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Tracking Patients with Metastatic Prostate Cancer for Genetic Testing: An Oncology Nurse Practitioner Navigation Project

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Abstract

Background: *Evidenced based guidelines recommend somatic and germline testing for patients with metastatic prostate cancer. These provide guidance for risk assessment and promote a tailored prescription for treatment with targeted therapies. Lack of timely navigation that supports patients so that they complete somatic and germline testing can hinder both outcomes, as well as impede proactive preventative care for families.*

Objectives: *This quality assurance initiative evaluated the Oncology Nurse Practitioner Navigator (ONPN) effectiveness in the coordination of a mPC pretreatment genomic testing protocol and to increase genetic testing documentation in the patient's medical record.*

Methods: *This was a secondary analysis of two genetic databases and medical records for a sample of patients. Prior to and after the Oncology Nurse Practitioner Navigator (ONPN) coordinated genetic testing, data was analyzed for the number of patients with documented germline and somatic testing and documentation in patient medical records that confirmed testing, from July 1, 2022, through May 18, 2023.*

Findings: *This VA quality assurance initiative established that before the ONPN care coordination, 197 patients needed germline and 250 needed somatic testing. After ONPN coordination, 21 patients needed germline and 6 patients needed somatic testing. Seventy-one notes were entered in the patients' medical records, of which 49(69%) were entered by the ONPN. Therefore, ONPN coordination of patient genetic testing increased the number of tests and medical record documentation.*

Keywords: Oncology Nurse Practitioner Navigator, Genetic Sequencing, Navigation Tool, Documentation Tool, Evidenced Based Care.

Background

Worldwide, prostate cancer is the most frequently diagnosed cancer in men, accounting for more than half of the countries of the world, with an estimated 1.4 million new cases in 2020 [1]. The American Cancer Society (ACS) predicts that there will be 288,300 new cases of prostate cancer in 2023 in the United States [1]. Since 2014 the incidence rate has increased by 3% per year, and 5% for advanced prostate cancer (ACS, 2023). CDC indicated the percentage of patients diagnosed with mPC increased from 4% to 8% from 2003-2017 [2].

Evidenced based guidelines such as National Comprehensive Cancer Network (NCCN) recommend somatic and germline testing as a standard of care for patients with metastatic prostate cancer [3]. These guidelines provide

a framework for risk assessment, as well as promote a tailored prescription for treatment with targeted therapies. Because genomic testing has become the standard of care for patients with metastatic cancer, Veteran initiatives have recognized sequencing as a national priority. Germline testing identifies inherited pathogenic mutations. It is performed by testing lymphocyte DNA from blood or a combination of lymphocyte DNA from blood and buccal cell from saliva. DNA germline mutations refer to the genetic substance within the DNA, half of which is obtained from the mother and half from the father. Somatic mutations are found in tumor tissue or blood and can change over time. Repeated testing of tumor DNA may be necessary to track these mutational changes along a patient's treatment trajectory [4].

Evidence indicates that somatic and germline testing has not been completed on prostate cancer patients due to timely identification of patients to test. Additionally, identification of suitable patients for testing warrants that a systematic plan is put into place [5]. Research that pertains to the most cost effective and efficient methods of obtaining sequencing patients for testing is scant. A study in Texas looked at N = 444 Hispanics who were randomly assigned to three different groups. These included standard mail outs, culturally tailored materials that were mailed out, as well as culturally tailored materials with interpersonal contact. It was determined that interpersonal conversation with culturally sensitive mail out material had the highest accrual (29.9%; $p < 0.05$). Though interpersonal communication had the highest rate of accrual, the authors concluded that more research is needed to determine the cost effectiveness of measures that are resource intensive [6]. Population based screenings present another avenue for patient identification of those with high-risk cancers including prostate cancer. The literature reports inequities pertaining to genetic service access [7]. A 3-arm randomized control trial is underway which is testing the use of a virtual genetics navigator and motivational interviewing by a genetics health coach. The sample includes prostate cancer patients, and the recruitment goal is N = 759 patients. The proportion of patients that complete testing within six months is the measured outcome [8].

The importance of ensuring that the reporting of the testing results is documented in a standardized manner cannot be underestimated. This ensures that clinicians have easy access to results for prescriptive measures [8]. The utilization of point of care tools has been shown to both improve the process of ordering genetic testing and decrease the use of tests commonly ordered by providers that are not geneticists. Thus, clear documentation contributes to the dissemination of knowledge in an efficient practical manner.

Care co-ordination is inherent in the Oncology Nurse Practitioner role function, as is utilizing the nursing process to create care plans based on precision medicine principles [9]. Research though limited has begun to show a trend for utilizing nurse practitioners as part of a genetics team [10]. As timely identification of patients that need testing as well as documentation of results is a goal of precision medicine, ONPN's are well suited for this role. Therefore, the purpose of this project was to evaluate ONPN effectiveness in the coordination of a mPC pre-treatment genomic testing protocol and to increase genetic testing documentation in the patients' medical record.

Methods

Project Design

The study design was a secondary data analysis. Several sources of information were accessed for this analysis. Information was obtained from two clinical databases located on the Veterans Administration National Precision Oncology (NPOP) Program website. The first database was a resource which showed all patients at the study site with metastatic prostate cancer. Variables of interest for this study included the presence or absence of sequencing, and if sequencing were present, the vendor and date. The second database included patients with testing as well as the testing results in abbreviated form. The patients' medical record was reviewed, as well as genetic results from a study folder, in addition to two genetic vendor portals. The study folders contained testing results for somatic and germline testing. The somatic testing was done through Foundation and/or OncoPlex somatic genetic gene panels [11,12]. The germline testing included patients tested with COLOR and/or OncoPlex Cancer Gene Panels [12,13].

Sample

Veterans diagnosed with metastatic prostate since 2015 were included in the database. Inclusion criteria included those with a diagnosis of metastatic prostate cancer who received care in the Seattle VA system.

IRB/Ethics Board Approval

The study was reviewed initially by a Quality Assurance (QA) member and IRB. It was determined that the ONPN would have list view access to the study result folders.

Procedures for Data Collection

The ONPN worked under a principal investigator (PI) physician who was in charge of the research protocols and team lead for prostate cancer patients. The aim of the data collection procedures was to obtain germline testing for all patients with metastatic prostate cancer, and to ensure that all patients who had testing had a note indicating the genetic testing results in the medical record. The two NPOP databases served as the starting point for the data collection for patients with metastatic prostate cancer.

Data Collection Instrument

The ONPN organized the information on an EXCEL spreadsheet that was posted on TEAMS for provider internal use. Initially it consisted of patient

identifier, presence of testing, results, CPRS gene note, barriers, a section for notes, as well as a call list if the patient needed testing. The testing consent and recruitment was handled by the research team. This VA is a training ground for oncology fellows who were under the direction of the PI. There is a National Oncology Network housed out of the Durham VA that is the central hub for overseeing evidenced based protocols that serves as the mecca for the dissemination of new knowledge. Best practice is to follow the prescription for prostate cancer treatment as outlined by a prostate cancer charting template that has a section for standardized reporting of gene note results.

Data Analysis Plan

Descriptive Statistics

Descriptive statistics were used to take an initial count of the number of patients that needed somatic and/or germline testing. This was reviewed by the PI who determined each patients' suitability for testing. Counts of patients that needed each of the tests were taken at regular intervals during the study. The platforms of germline and somatic tests completed were combined and tallied during each of the timelines (2022. July 1-December 31) (2023, January 1-May 18). A count was taken of the number of CPRS gene notes entered during each of the time periods, in addition to the number of gene notes entered by the ONPN.

Results

Initially Results Required Spreadsheet Revision Due to List Issues

Initial results of patients that needed testing and follow-up were reviewed by the physician supervisor who was also the PI for the study group (2023, April 4. Additionally, some of the patients on the list did not have M1 disease, were deceased, had not been seen in the past year, had migrated to other VAs, and/or were seen in the community. Furthermore, some of the patients were seen co jointly at the VA and by local oncologists in the community. In this case these patients were prescribed medication by the VA. At this point the physician supervisor requested that sorting be completed with additional EXCEL columns as follows:

- Patients with M1 disease
- Patients seen within the past year.
- Patients served locally including community and/or local VA.

Once access to the research folders was obtained for the ONPN, data was again added to the spreadsheet (2023, April 24; 2023 May 18). The data was further sorted for germline testing when it was determined that results had to be sorted into columns distinguishing germline from somatic testing. The ONP was trained by the physician supervisor to document standardized gene testing notes in CPRS which were entered (2023, April – May).

Decrease in the Number of Patients that Needed Testing

Initially there were N = 612 males; n = 370 of which were living. The mean age of the sample was 75 years of age. Of the n =370 patients; n = 370 had M1 prostate cancer. The sample was predominately White n = 229 (67%). The remainder of the sample was categorized as Other ancestry (Table 1).

CHARACTERISTIC	$\bar{x}$ μ	SD	RANGE
Age (years)	74.7	10.1	(49-97)
CHARACTERISTIC			
Sex		N	%
Male		612	100
Living		370	61
Deceased		242	40
Self-identified ancestry		n[a] 370	%
White		229	62
Other[b]		141	38
M_1 Disease[c]		331	89

Table 1: Sample Characteristics (N = 612)

[a]n refers to the number of living patients with prostate cancer

[b] Other ancestry includes Black, Asian, Native Hawaiian Korean, American Indian, and Unknown

[c] M_1 refers to the number of living patients with metastatic prostate cancer

The number of patients that needed germline testing decreased from n = 197 (2023, April 4) to n = 21(2023, May 22). Initially there were n = 250 (2023, April 4) patients that needed somatic testing. This was reduced to n = 6 patients (2023, May 22), (Table 2).

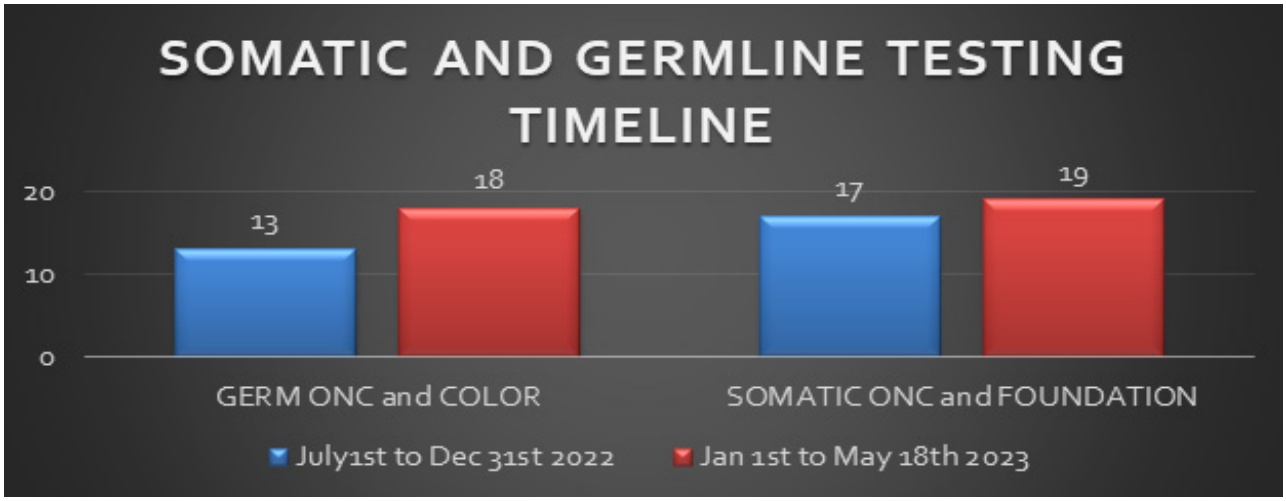
Table 2: Decrease in the Number of Patients that Needed Testing and Gene Notes

	4/4/2023	4/18/2023	5/18/2022	5/22/2023
Germline	197	64	35	21
Somatic	250	84	37	6
Gene Notes	102	34	0	

Data Sorting Categorizing Each Test Shows Improvement of Completed Testing

When further distinguishing between the germline and somatic testing was completed, the number of tests completed improved for each of the categories during each of the timelines (2022, July 1 – December 31) (2023, January 1 – May 18), (Figure 1).

Figure 1: Somatic and Germline Testing Timeline

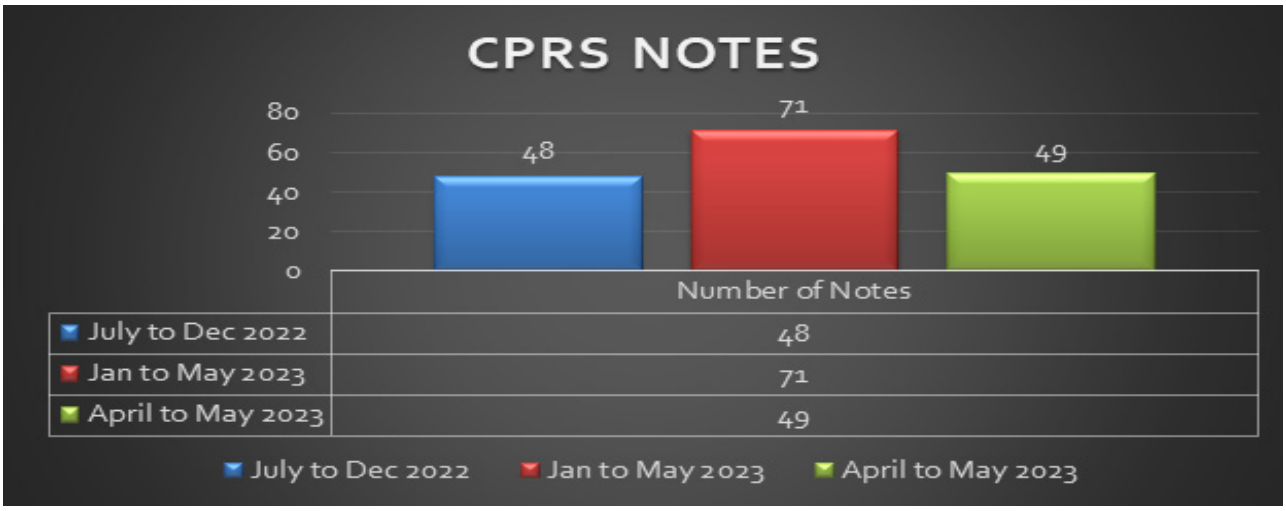


Combination of Oncotype and COLOR Germline Testing from Before and after the Project
Combination of Oncotype and FOUNDATION Somatic Testing Before and After the Project

Progressive Decline of Gene Notes, Accented During ONPN Note Entry Period

The number of patients that needed CPRS gene notes was n = 102 (2023, April 4). There was a progressive decline in the number of notes needed, and by the end of the project, all the patients that needed notes were sequenced (2023, May 18). The number of CPRS gene notes entered increased during the respective time periods increased from n =48 prior to study to n = 71 during the study period. Of the n = 71 notes that were entered during the study period n = 49 were entered by the ONP after the training received in April to the study end (Figure 2).

Figure 2: CPRS Gene Note Timeline



Number of Gene Notes Entered in CPRS before and During the Study (N = 48, N = 71)

Gene Notes Entered by ONPN after Training (49/71)

Discussion

The study showed that the addition of an ONPN as navigator increased both the number of patients that were sequenced as well as the number of genetic notes that were written. Additionally, a standard templated note for the documentation of the patient sequencing was utilized. This supports current literature that APRN practice models utilized for navigation lead to improvements in better compliance with NCCN guidelines for genetic testing and order turnaround time [14]. The importance of ensuring that the reporting of the testing results is documented in a standardized manner cannot be underestimated. This ensures that clinicians have easy access to results for prescriptive measures [15]. The utilization of point of care tools has been shown to both improve the process of ordering genetic testing and decrease the use of tests commonly ordered by providers that are not geneticists. Thus, clear documentation contributes to the dissemination of knowledge in an efficient practical manner.

Navigation tools are the mainstream for nurse navigation [16]. The tool used in this project was an EXCEL spread sheet. This tool provided a thumbnail sketch of the patients' status. It included the patient's cancer treatment, PSA, last clinical visit, genetic note, as well as the genetic testing performed. This proved useful as a central reference and provided a structured approach for documentation. A limitation of the tool is its lengthy process involved in reconciling it between the new test results, appointment status, and PSA results. Additionally, at times obtaining these results presented a challenge for the patients that were followed in the community. Consideration is strongly recommended regarding a software program that would automatically feed this information into the system.

The study pinpointed several issues that are emerging in the literature in the rapidly growing field of cancer genetics. It has been shown that ONPN navigation follows a systems approach, which addresses barriers encompassing the patient, facility, and community. In this study patient barriers encountered were the fact that some of the patients had migrated to other VA's or sought care at local community centers. Research is just beginning to emerge which demonstrates the most efficient method of reaching out to patients for genetic sequencing [6]. In this instance the study team coordinators and/or the oncology providers were the initial point of contact. This study confirmed that interpersonal contact was very successful. This author maintains, as does previous studies, that more research is needed to determine best practices pertaining to identification of patients that need testing that are cost effective measures [6].

In this study patients in hospice as well as those that had refused testing in the past after individual chart review, as well as review with the PI were not considered. Case reviews of cancer patients undergoing palliative report that the best timing and integration of genetic counseling is unclear. As up to 10% of cancers are of germline origin, patients may want to consider previously missed targeted treatments and/or give their family the benefit of preventative screening. Best practices for timing of testing need further research.

Community barriers to testing included accessing patients that had migrated out to the community. These patients did not have a relationship with the VA oncologists; however, it is important that they have access to the evidenced based practice that the VA is offering. Holt (2021) reports that a barrier that can ensue that pertains to integrating precision public health into the community is the poor uptake of evidenced based medicine. Reasons can include lack of a firm knowledge base, and/or lack of clinical utility [17]. This becomes an ethical and social issue as these patients rely on their providers for evidenced based care. Further research is needed to address methods to access these patients.

Facility challenges as aforementioned were due to the lengthy process of updating the spreadsheet. A database that updates the spreadsheet components automatically is this author's recommendation, as well as a Navigation model which can facilitate analysis of findings and integrate research with practice.

Implications for Nursing

Oncology nurses are responsible for ensuring that the care of our patients is evidenced based. This study demonstrated the effectiveness of an ONPN in organizing a streamlined approach for consolidating patient results and ensuring that patients obtain testing according to evidenced based standards. Additionally, it is important that documentation of results is centrally located. This study identified the templated note as one method of standardizing results for ease of view. This study outlined an initial protocol for practice that can be built upon through further research (Figure 3).

Figure 3: Gene Protocol for Practice

1.	Collaborate with team regarding roles and timeline
2.	Obtain IRB approval
3.	Initiate Spreadsheet
4.	Perform initial chart review and documentation on spreadsheet
5.	Analyze progress and barriers with team
6.	Adjust as indicated
7.	Repeat 4 – 6 regularly (monthly is the recommendation)
8.	Meet with data management regarding software application

It sets the groundwork for the development of a navigation tool that can be utilized for the organization of testing as well as a handy resource for expediting patient care. Further research is indicated as noted that will further refine the navigation tool.

Conclusion

The discipline of genetics is skyrocketing at a phenomenal rate. Studies such as this lay the groundwork for evidenced based care by incorporating research with practice. The value of an ONPN cannot be overemphasized, as structure is needed for translating this rapidly evolving field.

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