions (both positive and negative); and/or 4) other achievements. Include a discussion of stated goals not met. Description shall include pertinent data and graphs in sufficient detail to explain any significant results achieved. A succinct description of the methodology used shall be provided. As the project progresses to completion, the emphasis in reporting in this section should shift from reporting activities to reporting accomplishments.

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: This has been completed. 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.
3. Cohort Analysis and Manuscript Preparation.
   STATUS: This task is completed from an analytic perspective, and the only remaining task is to finalize the manuscript and submit to a peer-reviewed journal. After some delays in preparing the final analytic dataset in Year 1, and the departure and transfer of the PI to a new institution, we have been able to transfer the analytic files, replicate preliminary results with a new analyst, and complete the cohort analysis. In concert with the entire study team, we have decided to report these findings along with the interrupted Time Series Analysis (See Major Task 4 below).
4. Interrupted Time Series Analysis and Manuscript Preparation.
   STATUS: This task is nearing completion. We have generated the interrupted time series graph and model by converting referrals to a rate per 1,000 diagnoses. We are now working to conduct a series of robustness checks – varying the time lag, adjusting for seasonality, and identifying and incorporating time-varying confounders. We expect that a manuscript will be submitted to *Genetics in Medicine*, reporting on both the cohort analysis and the interrupted time series in early June 2022.

AIM 2 MAJOR TASKS:

1. Engage Stakeholders.
   STATUS: This task is ongoing, as planned. In Year 1 and early in Year 2 we met initially with a series of stakeholders to learn about how to best engage our planned partners for the qualitative research (Aim 2). Over the course of 3 meetings with a Prostate Cancer Support group, we gathered feedback on our approaches. From this group, we had one survivor who wanted ongoing engagement with the project. He has since been hired as a survivor-interviewer. He underwent a series of research trainings and has been active in conducting interviews and helping to train research assistants on the protocol. While ongoing, this activity has seen a lot of success this year in improving community engagement in the project.

TASKS COMPLETED BUT INTENDED FOR LATER REPORTING PERIODS:

1. Prepare for field work.
   STATUS: This task is complete. We have completed the IRB submission for Aim 2 qualitative interviews with clinicians (Year 1), and patients and family members (Year 2). We have also created a robust protocol, and trained staff (students and the survivor-interviewer) and have bi-lingual versions of all study materials.

2. Conduct Interviews.
   STATUS: Clinician interviews are complete. The patient and family member interviews are ongoing. Twelve interviews have been completed (5 Spanish, 7 English), and recruitment has been active. We have currently conducted 29 interviews of 62 (recruitment 47% complete). We are ahead of our projected target of 24 total interviews by the end of Year 2.

3. Transcribe Interviews.
   STATUS: Clinician interviews are completed. The patient and family member interviews are batch transcribed, and then reviewed, verified against the audio, and de-identified for analysis. This task is approximately 30% complete.

4. Complete Qualitative Analyses.
   STATUS: Clinician interviews have been fully analyzed as planned, using 3 coders and a consensus process. The findings from this analysis were presented in an oral presentation at the Society for Medical Decision-Making on October 19, 2021. The manuscript is currently under review at *Cancer*. Further analysis of the patient and family interviews, as well as a comparative analysis are planned for Months 30-34 and are on track.

What opportunities for training and professional development has the project provided?
If the project was not intended to provide training and professional development opportunities or there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe opportunities for training and professional development provided to anyone who worked on the project or anyone who was involved in the activities supported by the project. "Training" activities are those in which individuals with advanced professional skills and experience assist others in attaining greater proficiency. Training activities may include, for example, courses or one-on-one work with a mentor. "Professional development" activities result in increased knowledge or skill in one's area of expertise and may include workshops, conferences, seminars, study groups, and individual study. Include participation in conferences, workshops, and seminars not listed under major activities.

Nothing to Report.

How were the results disseminated to communities of interest?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how the results were disseminated to communities of interest. Include any outreach activities that were undertaken to reach members of communities who are not usually aware of these project activities, for the purpose of enhancing public understanding and increasing interest in learning and careers in science, technology, and the humanities.

Several dissemination activities have been conducted. We have been sharing results with the Boston Medical Center Prostate Cancer Support Group as we meet with them. Their feedback has helped shape patient interview guides as a result.

There have also been several peer reviewed presentations in the last year at national conferences. These include:

- "Determinants of Offering Genetic Testing for Men with Prostate Cancer among Specialty and Generalist Providers at a Safety-Net Hospital". *Society for Medical Decision-Making Annual Meeting.* October 19, 2021. Oral presentation.
- "Characterizing access to genetics referrals for prostate cancer in a safety net hospital." *AACR The Science of Cancer Health Disparities in Racial/Ethnic Minorities and the Medical Underserved*. October 4, 2021. Poster presentation.
- "The Provision of Genetics Services for Men with Prostate Cancer at a Large, Safety-Net Hospital." *National Society of Genetic Counselors Annual Meeting*. August 2021. Poster presentation.
- "Genetic service provision for men with prostate cancer within a safety-net setting: A qualitative study." *American Society for Human Genetics* Annual Meeting, July 2021. Poster presentation.

What do you plan to do during the next reporting period to accomplish the goals?
If this is the final report, state "Nothing to Report."

Describe briefly what you plan to do during the next reporting period to accomplish the goals and objectives.

In the coming reporting period, we will submit a manuscript for peer review reporting the full results from Aim 1 (June 2022). The target journal for this work is *Genetics in Medicine*. We will also report the results of these Aim 1 activities will be disseminated to our stakeholder partners.

In Months 25-28, we will continue and complete enrollment and data collection for both patient and family member interviews. We will transcribe, translate (for Spanish interviews) and verify all interview audio files (Months 25 – 30). We will finalize a codebook and coding manual, adapted from what we have already accomplished with clinician interviews (through Month 30). In Months 30-33 we will complete coding and conduct a comparative analysis across stakeholder groups (through Month 34). In the final months of the grant (Months 34-36), we will report preliminary results to stakeholders, and prepare and submit manuscripts.

4. **IMPACT:** D*escribe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:*

What was the impact on the development of the principal discipline(s) of the project?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how findings, results, techniques that were developed or extended, or other products from the project made an impact or are likely to make an impact on the base of knowledge, theory, and research in the principal disciplinary field(s) of the project. Summarize using language that an intelligent lay audience can understand (Scientific American style).

Nothing to report.

What was the impact on other disciplines?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how the findings, results, or techniques that were developed or improved, or other products from the project made an impact or are likely to make an impact on other disciplines.

Nothing to Report.

What was the impact on technology transfer?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe ways in which the project made an impact, or is likely to make an impact, on commercial technology or public use, including:

- *transfer of results to entities in government or industry;*
- *instances where the research has led to the initiation of a start-up company; or*
- *adoption of new practices.*

Nothing to Report.

What was the impact on society beyond science and technology?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how results from the project made an impact, or are likely to make an impact, beyond the bounds of science, engineering, and the academic world on areas such as:

- *improving public knowledge, attitudes, skills, and abilities;*

- *changing behavior, practices, decision making, policies (including regulatory policies), or social actions; or*
- *improving social, economic, civic, or environmental conditions.*

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 and beyond the life of this grant.

5. CHANGES/PROBLEMS: *The PD/PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, "Nothing to Report," if applicable:*

Changes in approach and reasons for change

Describe any changes in approach during the reporting period and reasons for these changes. Remember that significant changes in objectives and scope require prior approval of the agency.

There have been no changes in scope of the proposed aims. Our overall approach and activities remain consistent with the original proposal.

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

Describe problems or delays encountered during the reporting period and actions or plans to resolve them.

We did experience delays in completing the analysis for Aim 1 in Year 2. These delays started in Year 1 with some challenges in working with the data to create an analytic data set. These issues were overcome by collaboration with our genetic and oncology study team members. In Year 2 the PI (Dr. Gunn) transferred institutions (July/August 2021). During this period, the analyst also left the project to work at the CDC. Changing institutions delayed the hiring process for a new analyst. Since the start of the new analyst, we have been able to replicate our original findings, which ensures the robustness of our results, and proceed with the time-based analyses. These data will be reporting in the coming months in a peer reviewed journal.

The delays with patient engagement due to the COVID-19 pandemic will have an expected minor impact on our ability to complete the project. We have been able to move quickly and deliver training to our survivor-interviewer, and we are ahead of schedule with patient recruitment for Aim 2. We have not had success in finding a Haitian Creole speaker to join the project as staff. We continue to work with the School of Public Health and our professional networks to find someone who might be able to conduct activities in this language as well. Of note, most non-English speakers that we have identified through medical record recruitment are Spanish speaking, so the addition of a Haitian Creole speaker will add a modest number of patients to the sample. We remain committed to doing so, but will focus on fulfilling recruitment goals with Spanish-speakers should we be unsuccessful.

Changes that had a significant impact on expenditures
Describe changes during the reporting period that may have had a significant impact on expenditures, for example, delays in hiring staff or favorable developments that enable meeting objectives at less cost than anticipated.

Given the expanded engagement in conferences this year, we have been able to spend unused conference funds from earlier in the grant period and attend and present at more virtual conferences than anticipated. While we had unspent training and survivor-interviewer funds in Year 1, we have been able to spend these in Year 2. We have slightly re-budgeted to add a Dartmouth subcontract for Dr. Gunn and an analyst to continue their work on the project after Dr. Gunn's relocation. This has not significantly impacted the budget and we remain on target.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents
Describe significant deviations, unexpected outcomes, or changes in approved protocols for the use or care of human subjects, vertebrate animals, biohazards, and/or select agents during the reporting period. If required, were these changes approved by the applicable institution committee (or equivalent) and reported to the agency? Also specify the applicable Institutional Review Board/Institutional Animal Care and Use Committee approval dates.

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: *List any products resulting from the project during the reporting period. If there is nothing to report under a particular item, state "Nothing to Report."*

Publications, conference papers, and presentations
Report only the major publication(s) resulting from the work under this award.

Journal publications. *List peer-reviewed articles or papers appearing in scientific, technical, or professional journals. Identify for each publication: Author(s); title; journal; volume: year; page numbers; status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

Gunn CM, Li EX, Giganc GA, Pankowska M, Loo S, Zayhowski K, Wang CL. "Delivering Genetic Testing for Patients with Prostate Cancer: Moving Beyond Provider Knowledge as a Barrier to Care." *Cancer*. 2022 (under review). Federal Support Acknowledged.

Gunn CM, Giganc GA, Pankowska M, Hardy B, Zayhowski K, Wang CL. "Uptake of Genetic Testing in Men with Prostate Cancer: A Cohort Analysis in a Safety-Net Hospital." *Genetics in Medicine*. 2022 (in preparation). Federal Support Acknowledged.

Books or other non-periodical, one-time publications. *Report any book, monograph, dissertation, abstract, or the like published as or in a separate publication, rather than a periodical or series. Include any significant publication in the proceedings of a one-time conference or in the report of a one-time study, commission, or the like. Identify for each one-time publication: author(s); title; editor; title of collection, if applicable; bibliographic information; year; type of publication (e.g., book, thesis or dissertation); status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

Nothing to Report.

Other publications, conference papers and presentations. *Identify any other publications, conference papers and/or presentations not reported above. Specify the status of the publication as noted above. List presentations made during the last year (international, national, local societies, military meetings, etc.). Use an asterisk (*) if presentation produced a manuscript.*

- "Determinants of Offering Genetic Testing for Men with Prostate Cancer among Specialty and Generalist Providers at a Safety-Net Hospital". *Society for Medical Decision-Making Annual Meeting.* October 19, 2021. Oral presentation.*
- "Characterizing access to genetics referrals for prostate cancer in a safety net hospital." *AACR The Science of Cancer Health Disparities in Racial/Ethnic Minorities and the Medically Underserved*. October 4, 2021. Poster presentation.
- "The Provision of Genetics Services for Men with Prostate Cancer at a Large, Safety-Net Hospital." *National Society of Genetic Counselors Annual Meeting*. August 2021. Poster presentation.
- "Genetic service provision for men with prostate cancer within a safety-net setting: A qualitative study." *American Society for Human Genetics* Annual Meeting, July 2021. Poster presentation.*

Website(s) or other Internet site(s)

List the URL for any Internet site(s) that disseminates the results of the research activities. A short description of each site should be provided. It is not necessary to include the publications already specified above in this section.

Nothing to Report.

Technologies or techniques

Identify technologies or techniques that resulted from the research activities. Describe the technologies or techniques were shared.

Nothing to Report.

Inventions, patent applications, and/or licenses

Identify inventions, patent applications with date, and/or licenses that have resulted from the research. Submission of this information as part of an interim research performance progress report is not a substitute for any other invention reporting required under the terms and conditions of an award.

Nothing to Report.

Other Products

Identify any other reportable outcomes that were developed under this project. Reportable outcomes are defined as a research result that is or relates to a product, scientific advance, or research tool that makes a meaningful contribution toward the understanding, prevention, diagnosis, prognosis, treatment and /or rehabilitation of a disease, injury or condition, or to improve the quality of life. Examples include:

- *data or databases;*
- *physical collections;*

- *audio or video products;*
- *software;*
- *models;*
- *educational aids or curricula;*
- *instruments or equipment;*
- *research material (e.g., Germplasm; cell lines, DNA probes, animal models);*
- *clinical interventions;*
- *new business creation; and*
- *other.*

Nothing to Report.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?
Provide the following information for: (1) PDs/PIs; and (2) each person who has worked at least one person month per year on the project during the reporting period, regardless of the source of compensation (a person month equals approximately 160 hours of effort). If information is unchanged from a previous submission, provide the name only and indicate "no change".

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

Name: Catharine Wang
Project Role: Co-I (no change)

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

Name: Magda Pankowska
Project Role: Data Analyst
Ended Project Engagement July 2021

Name: Emma Li
Project Role: Graduate Student
Ended Project Engagement August 2021

Name: Stephanie Loo
Project Role: Graduate Student
Researcher Identifier (e.g., ORCID ID): 0000-0002-2733-7426
Nearest person month worked: 5
Contribution to Project: Ms. Loo, a doctoral candidate at the Boston University School of public health is conducting qualitative interviews, managing the day-to-day project tasks for Aim 2, and will conduct the qualitative analysis in collaboration with Dr. Gunn.

Name: Brianna Hardy
Project Role: Data Analyst
Researcher Identifier (e.g., ORCID ID): n/a
Nearest person month worked: 3
Contribution to Project: Ms. Hardy is responsible for conducting quantitative analyses under the supervision of Dr. Gunn and in consultation with the study team (Aim 1).

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

If the active support has changed for the PD/PI(s) or senior/key personnel, then describe what the change has been. Changes may occur, for example, if a previously active grant has closed and/or if a previously pending grant is now active. Annotate this information so it is clear what has changed from the previous submission. Submission of other support information is not necessary

for pending changes or for changes in the level of effort for active support reported previously. The awarding agency may require prior written approval if a change in active other support significantly impacts the effort on the project that is the subject of the project report.

Dr. Gunn has changed institutions from a primary affiliation at Boston Medical Center to Dartmouth College. She remains a PI at Boston Medical Center and holds an Adjunct Assistant Professor title there. The work continues as was planned with this change.

What other organizations were involved as partners?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe partner organizations – academic institutions, other nonprofits, industrial or commercial firms, state or local governments, schools or school systems, or other organizations (foreign or domestic) – that were involved with the project. Partner organizations may have provided financial or in-kind support, supplied facilities or equipment, collaborated in the research, exchanged personnel, or otherwise contributed.

Provide the following information for each partnership:
Organization Name:
Location of Organization: (if foreign location list country)
Partner's contribution to the project (identify one or more)

- *Financial support;*
- *In-kind support (e.g., partner makes software, computers, equipment, etc., available to project staff);*
- *Facilities (e.g., project staff use the partner's facilities for project activities);*
- *Collaboration (e.g., partner's staff work with project staff on the project);*
- *Personnel exchanges (e.g., project staff and/or partner's staff use each other's facilities, work at each other's site); and*
- *Other.*

None to report.

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: *For collaborative awards, independent reports are required from BOTH the Initiating Principal Investigator (PI) and the Collaborating/Partnering PI. A duplicative report is acceptable; however, tasks shall be clearly marked with the responsible PI and research site. A report shall be submitted to* ***https://ebrap.org/eBRAP/public/index.htm*** *for each unique award.*

QUAD CHARTS: *If applicable, the Quad Chart (available on https://www.usamraa.army.mil/Pages/Resources.aspx) should be updated and submitted with attachments.*

9. APPENDICES: *Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc.*

Attached are:

- Submitted Manuscript
- Qualitative Interview Guide
- Conference Abstracts

Cancer

Delivering Genetic Testing for Patients with Prostate Cancer: Moving Beyond Provider Knowledge as a Barrier to Care

Journal:	*Cancer*
Manuscript ID	Draft
Wiley - Manuscript type:	Original Article
Date Submitted by the Author:	n/a
Complete List of Authors:	Gunn, Christine; Dartmouth College Geisel School of Medicine, The Dartmouth Institute for Health Policy and Clinical Practice; Boston University School of Medicine, Evans Department of Medicine, Section of General Internal Medicine; Boston University School of Public Health, Department of Health Law, Policy, and Management Li, Emma; Boston University School of Medicine, Evans Department of Medicine Gignac, Gretchen; Boston University School of Medicine, Department of Medicine, Section of Hematology and Oncology Pankowska, Magdalena; Boston University School of Medicine, Evans Department of Medicine, Section of General Internal Medicine Loo, Stephanie; Boston University School of Public Health, Department of Health Law, Policy, and Management Zayhowski, Kimberly; Boston Medical Center, Department of Medical Oncology Wang, Catharine; Boston University School of Public Health, Community Health Sciences
Keywords:	prostatic neoplasm, qualitative research, genetic testing, practice guidelines, safety-net providers, bias
Abstract:	Introduction: The 2018 National Comprehensive Cancer Network guidelines for prostate cancer genetic testing expanded access to genetic services. Few studies have examined how this change has affected provider practice outside of large cancer centers. Methods: We conducted a qualitative study of multi-disciplinary health care providers treating patients with prostate cancer at a safety-net hospital. Participants completed an interview that addressed knowledge, practices, and contextual factors related to providing genetic services to patients with prostate cancer. The analysis used a modified grounded theory approach. Results: Seventeen providers completed interviews. Challenges in identifying eligible patients for genetic testing stemmed from a lack of a) systems that facilitate routine patient identification, and b) readily available family history data for eligibility determination. Providers identified non-medical patient characteristics that influenced their referral process, including health literacy, language, cultural beliefs, patient distress, and cost. Providers who see patients at different times

	along the cancer care continuum viewed benefits of testing differently. Conclusion: The use of digital technologies that systematically identify those eligible for genetic testing referrals may mitigate some but not all challenges identified in this study. Further research should determine how individual provider perceptions influence referral practices and patient access to genetics both within and across cancer specialties.

SCHOLARONE™
Manuscripts

Title: Delivering Genetic Testing for Patients with Prostate Cancer: Moving Beyond Provider Knowledge as a Barrier to Care

Running Title: Delivering Prostate Cancer Genetic Care

Authors:
Christine M. Gunn, MA, PhD[1,2,3]
Emma X. Li, MSc[4]
Gretchen A. Gignac, MD[4,6]
Magdalena Pankowska, MPH[2,4]
Stephanie Loo, MSc[3]
Kimberly Zayhowski, MSc[5]
Catharine Wang, MSc, PhD[7]

Affiliations:

[1] The Dartmouth Institute for Health Policy and Clinical Practice and Norris Cotton Cancer Center, Geisel School of Medicine at Dartmouth; Lebanon, NH

[2] Evans Department of Medicine, Section of General Internal Medicine, Boston University School of Medicine; Boston, MA

[3] Department of Health Law, Policy, and Management, Boston University School of Public Health; Boston, MA

[4] Evans Department of Medicine, School of Medicine, Boston University; Boston, MA

[5] Department of Medical Oncology, Boston Medical Center; Boston, MA

[6] Evans Department of Medicine, Section of Hematology and Oncology, Boston University School of Medicine; Boston, MA

[7] Department of Community Health Sciences, Boston University School of Public Health; Boston, MA

Corresponding Author:
Christine Gunn, MA, PhD
1 Medical Center Drive, WTRB 527
Lebanon, NH 03756
Christine.M.Gunn@dartmouth.edu
Phone: 603-646-5430

Funding: This work was supported by the Office of the Assistant Secretary of Defense for Health Affairs through the Prostate Cancer Research Program under Award No. #W81XWH-20-1-0110. Opinions, interpretations, conclusions, and recommendations are those of the author and are not necessarily endorsed by the Department of Defense.

Author Contributions: Conceptualization: C.G.; Data curation: C.G., E.L., M.P.; Formal analysis: C.G., E.L., M.P., C.W., K.Z., G.G.; Funding acquisition: C.G.; Methodology: C.G., C.W.; Project Administration: M.P., S.L.; Supervision: C.G., C.W.; Writing – original draft: C.G., E.L.; Writing – review & editing: C.W., G.G., K.W., M.P., S.L.

Conflict of Interest: None of the authors have any competing financial conflicts of interest to disclose.

Precis: This qualitative study of multidisciplinary providers treating prostate cancer patients identified non-medical patient characteristics that influenced how decisions about referral for germline genetic testing were made. The use of digital technologies that systematically identify those eligible for genetic testing referrals may mitigate some but not all challenges identified in this study.

Abstract

Introduction: The 2018 National Comprehensive Cancer Network guidelines for prostate cancer genetic testing expanded access to genetic services. Few studies have examined how this change has affected provider practice outside of large cancer centers.

Methods: We conducted a qualitative study of multi-disciplinary health care providers treating patients with prostate cancer at a safety-net hospital. Participants completed an interview that addressed knowledge, practices, and contextual factors related to providing genetic services to patients with prostate cancer. The analysis used a modified grounded theory approach.

Results: Seventeen providers completed interviews. Challenges in identifying eligible patients for genetic testing stemmed from a lack of a) systems that facilitate routine patient identification, and b) readily available family history data for eligibility determination. Providers identified non-medical patient characteristics that influenced their referral process, including health literacy, language, cultural beliefs, patient distress, and cost. Providers who see patients at different times along the cancer care continuum viewed benefits of testing differently.

Conclusion: The use of digital technologies that systematically identify those eligible for genetic testing referrals may mitigate some but not all challenges identified in this study. Further research should determine how individual provider perceptions influence referral practices and patient access to genetics both within and across cancer specialties.

Key words: prostatic neoplasms, genetic testing, practice guidelines, safety-net providers, qualitative research, bias

Manuscript Pages: 26

Tables: 2

Introduction:

Genetics care is becoming increasingly salient to achieving better cancer outcomes in the emerging field of precision medicine; defined as using personal characteristics such as genes to identify optimal treatment pathways. The National Comprehensive Cancer Network (NCCN) has recommended considering the use of germline genetic testing for patients with prostate cancer based on its value in informing treatment decisions since 2018.[1] Germline testing should be considered for patients with clinically low- to intermediate- localized disease accompanied by a family history of prostate cancer; or high- to very high-risk localized disease. Once regional or distant metastases are present, germline testing is recommended regardless of initial risk.

While the majority of prostate cancers occur in patients who do not have family history or an inherited gene mutation, it is estimated that 12-15% of prostate cancer patients carry an identifiable germline DNA damage repair defect.[2,3] Data suggest that prostate cancer patients with *BRCA1/2* mutations are at higher risk for progression during local therapy and metastases and have lower survival.[4] The ability to personalize treatment regimens based on somatic and germline genetic information is now possible (e.g. use of polyadenosine diphosphate–ribose polymerase (PARP) inhibitors), thus reducing the burden of lethal prostate cancer and improving quality of life and survival.[5,6] The extent to which genetic testing and precision treatment remains restricted to tertiary or comprehensive cancer centers dictates, in part, whether such services are available only to a small portion of resource- and access-privileged patients.[7] The promise of precision medicine cannot be realized without diffusion across the many settings in which patients receive risk counseling and treatment.

Clinical providers, as key implementers of NCCN Guidelines through identifying and referring patients to genetic counseling and/or testing, have been slow to adopt genetic testing in practice. A nationwide survey of oncologists practicing in Prostate Cancer Clinical Trials Consortium sites found considerable variation in provider recommendations for testing. The majority of oncologists surveyed (62%) reported considering all metastatic patients for germline genetic testing, while 27% would only test based on a family history or for inclusion in clinical trials. Fewer reported testing in high-risk localized or non-metastatic cases.[8] Examining care across provider specialty types, a survey of over 600 radiation oncologists and urologists found that urologists were significantly more likely than radiation oncologists to view genetic testing as important (46% vs. 20%) and report regular use of genetic testing (26% vs. 4%, all comparisons $p<0.001$).[9] Reasons for underutilization and variation in referral patterns may also include a lack of available and accessible genetics expertise,[8,10,11] which increasingly pressures oncologists and urologists to perform aspects of genetic evaluations in the absence of a sufficient supply of genetic counselors. It is clear from these studies that provider knowledge and attitudes about genetic testing for prostate cancer vary and may influence referrals, which remain lower than expected based on the distribution of clinical characteristics among patients diagnosed with prostate cancer.[12]

Much of the existing literature has focused on provider knowledge and attitudes on genetic testing itself, with studies sampling providers with specialized expertise in treating prostate cancer. There is less literature that depicts how provider perceptions of patients and their ability to navigate the testing process influence referrals for genetic

counseling and testing in community-based settings that serve diverse patient populations.[13] In a paper examining physician bias in breast cancer genetics, Ademuyiwa and colleagues found that medical oncologists believed that Black patients had higher mistrust and cost-related barriers to genetic testing, were less likely to follow through on genetic testing recommendations, and experienced more distress after testing relative to White patients.[14] This suggests that provider's delivery of genetics care may be influenced by factors other than knowledge. This study seeks to characterize health care providers' perceptions and decision-making about the use of genetic services for patients with prostate cancer at an urban, safety-net hospital serving predominantly racial and ethnic minority patients.

Methods:

This study used qualitative interviews to explore how multi-disciplinary health care providers treating prostate cancer patients considered referrals to genetics services for their patients. To answer this question, we constructed a qualitative interview guide based on clinical input and the Behavioral Model for Vulnerable Populations,[15] an adaptation of Andersen's Behavioral Model for identifying differences in health care utilization and outcomes based on pre-disposing characteristics (e.g., demographics, literacy, attitudes towards health care) and enabling factors (e.g., insurance, perceived barriers to care, competing needs), perceived need, and evaluated health. The interview guide covered the following topics: 1) Knowledge about genetic testing and guidelines; 2) Organizational incentives for genetic testing and processes to support it; 3) Discussions about genetic testing with patients; 4) Experience with the

referral process (barriers, facilitators); and 5) Personal and contextual factors that contribute to decision-making about making referrals for genetic services. Research assistants piloted the interview guide with practicing clinicians affiliated with the study. The local Institutional Review Board determined the study activities to be exempt based on federal criteria.

The study team generated a list of all practicing clinicians (medical doctors, nurse practitioners, physician assistants, or genetic counselors) who treated patients with prostate cancer and were thus eligible to be recruited. We purposively sampled at least two clinicians across five relevant medical specialty: general internal medicine, urology, radiation oncology, medical oncology, and genetics. With support from a clinical champion, we sent email invitations soliciting participation in a 45-minute qualitative telephone interview.

Interviews were conducted by either a research assistant who had received didactic and experiential training in qualitative methods, or a doctoral-trained qualitative health services researcher. The interviewer used a flexible approach to covering topics to allow for a conversational flow and to encourage the individual to share their experience in a manner that was most consistent with their thinking. Participants received a $40 debit card for their time at the conclusion of the interview.

Upon completion, the interviewer generated a summary to reflect contextual nuance not captured in the audio recording and initial impressions about most salient themes or topics. All audio recordings were securely uploaded and transcribed by a third party. To ensure fidelity and preserve anonymity, research assistants verified

transcripts and removed identifiers (names, locations) prior to analysis. De-identified transcripts were uploaded into NVivo version 1.5 for coding and analysis.

The analysis was guided by a modified grounded theory approach,[16] utilizing a mixture of open codes and those based on the Behavioral Model for Vulnerable Populations.[15] Two coders independently coded 4 transcripts, using provisional codes from the conceptual model and generating emergent codes based on individual responses. The study team reviewed the provisional and emergent codes to develop a codebook for the remaining interviews. Each transcript was coded by two coders, and discrepancies resolved in consensus meetings. After initial coding with open and conceptual codes, axial coding specified the properties and dimensions of the generated categories and codes.[17] Because only 2-4 interviews were collected within each specialty and the research question did not seek to address similarities or differences between groups, we did not pursue cross-specialty comparisons.

Results:

A total of 21 providers from general internal medicine, urology, radiation oncology, medical oncology and genetics were invited to participate, and 17 completed qualitative interviews (81% response rate). All interviews were completed between January and April 2021 and at least two providers from each specialty were included. Most participants (76%) were medical doctors, while the remaining were licensed nurse practitioners, physician assistants, and genetic counselors. Provider-identified gender was evenly distributed: 47% men, 53% women. The mean number of years in practice was 10.6 years. We identified three topics through open coding that individuals

described as influencing their referral decisions. Topics and associated themes are summarized in Table 1 and described in detail below.

Topic 1: Identifying Patients Eligible for Genetic Testing

A consistent topic discussed across all providers was challenges in identifying patients who were appropriate for genetic testing. One theme identified an absence of systems and/or processes to assist clinical teams in detecting eligible patients for referrals to genetics (Theme 1a):

> "If it were not for providers… just making sure that they think about it for individual patients and put a referral in, patients can easily… get missed, and I don't know if there's any overarching system to ensure that all patients are appropriately captured." (HCP 04)

> "There is no specific policy or procedure. It's just a provider. It's a provider decision tree… there is no reminder, there's no policy, there's nothing in the electronic record to alert you. So, certainly it's one of those things that if you're moving along your day quickly, it's something that might not get ordered unless after the fact." (HCP 05)

> "Yeah, I think that there's no clear consensus from [the] department of identifying these patients and then who's meeting criteria. So, it's pretty variable, so increases the variability." (HCP 07)

Providers attributed variability in referral patterns and noted that some patients were expected to be 'missed' given the lack of systems to facilitate this process.

A second theme (Theme 1b) acknowledged barriers to accessing relevant data, such as family history, that would facilitate providers recognizing the need for referrals to genetics:

> "I think one of the biggest challenges is making sure we actually have that family history. If, for example, the patient had pancreatic cancer in his family, and he brought it up with me. I wish I could say that I screened for it, but he said, 'Look, I had a brother and my father who had pancreatic cancer under the age of 50. How do I know that I'm not going to get pancreatic cancer?' And I was like, 'Oh, good question.'" (HCP 03)

> "Genetic counseling is kind of interesting, if you don't dig for the story, you're never going to figure it out. Like, 'tell me about your parents. Tell me about your siblings'… Yes, we know there's family history in the [medical record], but that's all just lip service… So, we're short sighted… we don't tell the story of the patient. And genetic counseling is completely about the story of the patient." (HCP 06)

In sum, identification of patients who may benefit from genetic testing was described as a fundamental challenge to effectively implementing genetics care for patients with prostate cancer. Without systems and data to identify patients, providers noted variability in who received referrals, an outcome they described as undesirable.

Topic 2: Decision Inputs Contributing to Referrals

The second aspect of genetic testing that participants described was the referral process that was initiated after it was decided that an individual might benefit from genetics services. The first theme (Theme 2a) highlighted the routine practice of consulting the NCCN Guidelines, demonstrating good knowledge about the criteria for referrals among this sample of providers:

> "It's just making sure we're following evidence-based recommendations and practice. You know, it's part of NCCN Guidelines to refer patients to genetics. So, that's definitely something I just consider with all patients." (HCP 02)

> "There are some [NCCN] Guidelines that are for men with high-risk prostate cancer based on their cancer parameters, and for men that might even be intermediate to high risk that genetic testing is recommended. I'm not doing it at that consistency. I'm doing it more on a case-by-case basis if I think there is a stronger predisposition to a germline genetic issue. But I do think that others are potentially ordering it more regularly based on the NCCN Guidelines." (HCP 05)

> "Number one, is that they meet the criteria for genetic testing, and that's usually listed at the NCCN Guidelines for prostate cancer, and based on certain factors prostate, the biology, histology, PSA, et cetera, family history." (HCP 07)

Genetics providers supported the idea that clinician knowledge about eligibility was generally good, as one genetic counselor stated,

> "I think the provider knowledge, I think it's really great that they know that this person qualifies, this person doesn't, and being able to refer them over. With that being said, again, it's mostly a few oncologists, who actually refer over to me. So, perhaps there are some that don't know about testing or don't know about the wide range of people who do qualify. But I will say, overall, the knowledge seems to be really good, and we do get quite a number of referrals." (HCP 12)

In addition to the NCCN Guidelines, provider perceptions of patient-specific considerations that contributed to the genetics referral decision were described (Theme 2b). These ranged in scope from how the provider perceived: patient understanding of genetics information, patient emotional burden, patient ability to afford genetic testing, and patient-provider language barriers. Table 2 provides examples of how providers considered these perceived patient factors on their own referral behaviors.

In sum, when participants described their referral practices, they recognized NCCN Guidelines as important to identify relevant clinical factors. However, provider perceptions of patient characteristics also influenced their decisions as to choosing when, how, and whether to refer patients for genetic testing.

Topic 3: Applicability of Genetic Test Results to Practice

Genetic testing can have several purposes, including informing treatment choice for the affected patient, as well as cascade testing for family members. Whether

providers offered referrals was based in part on their perceived value of the results for their recommendations to the patient. Those participants who emphasized a future value gained from genetic testing described hesitations in referring patients:

> “Rarely will [genetic results] actually impact the patient treatment, but it could certainly have implications for the patient's family. In particular, regarding their own assessment of risk and the need for appropriate screening for prostate cancer or for other genetically linked cancers, depending on the results of the genetic study… It doesn't generally guide my treatment and recommendations or the actual treatment that I provide much at all.” (HCP 04)

> “Oftentimes, people will get told that you have a genetic predisposition, but we can't tell you what it means, which is kind of a struggle that I heard… where you end up saying, “We give you a lot of information, but we don't really know how to act upon this information in any meaningful way.” (HCP 06)

A second group of providers emphasized immediate benefits gained from genetic information, and this group described this as a reason they provided referrals:

> “In some cases, if they're currently being treated, there might be treatment options that were not yet utilized based on the results of the testing. So, more specific care for the patient. And secondly, there may be other cancers related to that, to cancer predispositions syndrome, for which other screening and management would be recommended. And then thirdly, for cascade testing of relative.” (HCP 14)

> "So even though the patient in front of me has prostate cancer, they could be at risk for other cancers, so that's another reason why genetics testing is important. As I mentioned, I also note the importance of this for the family members, like early testing, screening, et cetera. And I also mention about potential therapeutic relevance because if their summary has *BRCA* mutation down the line they could be eligible for PARP inhibitor treatment." (HCP 15)

These orientations toward utility derived now versus in the future were noted by some to influence which specialties might be more likely to refer patients to genetics. Specifically, participants described testing as occurring later, more often by medical oncologists, rather than earlier, as germline genetic information had more immediate treatment implications for those undergoing systemic therapy:

> "Typically, more of the genetic testing in my patient population is ordered by the Medical Oncology team, because they seem to have a larger role in that part of it by the time, they're seeing it… It doesn't guide the care that I provide that much, because again, I mostly personally treat the earlier stages of prostate cancer, which is why I think you probably have the medical oncologist ordering more of the genetic testing. Because it doesn't have as much of an impact on surgical management, or you know radiation for localized management as it does for more systemic treatments... So, that's why it doesn't have a major impact on me per say. And that's probably why I think surgeons are ordering it maybe a little bit less in the grand scheme of things." (HCP 05)

For some, there was a preference for referral and testing to happen earlier, and in greater coordination with primary care and specialists:

> "So, you probably have to have some in-service or some instruction to all of the members of the prostate community, not just the medical oncologists or the radiation oncologist, but maybe from the primary care doctors, the urologists. I feel like those people do less referring to genetic testing because they assume that there's a high-risk prostate cancer is going to be identified, then there's going to be a medical oncologist who can handle all of that. But it'd be nice if everyone on the team knew the recommendations and were able to discuss with patients earlier on." (HCP 10)

In conclusion, provider perceptions of the utility of referring for genetics depended on where in the care timeline they were treating prostate cancer. Some noted that the impetus for referral related to immediate changes in decision-making, while others who were hesitant to refer perceived benefits would be derived solely at a future time in the patient's cancer treatment.

Conclusion:

In this qualitative study of multi-disciplinary health care providers, three distinct topics related to providing genetic services to prostate cancer patients were identified as important: identification of patients, decision inputs for providing a referral, and the utility of genetics results to practice. Challenges in identification stemmed from a lack of systems to support routine patient identification and the lack of readily available data to

support eligibility determination (e.g., structured family history). Referrals were supported by good knowledge and use of NCCN Guidelines. Providers did identify other non-medical patient characteristics that influenced their discussions and referral practices. Finally, whether providers perceived benefits of testing would be derived immediately or in the future was related to whether they referred patients. This meant that providers seeing patients later in their cancer (i.e., medical oncologists) were perceived to be most likely to be responsible for genetics care.

The absence of systems to identify patients who may benefit from referral to genetics services was universally noted as a critical barrier to providing equitable and high-quality care for prostate cancer patients. This phenomenon has been noted as a critical impediment to implementing precision medicine across disease sites.[18–20] A recent systematic review documented of 32 studies to improve genetic testing for those with hereditary cancers, 15 (47%) used family history and/or referral tools, and 10 of these (67%) also integrated clinical decision support tools.[21] Other similar primary care-based interventions are being tested to promote the routine screening of patients eligible for genetic testing.[23] The use of well-designed, standards-based CDS tools overcomes several challenges identified by providers in this study beyond systematic identification. It allows for adaptation in the context of evolving guidelines and science,[24] reducing reliance on individual provider knowledge. Systems such as these can reduce potential bias present in interpersonal elicitation of risks or bias that prevents referral despite risk elicitation.

Providers in this study indicated that NCCN Guidelines facilitated referrals for patients with prostate cancer. However, provider perceptions about patient

characteristics introduced factors beyond clinical need into their referral behaviors. Some of these perceived characteristics, such as perceived patient distress, likelihood of following through, health literacy, and ability to pay were similarly reflected in a recent national survey with breast oncologists. That study found that providers perceived different barriers to genetic counseling and testing, and held different attitudes towards African American compared to Black and White patients, reflecting inherent biases that may influence access to care.[14] When perceptions about predisposing characteristics (health literacy, cost) influence care, differences in utilization between minority or marginalized versus majority, privileged populations can widen.[15] Future work is critically needed to understand and quantify the extent to which these perceptions and biases influence referral patterns. Efforts to address provider biases could include standardized intake and family history elicitation tools[25] to reduce the influence of individual perceptions and focus on clinical and familial factors that should drive referral. Additionally, plain language and communication interventions[26,27] are also needed to support providers in delivering high-quality genetic information and counseling. Web-based tools targeting providers that offer patient intake questions combined with education may address many issues driving the inconsistent delivery of evidence-based genetics referrals identified in our study.[25]

Perceptions about the monetary cost of genetic testing and patients' ability to pay was emphasized by many of the participants as salient to making referrals. Others have documented that cost is a barrier to prostate cancer treatment and genetic testing,[13] and one that impacts racial and ethnic minorities more than White patients. For example, one study determined that financial hardship during cancer treatment was 23% higher in

Black versus White patients, and Black patients were 41% more likely to limit care due to cost.[28] In a national survey of oncologists, 1 in 4 oncologists rarely/never mentioned costs in discussing genetic testing, although respondents practicing in clinics with a higher proportion of patients who were uninsured or covered by Medicaid were more likely to discuss cost.[29] However, coverage rules and restrictions as well as cost-sharing for genetic testing varies widely across insurers,[30] and may be unknown by providers. Increasingly, there are sponsored programs that can mitigate or eliminate patient out-of-pocket costs for genetic services for eligible patients.[31] Promoting awareness of such programs such that cost is removed as a barrier is a key imperative. Further policy advocacy that limits cost-sharing and provides more uniform criteria for coverage associated with genetics care for cancer patients is also warranted.

Finally, the question of timing and utility of genetic information across the cancer care continuum was raised in this study of multi-specialty providers. Studies have shown that clinicians' interpretation and application of genetic results varies by their role, confidence in understanding results, and practice setting.[32] Similarly, survey research has demonstrated that 70% of urologists but only 40% of radiation oncologists feel confident in using genetic tests for treatment decision-making. Understanding how confidence in using genetic results affects perceptions of its utility for clinical care within and across specialties is warranted. At the same time, the optimal timing of genetic testing in the continuum of prostate cancer treatment is an area for future investigation[33] and may evolve with advances in genomic science and targeted treatment applications.

This study has some limitations. Responses reflect local practices at a single urban, safety-net hospital and individual provider perceptions. As a qualitative study, it

is intended to generate hypotheses and the topics that emerged as salient to these providers can inform future measurement of provider attitudes, beliefs, and behaviors across activities relevant to providing cancer genetics services. Due to the relatively small sample size within each provider type, we were unable to look at comparisons across specialties. Based on our findings and other research, this may be a fruitful area of investigation, especially given the questions raised about utility of genetic information across different phases of prostate cancer care.

In conclusion, this qualitative study adds to the literature on the provision of genetic services for patients with prostate cancer since the NCCN expanded eligibility for testing in 2018, sampling from a safety-net hospital serving a population of predominantly racial and ethnic minority patients. We documented variability in offering referrals to genetics services based on issues in systematic identification, provider perceptions about non-medical patient characteristics, and utility to clinical practice. Future research must consider how providers' use of genetics and communication skills impact patients' options for precision medicine at the individual and organizational levels, attending to the potential for treatment and outcome disparities across patient populations and clinical settings.

References

1. NCCN. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) Prostate Cancer. Published August 15, 2018. Accessed September 27, 2018. https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf

2. Nicolosi P, Ledet E, Yang S, et al. Prevalence of Germline Variants in Prostate Cancer and Implications for Current Genetic Testing Guidelines. *JAMA Oncol*. 2019;5(4):523-528. doi:10.1001/jamaoncol.2018.6760

3. Giri VN, Obeid E, Gross L, et al. Inherited Mutations in Men Undergoing Multigene Panel Testing for Prostate Cancer: Emerging Implications for Personalized Prostate Cancer Genetic Evaluation. *JCO Precis Oncol*. 2017;(1):1-17. doi:10.1200/PO.16.00039

4. Castro E, Goh C, Olmos D, et al. Germline BRCA mutations are associated with higher risk of nodal involvement, distant metastasis, and poor survival outcomes in prostate cancer. *J Clin Oncol Off J Am Soc Clin Oncol*. 2013;31(14):1748-1757. doi:10.1200/JCO.2012.43.1882

5. de Bono J, Mateo J, Fizazi K, et al. Olaparib for Metastatic Castration-Resistant Prostate Cancer. *N Engl J Med*. 2020;382(22):2091-2102. doi:10.1056/NEJMoa1911440

6. Survival with Olaparib in Metastatic Castration-Resistant Prostate Cancer | NEJM. Accessed February 4, 2022. https://www.nejm.org/doi/full/10.1056/NEJMoa2022485

7. Peterson EB, Chou WYS, Gaysynsky A, et al. Communication of cancer-related genetic and genomic information: A landscape analysis of reviews. *Transl Behav Med*. 2018;8(1):59-70. doi:10.1093/tbm/ibx063

8. Paller CJ, Antonarakis ES, Beer TM, et al. Germline Genetic Testing in Advanced Prostate Cancer; Practices and Barriers: Survey Results from the Germline Genetics Working Group of the Prostate Cancer Clinical Trials Consortium. *Clin Genitourin Cancer*. Published online April 18, 2019. doi:10.1016/j.clgc.2019.04.013

9. Kim SP, Meropol NJ, Gross CP, et al. Physician attitudes about genetic testing for localized prostate cancer: A national survey of radiation oncologists and urologists. *Urol Oncol Semin Orig Investig*. 2018;36(11):501.e15-501.e21. doi:10.1016/j.urolonc.2018.07.002

10. Raspa M, Moultrie R, Toth D, Haque SN. Barriers and Facilitators to Genetic Service Delivery Models: Scoping Review. *Interact J Med Res*. 2021;10(1):e23523. doi:10.2196/23523

11. Hoskovec JM, Bennett RL, Carey ME, et al. Projecting the Supply and Demand for Certified Genetic Counselors: A Workforce Study. *J Genet Couns*. 2018;27(1):16-20. doi:10.1007/s10897-017-0158-8

12. Siegel DA. Prostate Cancer Incidence and Survival, by Stage and Race/Ethnicity — United States, 2001–2017. *MMWR Morb Mortal Wkly Rep*. 2020;69. doi:10.15585/mmwr.mm6941a1

13. Weise N, Shaya J, Javier-Desloges J, Cheng HH, Madlensky L, McKay RR. Disparities in germline testing among racial minorities with prostate cancer. *Prostate Cancer Prostatic Dis*. Published online November 13, 2021:1-8. doi:10.1038/s41391-021-00469-3

14. Ademuyiwa FO, Salyer P, Tao Y, et al. Genetic Counseling and Testing in African American Patients with Breast Cancer: A Nationwide Survey of US Breast Oncologists. *J Clin Oncol*. 2021;39(36):4020-4028. doi:10.1200/JCO.21.01426

15. Gelberg L, Andersen RM, Leake BD. The Behavioral Model for Vulnerable Populations: application to medical care use and outcomes for homeless people. *Health Serv Res*. 2000;34(6):1273-1302.

16. Charmaz K. *Constructing Grounded Theory: A Practical Guide through Qualitative Analysis*. SAGE Publications, Inc.; 2006.

17. The Coding Manual for Qualitative Researchers. SAGE Publications Inc. Published October 27, 2021. Accessed October 28, 2021. https://us.sagepub.com/en-us/nam/the-coding-manual-for-qualitative-researchers/book243616

18. Meyer LA, Anderson ME, Lacour RA, et al. Evaluating Women with Ovarian Cancer for BRCA1 and BRCA2 Mutations: Missed Opportunities. *Obstet Gynecol*. 2010;115(5):945-952. doi:10.1097/AOG.0b013e3181da08d7

19. Whitcomb DC. Barriers and Research Priorities for Implementing Precision Medicine. *Pancreas*. 2019;48(10):1246-1249. doi:10.1097/MPA.0000000000001415

20. Klein ME, Parvez MM, Shin JG. Clinical Implementation of Pharmacogenomics for Personalized Precision Medicine: Barriers and Solutions. *J Pharm Sci*. 2017;106(9):2368-2379. doi:10.1016/j.xphs.2017.04.051

21. Morrow A, Chan P, Tucker KM, Taylor N. The design, implementation, and effectiveness of intervention strategies aimed at improving genetic referral practices: a systematic review of the literature. *Genet Med Off J Am Coll Med Genet*. 2021;23(12):2239-2249. doi:10.1038/s41436-021-01272-0

22. Del Fiol G, Kohlmann W, Bradshaw RL, et al. Standards-Based Clinical Decision Support Platform to Manage Patients Who Meet Guideline-Based Criteria for Genetic Evaluation of Familial Cancer. *JCO Clin Cancer Inform*. 2020;(4):1-9. doi:10.1200/CCI.19.00120

23. Bowen DJ, Wang C, Cole AM, et al. Design of a study to implement population-based risk assessment for hereditary cancer genetic testing in primary care. *Contemp Clin Trials*. Published online December 26, 2020:106257. doi:10.1016/j.cct.2020.106257

24. Roadmap for National Action on Clinical Decision Support | Journal of the American Medical Informatics Association | Oxford Academic. Accessed February 9, 2022. https://academic.oup.com/jamia/article/14/2/141/862323?login=true

25. Giri VN, Walker A, Gross L, et al. Helix: A Digitial Tool to Address Provider Needs for Prostate Cancer Genetic Testing in Clinical Practice. *Clin Genitourin Cancer*. 2022;000(xxx):1-10. doi:10.1016/j.clgc.2021.11.009

26. van der Giessen JAM, van Dulmen S, Velthuizen ME, et al. Effect of a health literacy training program for surgical oncologists and specialized nurses on disparities in referral to breast cancer genetic testing. *The Breast*. Published online April 22, 2021. doi:10.1016/j.breast.2021.04.008

27. Vasilevsky NA, Foster ED, Engelstad ME, et al. Plain-language medical vocabulary for precision diagnosis. *Nat Genet*. 2018;50(4):474-476. doi:10.1038/s41588-018-0096-x

28. Hastert TA, Kyko JM, Reed AR, et al. Financial Hardship and Quality of Life among African American and White Cancer Survivors: The Role of Limiting Care Due to Cost. *Cancer Epidemiol Biomarkers Prev*. 2019;28(7):1202. doi:10.1158/1055-9965.EPI-18-1336

29. Yabroff KR, Zhao J, de Moor JS, et al. Factors Associated with Oncologist Discussions of the Costs of Genomic Testing and Related Treatments. *J Natl Cancer Inst*. 2020;112(5):498-506. doi:10.1093/jnci/djz173

30. Zhen JT, Syed J, Nguyen KA, et al. Genetic testing for hereditary prostate cancer: Current status and limitations. *Cancer*. 2018;124(15):3105-3117. doi:10.1002/cncr.31316

31. Invitae Genetics. Detect Hereditary Prostate Cancer. Invitae. Published 2021. Accessed March 2, 2022. https://www.invitae.com/en/detect-hereditary-prostate-cance

32. Berrios C, Hurley EA, Willig L, et al. Challenges in genetic testing: clinician variant interpretation processes and the impact on clinical care. *Genet Med*. Published online July 13, 2021:1-11. doi:10.1038/s41436-021-01267-x

33. Das S, Salami SS, Spratt DE, Kaffenberger SD, Jacobs MF, Morgan TM. Bringing Prostate Cancer Germline Genetics into Clinical Practice. *J Urol*. 2019;202(2):223-230. doi:10.1097/JU.0000000000000137

Table 1: Summary of Identified Topics and Associated Themes

Topic	Theme
1. Identifying Patients for Testing	1a: Systems are lacking to support systematic identification of those eligible for testing 1b: Data to support eligibility determination is not readily available and time-consuming to acquire during visits
2. Decision Inputs for Referrals	2a: Use of NCCN Guidelines to guide referrals 2b: Patient characteristics that influence provider genetic referral practices
3. Applicability of Testing to Practice	3: Providers described the utility of genetic testing as either bringing immediate value to their practice, or having some future value, which influenced whether they would make referrals

Table 2: Examples of Theme 2a: The consideration of patient characteristics in provider referral practices

Patient characteristic	Example quote
Health Literacy and/or Language	"People who are… more motivated, I feel like are more likely to show up to that appointment and go through. Probably easier in an English-speaking population with good health literacy versus someone who might not have that same health literacy or English as their first language." (HCP 02) "I don't like this answer, but in total honesty, I will say that I think it's the service that generally patients get as they advocate for. And so, it creates a disparity if it's something that an educated English-speaking patient says, 'Hey, I know this is my family history, and I know I want to get further testing.' I'm much more likely to send it… I do think my limited English proficiency patients who come from a different setting, are much less likely to self-advocate for this. I'm not proud of that. I should be doing better screening upfront and have equity in my referrals, but just being totally honest about how things happen." (HCP 03) "I mean oftentimes with some of our patients there's such low health literacy and … it's just it's a challenge, just trying to have them understand. And then genetics on top of that… I mean that's difficult for them to really completely comprehend." (HCP 11)
Distress	"In the rare cases that I've had not offered testing due to their inability to understand what they were being consented for, and for their verbal communication of the distress they feel that results will have on them, I have scheduled follow up with them or offered follow ups with them." (HCP 09)
Cultural beliefs	"Trust in providers is a big aspect also, that could be important when patients are listening to the conversation about genetic testing, importance of genetic testing. I know from my own experience in my home country, there is this belief when somebody gets your blood and gets your DNA, they believe that with the DNA they would be able to know your weaknesses and create like weapons for certain aspects of a nation, which is always a paranoia. But if it's a patient concern it should be considered and addressed." (HCP 15)
Patient ability to afford testing	"Number one issue that we face is whether people who have [public insurance] have access to certain services. I don't know whether my patients with [public insurance] have access to genetic cancer testing. I would assume they probably do in [state], but the fact that I don't know that says something. Our patients are so liable to get bills inappropriately sent to them, and that are really medically devastating. I think there's some barrier on that front of just not knowing what is covered." (HCP 03) "If there are any costs, and they can't afford it, I mean, I don't know if cost is one that you say you definitely should not [get genetic testing]. I guess there's a risk benefit analysis that a clinician has to play in their mind, like if they can't afford it, is this something that is so worthwhile that they [should do the testing] even if they have to pay for it." (HCP 06)

Characterizing access to genetics referrals for prostate cancer in a safety net hospital

CM Gunn, G Gignac, M Pankowska, K Zayhowski, CL Wang

Genetic testing, as a key component of precision medicine, may reduce prostate cancer treatment-related disparities, but only if widely disseminated outside of tertiary cancer care settings. This study sought to characterize predictors of germline genetic testing referrals and use among patients diagnosed with prostate cancer at a safety-net hospital using electronic medical record data. Men who had a confirmed diagnosis of prostate cancer between January 1, 2011 and March 10, 2020 were identified via the tumor registry. Using a centralized clinical data warehouse, we collected data on age, race, ethnicity, primary language, marital status, clinical stage, and insurance. The primary outcome was receipt of a referral to genetic counseling. We hypothesized that men who were foreign-born, non-English speaking, identified as Black race or Hispanic ethnicity, and were older would be less likely to be referred for genetic testing. A secondary outcome was the completion of genetic testing. Descriptive statistics (means, standard deviations, frequencies) described the cohort. In multivariable analyses, logistic regression estimated odds ratios (OR) and 95% confidence intervals (95% CI) for factors hypothesized to influence referral to genetic testing: age, race (Black, White, Asian, Other), ethnicity (Hispanic vs. non-Hispanic), language (English vs. non-English), country of origin (US vs. Other), insurance (Medicare, Medicaid, Private, Other), and clinical cancer stage (Local, Regional, Metastatic). Overall, 1,877 patients were diagnosed with prostate cancer in the study period. The mean age was 65 years (SD=9). 44% identified as Black race, 32% White. Ethnic composition was 17% Hispanic, 80% Non-Hispanic. Almost half (49%) were married, 46% were foreign born, and 34% had Medicaid insurance at diagnosis. Two-thirds (67%) spoke English, and 33% were non-English speakers. The majority (65%) had local-only disease at diagnosis, 3% had regional disease, 9% metastatic, and 22% had missing clinical stage data. For the primary outcome, 163 (9%) of all patients received at least one genetics referral. In multivariate models, we found that those who were older (OR=0.95, 95% CI: 0.93, 0.98) and identified as White race (OR=0.60, 95% CI: 0.38, 0.96) had lower odds of receiving a referral. Those with regional or metastatic disease at diagnosis were significantly more likely to receive referral, as expected (OR= 4.45 and 4.78, respectively). No other demographics significantly predicted referral. Of the 163 men referred to genetics, 136 (83%) had at least one genetics encounter and 19 (14%) had genetic testing. In sum, few patients received referrals for genetic counseling and testing from 2010-2021, with 80% occurring post-guideline changes in 2018. When referrals were made, our sample had high rates of genetics encounters, although lower rates of testing completion. Low rates of referral and testing indicate opportunities to improve both identification of eligible patients and resolve barriers to completing genetic testing post-encounter.

AACR VIRTUAL CONFERENCE: 14TH AACR CONFERENCE
THE SCIENCE OF CANCER HEALTH DISPARITIES IN RACIAL/ETHNIC MINORITIES AND THE MEDICALLY UNDERSERVED
IN ASSOCIATION WITH THE AACR MINORITIES IN CANCER RESEARCH COUNCIL
October 6-8, 2021
AACR American Association for Cancer Research
FINDING CURES TOGETHER

Characterizing access to genetics referrals for prostate cancer in a safety net hospital

Christine M. Gunn, PhD
Assistant Professor, The Dartmouth Institute for Health Policy & Clinical Practice
Adjunct Assistant Professor, Boston University School of Medicine
Christine.M.Gunn@Dartmouth.edu

Background

- Genetic testing may reduce prostate cancer treatment-related disparities
- Access to genetics services is best characterized in large, tertiary cancer centers[1,2,3]
- This study aimed to characterize referrals to genetics for a cohort of men diagnosed with prostate cancer at a safety-net, academic medical center over a 10-year period

[1] Paller et al. (2019) *Clinical Genitourinary Cancer*. [2] Loeb et al. (2020) *Cancer Treatment and Research Communic*ations. [3] Loeb et al. (2021) *The P*[illegible]*state*.

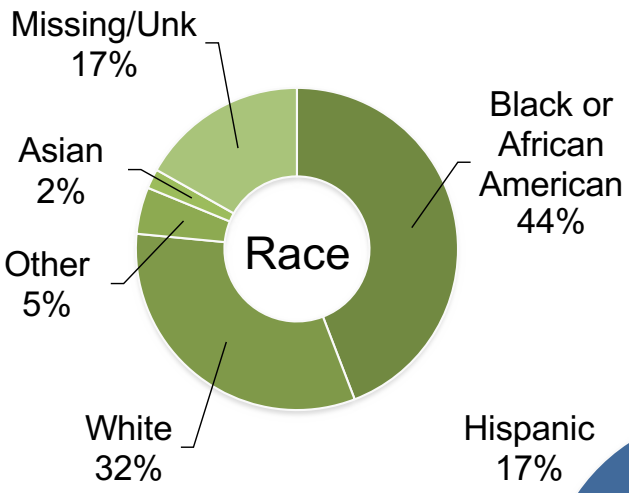
Methods

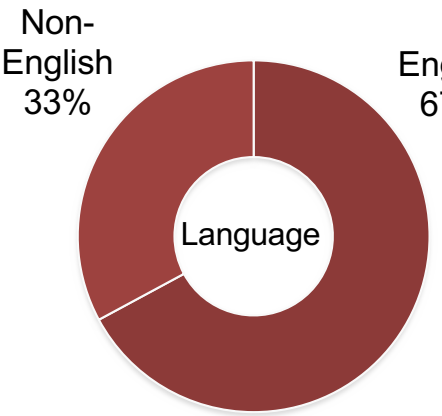
- **Inclusion:**
  - Men with diagnosis of prostate cancer between January 2011 and March 2020
- **Primary Outcome:**
  - Referral to genetics post-diagnosis (yes/no)
- **Secondary Outcomes:**
  - Genetics encounters
  - Testing completion
- **Analysis:**
  - Multivariate logistic regression estimated odds ratios (OR) and 95% confidence intervals (95% CI) with covariates:
    - Age
    - Race (Black, White, Asian, Other)
    - Ethnicity (Hispanic vs. non-Hispanic)
    - Language (English vs. non-English)
    - Country of origin (Foreign-born vs. US born)
    - Insurance (Medicare, Medicaid, Private, Other)
    - Clinical cancer stage (Local, Regional, Metastatic)

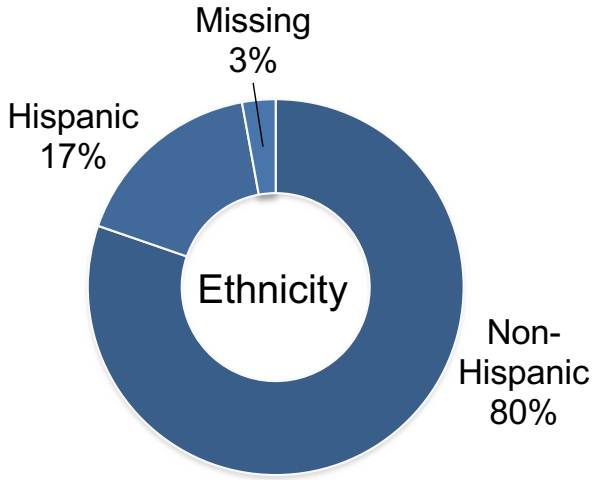
Cohort Characteristics

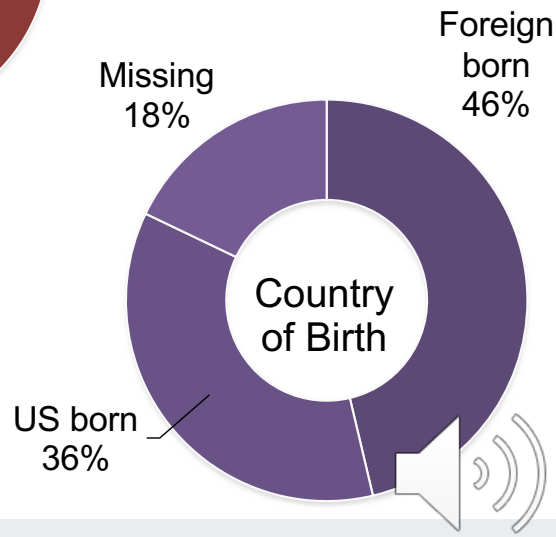
American Association for Cancer Research®
FINDING CURES TOGETHER®

1,877 men diagnosed with prostate cancer



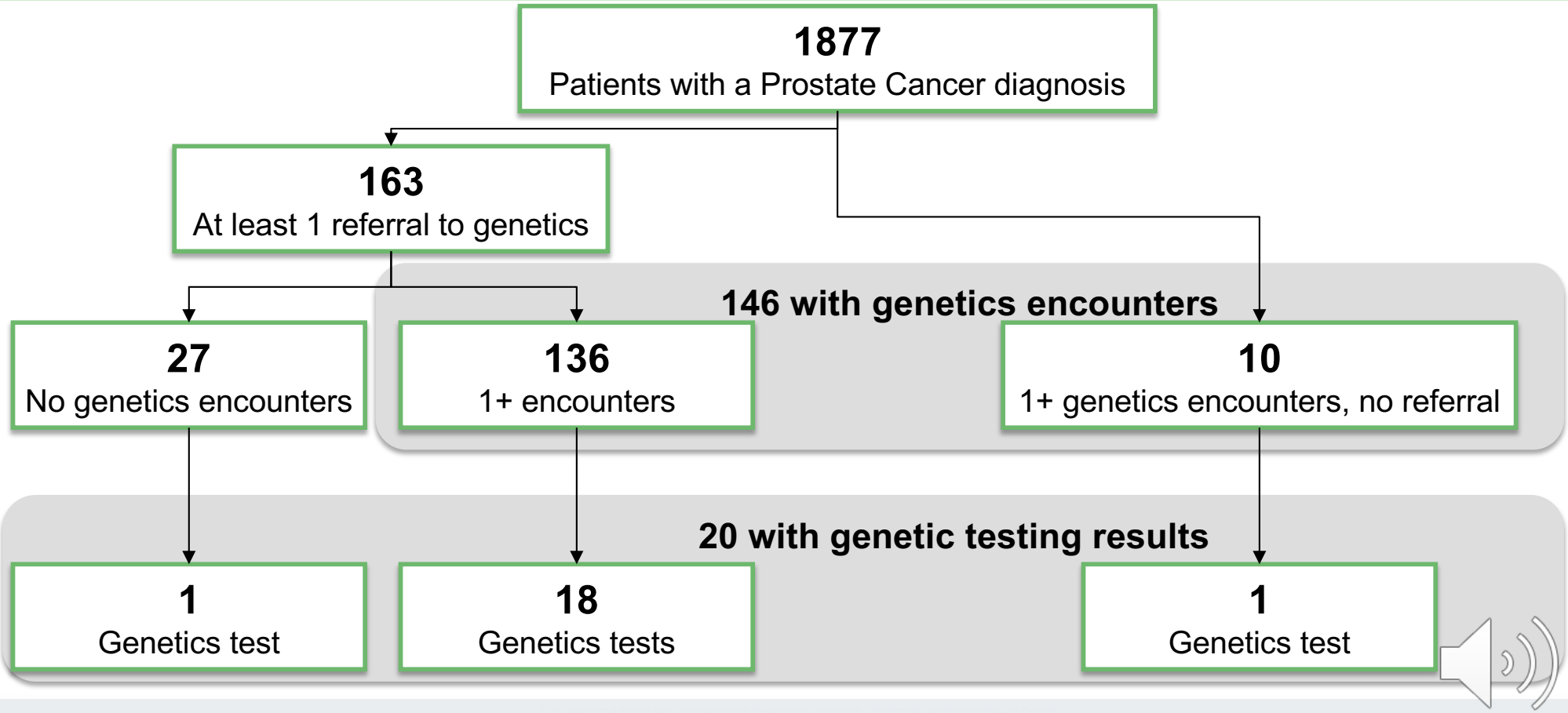






Results: Referrals, Encounters and Tests

American Association for Cancer Research®
FINDING CURES TOGETHER®



Results: Multivariate Regression

American Association for Cancer Research
FINDING CURES TOGETHER

Variable	Hypothesis	Result
Age	↓ Odds of referral	**OR: 0.95** (0.93, 0.98)
White race	↑ Odds of referral	**OR: 0.60** (0.38 –0.96)
Foreign born	↓ Odds of referral	No significant relationship
Non-English language		
Hispanic Ethnicity		
Higher clinical stage	↑ Odds of referral	$OR_{regional}$: **4.45.** (2.39, 8.25) $OR_{metastatic}$: **4.78** (3.05, 7.52)

Conclusions

AACR American Association for Cancer Research®
FINDING CURES TOGETHER®

- There was a high rate of genetics visits resulting from referrals (83%), yet only 13% completed tests
- Clinical factors appeared to be a driving factor in referrals
- Reasons for low uptake of testing are likely multi-factorial, and require engagement of patients, administrators, and clinicians

Acknowledgements

- This work was funded by the United States Department of Defense (W81XWH-20-1-0110)

- **Thank you to my co-authors:**
  - Catharine Wang, PhD
  - Gretchen Gignac, MD
  - Kim Zayhowski, MSc
  - Emma Li, MSc
  - Magdalena Pankowska, MPH

Introduction

- 2018 National Comprehensive Cancer Center Network (NCCN) Guidelines expanded germline genetic testing eligibility criteria for prostate cancer patients
- Clinical providers, as key implementers of NCCN guidelines have been slow to take up genetic testing in practice
- Little is known about how providers and clinics are providing cancer genetics services, especially in light of increasing eligibility for testing

Objectives

This qualitative study explored factors that influence the delivery of genetics care for prostate cancer patients among multi-disciplinary providers practicing at an academic, safety-net hospital

Methods

Eligibility & Recruitment:

- Eligible participants: MDs, NPs, PAs, and genetic counselors who provided care for patients with prostate cancer at Boston Medical Center
- Providers were purposively sampled from Urology, Medical Oncology, Radiation Oncology, Genetics, and Primary Care
- Up to 3 email invitations sent requesting participation

Data Collection:

- Semi-structured interviews (30 – 45 mins) used a flexible guide developed based on prior literature and pilot-tested
- Interviews were conducted via telephone, audio recorded, and professionally transcribed
- Participants compensated $40

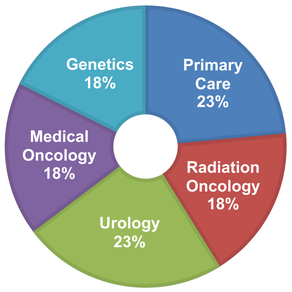
Data Analysis:

- Codebook developed based on interview guide, and organized into three levels of analysis: patient-, provider-, and systems-level
- Thematic analysis performed through interpretive description using two coders
- Themes and supporting quotes reviewed by the study team to ensure credibility of representation

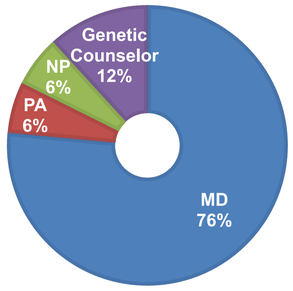
Results

Participant Characteristics (N=17)

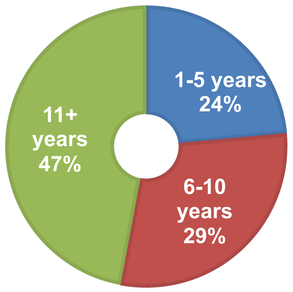
PROVIDER SPECIALTY



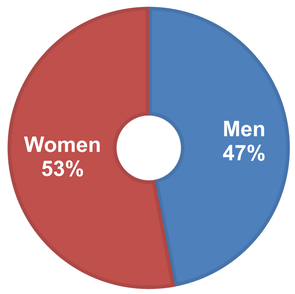
PROVIDER TYPE



YEARS IN PRACTICE



PROVIDER GENDER



Themes on Facilitators & Barriers to Genetics Care

Patient Level

Concern for family facilitated counseling

"I'll usually start with, 'Do you have children?' because that – tends to be like the striking point for people who want to get genetic testing."

Patient understanding, cost, and ability to attend appointments were key barriers to genetics care

"A lot more people would decline testing based on just the cost and deductibles, coinsurance, co-pays."

"Social barriers such as transportation, language barriers, things like that."

"I think levels of health literacy are very variable… We also have many non-English speaking patients."

Provider Level

Providers felt more willing to recommend if they perceived that the patient would benefit from testing

"I think the drawback of any of this type of testing is we are telling people something about their bodies that they cannot do anything about. All we are doing is seeding anxiety and concern."

"It's all about the outcome of the patient in front of you… So, if I think that it may have an impact on their treatment outcome or their treatment paradigm, that's kind of the main motivation."

Genetics knowledge was variable, and was a barrier for provider referrals

"We try to be up to date on the guidelines, if there's been a change or a revision… [most] are probably not as up to date on the genetic guidelines changing. So, we would rely on other staff and faculty to help us."

System Level

Coordinating mechanisms were a critical facilitator for completing testing

"Probably the main thing is just like the patient navigator. Like I said, identifying any barriers like transportation or things."

"You know just some administrative assistance [that's needed]."

Reliance on individuals to provide referrals limited genetics access

"There is no specific policy or procedure. It's just a provider… there is no reminder, there's no policy, there's nothing in the electronic record to kind of alert you. So, certainly it's one of those things that if you're moving along your day quickly, it's something that might not get ordered."

- Providers identifie
to identifying eligi
completing couns
- Barriers related to
patient and provid
address in the ab
care (e.g. EMR pr
regional, or metas

- Providers had vary
experiencing prost
prostate cancer gu
- Findings represen
explore the perspe

- More research on
referral, testing) in
needed
- Complementary m
and systems level
genetics care for r

This work is support
(W81XWH2010110)
University School of

Study Contact: Chr

Provider Practices in Offering Germline Genetic Testing for Men with Prostate Cancer at a Safety-Net Hospital

National Comprehensive Cancer Network Guidelines suggest most patients with prostate cancer may benefit from germline genetic testing, which can influence decisions about treatment. This study explores determinants of offering genetics referrals to patients receiving prostate cancer care among multi-disciplinary providers. We invited medical providers (MDs, NPs, PAs) providing care to patients with prostate cancer at an urban, safety-net hospital to participate in a 45-minute qualitative interview. Purposive sampling sought at least 2 providers per specialty: primary care, urology, radiation oncology, medical oncology, and genetics. Semi-structured telephone interviews were conducted using a flexible interview guide and professionally transcribed. The remaining interviews were independently coded, with 20% double coded to ensure rigor. A thematic analysis was performed using interpretive description. Themes were reviewed by the study team to ensure the credibility of theme representation and supporting quotes. 20 providers were invited to participate, 17 completed interviews. Four Primary care physicians and Urologists participated; along with 3 Radiation Oncology, Genetics, and Medical Oncology providers. Three themes described determinants of provider provision of germline genetic testing. Providers described their decision to offer testing as: 1) Based on individual discretion and awareness of guidelines for testing; 2) Influenced by their perceptions of the patient's ability to pay for testing, and understand its purpose; 3) Related to their perceptions of the utility or "actionability" of genetics results for patients and/or their families. Provider perceptions influence their decisions to offer genetic testing and may introduce potential bias in patient access to testing. Systems that routinely identify patients eligible for prostate cancer genetic evaluation offer opportunities to make genetic testing more equitable.

Table 1: Exemplary Quotes for Identified Themes

Theme	Quotes
Offering testing was based on individual discretion and awareness of guidelines	"The challenge is that you just have to have… the doctor consider it… because the patient is not really looking for it. The patient is not going to say, "Do I need to go see a genetic counselor?" So I would say it's really up to the doctor." - *Urologist, 19 years in practice*
	"We don't have any policies or procedures in place. It's up to the discretion of the provider… I think that there's no clear consensus from a department of identifying these patients and then who's meeting criteria. So, it's pretty variable, so increases the variability." - *Urologist, 9 years in practice*
	"Well, I mean it is a patient by patient, for me it's a patient by patient discussion. There are some National Cancer Center Network Guidelines that's for men with high risk prostate cancer based on their cancer parameters, and for men that might even be intermediate to high risk that genetic testing is recommended. I'm not doing it at that consistency. I'm doing it more on a case by case basis." - *Urologist, 14 years in practice*
Provider perceptions of patient ability to pay and understand test purpose	"I definitely would not say go to genetic counseling… if there are any costs, and they can't afford it… I guess there's a risk benefit analysis that a clinician has to play in their mind, like if they can't afford it, is this something that is so worthwhile that they got to go even if they have to pay for it… and I think the problem with genetic testing also is the ability to cognitively understand the reason of going there what are you going to come out from that with." - *Urologist, 27 years in practice*
	"I don't like this answer, but in total honesty, I will say that I think it's the service that generally patients get as they advocate for. And so, it creates a disparity if it's something that an educated English-speaking patient says, "Hey, I know this is my family history, and I know I want to get further testing." I'm much more likely to send it." -*Primary care physician, 7 years in practice*
	"During COVID, I find remote conversations for older men about complex topics like genetics to be a significant factor… of having success to access to this care. Many times I don't think our patients are understanding what I'm saying on the phone because they can't hear me or they don't know what genetics is." - *Genetic Counselor, 3 years in practice*
	"Sometimes, it's a matter of they're overwhelmed and they're getting too much information. So, if that's the case, I'll put in my note that they are appropriate for genetic testing, but that they're not ready for a referral at that point just as a way to note to myself to re-discuss this with them again in the future when they're perhaps less overwhelmed with the diagnosis and other aspects of treatment." - *Radiation Oncologist, 4 years in practice*
Provider perceptions about genetic results' utility for patients and/or families	"Like, if there's some sort of targetable mutation that might change their own management down the line. I don't really get into the specifics of that with patients, but that's something, you know, I consider." - *Radiation Oncology PA, 8 years in practice*
	"It doesn't guide the care that I provide that much, because again, I mostly personally treat the earlier stages of prostate cancer, which is why I think you probably have the medical oncologist ordering more of the genetic testing. Because it doesn't have as much of an impact on surgical management, or you know radiation for localized management as it does for more systemic treatments, which would be like intravenous types of treatments or injection treatments. So, that's why it doesn't have a major impact on me per say. And that's probably why I think surgeons are ordering it maybe a little bit less in the grand scheme of things." - *Urologist, 14 years in practice*
	"But I also have this, what I call the counter sense of genetic counseling that oftentimes, people will get told that you have a genetic predisposition, but we can't tell you what it means, which is kind of a struggle that I heard, for some diseases, where you end up saying, "We give you a lot of information, but we don't really know how to act upon this information in any meaningful way." Which is very frustrating for the patient, actually, I think." - *Urologist, 27 years in practice*
	"Well, I think the goals are multiple. Obviously, there's implications for the patient themselves, in learning more about their disease, which may impact themselves, screening for other malignancies depending on what we find, as well as their family members. As I mentioned before, potentially treatment implications BRCA and PARP inhibitors are one example of that. But I think that leads me to the next part, which is that future areas of research or targets for medications. Obviously, the more data we collect from men with prostate cancer, the more research can be done looking into that in more detail. And then also just advancing science and gathering more information about prostate cancer and in particular, at [Hospital 1], given our underserved population. I think they're a unique set of patients that it's valuable to be collecting information on." - *Medical Oncologist, 1 year in practice*

Genetic Testing for Men with Prostate Cancer: Patient Interview Guide

Please note: This is an interview guide, intended to be used flexibly, to allow for a conversational flow to the interview while covering the topics below. Prompts are included here as possible suggestions for elaboration if responses are short.

Thank you for talking to me today. We are here today to learn about your prostate cancer care experience at Boston Medical Center.

There are no right or wrong answers to the questions I'm going to ask today, I really just want to hear about your experience and thoughts. You may also feel free to share as much or as little as you feel comfortable. If there's something you prefer not to talk about, please let me know and we can move on.

Do you have any questions before we get started?

TOPIC 1: Prostate Cancer Experience

First, I'd like to hear about your prostate cancer experience.

How has having prostate cancer affected your everyday life?

When you were diagnosed, what did the doctors say about how serious your prostate cancer was? How did you feel about this?

How did you make decisions about your prostate cancer treatment?

Probes: Who was part of those decisions? What was most important to you when choosing a treatment?

Who have you leaned on to help you through your treatment?

Probes: Who has helped you with physical tasks? Who have you talked to for emotional support? What helped you most through treatment?

TOPIC 2: Initial Genetic Testing Discussions & Decision

Note to interviewers: In this section people may not use the term "genetics". Use language that reflects the participant's understanding, where possible. Some may talk about genetics directly, while others talk about risk, etc. If a participant talks about the doctor wanting them to get some other testing or talk to someone about their family history, explore this. The goal here is to learn more about their first impressions about genetics.

What is your understanding of what caused your prostate cancer?

At any point, did anyone talk to you about what might have caused your cancer?

How was it described?

Probes: What have people told you about you and your family's chances of getting prostate cancer? (*i.e. the fact that prostate cancer is more common in some families than others*)

What was your first impression when [person] talked to you about the idea? What questions did you ask?

What prior experience did you or others you know have with finding about more about your family risk?

How did that first discussion end? How did you feel about this?

What other conversations did you have about prostate cancer risk/genetics? With whom?

Probes: Family, medical professionals, friends, etc.

Where else did you go for information about prostate cancer risk/genetics, if anywhere?

What did you find? How did that change your thinking, if at all?

What did you trust about this source of information? What made you skeptical?

What factors did you think about when deciding about whether to take the next step?

From all that you learned about prostate cancer risk/genetics testing, how did you expect it to help you? Your family? Your doctor?

What did you end up deciding about getting genetic testing? Why did you choose [to proceed/not proceed with] learning more about genetics for your prostate cancer?

What was most important to you in making this decision?

Whose opinions did you most value?

What else was important for you about this decision?

Was this an easy or difficult decision for you to make? Why?

TOPIC 3a: Genetic Counseling Experience (For those who attended appointment):

Tell me about the next steps in meeting with someone to learn more about your prostate cancer risk/genetics.

Who did you meet with? How long did it take to get an appointment? What did you discuss?

What were you told about testing for prostate cancer risk/genetics?

Probes: What were you told about: the process, what to do, how long results would take, what would happen after, the costs?

How well did they do at explaining family risk/genetics to you? What did you like? What could have been done better?

What difficulties, if any, came up when you were waiting to see genetics? How did they get solved?

What would have made the process easier or smoother for you?

TOPIC 3b: Genetic Testing Experience (For those who follow through with testing):

Tell me about actually getting the test. What type of test did you receive? (*Test types: blood, saliva, tumor testing*)

What was easy about getting the test? What was more difficult?

How prepared were you for the process?

What happened after you completed the test?

How was this for you?

What would you have changed about it?

Tell me about the conversation you had with the person in genetics about your results.

What was as you expected? What surprised you?

How did you feel after receiving your results?

What questions did you have after getting your results, if any? Who did you (or would you) go to for answers?

Who did you share the results with, if anyone?

What have those conversations been about? How have they helped, if at all?

How will your results be used, from your understanding?

How have your results changed your treatment, if at all?

After going through this process, what have you learned?

Who was most helpful throughout the entire process of getting genetic testing? What made them so helpful?

What could have gone better?

How would you describe the process to someone who hadn't gone through it? What would you want to tell them?

Would you encourage others to get genetic testing?

TOPIC 3c: Follow up for people who did not choose testing

Tell me more about your decision to not get testing.

What most influenced your decision?

What follow up conversations did you have about testing with others, if you did at all?

How did you feel about these follow up conversations?

What did your doctor(s) say about this decision? Your family?

Was there something that could have been done better to help you make a decision about testing, even if it didn't change your mind?

What might prompt you to re-consider genetic testing in the future, if anything?

CLOSING QUESTIONS

Do you have any other thoughts about genetic testing that you'd like to share?

Those are all the questions I have for you today. Before we end, is there anything I have missed that you would like to share about the topics we have talked about today?

Thank you for being a part of this research and sharing all of your thoughts and experiences with me