Conference Abstracts

Peer MD Coaching Partnership Outcomes Between an NCI-designated Cancer Center Genetics Service and a Community Cancer Network Hospital

Lauren G Santos, MSIM[1], Tatyana Buzdnitskaya, BSN[2], Brad Rolf, MS, CGC[3], Mark E Sienko, MD[2], Jose A Ruiz-Bonilla, MD[2], Binay Shah, MD[2], Patrick D Jewell, MD[2], Lindsay G Jensen, MD[2], Martha Horike-Pyne, MD[4], Jo A Elrod, PhD, CCRP[1], Jennie R Crews, MD, MP[5], Mercy Y Laurino, MS, CGC, PhD[1], Kevin A Weeks, MD[2], Marianne E Dubard-Gault, MD, MS[4]

[1] Fred Hutchinson Cancer Center, Seattle, WA, USA, [2] Olympic Medical Cancer Center, Sequim, WA, USA, [3] Division of Medical Genetics, University of Washington, Seattle, WA, USA, [4] Department of Medicine, University of Washington, Seattle, WA, USA, [5] Fred Hutch Cancer Center, Seattle, WA, USA

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Purpose

Patients with cancer seen in rural and underserved areas disproportionately face barriers to access genetic services. Genetic testing is critical to inform treatment decisions, early detection of another cancer, and to identify at-risk family members who would benefit from screening and prevention.

Methods

We conducted a prospective cohort study to examine medical oncologist's genetic testing ordering trends at Olympic Medical Cancer Center (OMCC), a community network hospital. Phase I focused on observation of clinic processes. Phase II incorporated peer coaching from cancer genetics experts from Fred Hutchinson Cancer Center (FHCC) for OMCC medical oncologists. Number of genetic testing tests ordered was compared between phases.

Results

Of the total patients with cancer, 29 out of 415 (7.0%) received genetic testing in phase I and 25 out of 219 (11.4%) in phase II. Although it did not reach statistical significance (p=0.057), uptake of genetic testing increased by 22% between phases. 4 out of 19 (21.1%) patients with pancreatic cancer and 6 out of 35 (17.1%) patients with ovarian cancer received testing when NCCN recommends offering genetic testing to 100% of these patients.

Conclusion

Peer coaching intervention from cancer genetics experts led to increased ordering of genetic testing by medical oncologists. Efforts made to 1) standardize gathering of personal and family history of cancer, 2) review biomarker data suggestive of a hereditary cancer syndrome, 3) facilitate ordering tumor and/or germline genetic testing every time NCCN criteria are met, 4) encourage data sharing between institutions, and 5) advocate for universal coverage for genetic testing will help realize the benefits of precision oncology for patients and their families seeking care at community cancer centers.

INTRODUCTION

Patients with a cancer diagnosis seen in rural and underserved areas often face health disparities, encounter barriers to accessing healthcare services, and have worse health outcomes compared to patients in urban communities.[1] In the context of precision oncology and genetic services, patients with cancer seen in rural health facilities are less likely to learn about the benefit of tumor profiling.[2] Consequentially, they may lack awareness that inherited pathogenic variants guide cancer treatment or that a cancer genetics evaluation can help with screening, early detection, and preventative measures for them and their at-risk family members.[3,4] While some are referred for pre-test genetic counseling and testing, they often face obstacles in accessing testing and follow up services.[5-7]

Table 1. Simplified NCCN guidelines for germline genetic testing by disease group

Disease group	Simplified NCCN guidelines for germline genetic testing
Breast	-every breast cancer diagnosis under age 60 -any breast cancer diagnosis with a family history of any cancer
Colon	-every colon cancer diagnosis under age 50 -any colon cancer under age 70 with a family history of any cancer - somatic mutations in the Mismatch DNA Repair or Homologous Recombination DNA repair pathway.
Ovarian	-every diagnosis of ovarian cancer or family history of ovarian cancer.
Pancreatic	-every diagnosis of pancreatic cancer or family history of pancreatic cancer.
Prostate	-every prostate cancer diagnosis under age 70 who have either a family history or high-risk features such as a Gleason score >= 4+4 or positive lymph nodes - every patient with metastatic prostate cancer, -somatic mutations in the Homologous Recombination or Mismatch DNA repair pathway

Lack of genetic services for patients affected by cancer delays identification of inherited pathogenic variants, which may result in suboptimal clinical management recommendations. Identification of a pathogenic variant allows for individualized utilization of targeted therapies, risk stratification, prediction of response, tailored screening and surveillance recommendations, early detection, and risk reduction interventions.[8-11] Cancer genetic services empower patients and their family members to identify a hereditary cancer syndrome (HCS) and be proactive in their preventative health care. Family members at risk of cancer meet criteria for high-risk screening, surveillance, early detection, and prevention and benefit from a multidisciplinary holistic approach to decrease their cancer risks to as close to zero when possible.[12,13]

This pilot study was one of the first collaborations between the Cancer Genetics Service of FHCC, a NCI-designated comprehensive cancer center located in the greater Seattle area and one its affiliated network cancer center, Olympic Medical Cancer Center (OMCC) located on the Olympic peninsula in Washington. FHCC is a large metropolitan NCI-designated cancer center and OMCC is a regional community-based cancer center. Before April 1, 2022, FHCC was formerly known as Seattle Cancer Care Alliance (SCCA) and Fred Hutchinson Cancer Research Center (FHCRC). Our common goal was to address the gap of patient access to upfront cancer genetic services when they meet National Comprehensive Cancer Network (NCCN) criteria through a peer coaching intervention of medical oncologists. This study strengthened the established partnership between the two sites where OMCC medical oncologists had access to consultations and peer coaching from the cancer genetics service at FHCC.

METHODS

This study was performed in two phases over a total duration of 6 months (Phase 1: August 1, 2020 to October 31, 2020 and Phase II: November 1, 2020 to January 31, 2021). In 2019, there were 246 patients with a new diagnosis of breast, colon, ovarian, pancreatic, or prostate cancer seen at OMCC. The study team was led by a cancer geneticist with specialized training in oncology, a certified genetic counselor, clinical nurse coordinators, and a research coordinator. The study team collaborated with employees from Invitae, a CAP-accredited and CLIA-certified clinical diagnostic laboratory, who, prior to the start of Phase I, provided in-service education to OMCC oncology providers and staff on how to navigate the online portal to order genetic testing. Our study team selected Invitae as the testing laboratory due to their turn around time (2-3 weeks), assistance in prior authorization, and for their no-cost family testing program when one tests positive for a pathogenic variant. Invitae genetic testing was covered by study funds and provided to patients at no additional cost, regardless of whether peer coaching was provided to OMCC medical oncologists. All patients were offered the same hereditary cancer panel which analyzed 47 genes associated with increased risk to develop cancer. This panel was selected because it provided a comprehensive test for the main actionable HCS. The study team used a modified version of the NCCN guidelines (Table 1) as the OMCC clinical support team staff assisting patients are not trained in genetics and are pressed for time when gathering medical records and family history. For patients with a complicated medical and/or family history, the OMCC team offered a referral to FHCC for a formal cancer genetic evaluation.

Phase I focused on understanding OMCC's existing clinical processes to identify patients who meet the modified NCCN guidelines. Patients' and oncologists' visit details were reviewed and utilization of genetic testing by patients who had a current diagnosis of breast, ovarian, prostate, colon, and/or pancreatic cancer at the time of their clinic visit were tracked. We focused on these cancer diagnoses because NCCN guideline for genetic testing has been available for more than a decade and in order to have a large enough subset of patients in each group. Phase II included a peer coaching intervention for OMCC medical oncologists in counseling and ordering genetic testing for patient cases they brought forward. The study team reviewed de-identified medical and family history packets with the OMCC medical oncology providers at bi-weekly virtual meetings prior to or after patients' clinic visits. OMCC medical oncology providers would then discuss the importance of an inherited cancer risk testing to eligible patients and offered them genetic testing through Invitae at their discretion.

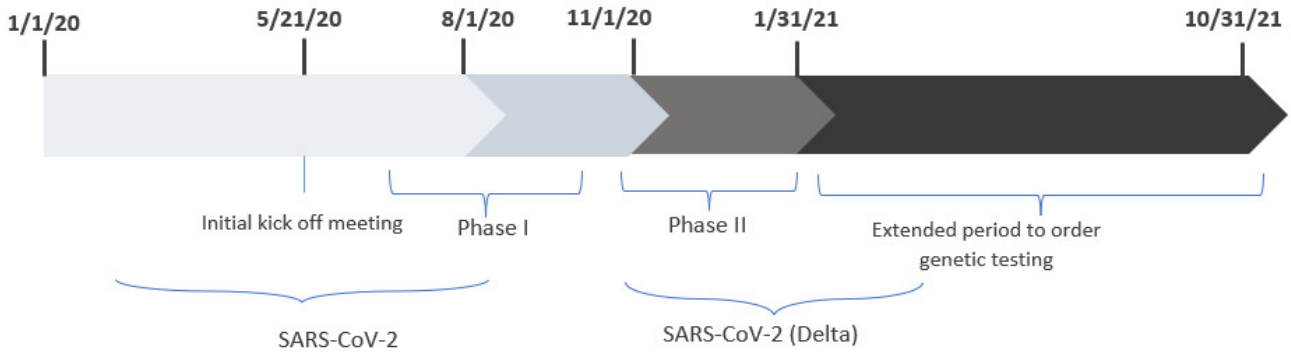

Figure 1. [14]

At the end of each phase, we measured how many OMCC patients with cancer met NCCN criteria for testing, how many patients received genetic testing with their oncologists, and how many were referred to FHCC's genetic service. The number of genetic tests ordered was then compared between phase I and phase II assessing whether peer coaching increased uptake of genetic testing. The data was collected through OMCC visit reports generated from the electronic health record system (EHR). Data was de-identified and informed consent was waived. This study was performed under Protocol 00010137 approved by the University of Washington Institutional Review Board.

MEASURES

We documented utilization of genetic testing for every patient seen at OMCC for medical oncology visits between 8/1/20 and 1/31/2021. We used a modified approach (based on 2020-2021 NCCN guidelines) to determine eligibility for genetic testing. This approach recommended genetic testing for 1) every patient diagnosed with breast cancer before age 60 years or any patient diagnosed with breast cancer at any age who also had a family history of cancer, 2) every patient diagnosed with ovarian cancer, 3) every patient diagnosed with pancreatic cancer, 4) every patient diagnosed with prostate cancer before age 70 years with either a family history or high-risk features (such as a high PSA level, Gleason score 4+4 or greater, any node positive/metastatic disease, somatic mutations in the Homologous Recombination (HRD) DNA repair or mismatch repair (MMR) DNA repair pathway, 5) every patient diagnosed with colon cancer before age 50 years (or before age 70 years if they had a family history of cancer or somatic mutations in the MMR or HRD DNA repair pathway).

We identified the patient study cohort by selecting patients with a new or active breast, ovarian, colon, pancreatic, and/or prostate cancer diagnosis seen in the medical oncology clinics at OMCC. Demographic, clinical history, family history data, and pathologic information were collected on all patients through EHR system-generated reports or directly through chart review. Most patients seen within phase I and phase II had an overlap of visits as they were seen for follow-up cancer care, making it difficult to differentiate when genetic testing was discussed and ordered within each distinct phase. Our initial EHR data collection included 1,349 patient encounters between 8/1/2020 and 10/31/2020 in phase I and 1,124 patient encounters between 11/1/2020 and 1/31/2021 in phase II (fig. 1). We separated patients with cancer based on the date at first encounter for cancer care, either before or after 08/1/2020 and only included distinct patient encounters with OMCC providers. Since we observed that many of the patients with cancer were seen for multiple visits over their first year of care, we separated the initial consult visits versus follow up visits. We then assigned consult patients to phase I or phase II using the date when genetic testing was ordered or, when no genetic testing was ordered, the date of the consult encounter was recorded. Patients with cancer diagnosed before 08/1/2020 who only had follow-up visits in both phase I and phase II *and* genetic testing were assigned based on the date their genetic test was ordered. Patients who only had follow-up visits within the project timeline and for whom no genetic testing was ordered were categorized as phase I.

The number of patients seen within or assigned to phase I and phase II were affected by the various social distancing mandates and health system policies related to the COVID-19 pandemic and limited our control over the number of patients seen in each phase during the project.

STATISTICAL ANALYSIS

We examined trends in the patient cohorts based on sex, age, race and ethnicity, cancer diagnosis, and family history. We correlated clinical, cancer diagnosis, family history and demographic variables with ordering of genetic testing in both phase I and phase II. Patients who met NCCN testing criteria were recorded. We compared the proportion of patients who received testing between phases and the types of genetic testing received before and after peer coaching intervention. To assess whether our peer coaching intervention between phases resulted in a statistically significant increase in genetic testing uptake, we used a chi-square test with a p-value threshold of $p<0.05$.

RESULTS

STUDY POPULATION

Cohort demographics are summarized in Table 2. The patient cohort included 634 distinct patients, with 415 patients in phase I and 219 patients in phase II. Ages of patients from both phases ranged from 39-90 years, with a median age of 73 years. In phase I, there were 54 (13.0%) initial consults, and 361 (87.0%) follow-up visits out of 415 patients. Phase II had 65 (29.2%) and 155 (70.8%), respectively. 409 (64.5%) patients were recorded as female and 225 (35.5%) as male. The study population was predominantly of White ancestry. Among both phases, there were 353 (55.7%) patients with breast cancer, 184 (29.0%) with prostate cancer, 43 (6.9%) with colon cancer, 35 (5.5%) with ovarian cancer, and 19 (2.5%) with pancreatic cancer. 67 (10.6%) of all patients had stage 0 or 1 disease, 47 (7.4%) had stage 2, 37 (5.8%) had stage 3, and 528 (71.8%) of patients' cancer stage was unavailable to the FHCC cancer genetics study team. 218 (34.4%) patients had family history of cancer documented in the chart. 100 (24.1%) in Phase I and 48 (21.9%) in phase II met modified NCCN criteria for genetic testing. 12 (1.9%) patients were documented to have died during the study.

UPTAKE OF GENETIC TESTING

Overall, 29 (7.0%) of patients out of 415 received genetic testing in phase I and 25 (11.4%) out of 219 in phase II. Of those 29 patients in phase I who received testing, 20 (69.0%) had germline genetic testing and 9 (34.6%) had somatic testing. 7 (24.1%) patients had a pathogenic variant, 13 (44.8%) were negative and 9 (31.0%) had a variant of uncertain significance (VUS) in phase I. Of those 25 patients in phase II who received genetic testing, 23 (91.0%) had germline genetic testing and 2 (8.0%) had somatic testing. 2 (8.0%) patients had a pathogenic, 14 (56.0%) were negative, and 9 (36.0%) had a VUS in phase II. The uptake of germline genetic testing increased by 22% between Phase I and Phase II among total patients who received testing but difference between observed and expected values did not reach statistical significance (p=0.057).

TRENDS

A three-generation family history of cancer at cancer diagnosis is critical to estimate pre-test likelihood of a HCS. Uncovering a HCS can guide oncologists in choosing targeted therapy with the highest likelihood of benefit for the patient and start the conversation around benefits of germline genetic testing for their unaffected at-risk relatives. We analyzed the relationship between documentation of family history in the EHR and uptake of germline genetic testing. Proportion of patients who had 1) a documented family history of cancer in the EHR, 2) documentation they had no family history of cancer in the EHR, and 3) an unknown family history of cancer (either not documented in the EHR or unavailable to the FHCC cancer genetics study team) were almost identical in both phases. Percentage of documented family history of cancer did not increase with the peer coaching intervention in phase II (57.6% undocumented in phase I versus 57.1% undocumented in phase II).

Peer coaching intervention appears to have helped bring the germline testing conversation back to the forefront of patients' cancer care. Despite there being no observed increase in documentation of family history in the EHR, there was a correlation between provider awareness of updated

Table 2. Patient Demographics and Clinical Characteristics by Phase

Phase	I	II
All	415	219
Gender		
Male	156 (37.6%)	69 (31.5%)
Female	259 (62.4%)	150 (68.5%)
Age		
Mean	72.1	70
Median	73	70
Range	47-83	38-90
Race		
White	382 (92.0%)	203 (92.7%)
Black or African American	0	NR*
Asian	7 (0.02%)	NR
American Indian/Alaska Native	5 (0.01%)	NR
Other	9 (2.2%)	NR
Unknown/ Declined to answer	12 (2.9%)	5 (2.3%)
Cancer diagnosis		
Breast	213 (51.3%)	140 (63.9%)
Prostate	138 (33.3%)	46 (21.0%)
Colon	23 (5.5%)	20 (9.1%)
Ovarian	29 (7.0%)	6 (2.7%)
Pancreatic	12 (2.9%)	7 (3.2%)
Cancer stage		
0/1	44 (10.6%)	23 (10.5%)
2	33 (8.0%)	14 (6.4%)
3	27 (6.5%)	10 (4.6%)
4	21 (5.1%)	NR
Unknown	290 (70.0%)	168 (76.7%)
Genetic test results		
Received Testing	*29 (7.0%)*	*25 (11.4%)*
Pathogenic and Likely Pathogenic	7 (24.1%)	2 (8.0%)
Negative	13 (44.8%)	14 (56.0%)
VUS/Inconclusive	9 (31.0%)	9 (36.0 %)
Did not receive testing	*386 (93.0%)*	*194 (88.6%)*
Family history of cancer		
Yes	142 (34.2%)	76 (34.7%)
No	34(8.2%)	18 (8.2%)
Pedigree unavailable	239 (57.6%)	125 (57.1%)
NCCN criteria		
Met	100 (24.1%)	48 (21.9%)
Not Met/Unsure	315 (75.9%)	171 (78.1%)

**NR = Not Reported*

testing guidelines and utilization of germline testing for patients diagnosed with cancer prior to the 8/1/2020 start date of this study. There was no significant difference in the distribution of cancer types between phases. We were not able to draw meaningful differences in uptake of genetic testing between ancestries or by cancer stage because of small numbers or missing data. Uptake of germline genetic testing was highest among patients with pancreatic cancer and ovarian cancer. 4 out of 19 (21.1%) patients with pancreatic cancer and 6 out of 35 (17.1%) patients with ovarian cancer receiving testing. This may be due to updated NCCN guidelines starting 1/1/20 recommending all patients with pancreatic cancer and ovarian cancer are offered genetic testing.[15] Additionally, based on the 2020 Commission on Cancer (CoC) standard 4.4,[16] all CoC-accredited cancer centers in the United States are required to track and report the number of genetic counseling referrals for all patients of a specific cancer group; OMCC elected to focus on pancreatic cancer.

Table 3. Documentation of Family History and Uptake of Germline and Somatic Testing by Phase

	Y	N
Phase I (8/1/20-11/1/2020)		
Family history	142 (34.2%)	273
No family history	34 (8.2%)	381
No information	239 (57.6%)	176
Germline testing	20 (4.8%)	395
Somatic testing	9 (2.2%)	406
Total of all testing	29 (7.0%)	386
Phase II (12/1/20- 2/1/20)		
Family history	76 (34.7%)	143
No family history	18 (8.2%)	201
No information	125 (57.1%)	94
Germline testing	23 (10.5%)	196
Somatic testing	2 (0.9%)	217
Total of all testing	25 (11.4%)	194

DISCUSSION AND LIMITATIONS

This project was the first partnership effort of its kind between FHCC Ccancer genetics service and one of our community-based cancer center affiliate sites. Peer coaching intervention led to a 22% increase in uptake of germline genetic testing for patients with cancer being treated at OMCC. While not statistically significant, this increase represents a marked improvement in access to genetic testing for patients and their families over a short study period. A key takeaway is that genetic testing was documented for 1 in 5 patients with pancreatic cancer and 1 in 6 patients with ovarian cancer, when NCCN recommends that 100% of these patients be offered genetic testing. This highlights a need for continued coaching and partnership.

We acknowledge that it is possible that testing for certain patients may have occurred with another genetic testing laboratory or before the study start date on 8/1/20. In some cases, copies of genetic reports were unavailable to the study team due to not having access to other lab portals or to the faxed copies of results stored within OMCC's EHR. Uptake of genetic testing was lowest in our study among patients with prostate cancer (6.5%). One explanation may be that this study overlapped with another local study led by Dr. Heather Cheng offering sponsored germline genetic testing to all men in Washington State with metastatic prostate cancer specifically to patients with prostate cancer, called "Genetic Testing for Men with Prostate Cancer" (GENTleMEN study NCT 03503097).[17] Additionally, the complexity of the most recent NCCN guidelines for genetic testing for patients with prostate cancer may have added additional challenges to offering testing for this subset of patients.

Most health insurers require molecular oncology or germline genetic testing be prior-authorized and this work falls onto an already busy clinical staff. Even when insurance approval is obtained in advance, patients with cancer are not guaranteed coverage and they are at risk of being charged large out-of-pocket costs, making them wary to pursue or forego genetic testing altogether. According to the United States Census, the median income for Sequim, Washington in Clallam County between 2016-2020 was $39,509, compared to $97,985 in Seattle, Washington in King County.[18] The lower median income would likely pose additional financial challenge for OMCC patients if genetic testing costs were not covered by insurance and billed directly to them. Hence, availability of no-cost germline genetic testing may have also helped with uptake of genetic testing for patients with cancer at OMCC.

The median age of the OMCC study population was 73 years, whereas the typical age range of patients seen at our main campus is between 60-64 years. As the study progressed, it became clear that even the simplified NCCN guidelines we implemented (Table 3) were not as helpful to identify older patients with a HCS. Older patients most often presented with a common cancer and had limited information about deceased relatives, making it difficult to differentiate them from their peers without a HCS. Over the past decade, cancer genetics researchers have found a higher number of people with cancer carrying a HCS than anticipated. 1 in 8 people at cancer diagnosis agnostic of cancer type have a HCS[19] and 1 in 5 people with 2 or more cancer diagnoses have a HCS.[20] Documentation of a prior history of cancer was sparse as well, making it more likely medical oncologists would miss the opportunity to identify someone who should have been identified to carry a HCS at their first cancer diagnosis.

One limitation the study team faced was the difficulty in gathering a comprehensive family history from OMCC's EHR despite availability of a family history questionnaire or a pedigree tool. Since family history was typically documented at initial consult visits, important details, such as polyp history, type of cancer or age at diagnosis, were not updated in the follow up notes or not added at all. This lack of standardization in documentation of family

history information in the EHR is not unique to OMCC. These findings align with a recent study analyzing location of family history information in the EHR that would guide cancer prevention efforts across the University of Washington Medicine system.[21] Historically, no family members' records were included in patients' charts due to privacy and confidentiality issues, even when clinically relevant for a patient's cancer treatment or documentation of medical necessity. It was not until 2018 that Health Insurance Portability and Accountability Act (HIPAA) standards were updated to allow inclusion of family records in patients' EHR.[22]

OMCC does not have a surgical pathology team onsite, biopsies or surgical specimen are sent to an outside laboratory and pathology reports are scanned into the chart as a PDF document. Information such as Gleason score, MMR protein immunohistochemistry (IHC) stains or pathological TNM stage have to be manually copied into provider notes for this information to carry over. Missing details can delay or even prevent a referral to genetics or genetic test order when a patient has a higher pre-test risk to carry a HCS or when they meet NCCN criteria for genetic testing. Ordering of genetic testing is performed on many different web portals that are not digitally integrated within the EHR. This adds yet another step for clinical staff supporting medical oncologists making it possible that not every single genetic testing report was scanned in or added to the packets that were faxed over for our study team review.

EHR systems were not built to integrate comprehensive family history of cancer, molecular tumor profiling results, and inherited genetics testing. Pedigree tools exist in the EHR but they are not user-friendly and do not automatically populate the information in a visual format that would raise the suspicion of a HCS. Despite periodic upgrades, EHR systems have not yet kept up with supporting medical oncologists who need an increasing amount of sophisticated data for their day-to-day practice of caring for patients with cancer. The challenges we faced during our study highlight the growing need for standardized collection and storage of family history information, tumor profiling data, and inherited genetic results in a single shared location to maximize benefits of the advances made in cancer care regardless of where the patient is cared for. Increasing visibility of patients with cancer who meet NCCN criteria for hereditary testing will also help patients and at-risk family members implement proactive strategies to detect cancer early or prevent it when possible.

Lastly, this study overlapped with the initial major outbreaks of the Sars-CoV-2 pandemic. Our respective medical oncology teams were stretched for time caring for patients with COVID-19 and many steps in our collaboration were delayed. While we were not able to meet with the OMCC medical oncology team in person, we were able to establish recurring virtual meetings throughout the course of this study for regular communication relating to clinic processes and to review patient cases together. We envision remote cancer genetic consults to be added to multidisciplinary tumor boards as a way to deliver genetic services to patients with cancer in rural and underserved areas.

CONCLUSION

In this study, there was an increase in uptake of genetic testing by OMCC medical oncologists for their patients with cancer even if measured difference did not reach statistical significance (p=0.057). Efforts to standardize gathering personal and family history of cancer, review of biomarker data suggestive of a HCS, develop workflows to facilitate ordering tumor profiling and/or germline genetic testing every time NCCN criteria are met, advocacy for universal coverage of genetic testing, and open data-sharing between institutions caring for patients with cancer will help realize the benefits of precision oncology for patients and their families seeking care in rural and underserved areas.

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