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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 multidimensional 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.

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1. INTRODUCTION:

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

2. KEYWORDS:

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

3. ACCOMPLISHMENTS:

What were the major goals of the project?

Our first project aim was to characterize the use of germline genetic testing in patients diagnosed with prostate cancer in a safety-net setting using electronic medical record data from 2011 – 2021. The major goals of the aim for this year were to 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. We submitted the resulting manuscript to the Journal of the American Medical Association – Oncology (JAMA Oncology), and then to the Journal of the National Comprehensive Cancer Network, where it was rejected. We then submitted to JCO Oncology Practice, where we received a decision of revise and resubmit. The manuscript was most recently resubmitted at the beginning of March 2023 (publication pending, see Appendix).

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 3), we aimed to complete data collection and analyses of the qualitative interview data. Interviews for patients were completed in December 2022 and were conducted in either English, Spanish, or Haitian Creole. We continued to attempt to recruit family members (slated completion in June 2022), but received a very low response rate. We closed recruitment in March 2023, having completed 5 of the 16 planned family member interviews.

What was accomplished under these goals?

In the third 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 was completed December 2020.

2. Clean data and complete quality verification.

   STATUS: This was completed early 2021.

3. Cohort Analysis and Manuscript Preparation.

   STATUS: This task is completed and manuscript was first submitted September 2022 (publication acceptance pending) .

4. Interrupted Time Series Analysis and Manuscript Preparation.

   STATUS: This task is completed and manuscript was first submitted September 2022 (publication acceptance pending).

AIM 2 MAJOR TASKS:

1. Engage Stakeholders.

   STATUS: This task is completed. Throughout our qualitative tasks, we hired one survivor who engaged as a team member, providing feedback, conducting interviews, and sharing input on results. He underwent a series of research trainings and has been active in conducting interviews and helping to train research assistants on the protocol.

2. Transcribe Interviews.

   STATUS: This task was completed March 2023, including the transcription of all 17 health care provider interviews, 32 patient interviews, and 5 family member interviews.

3. Complete Qualitative Analyses.

   STATUS: Clinician interviews have been fully analyzed and a paper published, using 3 coders and a consensus process. An oral presentation was given at the Ethical, Legal and Social Implications Congress in May 2022 by Dr. Wang. All patient and family member interviews have undergone preliminary coding by at least 2 coders, and consensus was obtained on all coded data. Preliminary findings were presented via posters in Year 3 at the National Society of Genetic Counselors (November 2022), Society for Medical Decision-Making (SMDM, October 2022), American Society of Human Genetics (November 2022), the American Public Health Association (November 2022), the American College for Medical Genetics (March 2023), the Society for Behavioral Medicine (April 2023), and the European Society for Human Genetics (May 2023). Final analysis of the patient and family interviews are planned to produce a minimum of 2 papers. These papers will be submitted in the no-cost extension year (2023), which is slightly delayed from the anticipated timeline of Months 34-36.

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

Nothing to Report.

How were the results disseminated to communities of interest?

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 (twice per year) . Their feedback has helped shape patient interview guides and interpretation of results. We continue to engage with our survivor-interviewer, who conducted interviews and has provided input on preliminary findings.

In March 2023, Dr. Gunn had a preliminary call with Charles Ryan, MD, CEO of the Prostate Cancer Foundation. They discussed the possibility of reporting the results of this study through their webinar series, which usually attracts about 1,000 viewers (mostly interested prostate cancer patients, survivors, and advocates) . We plan to continue to pursue this and similar opportunities for broader dissemination as we complete analyses.

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

We have requested a no-cost extension to complete the final 2-3 manuscripts using the qualitative data collected from patients and family members. In Months 37-42 we will conduct both single-stakeholder and a comparative analysis across stakeholder groups. In the final months of the extension (Months 43-48), we will finalize and submit manuscripts, conduct revisions, and explore secondary analyses of the data.

4. IMPACT:

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

Nothing to report.

What was the impact on other disciplines?

Nothing to Report.

What was the impact on technology transfer?

Nothing to Report.

What was the impact on society beyond science and technology?

While the impact of engagement with prostate cancer survivors on this project is in its early stage, there is great potential for our activities with our partners to improve knowledge about genetic testing across communities. In conducting trainings, we are also building the capacity of our partners to engage in the research process and are planning to ensure there are ongoing opportunities for those who engage with us to connect to other advisory boards or groups seeking patient input into the research process. In hiring a community member to conduct research activities, we did work closely with our institutional review board to establish training practices that balanced the need for human subjects training without overburdening our survivor interviewer. We anticipate that the impact of these activities will manifest beyond the life of this grant.

5. CHANGES/PROBLEMS:

Changes in approach and reasons for change

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

The delays with patient engagement due to the COVID-19 pandemic continued to have an impact on our ability to complete the project. We did have success engaging a survivor-interviewer, and in Year 3 were able to add linguistic expertise in Haitian Creole. This allowed us to recruit across all three planned languages (English, Spanish, and Haitian Creole) . We were able to recruit fewer Haitian Creole patients relative to Spanish and English speakers, but this is in part expected due to it being a less prevalent language in the BMC catchment population.

In Year 3, we did not meet our recruitment goal of 16 family member interviews. We believe this was due in part to most genetics visit being conducted via phone during Year 3, which meant far fewer family members were involved directly in genetic care visits. Despite this structural barrier to engaging with family members who participated in care, we initiated several activities to improve recruitment. We partnered directly with cancer genetic counselors seeing patients in person to offer participation to family members who attended visits. We followed up with patient interviewees via phone to recruit their family members and offered to connect with family members at the end of every patient interview. Finally, in January 2023 we conducted a final outreach initiative, sending letters to eligible patients (those referred to genetics in the past year) to offer participation to their family members, even if the patient themselves had not participated. In the end, we recruited 5 family members and will use their data in conjunction with the patient data.

Changes that had a significant impact on expenditures

We did accrue some cost savings from not recruiting the full family member cohort. Ms. Loo, who was funded on the grant until March 2023 also completed her doctoral studies in December and we did not spend her full stipend. Over the course of the grant we had fewer survivor interviewers than anticipated. We also used students from the Masters of Public Health Program and the Masters in Genetic Counseling program to support research activities, which was associated with a cost savings. Since analysis is unfinished at this point in time, we have requested a no-cost extension to fund PI and a doctoral student's time to continue analyses and write additional manuscripts.

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

Significant changes in use or care of human subjects

Nothing to Report.

Significant changes in use or care of vertebrate animals

Nothing to Report.

Significant changes in use of biohazards and/or select agents

Nothing to Report.

6. PRODUCTS:

Publications, conference papers, and presentations

Report only the major publication(s) resulting from the work under this award.

Journal Publications:

- Gunn CM, Li EX, Gignac 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 Control*. 2023;30. doi: 10.1177/10732748221143884. Published. Federal Support Acknowledged.
- Gunn CM, Gignac GA, Hardy B, Zayhowski K, Pankowska M, Loo S, Wang CL. Characterizing referrals for prostate cancer genetic services in a safety net hospital. *JCO Oncology Practice.* 2023. Revision under review. Federal Support Acknowledged.
- Zayhowski K, Gunn CM, Loo SS, Gignac GA, Nahorniak M, Wang CL. A Qualitative Study of Prostate Cancer Patient Experiences with Genetic Testing Results Return. Genetics in Medicine (in preparation) . Federal Support Acknowledged.

Peer Reviewed Conference Presentations:

- "Provider Practices in Referring for Germline Genetic Testing for Men with Prostate Cancer at a Safety-Net Hospital" ELSI Congress. June 2, 2022, New York, NY. Federal Support Acknowledged.
- "Prostate Cancer Patient Experiences with Germline Genetic Testing: A Qualitative Study." Society for Medical Decision-Making Annual Meeting. October 25, 2022, Seattle, WA. Federal Support Acknowledged.
- "Genetic Testing Referrals for Prostate Cancer in a Safety Net Medical Center: How have NCCN Guidelines Changed Practice?" Society for Medical Decision-Making Annual Meeting. October 25, 2022, Seattle, WA. Federal Support Acknowledged.
- "Use of Genetic Services Among Patients with Prostate Cancer at a Safety-Net Hospital: A Mixed Methods Study." National Society of Genetic Counselors Annual Conference. November 17, 2022, Nashville, TN. Federal Support Acknowledged.
- "Prostate Cancer Patient Experiences with Genetic Testing upon Referral: A Qualitative Study." American College for Medical Genetics Annual Clinical Genetics Meeting. March 16, 2023, Salt Lake City, UT. Federal Support Acknowledged.
- "Prostate Cancer Patient Experiences with Germline Genetic Testing: A Qualitative Study" Society for Behavioral Medicine. April 24, 2023, Phoenix, AZ. Federal Support Acknowledged.

Books or other non-periodical, one-time publications.

Nothing to Report.

Other publications, conference papers and presentations.

Upcoming Presentations:

- "A Qualitative Study of Prostate Cancer Patient Experiences with Genetic Testing Results Return." European Human Genetics Conference. June 11, 2023, Glasgow, Scotland, UK. Federal Support Acknowledged. (Paper in preparation)

Website(s) or other Internet site(s)

Nothing to Report.

Technologies or techniques

Nothing to Report.

Inventions, patent applications, and/or licenses

Nothing to Report.

Other Products

Nothing to Report.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

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

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

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

Name: Stephanie Loo
Project Role: Graduate Student (no change)

Name: Brianna Hardy
Project Role: Data Analyst
Ended role on Project August 2022

Name: Sarah Bredy
Project Role: Research Assistant
Scope of work: Ms. Bredy translated interview guides and recruitment materials into Haitian Creole, was responsible for recruitment and interviews for Haitian Creole speakers, conducted English interviews with patients and family members, and verified the accuracy of transcription and translations.

Name: Mary Nahorniak
Project Role: Qualitative Research Assistant
Scope of work: Ms. Nahorniak served in a part-time role from January 2023 through the end of the reporting period (March 31, 2023). She was responsible for family member recruitment, conducting qualitative interviews, and coding qualitative interview data under the supervision of Dr. Gunn.

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

Nothing to report.

What other organizations were involved as partners?

None to report.

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS:

QUAD CHARTS:

9. APPENDICES:

Attached are:

- Published Journal Article
- Conference Abstracts
- Submitted Manuscripts
- Qualitative Codebook

Original Research Article

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

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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. A thematic analysis using both inductive and deductive coding was undertaken.

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.

Keywords

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

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Introduction

Genetic 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.[1] The National Comprehensive Cancer Network (NCCN) recommends the use of germline genetic testing for patients with prostate cancer since 2018.[1] Germline testing is used to identify inherited pathogenic variants in DNA, which can guide screening, familial testing, and treatment decision-making. This is in contrast to somatic testing, which focuses on tumor-specific pathogenic variants that may identify an indication for further germline testing and can guide some therapeutic decisions.[2] Germline testing should be considered for patients with clinically low-to intermediate-localized disease with a family history of prostate cancer; or high-to very high-risk localized disease. For regional or distant metastatic disease, germline testing is recommended regardless of initial risk.

While most prostate cancers occur in patients without a family history or inherited pathogenic variant, 12-15% of prostate cancer patients carry an identifiable germline DNA damage repair defect.[2,3] Prostate cancer patients with *BRCA1/2* pathogenic variants are at higher risk for progression during local therapy, metastases, and have lower survival.[4] Personalizing 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.[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.

Oncology clinical providers, as key implementers of NCCN Guidelines, have been slow to adopt genetic testing in practice.[8,9] 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 family history or for inclusion in clinical trials. Fewer reported testing in high-risk localized or non-metastatic cases.[8] 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 $P < .001$).[10] Reasons for underutilization and variation in referral patterns may also include a lack of available genetics expertise.[8,11,12] Insufficient access to genetic counselors pressures oncologists and urologists to perform aspects of genetic evaluations. These factors likely contribute to lower than expected rates of genetic testing based on the population of eligible patients diagnosed with prostate cancer.[13]

Most existing literature has focused on provider knowledge, attitudes and facility using on genetic tests, with studies sampling providers with specialized expertise in treating prostate cancer.[8,10,14,15] Given the known racial and ethnic disparities in use of germline genetic testing for prostate cancer,[16,17] understanding factors such as how patient characteristics, organizational supports for testing, and interpersonal factors influence the implementation of genetic testing in diverse, community practices is needed.[18] In the breast cancer literature, one study found that clinicians 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, although there were no differences in self-reported referral practices by patient race.[14] Other research has found that clinicians are prone to affective forecasting bias and other heuristics in making decisions about recommending genetic counseling and testing,[19,20] overestimating the negative effects of learning about an inherited pathogenic variant relative to its true impact.[21-23] These findings suggest that providers' delivery of genetic services may be influenced by factors other than knowledge, and these factors are not well-characterized across diverse populations.[18] This study seeks to characterize health care providers' 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 multidisciplinary health care providers treating prostate cancer patients considered referrals to genetic services for their patients. To answer this question, we constructed a qualitative interview guide based on and the Behavioral Model for Vulnerable Populations,[24] 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 and evaluated need*, and *evaluated health*. The application of the Behavioral Model for Vulnerable Populations related each of these concepts to the process of genetic testing. *Predisposing characteristics* were defined as in the model as features of the individual: demographics, health beliefs, social structures, literacy, living conditions and psychological resources (coping); while *enabling factors* were personal and family resources such as insurance and access to health resources, including genetic counseling services. *Perceived need* related to the subjective evaluation of the need for genetic testing by the provider and *evaluated need* was defined as clinical or evidence-based criteria guiding genetic services. The interview guide (Supplement 1) covered the following topics from the provider's perspective: 1) Knowledge about genetic testing and guidelines (an enabling factor); 2) Organizational incentives for genetic testing and processes to support it (an enabling factor); 3) Discussions about genetic testing with patients (need and use of health services domains); 4) Experience with the referral process (satisfaction with care domain); and 5) Personal and contextual factors that contribute to decision-making about making referrals for genetic services (pre-disposing characteristics). Research assistants piloted the interview guide with practicing clinicians affiliated with the study, who provided input on factors that they viewed as important to local referral practices. 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 at an urban, safety-net hospital and were thus eligible to be recruited. The hospital in which the research was conducted is private, not-for-profit, and serves an urban population. Three-quarters of patients are considered to be medically-underserved and rely on government payors for insurance (e.g. Medicaid). A majority of patients are racial or ethnic minorities, and 27% of patients speak a primary language other than English. We purposively sampled at least two clinicians across five relevant medical specialties: 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 one-on-one qualitative telephone interview.

Interviews were conducted by study team members not involved in the clinical process; either a research assistant who had received didactic and experiential training in qualitative methods (EL), or a doctoral-trained qualitative health services researcher (CG). 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.

Qualitative Analysis

A thematic analysis was conducted,[25] utilizing a mixture of emergent codes and those based on the Behavioral Model for Vulnerable Populations.[24] 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, we grouped codes and specified themes, describing the properties and dimensions of the generated codes.[26] 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, themes and associated domains from the conceptual model 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. These themes related to *enabling factors* at the health system level (e.g. availability of health services that support genetic testing) and tools to assess *evaluated need* for genetic services at the individual level. One theme identified an absence of systems and/or processes, an *enabling factor*, to assist clinical teams in detecting eligible patients for referrals to genetic services (Theme 1a):

> "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)

Table 1. Summary of Identified Topics and Associated Themes.

Topic	Theme	Behavioral model domain	Example quote
1. Identifying Patients for Testing	1a:Systems are lacking to support systematic identification of those eligible for testing	Enabling factor	"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)
	1b:Data to support eligibility determination is not readily available and time-consuming to acquire during visits	Evaluated need	"When we do a history with a patient, we literally have 30 seconds - tell me your problem, and I'm going to start checking the boxes and ordering tests. But genetic counseling is kind of interesting, if you don't dig for the story, you're never going to figure it out… Yes, we know there's family history in the [medical record], but that's all just lip service." (HCP 06)
2. Decision inputs for referrals	2a: Use of NCCN guidelines to guide referrals	Enabling factor	"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)
	2b: Patient characteristics that influence provider genetic referral practices	Pre-disposing characteristics	"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)
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	Perceived need	"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 genetic testing is important. I Also note the importance of this for the family members, like early testing, screening… 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)

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 *evaluating need* for referrals to genetic counseling:

> "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 genetic 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 genetic 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. Here, physician knowledge served as an *enabling factor*:

> "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)

Genetic services providers supported the idea that clinician knowledge about eligibility was generally good, as one genetic provider 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, or *pre-disposing factors*, that contributed to the genetic counseling 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 particular, providers detailed that non-English patients are less likely to be referred because of barriers related to interpreters and their perceived ability to understand the information:

> "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." (HCP 03)

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 clearly 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 need* 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)

These orientations toward *perceived need or* utility derived now versus in the future were noted by some to influence which specialties might be more likely to refer patients to genetic counseling and/or testing. Specifically, participants described testing as occurring later, more often by medical oncologists, rather than earlier, as germline genetic

Table 2. Examples of Theme 2b: 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)
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)

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 genetic services 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.

Discussion

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 genetic 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, an *enabling factor* that is known to contribute to health utilization and outcomes as posited by the Behavioral Model.[24] Providers did identify other non-medical patient *pre-disposing factors* that influenced their discussions and referral practices, such as non-English language, health literacy, cost, and perceived distress. These factors are consistent with those that the Behavioral model suggests give rise to health disparities. Finally, whether providers perceived benefits of testing would be derived immediately or in the future was related to whether they referred patients. This fits with Gelberg's conceptualization of *perceived need*, although our findings emphasize a temporal element to this contributor to the use of genetic services. This meant that providers seeing patients later in their cancer treatment (i.e., medical oncologists) were perceived to be most likely to be responsible for referring to genetic care.

The absence of systems to identify patients who may benefit from referral to genetic services was universally noted as a 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.[27-29] 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 (CDS) tools.[30] Other similar primary care-based interventions are being tested to promote the routine screening of patients eligible for genetic testing.[31] 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,[32] 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. Decision-making literature has demonstrated that clinicians tend to overestimate the negative consequences of genetic testing for their patients ('impact bias').[19] In this study providers noted factors, such as perceived patient distress, likelihood of following through, health literacy, and ability to pay as considerations in their provision of referrals. These factors were similar to those identified 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 White patients, reflecting inherent biases that may influence access to care.[14] In our study, language was a commonly identified consideration, which is unsurprising given that approximately 27% of the hospital's patients primarily speak a language other than English. Other research has noted linguistic barriers to receiving genetic counseling, and only 6% of genetic counselors in the United States practice in Spanish.[33] Ensuring appropriate linguistic access to high quality counseling, from the time of referral discussions through testing and results disclosure is needed, as research has highlighted the benefits of genetic counseling in one's native language.[34]

When perceptions about predisposing characteristics (health literacy, language, cost) influence care, differences in utilization between minority or marginalized versus majority, privileged populations can widen.[24] Future work is critically needed to understand and quantify the extent to which these perceptions and biases influence referral patterns across groups (e.g. non-English speakers). Minimizing clinician biases that influence referral practices is necessary to remove both perceived and actual barriers to genetic services for structurally marginalized patients.[19] Implementing interventions that address *enabling factors* may reduce the impact of *predisposing factors* on health outcomes, although the most impactful solutions will address both. Efforts to address provider biases could include standardized intake and family history elicitation tools[35] to reduce the influence of individual perceptions and focus on clinical and familial factors that should drive referral. Additionally, plain language and communication interventions[36,37] are 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 genetic referrals identified in our study.[35]

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,[18] 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.[38] 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.[39] However, coverage rules and restrictions as well as cost-sharing for genetic testing varies widely across insurers,[40] 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.[41] 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 genetic 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.[15] Similarly, survey research has demonstrated that 40-70% of clinicians feel confident in using genetic tests for treatment decision-making.[10] Understanding how confidence in using genetic results affects perceptions of its utility or perceived need 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[42] 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, biases, and behaviors across activities relevant to providing cancer genetic services. We used the Behavioral Model to guide our conceptualization and analysis, and other factors may be unaccounted for in these results, especially those best addressed from the patient perspective. 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.

Conclusions

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 genetic services based on the ability of the health system resources to identify patients in need of genetic counseling (an *enabling factor*), provider perceptions about non-medical patient *predisposing characteristics*, and utility to clinical practice (*perceived need*). Future research must consider how providers' role and heuristics influence how and when they offer genetic services and impacts equity in patients' options for precision medicine, attending to the potential for treatment and outcome disparities across patient populations and clinical settings.

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.

Declaration of Conflicting Interests

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Ethical Approval

The Institutional Review Boards at the Boston University Medical Campus (H-40698 approved March 5, 2021) and Dartmouth College (STUDY00032381, approved October 21, 2021) reviewed this study and determined activities to be exempt based on federal criteria.

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Supplemental Material

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ACMG Abstract

Use of Genetic Services Among Patients with Prostate Cancer at a Safety-Net Hospital: A Mixed Methods Study

CM Gunn, S Loo, K Zayhowski, G Gignac, CL Wang

Introduction. Prostate cancer genetic testing guidelines expanded eligibility criteria in 2018, increasing the availability of this technology to guide patient treatment. Understanding health system and patient uptake is important to address individual, inter-personal, systemic or structural barriers towards genetic testing. This mixed-methods study aimed to: 1) characterize genetics referral patterns and predictors of referrals over time; and 2) qualitatively understand prostate cancer patient experiences in making decisions about genetic testing in a safety-net hospital setting.

Methods. Quantitative data included a retrospective cohort of individuals with a prostate cancer diagnosis between 2011 and 2020 using the medical record and tumor registry. Multivariable logistic regression identified patient characteristics associated with a documented referral to genetics, adjusting for race, ethnicity, country of birth, language, insurance and prostate cancer clinical stage. An interrupted time series using Poisson regression examined whether guideline changes resulted in higher rates of referral one-year post-implementation. Qualitative interviews were conducted with adult English, Spanish, or Haitian-Creole speaking prostate cancer patients referred to genetic counseling in the past 12 months. Semi-structured telephone interviews focused on participants' experience with and decision-making about genetic counseling and testing. An inductive thematic analysis generated themes arising from interview transcripts.

Results. The cohort consisted of 1,877 patients with a prostate cancer diagnosis. Mean age was 65 years; 44% identified as Black, 32% White; 17% Hispanic or Latino. About half were married (49%) and foreign born (46%). The predominant insurance type was Medicaid (34%) followed by Medicare or Private insurance (25% each). Most patients were diagnosed with local disease (65%), while 3% had regional, and 9% had metastatic disease. Of these 1,877 patients, 163 (9%) had at least one referral to a genetic counselor. In multivariable models, higher age was negatively associated with referral (OR: 0.96, 95% CI: 0.94, 0.98), while identifying as Black vs. White race (OR: 1.66, 95% CI: 1.05-2.36) and having regional (OR: 4.45, 95% CI: 2.40, 8.25) or metastatic disease (OR: 4.64, 95% CI: 2.98 – 7.24) vs. local only were significantly associated with referral. The Poisson time series analysis demonstrated a 138% rise in referrals one year after guideline implementation (RR= 3.992; 97.5% CI 2.20-7.24; p-value<0.001), adjusting for seasonal trends in referral patterns and model over-dispersion.

Twenty-seven individuals were interviewed (6 Spanish, 2 Haitian Creole, 19 English). Fifteen participants reported receiving genetic testing. Two themes emerged. First, genetic counseling was often offered in the midst of treatment when many visits were occurring. This led participants to feel overwhelmed: "I got other issues on my mind, like how am I going to survive? No sense of tracing it back if you're trying to deal with staying alive". Participants

expressed uncertainty about how much genetic testing would help them, and they were most interested in participating in care that was central to their survival. Second, participants who underwent testing reported receiving little follow up. These participants, and especially those with a family history of cancer, were confused in interpretating negative testing results and sought more support in understanding testing implications: “[The results letter] didn't make a whole lot of sense to me. I don't understand what I was looking at really.”

Conclusions. Prostate cancer genetic testing is important in providing high quality cancer care. The strongest predictor of referral was clinical stage, suggesting opportunities to educate providers about guideline eligibility for patients with local or regional disease who may benefit from genetic counseling and testing. Patients in our study revealed both pre- and post-testing communication gaps that appeared to create misperceptions about genetic risk and may explain limited engagement in genetic services.

NSGC Abstract

Abstract Type: Original Research

Abstract Title: A Qualitative Examination of Prostate Cancer Patient Experiences with Referral for Genetic Testing

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Background: Prostate cancer guidelines recommending genetic testing expanded eligibility criteria in 2018, increasing the availability of this technology which can guide patient treatment decision-making. Understanding patients' experiences with and decision-making about undergoing genetic testing is important, particularly when seeking to address individual, inter-personal, systemic or structural barriers towards genetic testing. We conducted a qualitative study to understand prostate cancer patient experiences in making decisions about genetic testing in a safety-net hospital setting.

Methods: Qualitative interviews were conducted with adult English or Spanish-speaking prostate cancer patients who were referred to genetic counseling in the past 12 months. Participants were invited via mailed letters and telephone. Semi-structured telephone interviews focused on participants' experience with and decision-making about genetic counseling and testing following referral. Audio recordings of interviews were professionally transcribed. An inductive thematic analysis generated themes arising from interview transcripts. Themes were reviewed and finalized by the full study team to ensure credibility of the findings.

Results: Twenty individuals were interviewed (6 Spanish, 14 English). Ten participants reported receiving genetic testing following counseling, 7 did not pursue testing, and 3 were unsure if they had received testing. Two themes emerged regarding prostate cancer patient decision-making around genetic testing. First, genetic counseling was often offered in the midst of treatment when many visits were occurring. This led participants to feel overwhelmed: "I got other issues on my mind, like how am I going to survive? No sense of tracing it back if you're trying to deal with staying alive". Second, participants who underwent testing and had no genetic mutation reported receiving little follow up. These participants, and especially those with a family history of cancer, were confused in interpretating their testing results

and sought more support in understanding the implications of testing: “[The results letter] didn't make a whole lot of sense to me. I don't understand what I was looking at really.”

Conclusion: Understanding how to support informed decisions about prostate cancer genetic testing is important in providing high quality cancer care. Our work revealed several pre- and post-testing communication gaps patients that appeared to create misperceptions about genetic risk and disengagement in genetics services.

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44th Annual Meeting
& Scientific Sessions

ABSTRACT PREVIEW: PROSTATE CANCER PATIENT EXPERIENCES WITH GERMLINE GENETIC TESTING: A QUALITATIVE STUDY

Prostate Cancer Patient Experiences with Germline Genetic Testing: A Qualitative Study

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Abstract Body

Purpose: Prostate cancer guidelines recommending genetic testing expanded eligibility criteria in 2018, increasing the availability of this technology that can guide patient treatment decision-making. Understanding patients' experiences with and decision-making about undergoing genetic testing is important, particularly when seeking to address individual, inter-personal, systemic or structural barriers towards genetic testing. We conducted a qualitative study to understand prostate cancer patient experiences in making decisions about genetic testing in a safety-net hospital setting.

Methods: Qualitative interviews were conducted with adult English, Spanish, and Haitian-speaking prostate cancer patients who were referred to genetic counseling in the past 12 months. Participants were invited via mailed letters and telephone. Semi-structured telephone interviews focused on participants' experience with and decision-making about genetic counseling and testing following referral. Audio recordings of interviews were professionally transcribed. An inductive thematic analysis generated themes arising from interview transcripts. Themes were reviewed and finalized by the full study team to ensure credibility of the findings.

Results: Twenty-seven individuals were interviewed (6 Spanish, 2 Haitian Creole, 19 English). Fifteen participants reported receiving genetic testing, 9 did not, 3 were unsure. Three themes emerged regarding prostate cancer patient decision-making around genetic testing. (1) Genetic counseling was often offered in the midst of treatment, which led participants to feel overwhelmed: "I got other issues on my mind, like how am I going to survive? No sense of tracing it back if you're trying to deal with staying alive". Some patients de-prioritized testing, expressing uncertainty about its purpose and role in treating their cancer. (2) Those who saw genetic counselors were satisfied with their discussions and found the testing easy to complete: "That was fast and very simple. Just take out the blood and and that's it." (3) There was little follow up communication to assist patients in understanding their genetic results. Participants were confused about how to interpret negative testing results and sought more support in the post-test period. Those with a family history of cancer were especially confused in interpreting negative testing results : "No, I don't have the genes that's what gets me. Three of my other relatives, have [cancer]... I don't have the gene, but they got it. They got cancer."

Conclusions: Understanding how to support informed decisions about prostate cancer genetic testing is important in providing high quality cancer care. Patients in our study revealed pre- and post-testing communication gaps that appeared to create misperceptions about genetic risk and limited engagement in genetics services.

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Select two keywords from the drop-down lists that best capture your abstract.

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SMDM Abstract 1

Prostate Cancer Patient Decision-Making about Germline Genetic Testing: A Qualitative Study

Authors: S Loo, J Barria, R Raymundo, K Zayhowski, G Gignac, C Wang, C Gunn (*Presenting*)

Purpose: Prostate cancer guidelines recommending genetic testing expanded eligibility criteria in 2018, increasing the availability of this technology that can guide patient treatment decision-making. Understanding patients' experiences with and decision-making about undergoing genetic testing is important, particularly when seeking to address individual, inter-personal, systemic or structural barriers towards genetic testing. We conducted a qualitative study to understand prostate cancer patient experiences in making decisions about genetic testing in a safety-net hospital setting.

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Conclusions: Understanding how to support informed decisions about prostate cancer genetic testing is important in providing high quality cancer care. Patients in our study revealed several pre- and post-testing communication gaps that appeared to create misperceptions about genetic risk and limited engagement in genetics services.

SMDM Abstract 1

Table 1. Exemplary Quotes for Identified Themes

Theme	Quotes
Too overwhelmed by prostate cancer treatment process to consider genetic testing	“They did mention [genetic testing], but I don't think we have gone through it. I did see there's some program or something you could go through to see if any family member has it or been close to have it or anything like that. But we never go through with that because there was so much things taking up my time every day. I got to go to the doctor every day.” - *Patient 14*
	“It was recommended that I should get… genetic testing done. But I probably will. I mean I don't wanna do it right now only because I'm fighting one devil. I know that there are some others or maybe some others on the horizon that might even affect my own kids. But after mentioning my kids, like my son …. I thought about it and it was a personal decision. I wanna know, but I don't wanna know.” – *Patient 13*
	“No. I mean, what's the point [*of getting genetic testing*]? I mean, I got it. I got prostate cancer. My concentration, the bulk of it was geared to trying to get well. Not tracing it back as a preventive measure because nobody's going to listen to you. I mean, I got sons. I tried to reach out to them and tell them that you might be a candidate for cancer, specifically prostate cancer. They don't want to listen. So I don't know what else you can do. I said I wasn't interested at the time. I said I got other issues on my mind. Like how am I going to survive? Stuff like that and no sense of tracing it back if you're trying to deal with staying alive. In other words. it was unimportant to me at the time.” – *Patient 7*
Lack of follow up with genetic testing	“I think they might have [*ordered genetic testing*]. Actually, they might -- they might have but, you know, something I don't keep up with. I think I might have... They've got a procedure, I just let him do it. If it's for the best I just tell him you go ahead and do it … if they want to find something out, let him go ahead.” – *Patient 15*
	“Yeah, I did [*genetic testing*] through the mail. I send it back through the mail, swab. I did a test about 2 months ago and I did not get the results. I haven't heard from [*the doctor*] or anything.” – *Patient 8*
	“There was no conversation. I got the results in the mail and they said I wasn't... and I didn't get infected like that from my father, my mother, my sister, my brother. It was just the fact that I had it and I could give I was grateful that they went and did that testing to find out, you know, more than I had known at the time.” – *Patient 5*
	“Nothing. I waited-- I waited. I got some mail from them later, couple weeks later. It was the results of what the blood work showed. I looked at it. You know, I read it. It didn't make a whole lot of sense to me. I don't-- I don't understand what I was looking at really.” *-Patient 1*

Genetic Testing Referrals for Prostate Cancer in a Safety Net Medical Center: How have NCCN Guidelines Changed Practice?

Christine Marie Gunn[1], Brianna Hardy[1], Gretchen Gignac[2], Kimberly Zayhowski[3], Stephanie Loo[4], Catharine L Wang[5]

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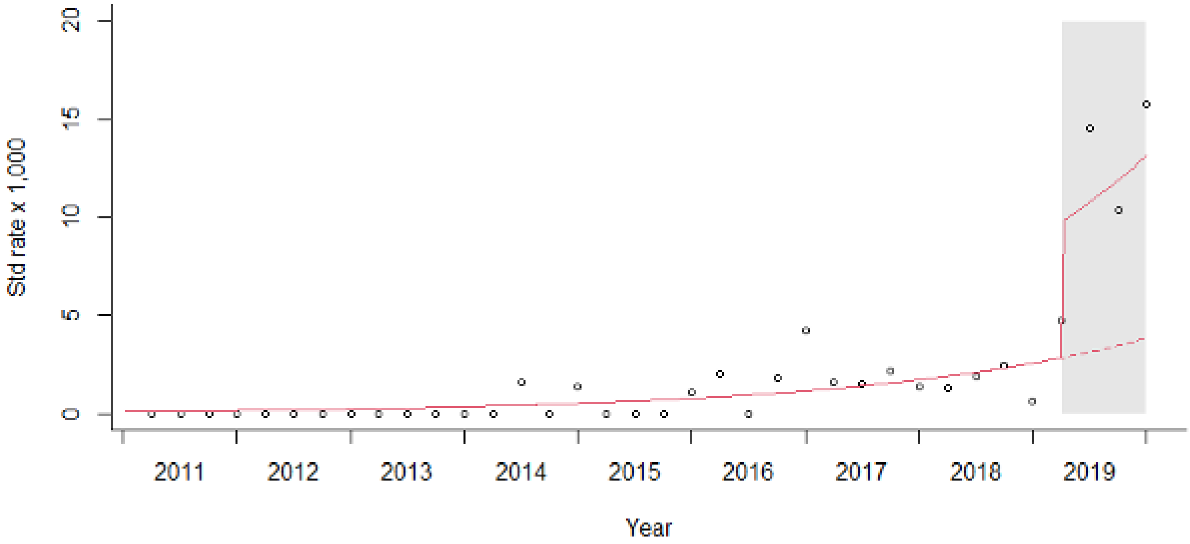
Purpose:In 2018, guidelines expanded eligibility for germline genetic testing for people with prostate cancer. This study characterizes genetics referral patterns and predictors of referrals among patients with prostate cancer diagnosed at an urban, safety-net medical center.
Methods:Using a retrospective cohort, we identified individuals who received a prostate cancer diagnosis between January 1, 2011 and March 1, 2020 through the medical record and tumor registry. The primary outcome was defined as the presence of a referral to genetics after the diagnosis of prostate cancer. Using multivariable logistic regression, we identified patient characteristics associated with referrals to genetics, adjusting for race, ethnicity, country of birth, language, insurance and prostate cancer clinical stage. We plotted trends in quarterly referral rates standardized as the number of referrals per 1,000 prostate cancer patients. An interrupted time series using Poisson regression examined whether guideline changes resulted in higher rates of referral one year after implementation.
Results:A total of 1,877 patients with a prostate cancer diagnosis were identified. The mean age of the cohort was 65 years; 44% identified as Black, 32% White; 17% Hispanic or Latino. About half were married (49%) and foreign born (46%). The predominant insurance type was Medicaid (34%) followed by Medicare or Private insurance (25% each). Most patients were diagnosed with local disease (65%), while 3% had regional, and 9% had metastatic disease. Of these 1,877 patients, 163 (9%) had at least one referral to a genetic counselor. In multivariable models, higher age was negatively associated with referral (OR: 0.96, 95% CI: 0.94, 0.98), while identifying as Black vs. White race (OR: 1.66, 95% CI: 1.05-2.36) and having regional (OR: 4.45, 95% CI: 2.40, 8.25) or metastatic disease (OR: 4.64, 95% CI: 2.98 – 7.24) vs. local only were significantly associated with genetics referral. The Poisson time series analysis demonstrated a significant rise in referrals one year after guideline implementation (Figure 1), even after adjusting for seasonal trends in referral patterns and model over-dispersion.
Conclusions:While genetic testing referral rates were low overall based on eligibility (9%), referrals did increase one year post-guideline implementation. The strongest predictor of referral was clinical stage, suggesting opportunities to provide education that raises awareness about guideline eligibility for patients with local or regional disease who may benefit from genetic counseling and testing.

Keywords: genetic testing, prostate cancer, guidelines, health services research

Figure 1

Figure 1: Change in Rate of Genetic Referrals per 1,000 Prostate Cancer Diagnoses (2011 – 2020)*



*Change in trend significant at $p<0.001$

╌╌╌╌ Dashed lined indicates predicted counterfactual based on prior trend,

─── Solid line is actual trend, adjusted for seasonality and over-dispersion.

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Characterizing referrals for prostate cancer genetics services in a safety net hospital

--Manuscript Draft--

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Abstract:	Background Little is known about the uptake of germline genetic testing for patients with prostate cancer after guideline changes in 2018. This study aims to characterize genetics referral patterns and predictors of referrals among patients with prostate cancer. Patients and Methods A retrospective cohort study using electronic health record data was conducted at an urban safety-net hospital. Individuals diagnosed with prostate cancer between January 2011 and March 2020 were eligible. The primary outcome was the presence of a referral to genetics after diagnosis. Using multivariable logistic regression, we identified patient characteristics associated with referrals. Interrupted time series analysis using a segmented Poisson regression examined whether guideline changes resulted in higher rates of referral after implementation. Results The cohort included 1,877 patients. Mean age was 65 years; 44% identified as Black, 32% White; 17% Hispanic or Latino. The predominant insurance type was Medicaid (34%) followed by Medicare or private insurance (25% each). Most were diagnosed with local disease (65%), while 3% had regional, and 9% had metastatic disease. Of

	the 1,877 patients, 163 (9%) had at least one referral to genetics. In multivariable models, higher age was negatively associated with referral (OR: 0.96, 95% CI: 0.94, 0.98), while identifying as Black vs. White race (OR: 1.66, 95% CI: 1.05-2.36) and having regional (OR: 4.45, 95% CI: 2.40, 8.25) or metastatic disease (OR: 4.64, 95% CI: 2.98 – 7.24) vs. local only were significantly associated with genetics referral. The time series analysis demonstrated a 138% rise in referrals one year after guideline implementation (Relative Risk = 3.992; 97.5% CI 2.20-7.24; p-value<0.001). Discussion Genetic testing referral rates increased post-guideline implementation. The strongest predictor of referral was clinical stage, suggesting opportunities to raise awareness about guideline eligibility for patients with advanced local or regional disease who may benefit from genetic counseling and testing.
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Title: Characterizing referrals for prostate cancer genetics services in a safety net hospital

Running Head: Genetic Testing Referrals in Prostate Cancer

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ABSTRACT

Background: Little is known about the uptake of germline genetic testing for patients with prostate cancer after guideline changes in 2018. This study aims to characterize genetics referral patterns and predictors of referrals among patients with prostate cancer.

Patients and Methods: A retrospective cohort study using electronic health record data was conducted at an urban safety-net hospital. Individuals diagnosed with prostate cancer between January 2011 and March 2020 were eligible. The primary outcome was the presence of a referral to genetics after diagnosis. Using multivariable logistic regression, we identified patient characteristics associated with referrals. Interrupted time series analysis using a segmented Poisson regression examined whether guideline changes resulted in higher rates of referral after implementation.

Results: The cohort included 1,877 patients. Mean age was 65 years; 44% identified as Black, 32% White; 17% Hispanic or Latino. The predominant insurance type was Medicaid (34%) followed by Medicare or private insurance (25% each). Most were diagnosed with local disease (65%), while 3% had regional, and 9% had metastatic disease. Of the 1,877 patients, 163 (9%) had at least one referral to genetics. In multivariable models, higher age was negatively associated with referral (OR: 0.96, 95% CI: 0.94, 0.98), while identifying as Black vs. White race (OR: 1.66, 95% CI: 1.05-2.36) and having regional (OR: 4.45, 95% CI: 2.40, 8.25) or metastatic disease (OR: 4.64, 95% CI: 2.98 – 7.24) vs. local only were significantly associated with genetics referral. The time series analysis demonstrated a 138% rise in referrals one year after guideline implementation (Relative Risk = 3.992; 97.5% CI 2.20-7.24; p-value<0.001).

Discussion: Genetic testing referral rates increased post-guideline implementation. The strongest predictor of referral was clinical stage, suggesting opportunities to raise awareness about guideline eligibility for patients with advanced local or regional disease who may benefit from genetic counseling and testing.

1. BACKGROUND

Hereditary prostate cancer accounts for 30 to 40% of early onset disease[1] and more than 15% of prostate cancer patients carry an identifiable pathogenic variant.[2,3] Prostate cancer patients with pathogenic variants are at higher risk for progression during local therapy, metastases, and have lower survival.[4] Providers may opt to treat patients with identified pathogenic variants with earlier, more aggressive treatment using platinum-based chemotherapy, or PARP inhibitors.[5–7] The ability to personalize regimens based on genetic information (i.e. precision medicine) holds the potential to deliver more effective treatment, thus reducing the burden of lethal prostate cancer and improving quality of life and survival.

Since 2018, the National Comprehensive Cancer Network (NCCN) Guidelines expanded recommendations to consider the use of germline genetic testing for patients with prostate cancer based on its value in informing treatment decisions. Germline testing is currently recommended for patients with clinically low- to intermediate- localized disease accompanied by a family history of prostate cancer; or high- or very high-risk localized disease. Once regional or distant metastases are present, germline testing is recommended regardless of initial risk.[8]

The expansion of eligibility in NCCN Guidelines for germline genetic testing may lead to improved outcomes for patients, but delays in reaching medically underserved groups will undermine progress. In fact, existing treatment disparities in prostate cancer may become exacerbated by the increasing use of genetic testing to target therapies.[9] 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.[10] The promise of precision medicine cannot be realized without diffusion across the many settings in which patients receive treatment. Many barriers, including insufficient expertise, availability of genetic counseling, and wait times for genetics referrals, impede the use of genetic testing.[11]

A nationwide survey of oncologists practicing in Prostate Cancer Clinical Trials Consortium sites, where rapid uptake of guidelines is expected, found considerable variation in recommendations for testing based on patient characteristics: While 62% of oncologists surveyed reported considering all metastatic patients for germline genetic testing, 27% would only test based on a family history or for inclusion in clinical trials. Few reported testing in high-risk localized or non-metastatic cases.[11] Other survey data have found that urologists vs. radiation oncologists and those practicing in academic medical centers vs. community hospitals were more likely to use genetic testing for patients with localized prostate cancer.[12,13] Given that the literature is suggestive of variation in the uptake of genetic testing for patients with prostate cancer, this study sought to: 1) characterize predictors of germline genetic testing referrals among patients diagnosed with prostate cancer in a safety-net hospital using electronic health record data from 2011 – 2020; and 2) determine the extent to which referral rates may have changed following expanded NCCN guidelines for genetic testing released in 2018.

2. METHODS

2.1 Cohort Composition

We compiled a retrospective cohort of patients diagnosed with prostate cancer at a large, urban, safety-net hospital between January 1, 2011 and March 1, 2020. We used data from the electronic health record and tumor registry to identify predictors of receiving a referral for germline genetic testing after being diagnosed with prostate cancer. All data elements were compiled by the hospital clinical data warehouse, and the de-identified dataset was determined to meet criteria for ‘not human subjects research’ by the Institutional Review Board. The selection of predictors was based on a disparities-focused adaptation of the Behavioral Model for health care utilization[14] and prior literature.[15] It was hypothesized that foreign-born, non-English speaking, non-White race, and older patients would be less likely to be referred to genetics. To examine whether changes in the NCCN guidelines in 2018 were associated with increases in referrals to genetics, we used an interrupted time series design. We hypothesized that the rate of genetic referrals would increase significantly in years following NCCN guideline changes.

We defined the outcome dichotomously as the presence or absence of a referral placed to medical genetics following the diagnosis of prostate cancer. Independent variables of interest included age, race, ethnicity, country of birth, language, insurance, and clinical stage. Age was defined at the time of diagnosis and measured continuously. Race, ethnicity, country of birth, and primary language were categorical variables reported in the electronic health record, originally elicited from participants. Insurance represented the type of insurance at the time of prostate cancer diagnosis, categorized as private, Medicaid, Medicare, or other/unknown. Clinical stage was derived from tumor registry data reporting of the clinical TNM stage at diagnosis. These categories were collapsed into local only, regional disease, metastatic disease, or missing.

2.2 Cohort Analysis

We conducted a univariate descriptive analysis (e.g., frequencies, means, medians) followed by bivariate comparisons to evaluate factors associated with referral to genetics. In multivariable analyses, logistic regressions estimated odds ratios (OR) and 95% confidence intervals (95% CI) for factors in the lead-up from the index date of prostate cancer diagnosis to genetics referral. The multivariable model included the five pre-disposing or enabling variables for which we had an *a priori* hypothesis regarding the relationship with receipt of a referral: age, race (White, Black, other), ethnicity (Hispanic vs. non-Hispanic), country of birth (US vs. non-US), language (English vs. non-English), insurance (Medicare, Medicaid, private, other) and clinical stage (local, regional, metastatic). We examined predictors for evidence of collinearity using Eigenvalues and variance inflation values. None of these tests were suggestive of collinearity, and so all variables were retained in the multivariable model. All analyses were carried out using SAS Version 9.3 (Cary, NC).

2.3 Interrupted Time Series Analysis

We hypothesized that the rate of genetic referrals would increase after 2018, when new guidelines broadened the use of genetic testing for prostate cancer. We standardized the rate of genetics referrals as referrals per 1,000 patients to account for shifting numbers of eligible cases over time. The denominator for each period, defined as a quarter-year, included any individual with a diagnosis prior to the end of the quarter, and no prior referral in an earlier quarter. The numerator included any individual included in the denominator who had a referral within that quarter. The standardized trend established the pre-intervention trend and was used to estimate the counterfactual, which was the expected trend in the absence of guideline changes.

New NCCN guidelines were published in the first quarter of 2018. Allowing for a 6-month lag period for dissemination, the ‘intervention period’ for the base model began in July 2018. Segmented Poisson regression models tested for a change in trend between the baseline and intervention periods. In the main outcome model, we tested for a change in slope for the rate of referrals. While interrupted time series designs typically do not require adjustment for traditional covariates, as their population distribution changes gradually across time, we considered incorporating time varying confounders identified in cohort analysis, but none were identified. Models adjusted for seasonality using a Fourier term.[16,17] We tested for over-dispersion of the outcome, which is a common issue with Poisson regression. Using a residual plot, we assessed autocorrelation. Because guideline dissemination is non-linear and may vary, we tested alternative lag periods of 3 months and 12 months, to assess whether the intervention impact changed with shorter or longer uptake lags.

3. RESULTS

The retrospective cohort included 1,877 patients diagnosed with prostate cancer in the defined period (*Table 1*). Mean age at diagnosis was 65 years (SD=9). Consistent with the population served by the hospital, 44% identified as Black or African American, 32% White, 5% Other, and 2% Asian. Most (80%) were not Hispanic or Latino, with 17% identifying as Hispanic or Latino ethnicity. About half (46%) were foreign born, 36% identified as domestically-born, and 18% had missing country of birth. More than half (67%, n=1260) spoke English as their primary language. In terms of insurance, 34% had Medicaid, 25% Medicare, 25% private insurance, and 16% other or unknown insurance. Clinical stage distribution indicated that 65% had local only disease, 3% regional, and 9% metastatic. Stage information could not be determined for 22% of the cohort.

Figure 1 displays the referral, genetic counseling, and testing counts among the cohort. Of the 1,877 prostate cancer diagnosed individuals, 163 (9%) had at least one genetics referral documented post-diagnosis. The majority of those with a referral had one referral (91%), but 7% (n=11) received 2 referrals, and 2% (n=3) had 3 documented referrals. Most referrals (87%) occurred from 2018 – 2020, subsequent to the expanded NCCN guidelines. The proportion of those with a subsequent genetic counseling encounter was 136 (83%), with an additional 10 encounters occurring without a documented referral. In total we identified 20 genetic testing results in the electronic health record, representing 12% of those with genetic encounters, and 1% of the overall cohort. Table 2 displays the characteristics associated with referral to genetics, both unadjusted bivariate logistic regression models, as well as those adjusting for characteristics hypothesized to be associated with referral. The fully adjusted model indicated that age was negatively associated with genetic referral: For each one-year increase in age at diagnosis, the odds of referral were 4% lower (OR: 0.96, 95% CI: 0.94-0.98). Contrary to our hypothesis, being Black or African American race was associated with a significantly greater odds of referral (OR: 1.66, 95% CI: 1.05, 2.63). We found no significant differences in referrals associated with ethnicity, country of birth, language, or insurance, although patients with Medicaid had a 1.63 higher odds of referral relative to those with private insurance in bivariate comparisons (95% CI: 1.07, 2.48). Clinical stage was the strongest predictor of referral: Compared to having local only disease, regional (OR: 4.51, 95% CI: 2.44, 8.34) and metastatic (OR: 4.64, 95% CI: 2.98, 7.24) disease were significantly and positively associated with genetics referral.

For the interrupted time series Poisson regression, the initial model using 6-months post-guideline change demonstrated no significant increase in referrals. The model using the one-year (January 2019) breakpoint, did demonstrate a significant increase in referrals relative to the counterfactual, adjusting for seasonality and overdispersion (*Figure 2*). Specifically, the model demonstrated an increase in referrals by 138.4% (Relative Risk = 3.992; 97.5% CI 2.20-7.24; p-value=0.00).

4. DISCUSSION

Among a cohort of patients diagnosed with prostate cancer between 2011 and early 2020, we found that 9% had a documented referral to genetics, 83% of whom attended an appointment with a genetic counselor. Actual documented completion of genetic testing within the medical record was low: only 1% of the cohort (12% of those with referrals) had a documented result. The strongest predictors of referral to genetics were clinical stage, whereby those with regional or metastatic disease were more likely to receive a referral. Other predictors associated with referral included lower age, identifying as Black or African American, and being insured by Medicaid. Using an interrupted time series, we documented a significant increase in genetic referral rates one year after NCCN guidelines expanded eligibility for patients with prostate cancer.

Across the longitudinal cohort, rates of referral were overall low at 9%, although most referrals (87%) occurred after the year that NCCN guidelines expanded. Of note, we did not definitively establish eligibility for testing, in part due to the lack of specific or structured information on family history of cancer in the medical record. As such, we would not expect all patients in this cohort to be eligible for or receive testing, and thus the lower rate of testing observed in this cohort does not directly compare to studies that use eligible patients as the denominator. For example, a small study at the University of Alabama at Birmingham (UAB) found that 39% of the 38 eligible prostate cancer patients in 2019 were referred to genetics services.[18,19] The UAB cohort reported that 11% of referred patients received testing, similar to our cohort's 12% rate of genetic testing following counseling.[18] Other studies, such as a UCSF-based study, found the proportion of those tested following counseling was much higher, at 60%.[15] Notably, the UCSF sample was predominantly White (76%), while both the study conducted at UAB and this study had higher proportions of Black patients (32% and 44% respectively) and are not NCI-designated comprehensive cancer centers. These contextual factors may contribute to variation in rates of genetic testing following counseling across studies and should be examined to determine factors that promote testing completion, which was beyond the scope of this study. A shortage in the genetics workforce is a well-documented challenge in implementing genetic testing for prostate cancer,[20] and the role that access and availability to counseling and testing plays in testing completion is of import to optimizing the equitable use of genetics for patients with prostate cancer.

This study found a strong association between clinical stage and referral, with patients with regional and metastatic disease more likely to be referred relative to those with local disease. This is consistent with provider surveys, where most providers indicate they make genetics referrals for patients with metastatic disease.[11,12] Other predictors included lower age, a factor that is consistent with literature, and Black race. The reasons for the significantly higher rate of referral for people who identified as Black could be due to the higher likelihood of a BRCA1/2 mutation,[21] later stages at diagnosis, and/or higher mortality in this group,[22] which may have prompted more providers to refer these patients for testing. However, in breast cancer studies, where BRCA1/2 mutation testing has been standard of care for a longer duration, White patients are more likely to receive genetic services relative to minority populations.[23,24] Further, unlike Borno and colleagues, we found no association between non-English language and use of genetic services.[15] Our findings could be in part a function of the safety-net hospital setting in which the research was conducted, as more than 75% of the patient population comes from a medically-underserved group, including being Black, non-English-speaking, foreign born, or insured by Medicaid. Organizational factors of the hospital were not examined explicitly, but could play an important role in referral practices. We are currently conducting qualitative interviews with clinicians and patients to gain a better understanding of system and interpersonal factors that may influence the delivery of genetic care for patients with prostate cancer.

As expected, the rate of genetics referrals increased substantially (138%) one year after guidelines expanded eligibility for testing. While other studies measuring guideline change were not identified, this magnitude of change is similar to a study by Moody and colleagues that demonstrated a 118% increase in genetic referral rates following provider education.[25] Of note, beginning in 2019, the hospital participated in a nationwide program whereby a biotechnology company provided funding to eliminate patient costs associated with prostate cancer genetic testing for patients who met criteria for testing. However, the availability of this cost reduction program coincided with the increases identified in the time series analysis. Thus, we cannot ascertain the individual effect of guideline changes versus the reduction in testing costs associated with the program. Future research should assess the effect of the sponsored testing program which ended in April 2022, to parse out guideline vs. other historical policy changes on genetic referrals and testing utilization.

As a single-center study reliant on electronic health record data, these results should be interpreted with caution. As noted above, the inability to definitively determine eligibility per NCCN guidelines, the lack of explicit consideration of family history, the influence of historical events, and organizational factors were not directly assessed in this study. We could not examine predictors of genetic counseling and testing in multivariable models given their relatively rare occurrence. Whether the relative rarity of these events was related to lack of use or documentation remains unknown. Our ongoing research seeks to qualitatively explore patient and provider reported experiences with decision-making about prostate cancer genetic testing, which will complement these findings and potentially identify additional constructs that impact referral for future study.

5. CONCLUSIONS

This study offers insight into demographic and clinical factors affecting referral and demonstrates the short-term impact of expanding guidelines for patients with prostate cancer. Future work is needed to broaden the scope of factors in relation to referrals and subsequent testing outcomes using a multi-level approach and assess the long-term impact of providing genetic care for prostate cancer on cancer outcomes.

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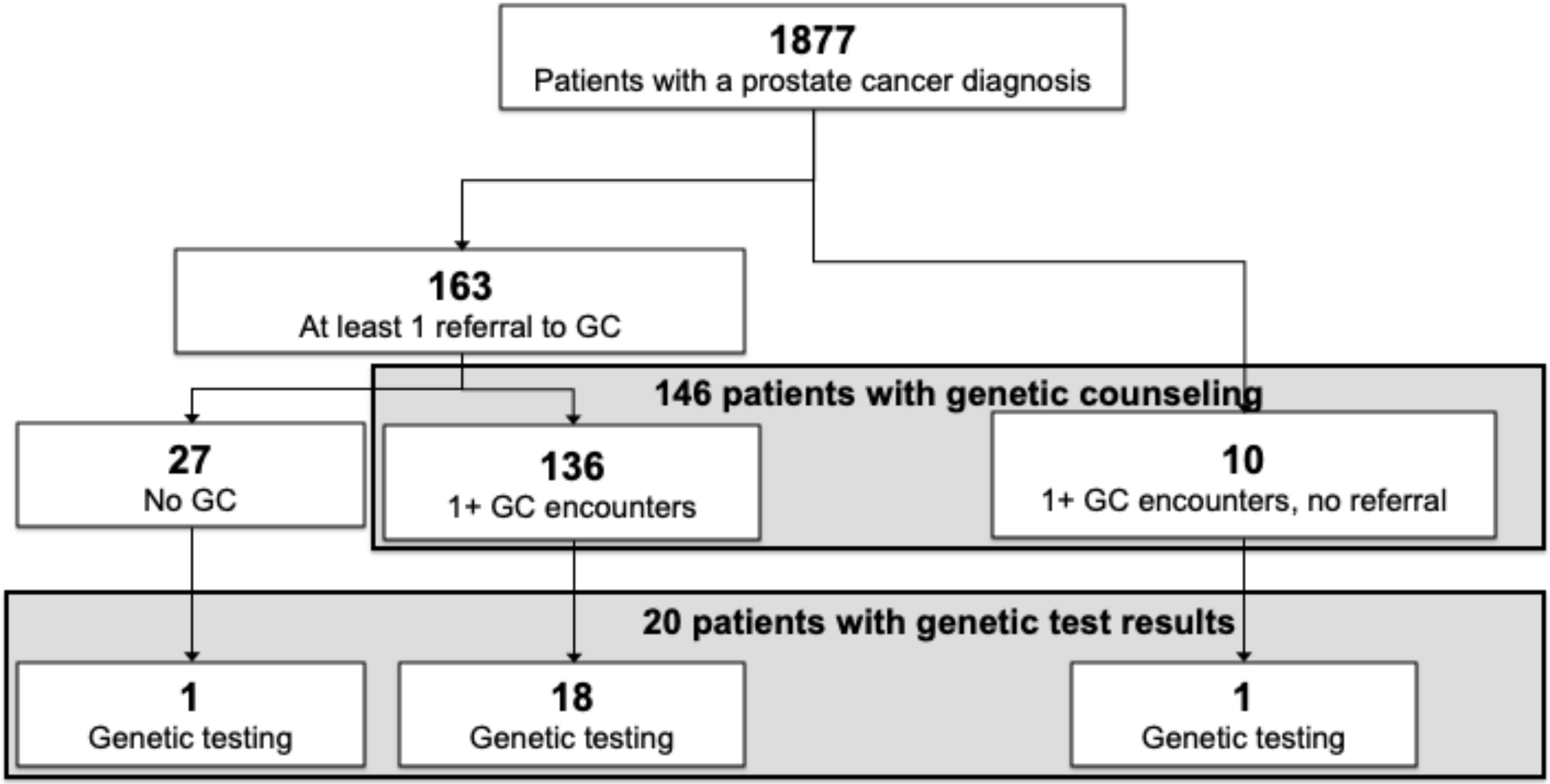
Figure 1



GC=Genetic Counseling; All numbers represent individual patients

Figure 2

Click here to access/download;Figure;DoD Figure 2.pdf

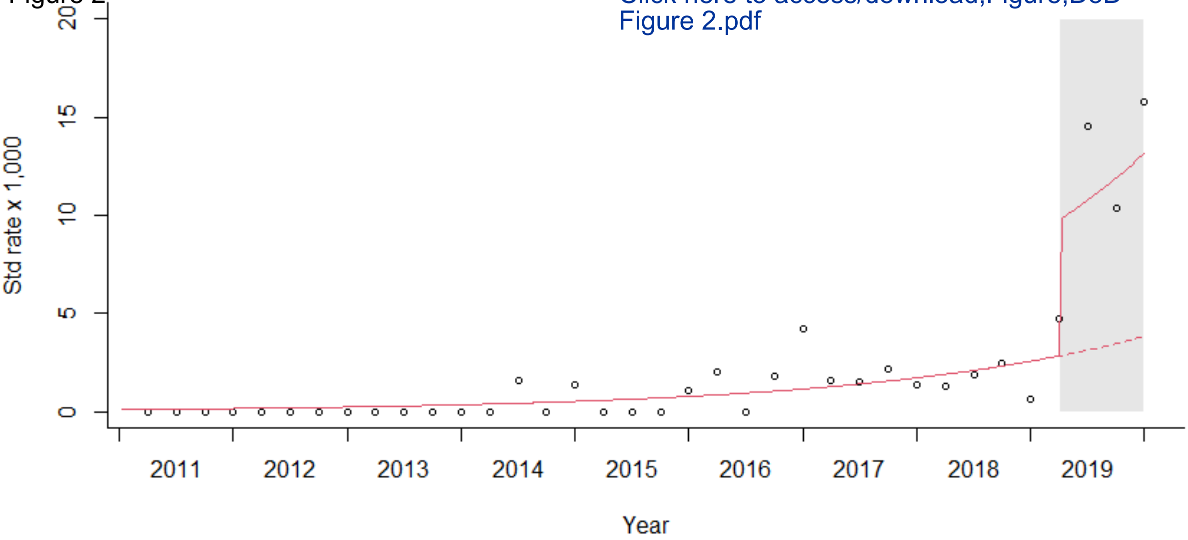


Table 1: Individual characteristics of patient cohort, January 2011- March 2020 (n=1,877)

Demographic Characteristics	
Age M (SD)	65 (9)
Race % (n)	
Black or African American	44% (829)
White	32% (607)
Other	5% (88)
Asian	2% (37)
Unknown/Missing	17% (316)
Ethnicity % (n)	
Not Hispanic or Latino	80% (1507)
Hispanic or Latino	17% (316)
Unknown/Missing	3% (54)
Marital Status % (n)	
Married or Significant Other	49% (915)
Single	34% (634)
Divorced, Legally Separated, or Widowed	13% (248)
Other or Unknown	4% (80)
Country of Birth % (n)	
Foreign born	46% (869)
US born	36% (672)
Unknown/Missing	18% (336)
Language % (n)	
English	67% (1260)
Non-English or Unknown	33% (617)
Insurance % (n)	
Medicaid	34% (638)
Medicare	25% (478)
Private	25% (469)
Other or Unknown	16% (292)
Clinical TNM Staging % (n)	
Local only	65% (1221)
Regional	3% (65)
Metastatic	9% (170)
Missing	22% (421)

Table 2: Characteristics associated with referral to genetics

	Unadjusted bivariate logistic Regression models OR (95% CI)	Fully adjusted multivariable logistic regression model OR (95% CI)
Age	0.98 (0.96 – 1.00)	**0.96 (0.94 – 0.98)**
Race		
White	ref.	ref.
Black or African American	**2.19 (1.44 – 3.32)**	**1.66 (1.05 – 2.63)**
Asian	1.59 (0.46 – 5.44)	1.38 (0.37 – 5.13)
Other	1.80 (0.80 – 4.04)	0.98 (0.38 – 2.55)
Unknown/Missing	**1.89 (1.12 – 3.16)**	1.33 (0.71 – 2.49)
Ethnicity		
Not Hispanic or Latino	ref.	ref.
Hispanic or Latino	1.33 (0.89 – 1.99)	1.63 (0.92 – 2.89)
Unknown/Missing	0.89 (0.31 – 2.49)	1.10 (0.34 – 3.59)
Country of Birth		
US born	ref.	ref.
Foreign born	1.33 (0.93 – 1.90)	1.14 (0.72 – 1.81)
Unknown/Missing	0.97 (0.58 – 1.62)	1.19 (0.65 – 2.18)
Language		
English	ref.	ref.
Non-English or Unknown	1.25 (0.89 – 1.74)	0.96 (0.61 – 1.51)
Insurance		
Private	ref.	ref.
Medicaid	**1.63 (1.07 – 2.48)**	1.20 (0.76 – 1.89)
Medicare	1.04 (0.64 – 1.68)	1.03 (0.62 – 1.73)
Other or Unknown	0.77 (0.42 – 1.40)	0.66 (0.35 – 1.24)
Clinical TNM Staging		
Local only	ref.	ref.
Regional	**4.14 (2.30 – 7.47)**	**4.51 (2.44 – 8.34)**
Metastatic	**3.52 (2.34 – 5.20)**	**4.64 (2.98 – 7.24)**
Missing	**0.24 (0.12 – 0.50)**	**0.27 (0.13 – 0.58)**

Prostate Cancer Genetic Testing Codebook

Codes

Name	Description	Files	References
Belief of Prostate Cancer Cause	Any mention by the patient of what they believed may have contributed to their prostate cancer diagnosis. This can include genetics and family risk, as well as other factors such as race, diet, exposure to dangerous substances, etc. It may also include descriptions of conversations in which a doctor/health care professional told them that their cancer was caused by something.	32	88
Health Status	How does genetics information (positive or negative) help one understand health. What affect did knowing or not knowing about genetics have on their perception of their overall health and well-being, and that of their family. This is not about treatment decisions, but more broadly how people understand genetic information to indicate health.	5	6
Personal Treatment Values	All mentions of what is most important to the prostate cancer patient when it comes to their treatment options, like chemotherapy or surgery. Examples of this would be perceived invasiveness of treatment options, their desire to “get rid” of the cancer no matter the cost, or concerns around effects of treatment on sexual, urinary, or other functions that factor into their choice of treatment.	30	96
Impact of Prostate Cancer Treatment	How prostate cancer treatment has affected patient’s lives, including, but not limited to, daily function, such as day-to-day tasks, work/employment. This can also include side effects of treatment, impacts on sexual or urinary function when the participant discusses how this impacts their life.	28	91
Information Seeking - General	All sources and information that was elicited to guide decision-making about treatment options by the patients. This can include information the patient found that related to the advantages or disadvantages of a certain treatment option, or general information on prostate cancer that would help them better understand their current health status.	20	52

Name	Description	Files	References
Information Seeking – Genetic Specific	All sources and information that was elicited to guide decision-making about specifically around genetic counseling/testing by participants. It may also include how helpful or confusing the information was in helping the person understand and make a choice about genetic care.	13	22
Need		0	0
Family Discussions	All discussions that patients had with family or friends about genetic testing - including who, the purpose and content of discussions, or circumstances around that discussion. Include expressions of not having discussions with anyone outside of their provider. This can also include any discussion about family history, screening for prostate cancer, or PSA testing that the patient had with another family member.	32	105
Need for Genetic Testing	This code includes expressions of people's motivation for testing and their understanding for the importance/use of genetic results. It's less about general knowledge, but how necessary testing was/was not for them. In applying need to their situation, please use the relative priority code.	27	77
Relative Priority	The relative priority that a participant places on genetics. May also include descriptions of how they prioritize one need relative to genetic testing at a given moment in time.	13	47
Seriousness of Prostate Cancer	Participant descriptions of how serious their prostate cancer is in terms of a threat to their health and well-being. This may relate to the specific stage as well as general perceptions of how good or bad their prognosis is currently or at the time of their diagnosis.	29	71
Pre-disposing & Enabling Factors		0	0
Attitudes - Genetic Testing	Attitudes that are specific to genetic services/care/testing. This can be related to prostate cancer or other forms of genetic testing. This should not include ideas about the value that genetic testing brings to their specific situation (that goes in Need for Genetic Testing or Relative Priority). Exclude general feelings about health care/medicine - these go in Attitudes- Health services.	29	68
Medical Decision Philosophy	Any time a participant mentions their personal beliefs/mindset/thinking behind how they make decisions about their health and medical care. This can include any mention of whether or not they defer to their doctor/medical personnel to make all their decisions on treatment, or if they base their decisions off of personal or	30	79

Name	Description	Files	References
	family/friends' advice/beliefs. Here we are trying to capture a person's general orientation to participating in medical decisions, so they may be prostate cancer-specific, or not.		
Attitudes - Health services	Any description of attitudes or beliefs that participants have towards the medical system, health care, western, or alternative/complementary medicine. These may be prostate or cancer specific, or more general.	21	47
Health Values	All mention of health values or the importance people place on their health. This is specific to health itself, not medical care. Examples may include "Health is the most important thing we have", or "I don't worry too much about my health because there's nothing I can do to change it." Both high and low value placed on health are included here. Do not include descriptions of how healthy one is/isn't.	20	50
Knowledge about Genetics	Any time someone describes knowledge related to genetic testing (what it does, who it's for, its purpose, what is involved). This code also includes knowledge about prostate cancer guidelines for testing - what made them eligible to see genetics. Misinformation may also be included here. Do not include attitudes (positive or negative feelings about testing) - these go in Attitudes - Genetic testing.	27	63
Psychological & Social Support	All mention of who or how much, and what type of support people have to manage their health and cancer. Focus should be less on individual people, but more on the nature and quality of that support. This is separate from who helped them make decisions (although some overlap may exist here).	34	138
Satisfaction with Care		0	0
Access & Availability	This code includes any barriers and facilitators to accessing genetic testing or genetic counseling.	15	35
Coordination	Indications of how well coordinated genetic care (referrals, results return, information sharing) was between doctors or how well the patient could easily coordinate genetics care in the context of their other treatment. A general feeling of how much "hassle" was associated with getting genetics care.	9	13
Financial	Barriers and facilitators to paying for genetic testing, or general feelings about how expensive (or not) testing was. It could include how much this was considered in the decision, as well as realized costs.	11	15

Name	Description	Files	References
Interpersonal Experience	Expressions about the quality of communication and inter-personal aspects of genetic care and testing. These would include communication or features of people with whom patient interacted that are expressed to have influenced the experience of care.	20	69
Use of Health Services		0	0
Care AFTER Genetic Testing	Descriptions of communications or learning about the results of genetic testing. This may include visits or other asynchronous forms of communications (letters).	24	116
Genetic Counseling - Discussions about Testing	Any descriptions about the process and experience of speaking with the genetic counselor or provider who spoke to them about genetic testing. Do not include descriptions of testing itself. This could also include discussions about testing, experience with access (wait time), the quality of counseling, and follow up. who had the discussion, the quality of	31	169
Obtaining Genetic Testing	This code includes all descriptions of obtaining genetic testing. It may include how and when, and how difficult/easy it was to obtain genetic testing.	21	74
Testing Influence on Treatment	Descriptions on how testing influenced the care that the patient did receive or plans on receiving. What impact did testing have on their treatment for prostate cancer? May also include other health decisions impacted by genetic testing results.	20	33