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Evaluation of Patient and Provider Satisfaction with a Point of Care Genetic Testing Model for Cancer Patients

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EVALUATION OF PATIENT AND PROVIDER SATISFACTION WITH A POINT OF CARE GENETIC TESTING MODEL FOR CANCER PATIENTS

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ABSTRACT

The ever-increasing demand for cancer genetics services is driven by expanded patient eligibility criteria and the utility of hereditary cancer genetic testing (HCGT) in informing treatment plans and long-term risk management. This demand is currently unmet due to the limited supply of genetic counselors; therefore, alternative service delivery models are being explored to improve access to HCGT. This study used a mixed-methods approach to concurrently evaluate patient and provider satisfaction with a point-of care testing (POCT) model at NYU Langone Health. In this POCT model, cancer patients who were eligible for HCGT received pretest education from an educational video and handout before discussing and consenting to HCGT with their oncology provider. Genetic counselors provided post-test genetic counseling and risk assessment. Patient satisfaction was evaluated via post-test surveys for two study arms, POCT and Non-POCT. Chi-square analysis was used to evaluate differences in satisfaction survey responses between arms. Provider satisfaction was evaluated via a survey using a mixed-methods approach involving descriptive statistics and reflexive thematic analysis of free-text responses. In total, 116 patients (Non-POCT=63 and POCT=53) and 25 providers completed their respective satisfaction surveys between August 2023 and January 2024. There were no significant differences in patient satisfaction between POCT and Non-POCT arms in all survey categories. Similarly, there were no significant differences when comparing patient satisfaction between breast and non-breast cancer patients within the POCT arm. Providers reported high satisfaction and competency with the POCT model. Overall, 57% percent of providers found it easy to use, 71% felt comfortable identifying eligible patients, and 60% felt comfortable obtaining informed consent. Providers also perceived high patient satisfaction as 85% reported that patient satisfaction was either unchanged or significantly increased. Providers'

perceived benefits of POCT included expedited HCGT results while barriers included time and/or space constraints. Overall, the patient and provider responses observed in this study provide evidence for the successful implementation of a POCT model for cancer patients pursuing HCGT.

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INTRODUCTION

Given the utility of hereditary cancer genetic testing (HCGT), there is an ever-increasing demand for cancer genetics services. HCGT can inform time-sensitive treatment plans for patients with new cancer diagnoses in addition to giving insight into a patient's risk and their relatives' risk to develop other associated cancers. For example, HCGT can impact treatment plans for breast cancer patients who are found to carry a *BRCA1/2* pathogenic variant by altering their surgical management (breast-conserving surgery vs. bilateral mastectomy) and/or introducing systemic therapy via poly ADP-ribose polymerase (PARP) inhibitors (National Comprehensive Cancer Network (NCCN)® 2024; Tutt et al. 2021). NCCN has established evidence-based guidelines to determine eligibility for genetic testing for hereditary cancer syndromes (NCCN® 2024). The American Society of Clinical Oncology (ASCO) recently released updated guidelines stating that all newly diagnosed breast cancer patients ≤65 years of age, and select patients >65, should be offered HCGT for *BRCA1/2* (Bedrosian et al. 2024). Despite expanded eligibility criteria, only 50% of breast cancer patients that meet eligibility criteria receive HCGT (Ropka et al. 2006). Similarly, a recent systematic review and meta-analysis of 35 studies reported that only 39% of eligible ovarian cancer patients were referred for genetic counseling and only 30% completed HCGT (Lin et al. 2021). This data emphasizes the importance of increasing access to HCGT.

This demand for cancer genetics services is juxtaposed against the currently limited supply of genetic counselors that are available to provide these services (Hoskovec et al. 2018). Efforts have been made to try to meet this demand and increase access to HCGT for all eligible patients via the integration of alternate service delivery models (SDMs) (McCuaig et al. 2018). The goal of these models is to provide a streamlined, cost-effective, and timely method for

obtaining informed consent from cancer patients for HCGT. Therefore, these models differ from the traditional genetic counseling workflow involving pre- and post-test counseling appointments facilitated by genetic counselors. SDMs can range from the use of telegenetics appointments to the integration of other healthcare providers in the informed consent process for HCGT (McCuaig et al. 2018). Several randomized noninferiority trials have demonstrated that telegenetic/telephone genetic counseling appointments are non-inferior to in-person consults (Buchanan et al. 2015; Kinney et al. 2016; Schwartz et al. 2014). This initial exploration into the utility of SDMs highlighted their potential to deliver the same patient satisfaction and education as measured via the Genetic Counseling Satisfaction Scale and knowledge-based questions, respectively (Buchanan et al. 2015; Kinney et al. 2016; Schwartz et al. 2014). Psychosocial outcomes such as anxiety, decisional conflict, and cancer-specific distress were non-inferior between telegenetic service delivery and in-person appointments (Kinney et al. 2016; Schwartz et al. 2014). Another example of SDMs is the utilization of pre-test group genetic counseling sessions with shortened private post-test sessions. Hynes et al. (2020) evaluated a group-based SDM and found that patients were comfortable with this workflow and felt like they understood their risks prior to receiving HCGT.

Recent research has shifted to evaluating genetic testing-based SDMs which omit genetic counselor involvement in the pretest appointment and directly integrate other healthcare providers in the informed consent and testing process. In a study evaluating an alternative SDM for patients with new ovarian cancer diagnoses, Gleeson et al. (2013) found that patients preferred receiving pretest information directly from their medical oncologist with a focus on how HCGT could affect their treatment. Ultimately, the purpose of education via this model is not to mirror a traditional genetic counseling session; rather, it is to provide enough information

to obtain informed consent for HCGT (Gleeson et al. 2013). This highlights that the specific information needs of patients who have been recently diagnosed with cancer differ from those who are unaffected.

Many studies have demonstrated high patient and provider satisfaction with these alternative SDMs. George et al. (2016) piloted one of the first SDMs in which non-genetics providers facilitated the HCGT informed consent process for ovarian cancer patients in the UK via a model that they termed "mainstreaming". The majority of participants were satisfied with their decision to pursue HCGT via mainstreaming and reported that they were happy to have had fewer appointments overall (George et al. 2016). Since then, other studies reviewing the implementation of mainstreaming models have reported reduced turnaround times for genetic testing results as well as increased patient knowledge and satisfaction (Hamilton et al. 2021; McCuaig et al. 2021; Russo et al. 2021; Scheinberg et al. 2021). Some studies have also investigated the provider experience with alternative SDMs for genetic counseling. They report that most providers felt comfortable consenting patients for HCGT and reported high self-efficacy in regard to ordering HCGT within these models (Bokkers et al. 2022; Scheinberg et al. 2021).

Although there is evidence for the many benefits of genetic testing-based SDMs, there is a lack of consistency in the literature regarding the extent of non-genetic healthcare provider involvement in the informed consent and testing process. In some SDMs, providers directly deliver pretest education. In others, educational materials (e.g., videos, brochures) are given to patients and the role of the providers is to obtain informed consent and answer outstanding questions (Espinoza Moya et al. 2022). These inconsistencies make it difficult to synthesize findings and make definitive conclusions about the patient and/or provider experience with these

genetic testing-based SDMs. There are limitations in the current body of literature on SDMs, including small sample sizes and homogeneous populations as well as limited cancer types being eligible for the SDM workflow (usually breast, ovarian, and prostate). All of the above limit the generalizability of the available data. Additionally, to our knowledge there are few studies that have simultaneously evaluated both the patient and provider experience with a given SDM (Scheinberg et al., 2021). More research is needed involving larger sample sizes of diverse patient populations, both in terms of ethnicities and cancer diagnoses. It is also important to evaluate both the patient and provider experience with the same model since all participants must be engaged to promote effective adoption and sustainment of the model.

The High-Risk Cancer Genetics Program (HRCGP) at NYU Langone Health (NYULH), a National Cancer Institute-designated comprehensive cancer center, has implemented a Point of Care Testing (POCT) model to streamline HCGT for cancer patients. This model was initially piloted with two breast cancer providers in Manhattan (Renkes and Tran, 2022). During this pilot study, turnaround time for HCGT was significantly reduced when comparing between POCT and Non-POCT patients (11.35±3.10 vs. 15.15±5.87 days, respectively, $p<0.0001$) (Gerrard et al. 2023). The POCT model has since expanded to additional disease management groups (DMGs) including prostate, genitourinary, ovarian, gastrointestinal, and gynecological. In this alternative SDM, patients obtain pretest education for HCGT via a video and a handout during their oncology appointment. Patients provide informed consent and then have their blood drawn for genetic testing at their healthcare provider's office. Post-test genetic counseling consists of results disclosure and comprehensive risk assessment facilitated by a genetic counselor. The aims of this study were to 1) evaluate patient satisfaction and acceptability of POCT and 2) assess provider satisfaction, utilization, and implementation of POCT within the NYULH system.

METHODS

Study Design

This study evaluated patient satisfaction and acceptability of HCGT workflows for two study arms using an observational study design and convenience sampling. We compared patients of two service delivery arms: 1) Patients receiving pre-test education and testing information at the time of their medical oncology appointment (Point of Care Testing) and 2) Patients receiving pre-test education and testing in a traditional genetic counseling model (Non-POCT). For provider satisfaction with POCT, we utilized a mixed-methods approach. Approval for this study was obtained by the Sarah Lawrence Institutional Review Board (IORG# 00008153) under protocol number F_2021_6.

Participants

The POCT workflow was piloted in April 2022, and was available for all breast cancer patients in early 2023. It expanded to all DMGs by August 2023. Patient data collected for this study occurred between August 2023 and January 2024. Patients were identified as eligible for POCT by their healthcare provider at their oncology appointment. Eligibility criteria for POCT included age 18 years or older; English- or Spanish-speaking; personal history of cancer (breast, genitourinary, ovarian, gastrointestinal, gynecological, head and neck, melanoma, neuro-oncology, and thoracic cancer) as well as meet NCCN or other established guidelines for HCGT. Providers determined if patients were eligible, then offered them the option to undergo HCGT via POCT. Of all the patients that completed follow-up surveys between August 2023 and January 2024, 53 were POCT and 63 were Non-POCT. Non-POCT patients included those who had a language preference other than English or Spanish, who preferred pre-test genetic

counseling, and/or whose provider felt they would be better suited for the traditional genetic counseling model.

71 providers within the NYULH system were invited to share their feedback on the POCT model. Survey responses were collected from February to March 2024. Eligible providers included physicians, nurses, nurse practitioners, practice managers, etc. who have a direct role in the implementation of the POCT model. Of the 71 providers that received the survey by email, 25 providers responded.

Procedures

During their oncology appointments, patients that were eligible for the POCT arm were offered pretest education for HCGT through curated educational materials. These included a 2-page handout created by the HRCGP (Appendix 2.1) and a 5-minute video created by Ambry Genetics (Appendix 2.2). The handouts were deemed to be approximately eighth-grade reading level as per the NYULH Health Literacy team. Patients watched the video on their smartphone or on iPads provided by the HRCGP. The education materials provided an overview of hereditary cancer, benefits and limitations of HCGT, insurance coverage, GINA, and possible results from testing. Patients then consented to HCGT and provided a blood sample for testing. Providers placed same-day referrals to the HRCGP and genetic testing was ordered by the HRCGP. Patients were contacted within 1-2 days, by a member of the HRCGP, to review their medical and family history. At that time, they scheduled a post-test genetic counseling appointment for results disclosure and risk assessment. Following results disclosure, patients were sent a feedback survey to assess their satisfaction with their HCGT experience (Appendix 3.1).

All breast cancer patients in the POCT arm received HCGT via two panels: an expedited 8-gene panel (Ambry BRCAPlus) and a 77-gene panel (Ambry CancerNext-Expanded

+RNAinsight). All non-breast cancer patients in the POCT arm received the 77-gene CancerNext-Expanded +RNAinsight panel only. The BRCAPlus panel consists of 8 genes associated with a high or moderate risk for breast cancer including *BRCA1, BRCA2, ATM, CHEK2, CDH1, PALB2, PTEN,* and *TP53*. The CancerNext-Expanded +RNAinsight panel was performed for all cancer patients in the POCT arm and included the following genes: *AIP, ALK, APC, ATM, AXIN2, BAP1, BARD1, BLM, BMPR1A, BRCA1, BRCA2, BRIP1, CDC73, CDH1, CDK4, CDKN1B, CDKN2A, CHEK2, CTNNA1, DICER1, EGFR, EGLN1, EPCAM, FANCC, FH, FLCN, GALNT12, GREM1, HOXB13, KIF1B, KIT, LZTR1, MAX, MEN1, MET, MITF, MLH1, MSH2, MSH3, MSH6, MUTYH, NBN, NF1, NF2, NTHL1, PALB2, PDGFRA, PHOX2B, PMS2, POLD1, POLE, POT1, PRKAR1A, PTCH1, PTEN, RAD51C, RAD51D, RB1, RECQL, RET, SDHA, SDHAF2, SDHB, SDHC, SDHD, SMAD4, SMARCA4, SMARCB1, SMARCE1, STK11, SUFU, TMEM127, TP53, TSC1, TSC2, VHL,* and *XRCC2*.

Non-POCT patients were referred by their oncology provider to the HRCGP for a traditional pre-test appointment facilitated by a genetic counselor during which genetic testing was discussed and ordered by the HRCGP. Non-POCT breast cancer patients also received two panels; an expedited 8-gene panel and typically an additional expanded panel. All other cancer patients in the Non-POCT arm received one hereditary cancer gene panel only. In most cases, the panels ordered for the Non-POCT arm matched those ordered in the POCT arm. Occasionally, the genetic counselors facilitating the Non-POCT workflow ordered a different panel based on their risk assessment for the patient. As in the POCT arm, Non-POCT patients were sent a feedback survey following results disclosure to assess their satisfaction with their HCGT experience (Appendix 3.1).

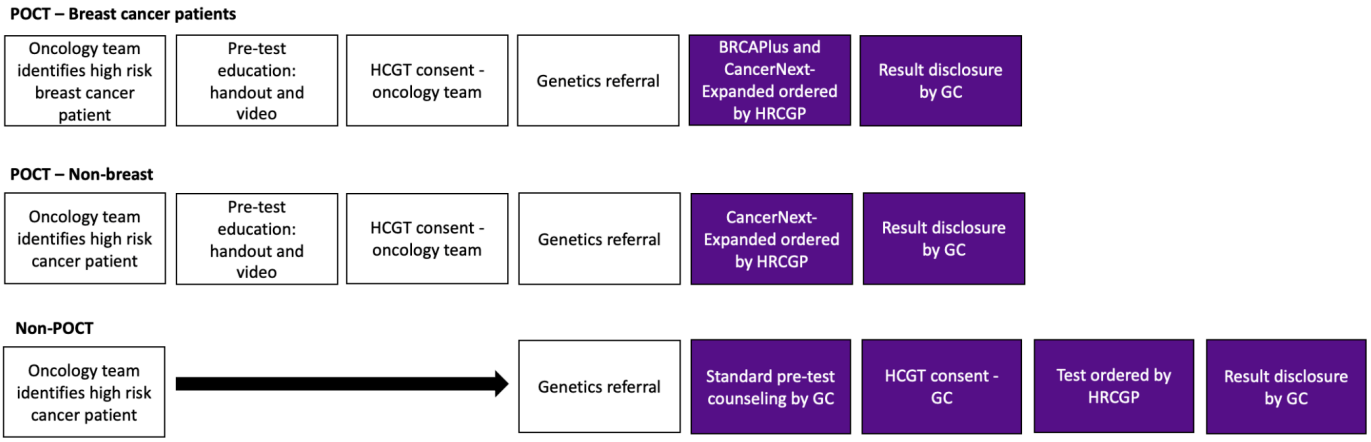

Figure 1 Schematic of study design.
GC: Genetic Counselor, purple indicates patient exposure to Genetic Counselor

Instrumentation

Patients were sent an 11-item survey (Appendix 3.1) to gather their feedback on the process of undergoing HCGT. Patients were asked to rate their agreement with statements about their experiences with HCGT via the POCT or Non-POCT pathways using a 5-point Likert scale (1 being "Strongly disagree" and 5 being "Strongly agree"). Patients were asked about the convenience and timeliness of HCGT, understanding of the information provided, inclination to recommend this process to family members, and lastly, satisfaction with various aspects of the workflow (amount of information, resources, value of the session, etc.).

Providers were sent a 39-item survey (Appendix 3.2) to gather their feedback on POCT. Providers were asked about the implementation of POCT; their perceptions about the usability and sustainability of the model; the extent of support from the HRCGP, as well as comparing POCT to other workflows (e.g., routine genetics referrals). Providers were also invited to answer open-ended questions to share their feedback about the benefits of the model, barriers for implementation in their clinic, and their recommendations for improvements to the model in addition to general feedback/comments.

Data Analysis

Pearson′s Chi-squared test for categorical variables and Mann-Whitney U tests for categorical variables were used to compare responses between study arms for the patient satisfaction survey. Analyses were completed via STATA/SE 18.0 software (StataCorp LLC, College Station, TX) with a 2-sided significance level of $p < 0.05$. Descriptive statistics were used to detail the demographics of the patients and providers, to highlight the types of genetic testing results, and to describe the provider survey responses. Providers' free-text responses were analyzed using reflexive thematic analysis while understanding the limitations of our biases and perspectives in interpreting the data. Each free-text response was coded by assigning labels to providers' free-text responses (or sections of responses). Providers were directly asked to share their opinion about the benefits, barriers, potential improvements, and patient feedback, therefore, each response was analyzed and coded within the framework of these themes.

RESULTS

Patient Demographics

A total of 116 patients in both study arms (POCT and Non-POCT) completed the follow-up satisfaction surveys. The Non-POCT arm consisted of 63 cancer patients who received HCGT via the traditional genetic counseling workflow. 53 patients completed the POCT model including 15 breast cancer patients (Breast POCT) and 38 other cancer patients (Non-Breast POCT). Of the patients whose race and ethnicity information were known, the majority identified as Non-Hispanic/Latino White (Appendix 4.1). The primary language spoken by most patients was English; however, 10% of patients in the Non-POCT arm reported speaking other languages (Appendix 4.1). The average (±SD) age of patients in the POCT arm was 68.7±12.7 and 62.7±10.3 in the Non-POCT arm (Appendix 4.1).

Patient Satisfaction Follow-up Survey

Patient satisfaction survey results comparing the POCT vs. Non-POCT arms are presented in Appendix 5.1. Between August 2023 and January 2024, a total of 254 patients completed the POCT workflow and of them, 53 (22%) patients responded to the satisfaction survey. During that period, 63 patients in the Non-POCT arm responded to the satisfaction survey. There were no significant differences in patient satisfaction in all categories when comparing the POCT and Non-POCT arms (Appendix 5.1).

We also compared survey responses between breast and non-breast cancer patients within the POCT arm (Appendix 5.2). In the POCT model, breast cancer patients have more encounters with their genetic counselor compared to other cancer patients (two results disclosure appointments corresponding to results from the expedited and expanded panels). It was important to investigate if having fewer points of contact (i.e., the non-breast cancer patients

within the POCT arm) impacted patient satisfaction. Overall, there were no significant differences in all categories between the breast and non-breast cancer patients within the POCT arm.

HCGT Results

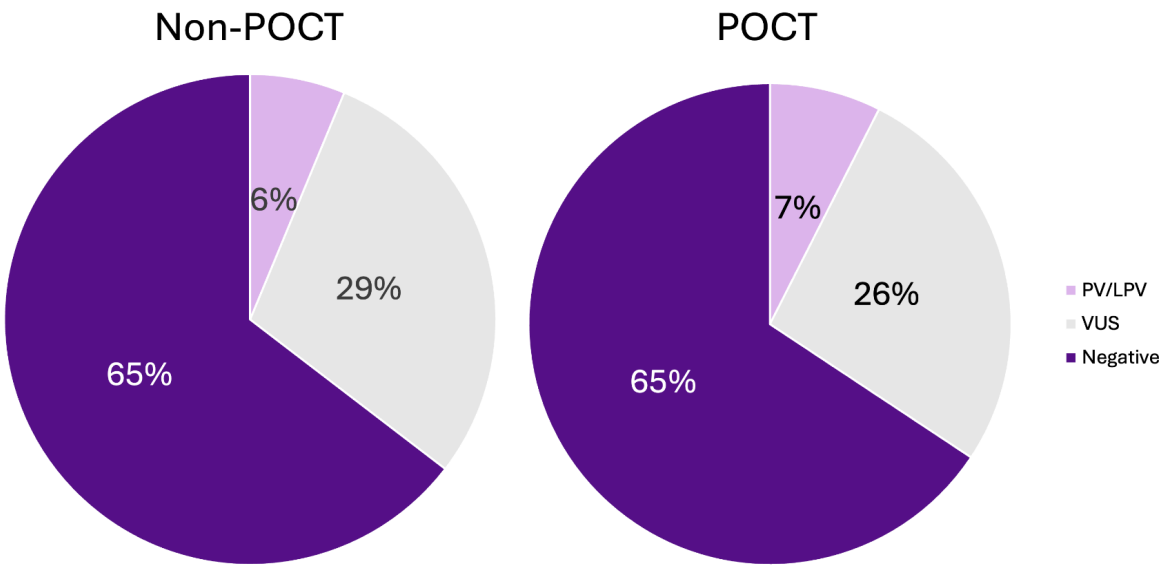

Figure 2 HCGT results for Non-POCT and POCT.
PV/LPV: Pathogenic/Likely Pathogenic Variant, VUS: Variant of Uncertain Significance.

We analyzed the HCGT results for 116 patients that submitted satisfaction surveys. Breast cancer patients in both the POCT or Non-POCT arms were tested via two HCGT panels (an expedited breast cancer–related panel and an expanded panel); therefore, if they received both panels, duplicate results between tests were only counted once. Of the Non-POCT patients, 3 patients (6%) tested positive for a pathogenic/likely pathogenic variant (PV/LPV) in the *MUTYH*, *MSH3*, and *CHEK2* genes, 14 (29%) had at least one variant of uncertain significance (VUS), and 31 (65%) tested negative (Figure 2). In the POCT arm, 5 (7%) patients tested positive for a PV/LPV in *ATM*, *BLM, LZTR1, MSH3*, and *MUTYH*, 18 (26%) had at least one VUS, and 44 (65%) tested negative (Figure 2).

Provider Demographics

In total, 25 providers participated in the study (Appendix 4.2). The majority were nurse practitioners (56%) or physicians (28%) who practiced in Manhattan (80%). Most providers practiced in the breast disease management group (DMG) (76%), followed by gastrointestinal (12%), gynecological (8%), and genitourinary (4%).

Provider Satisfaction Survey

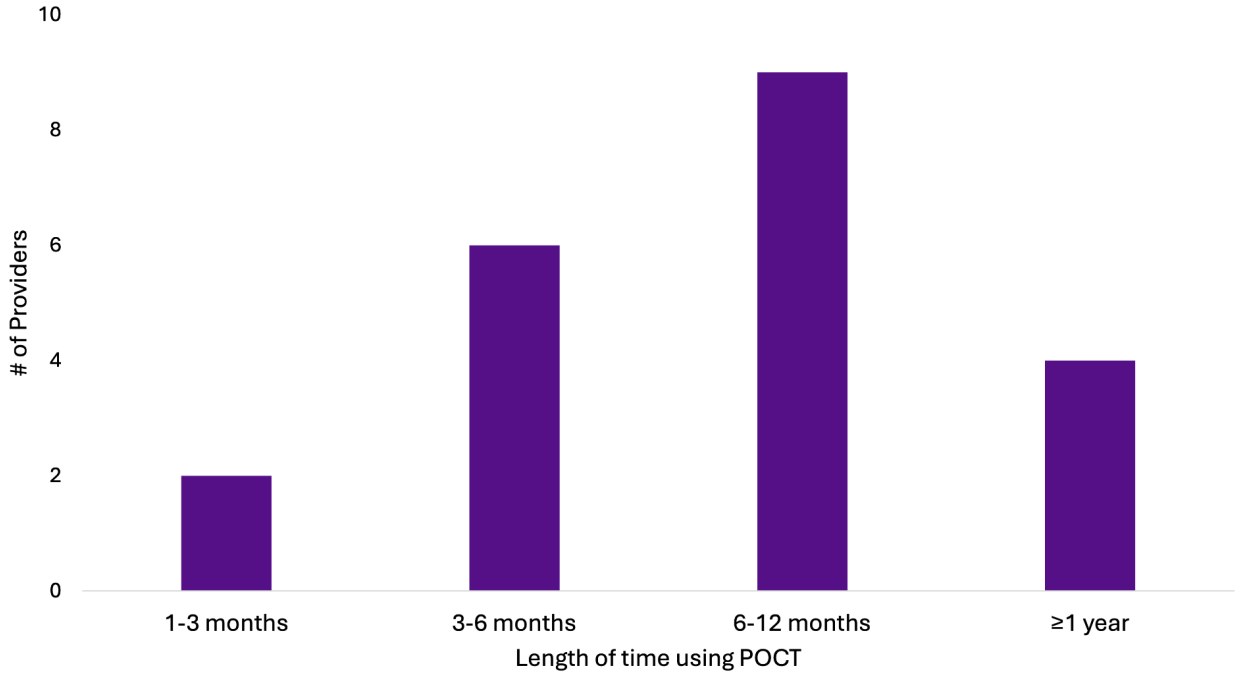

Figure 3 Length of time using the POCT model as reported by providers

Implementation of POCT

The provider satisfaction survey responses are listed in Appendix 3.2. Providers were asked to share their feedback about the implementation, sustainment, and overall experience of the POCT model in addition to comparing this model to the workflow for routine genetics referrals. A total of 71 providers were invited to share their feedback regarding the POCT model, of whom 25 participated (35% response rate). First, providers were asked whether they had referred patients via POCT and if not, to provide reasons for opting not to use the model. The

majority of the providers (21/25, 84%) had referred patients via POCT. For those who had not used the model, 2/4 (50%) stated that a lack of time was a primary barrier against implementation of POCT. Other reasons included a lack of resources (i.e., office space, tablets to view the video), and language barriers for the educational materials. The length of time using the workflow varied among providers (Figure 3). Out of the 21 providers using POCT, all had been using the model for over a month with the majority having used it for 6-12 months (9/21, 43%). The majority of participants (12/21, 57%) selected that it was "Somewhat easy" or "Very easy" to use the workflow. In contrast, 7/21 (33%) reported that it was "Very difficult" or "Somewhat difficult" to utilize. Providers cited that the difficulties with utilizing the workflow were due to lack of time or space within their clinics and the additional workload for them. One provider stated, "Time is the main issue as we are addressing many other things during [the] oncology visit and do not always have time to properly discuss genetic testing. Language barrier has also been an issue for some patients" (P16, Nurse Practitioner, Gynecology).

Support from HRCGP

During the initial launch of POCT, providers were given resources from the HRCGP and were asked to rate their satisfaction with these resources on a scale from 1 to 5, with 1 being "Very unsatisfied" and 5 being "Very satisfied". The average satisfaction level was 3.3 ± 1.5. The HRCGP was also available for providers to ask questions. Out of 21 providers, 15 (71%) did not have any questions for the team. Regarding the responsiveness of the HRCGP, 5/11 (46%) of providers reported that it was "Very easy" to receive help with their questions. That said, 4/11 (36%) were uncertain about how easy/difficult it was to get answers from the HRCGP about their questions. Of the providers who had questions for Genetics, 8/10 (80%) had more than one question. Most questions were regarding the workflow in general (9/10, 90%), followed by the

logistics of the blood draws (5/10, 50%) and patient eligibility (4/10, 40%). Most providers agreed that the current level of support from Genetics was sufficient overall (13/20, 65%). Their top issues that required additional support included "Workflow questions" (6/20, 30%) and "Test ordering" (5/20, 25%).

Provider Competency with POCT

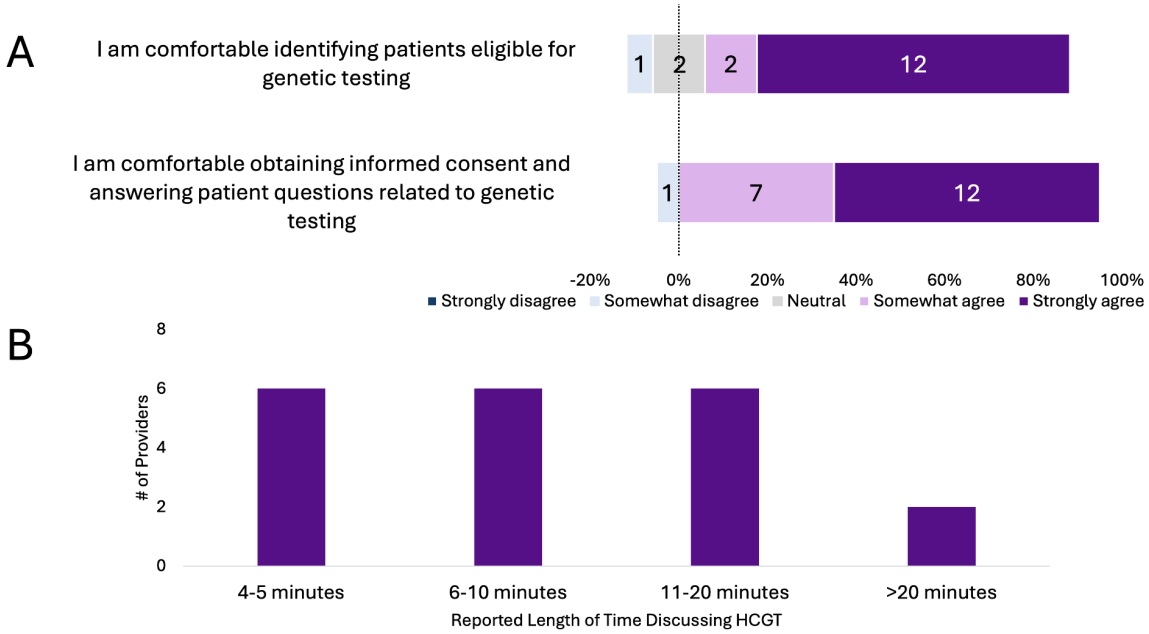

Figure 4 Provider perception of competency (A) and reported length of time spent discussing HCGT (B) within the POCT model

As demonstrated in Figure 4A, the majority of providers "strongly agree[d]" that they felt comfortable identifying eligible patients (12/17, 71%) and obtaining informed consent (12/20, 60%). Six of 20 (30%) providers spent 4-5 mins, 6-10 mins, and 11-20 mins each discussing HCGT on average with patients, while 2/20 (10%) spent over 20 mins on average (Figure 4B). Of the 12 providers who spent ≤10 mins discussing with patients, 9 (75%) were from the Breast DMG. Most providers (17/20, 85%) reported that POCT takes more time to complete compared to routine genetics referrals and 3/20 (15%) reported that it was about the same amount of time as routine genetics referrals.

Provider Perception of Patient Satisfaction and Comfortability with HCGT

Next, we asked providers to reflect on patient satisfaction in the POCT model compared to routine genetics referrals. The majority of providers reported "No change" (12/20, 60%), followed by "Significantly increased" (5/20, 25%). Of note, 1 provider reported that patient satisfaction was "Somewhat decreased". Most providers agreed that their patients were either "Somewhat comfortable" or "Very comfortable" with HCGT after watching the video (15/20, 75%). Of note, 2 (10%) providers reported that some of their patients were "Somewhat uncomfortable" or "Very uncomfortable" proceeding with HCGT after watching the video. On average, providers estimated that around 52% ± 41% of patients had questions before consenting for HCGT.

Benefits, Barriers, Improvements, and General Feedback

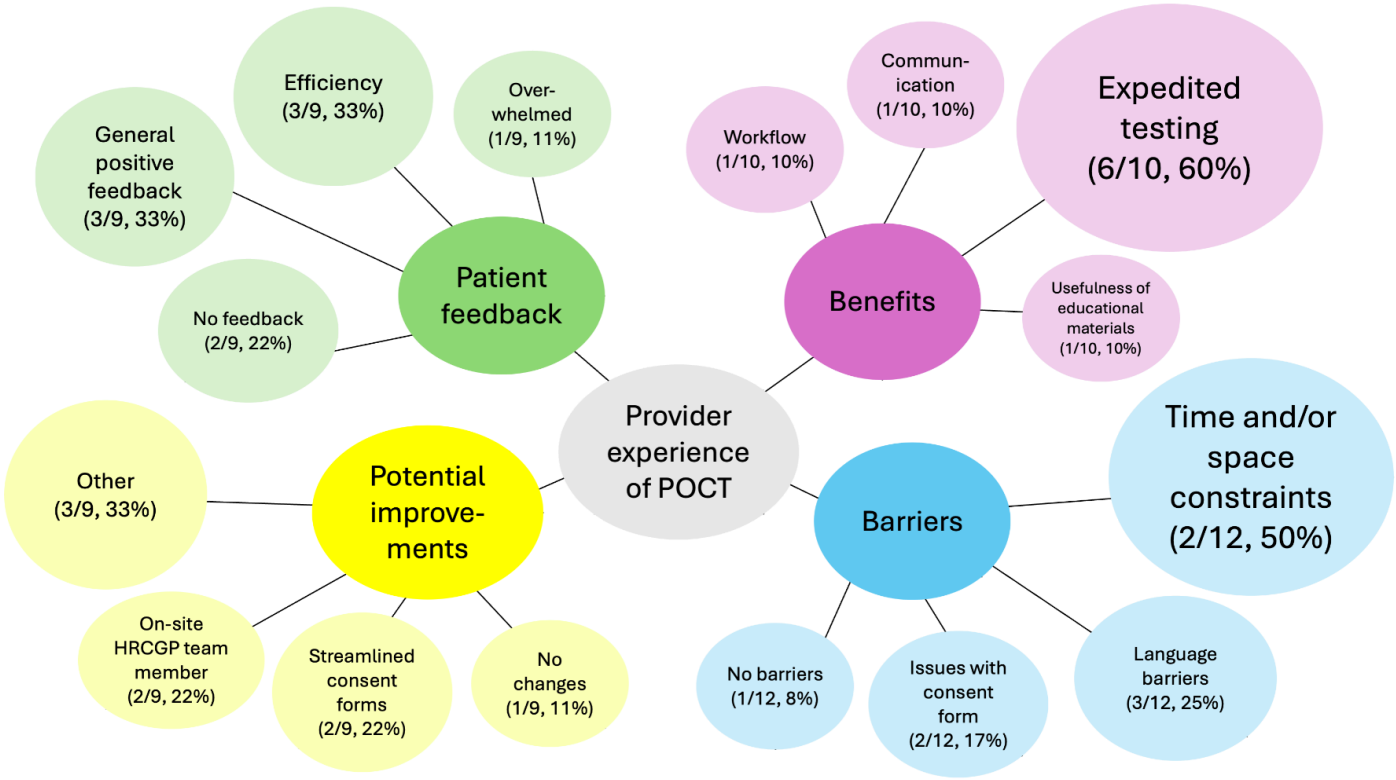

Figure 5 Thematic map from reflexive thematic analysis of provider free-text responses. The specific aim is shown at the center, with outward branching themes and codes from qualitative analysis, represented in different colors (Pink: perceived benefits of POCT; Blue: perceived barriers; Yellow: potential improvements; Green: patient feedback).

Providers were also provided with free-text questions to share their perceived benefits of POCT, barriers to implementation, potential improvements to the model as well as patient feedback and general feedback about the model (Figure 5, Appendix 5.4). The most common benefit of POCT was the expedited impact on testing/results disclosure as commented by 6/10 (60%) of providers. One provider wrote, "It expedites testing which is always a good thing" (Participant 10, Nurse Practitioner, Breast), and another provider similarly stated "Expedited results for surgical planning" (P21, Nurse, Breast). In terms of barriers, providers reported that a lack of time and/or space (6/12, 50%) was the most common barrier with POCT as highlighted by one provider who stated, "Patient volume/limited number of exam rooms to allow for extra to

watch the videos/etc." (P21, Nurse, Breast). Three of 12 (25%) providers also wrote that the educational materials are "not available for other languages" (P15, Physician, Breast), highlighting language barriers with the model. Of note, one provider (1/12, 8%) stated that there were no barriers to POCT (P6, Nurse Practitioner, Breast).

Providers were also given the opportunity to suggest changes to the current workflow including changes to the HCGT consent forms (2/9, 22%), having an on-site HRCGP member (2/9, 22%). Two providers (2/9, 22%) stated that there were no changes needed to the current workflow but one added that there were "clinic workflow issues" (P21, Nurse, Breast). Some providers also shared feedback about POCT that they received from their patients, most of which was positive overall (3/9, 33%), especially regarding improved efficiency (3/9, 33%). One provider wrote, "[Patients] like that they don't need to come in for an extra visit" (P21, Nurse, Breast). Another stated, "All patient[s] like the video and they like the efficiency of how and when they are reached out to by genetics staff" (P3, Medical Assistant, Breast). In contrast, one provider stated, "Patient is overwhelmed with too many visits" (P22, Nurse Practitioner, Breast).

DISCUSSION

Patient Satisfaction with POCT

When comparing survey responses for POCT and Non-POCT patients, no significant differences were noted in patient-reported outcomes between arms. Importantly, this demonstrates that the POCT model is comparable to the traditional genetic counseling workflow. Prior to the initiation of POCT, it was proposed that higher levels of patient satisfaction may be seen due to the expedited return of results and increased efficiency of pretest education. Given that POCT patients did not report higher levels of satisfaction, it is possible that patients felt the benefits of POCT were offset by a lack of time to discuss HCGT with their providers and may be less informed. This should be investigated with a larger sample size. Also, 6 individuals in the Non-POCT category were non-English speaking patients compared to all English speaking patients in the POCT category (Appendix 4.1) which could have impacted satisfaction due to a language barrier.

Breast cancer patients who completed POCT were also compared to other cancer patients because breast cancer patients had more time with a genetic counselor (spoke with a genetic counselor at two time points given the two panels that were ordered) and the workflow had been implemented for a longer duration, both of which could impact patient satisfaction. When the responses for each question were compared, the POCT breast cancer patients demonstrated slightly higher satisfaction in some categories, but this was not statistically significant. The overall sample size for POCT was smaller in comparison to the Non-POCT which may explain the lack of statistical significance.

When looking at similar research, one study showed that there were no differences in patient satisfaction and no differences regarding the decision to proceed with HCGT. Russo et al.

(2021) investigated a patient-choice SDM comparing video-based education and traditional genetic counseling and found that patient satisfaction was equivalent, which was also reflected in our study. The majority of patients opted for video based education over the traditional pre-test genetic counseling appointment (Russo et al. 2021). Other studies showed high patient satisfaction with a condensed workflow including pre-test education involving a video and brochure, similar to the POCT model, but did not directly compare results to patients who had testing through the traditional model (Hamilton et al. 2021). In both studies, patient satisfaction did not change based on the type of SDM which is consistent with our findings.

Regarding HCGT results, we did not observe differences in satisfaction scores stratified by type of result between the POCT and Non-POCT arms (Figure 2). This trend is reflected in an evaluation of the initial POCT pilot study (Gerrard et al. 2023) and in other studies with a similar SDM design (Hamilton et al. 2021; Russo et al. 2021; Scheinberg et al. 2021). Therefore, HCGT results are unlikely to impact patient-reported satisfaction outcomes between arms.

Provider Satisfaction with POCT

The providers surveyed for this study reported high satisfaction with the POCT model. This is reflected in their free-text responses which highlighted the benefits of POCT including expedited testing, usefulness of the educational materials, ease of using the workflow, and streamlined communication. Most providers demonstrated high perceived competency in identifying eligible patients (14/17, 82% responded with "(strongly) agree") and obtaining informed consent (19/20, 95%) (Figure 4A). This is similar to previous literature that reported 88% of providers surveyed about a POCT-like model for men with prostate cancer felt confident consenting patients (Scheinberg et al. 2021). Similarly, Bokkers et al. (2022) showed that providers had high positive attitudes, self-efficacy, and perceived knowledge with using their

version of a POCT model for ovarian cancer patients. That said, some providers in our study reported that they were either uncertain or not comfortable identifying patients meeting eligibility criteria. This highlights the importance of genetic counselor involvement in the model given their specific expertise identifying patients eligible for HCGT.

When asked about the time spent discussing HCGT with patients, providers' responses varied. The majority of providers in our study (60%) reported spending ≤10 minutes discussing HCGT (Figure 3). The majority of these providers, 75% (9/12) were from Breast practices that have offered POCT to their patients for the longest duration of time. It is expected that they are more likely to be efficient in obtaining informed consent. This time frame is similar to other studies as the majority of providers spent between 5-10 minutes to obtain informed consent (Bokkers et al. 2022; Gleeson et al. 2020). In our study, it is unclear if providers included the video duration in their estimation. This may explain why 30% of providers reported that they spent between 11-20 minutes with patients and 10% spent over 20 minutes. The variability in reported time spent should be further investigated to better understand the factors that dictate the time spent discussing with HCGT patients.

Most providers stated that compared to routine genetics referrals, POCT requires more time (85%) which is expected given the additional tasks required by the provider upfront in POCT compared to routine genetics referrals. Approximately 15% of providers stated POCT required the same amount of time. In comparison, Gleeson et al. (2020) reported that 52% of providers perceived that their streamlined SDM increased their workload while 41% perceived that it had no impact on their workload. The SDM described by Gleeson et al. (2020) was designed for *BRCA1/2* testing in patients with high grade, non-mucinous epithelial ovarian cancer. This model was more simplistic given the highly specific eligibility criteria and limited

genetic testing offered. In contrast, providers using the POCT model must be aware of multiple eligibility criteria and be able to discuss more expansive HCGT with patients. This likely contributes to the extra workload for referring providers within the POCT model compared to routine genetics referrals and compared to the SDM outlined by Gleeson et al. (2020). As eligibility criteria and HCGT panels continue to broaden, this study provides a more accurate representation of the provider experience with identifying eligible patients and obtaining informed consent within a POCT model. This also offers a glimpse into the potential impact of population-based testing as this will likely put a strain on resources available for deployment of testing and sustainment to meet clinical care needs of patients. We can see in this controlled setting that resource limitations (e.g., time and clinic space) are major barriers for most providers.

As reflected in the patient satisfaction survey responses, almost all providers felt that patient satisfaction was high (the same or greater than the traditional model/routine genetics referrals). The same was also true for provider perception of patient comfortability with proceeding with HCGT after viewing the education materials. Patient satisfaction and comfortability is also reflected in the positive feedback from patients as noted by 66% of providers in their free-text responses (Figure 5). Overall, this provides evidence that the POCT model can achieve high satisfaction as reflected by both patients and providers. It should be noted that one provider shared that their patients were overwhelmed with the number of oncology visits. This patient experience is well documented in the literature; factors such as patient age and competing healthcare priorities can impact patient informational needs and their ability to shoulder burden (Ankem 2006; Tran et al. 2020). In an SDM for ovarian cancer patients, George et al. (2016) reported that patients preferred fewer overall visits with the

streamlined model, and this sentiment was similarly reflected by another provider in our study. Streamlined SDMs, including POCT, help to reduce the overall number of appointments that oncology patients need to go through which could hypothetically reduce some of their sense of overwhelm and anxiety though future research is needed to provide evidence for this.

Regarding the educational materials, providers reported that an average of 52% ± 41% of patients had questions after watching the pretest video. The high variability in this measure is likely due to the variable range in provider knowledge, comfort discussing HCGT, and experience with using the POCT model. This highlights the importance of patients having access to their providers during the informed consent process to ask questions as needed. Though most providers reported that their patients were comfortable proceeding with HCGT after watching the video, 2 providers noted that some of their patients were "Somewhat uncomfortable" or "very uncomfortable". It is unclear as to the specific reasons why these patients felt uncomfortable with proceeding with HCGT, which should be further investigated. It is possible that these patients had more questions for their provider after viewing the educational materials, but it is unclear if their providers then felt comfortable answering their questions. It should be noted that the education materials (e.g., video and handout) are designed to complement provider discussion about HCGT and to ensure that there is some standardization in those discussions. The most recent guideline released by the American Society of Clinical Oncology (ASCO) states that though alternative SDMs can improve access to HCGT, patients with significant questions should still be referred to genetics services (Bedrosian et al. 2024). Therefore, patients should always have the option to be referred to a genetics professional if they are not comfortable proceeding with POCT.

Of the 57% of providers that said it was easy to utilize the POCT model, the vast majority (11/12) were from the Breast DMG. This POCT model was initially piloted in the Breast DMG in 2022 (Renkes and Tran 2022), and has continued since then. These providers have had more experience with the workflow and with troubleshooting clinic-specific issues. Also, 50% of providers shared that there were some clinic-specific issues with the workflow. The most common issue was time and/or space constraints. These barriers are also reflected in the literature as 78% of providers surveyed about a POCT-like model for men with prostate cancer stated that a lack of time was the most significant barrier to widespread implementation of the model (Scheinberg et al. 2021). Providers also mentioned a lack of resources (i.e., space in their clinics) as another barrier for the model. This was also reported in a systematic review of the barriers and facilitators for SDMs involving non-genetics providers (White et al. 2020). Other barriers from this systematic review that were not reflected amongst our provider cohort included limitations to genetics knowledge and skill, lack of guidelines, and concerns about discrimination and psychological harm (White et al. 2020). We also evaluated providers' suggestions for improvement of the POCT model of which one theme that emerged was "streamlined consent forms" via digital/pre-filled consent forms. It should be noted that New York State Law requires written informed consent for genetic testing (New York State Senate 2014). This highlights barriers to the efficiency of the POCT model that lie beyond the ability of the HRCGP to implement. This law also demonstrates that even within a streamlined approach to HCGT, education and information are mandatory and cannot be omitted in the workflow for the sake of expedited testing. Other systemic barriers to streamlined SDMs have been previously reported, of note, financial constraints or limited resources to support the sustainability of these models were the most prominent (Gleeson et al. 2020). Scheinberg et al. (2021) reported that 88% of

providers in their study suggested improvements such as involving nurses and including written testing packages, both of which are included in the workflow for our study. This highlights the importance of reviewing the literature to identify barriers reported in other settings and addressing them during the implementation of new models.

Study Limitations

Limitations of this study include a small sample size for both the patient and provider survey. The patient population was not diverse, reflected by a majority of patients being non-Hispanic/Latino White individuals. In terms of the provider survey, there is a lack of generalizability as some responses reflected clinic-specific barriers and lack of resources. Another limitation is that the POCT workflow is not currently offered in languages other than English and Spanish which was often described as being a difficulty for workflow utilization. This highlights the importance of further developing the POCT model to ensure that it is accessible and equitable for all patient populations.

Future Directions

For the POCT model, educational materials geared towards other languages aside from English and Spanish are crucial in achieving equitable care for all patients. Lack of diversity was apparent in the patient demographics from the patient satisfaction survey and also noted in provider survey responses in terms of barriers to the POCT model. Many POCT-like models are only being explored in English-speaking patients, therefore, we cannot assume that this model would be acceptable for patients from other backgrounds. More research is needed on the uptake of this SDM by other communities. This, combined with a diverse sample, will help expand the generalizability of this study. Additionally, previous research for SDMs and genetic counseling workflows have analyzed psychological outcomes in relation to HCGT utilization via validated

scales to assess psychological impact, such as the Multidimensional Impact of Cancer Risk Assessment (MICRA) or Hospital Anxiety and Depression Scale (HADS) (Cella et al. 2002; Spinhoven et al. 1997). Future research could investigate the psychological impact of POCT on our patient population to gain a thorough understanding of the patient experience with this model. One of the imminent benefits of the POCT model, as reflected in the provider responses, is expedited turnaround times for HCGT and results disclosure. Although this was not evaluated in this study, an evaluation of the POCT pilot previously demonstrated that the turnaround time for HCGT was significantly reduced for POCT patients compared to Non-POCT patients (Gerrard et al. 2023). This outcome could be further analyzed between the POCT and Non-POCT arms in this study.

It should also be noted that some providers were not comfortable with obtaining informed consent for HCGT for their patients. Further research is needed to understand this lack of comfort with obtaining informed consent. It is critical that providers are knowledgeable and confident in delivering this information while also understanding the potential implications it has for patients.

CONCLUSION

Overall, this study provides insight into the experience of both patients and providers with a point-of-care testing service delivery model at NYULH. Previous studies have demonstrated high satisfaction for either patients or providers with other "POCT-like" models. Few have simultaneously investigated both the patient and provider experience with the same model. In our study, both patients and providers had positive feedback and high satisfaction with the POCT model. Through this concurrent data analysis, we achieved a more thorough understanding of the benefits and barriers of this model and their unique interactions amongst patients and providers. Studying both arms together also underscores the importance of engagement throughout the healthcare continuum between patients, oncology providers, and the cancer genetics team. As such, these models are not simply "one size fits all;" rather, they are contingent on the ability of teams to collaborate and address their unique barriers and limitations to facilitate a streamlined experience for all patients. This study contributes to the existing evidence that point-of-care service delivery models are feasible, and can help bridge gaps left by the shortage of genetic counselors. It is also important to note that genetic counseling support is necessary for the feasibility and sustainment of this model and that similar SDMs can't act as a replacement for genetic professionals. This study demonstrates promising applications of SDM, leveraging the utility of HCGT without negatively impacting the patient and provider experience.

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APPENDICES

Appendix 1: Frequently used acronyms, in alphabetical order

Acronym	Definition
DMG	Disease Management Group
HCGT	Hereditary cancer genetic testing
HRCGP	High-Risk Cancer Genetics Program
NCCN	National Comprehensive Cancer Network
NYULH	NYU Langone Health
POCT	Point-of-Care Testing
SDM	Service delivery model

Appendix 2.1: Pretest informational handout for cancer patients.

Hereditary Cancer and Genetic Testing

Please by scan the QR code below to watch a video about genetic testing. This handout is a summary of the information in the video.

Background

Most cancers happen by chance. Hereditary cancers are caused by changes (also known as *mutations* or *pathogenic variants*) in genes that usually protect us **against** cancer. When there is a mutation in one of these genes, it puts us at a higher risk for developing cancer.

Is Cancer Risk Inherited?

About 1 in 10 patients diagnosed with cancer carry a gene mutation related to cancer risk. These patients may or may not have family history of cancer. People who have a mutation in a gene related to cancer can be at higher risk of developing other cancers.

What Genes are Related to Cancer?

There are several genes that have been associated with hereditary cancer. Many people have heard of the **BRCA1** and **BRCA2** genes. However, there are other genes associated with hereditary cancers, including BRIP1, MLH1, MSH2, MSH6, PMS2, EPCAM, RAD51C, RAD51D, PALB2, DICER1, SMARCA4, STK11, and TP53.

How Can Genetic Testing Help?

There are several reasons why someone may want to know if they have a mutation in a gene associated with cancer:

1. To understand why they developed cancer or may develop another cancer in the future.

2. To help with decisions about their cancer treatment such as targeted therapy or cancer screening (early detection) and prevention.

3. To find out the chance that close relatives may someday develop cancer and their options for screening or prevention.

What are the Concerns about Genetic Testing?

Genetic testing cannot predict when or if cancer will develop. It can only tell if a person has inherited a gene mutation that puts them at a higher risk to develop cancer.

There are state and federal laws that protect against genetic discrimination. The Genetic Information Nondiscrimination Act (GINA) law offers protection against discrimination from individual and group health insurance. It also protects against employment discrimination. GINA does not cover active military insurance and life/disability insurance or other supplemental insurance policies.

The technology for genetic testing has limitations. Due to these limitations, there is a small chance

that a mutation is present in the tested gene but was not found. It is also possible that a mutation in another gene (not yet available for testing) could be present in a family. You can contact your genetic counselor to see if there have been any changes to testing or if new testing is available.

Insurance Coverage

Many insurance plans cover genetic testing and the genetic testing lab we use is in network with most U.S. health plans. Your out-of-pocket cost may vary based on your individual plan. The average cost for testing is less than $100, and most patients pay $0. The lab will contact you if your out-of-pocket cost is over $100.

What Genetic Testing will be Ordered?

The **CancerNext-Expanded** test looks at 77 genes. These genes are associated with many different cancer types. Genes on this test include high-risk, moderate-risk, or low-risk genes. High or moderate-risk genes have recommendations for screening and prevention of cancer. Some of the genes on these panels have less information available. Recommendations for cancer screening or prevention may change over time. **Test results usually come back in 3-4 weeks.***

Genes included: AIP, ALK, APC, ATM, AXIN2, BAP1, BARD1, BLM, BMPR1A, BRCA1, BRCA2, BRIP1, CDC73, CDH1, CDK4, CDKN1B, CDKN2A, CHEK2, CTNNA1, DICER1, EGFR, EGLN1, EPCAM, FANCC, FH, FLCN, GALNT12, GREM1, HOXB13, KIF1B, KIT, LZTR1, MAX, MEN1, MET, MITF, MLH1, MSH2, MSH3, MSH6, MUTYH, NBN, NF1, NF2, NTHL1, PALB2, PDGFRA, PHOX2B, PMS2, POLD1, POLE, POT1, PRKAR1A, PTCH1, PTEN, RAD51C, RAD51D, RB1, RECQL, RET, SDHA, SDHAF2, SDHB, SDHC, SDHD, SMAD4, SMARCA4, SMARCB1, SMARCE1, STK11, SUFU, TMEM127, TP53, TSC1, TSC2, VHL, and XRCC2

Possible Results of Genetic Testing

- **Positive (Pathogenic Variant)**: a mutation in a cancer-predisposing gene was found. Follow-up discussion will include review of cancer risks, ways to reduce risk, and what this means for treatment. Close family members such as parents, siblings and children may be at risk of having this mutation. For these ‘at-risk’ relatives, we would recommend genetic counseling and possible genetic testing.
- **Negative (No pathogenic variant):** no mutation was found.
  There still may be a chance that a mutation is present but was not detected. Mutations in other genes (that research has not identified) are also possible. Interpretation of a negative test result may vary in certain cases. Recommendations for family members depends on the family history of cancer. Testing for other relatives may not be needed unless they have a personal history of cancer.
- **Inconclusive (Variant of uncertain significance, or VUS)**: This result means that there was a change (variant) found in a gene. However, the lab does not have enough information about the variant to know if it is associated with increased cancer risk. We do not recommend using a VUS result to make decisions about medical care.
  *When your results come back, the genetic counselor will give you a tailored risk assessment and recommend ways to manage this risk. Your assessment will be based on genetic test results, personal and family history.

Appendix 2.2: Link to pre-test informational video

For the following DMG Groups: General Link
(Breast, GynOnc, GU, GI, Thoracic, Head/Neck, Neuro, Melanoma/Sarcoma, Hematology, Radiation Oncology)
Video Info:
RedCap Video and Survey: https://redcap.link/genetics.ma
Youtube: https://youtu.be/_8FIFBRo8fI

Appendix 3.1: Patient satisfaction survey

Pre-Test Information for You

Language	◯ English ◯ Español

Dear Patient,
Your doctor has mentioned genetic testing may be suitable for you. Information presented in this video will help you better understand why genetic testing may be suitable for your clinical care.

Please watch this brief video and let your doctor know if you have any questions. For video subtitles, select the "settings" icon located at the bottom of the video, then select "English" to turn on subtitles.

Once you have finished viewing, please tap on the "submit" button at the bottom of the screen. Our care team will contact you for next steps, following your testing.

Thank you!
Perlmutter Cancer Center

Estimado paciente,
Su médico ha mencionado que las pruebas genéticas pueden ser adecuadas para usted. La información presentada en este video lo ayudará a comprender mejor por qué las pruebas genéticas pueden ser adecuadas para su atención clínica.

Mire este breve video e informe a su médico si tiene alguna pregunta. Para subtítulos de video, seleccione el ícono de "configuración" ubicado en la parte inferior del video, luego seleccione "Español" para activar los subtítulos.

Una vez que haya terminado de ver el video, toque el botón "enviar" en la parte inferior de la pantalla. Nuestro equipo de atención se comunicará con usted para conocer los próximos pasos, luego de su prueba.

¡Gracias!
Centro de Cáncer Perlmutter

First Name	_____
Nombre	_____
Last Name	_____
Apellido	_____
Provider Office Location	◯ Brooklyn ◯ Long Island ◯ Manhattan ◯ Queens
Ubicación del consultorio médico	◯ Brooklyn ◯ Long Island ◯ Manhattan ◯ Queens

Please indicate reason for your genetics consultation:	◯ Breast Cancer ◯ Gastrointestinal Cancer (e.g. Colon, Stomach) ◯ Genitourinary Cancer (e.g. Prostate, Kidney) ◯ Gynecological Cancer (e.g. Ovarian, Endometrial) ◯ Head/Neck Cancer ◯ Hematological Cancer (e.g. Blood) ◯ Melanoma/Sarcoma (e.g. Skin, Bone) ◯ Neurological Cancer (e.g. Brain) ◯ Radiology Oncology ◯ Thoracic Cancer (e.g. Lung)
Por favor indique su motivo de consulta genética:	◯ Cáncer de Seno ◯ Cáncer de colorrectal, Cáncer de estómago ◯ Cáncer de próstata, Cáncer de riñón ◯ Cáncer de ovarios, Cáncer de uterino ◯ Cánceres de cabeza y cuello ◯ Cánceres hematológicos (de la sangre) ◯ Cáncer de piel, Cáncer de hueso ◯ Cáncer de cerebal ◯ Oncología Radioterápica ◯ Cáncer de pulmón
Did you watch an educational video prior to receiving genetic testing?	◯ Yes ◯ No
¿Viste el video educativo antes de hacerte la prueba genética?	◯ Sí ◯ No
Did the educational video and handout provide enough information for you to consent to genetic testing in the doctor's office?	◯ Yes ◯ No
¿El video educativo y el folleto brindaron suficiente información para que usted autorice las pruebas genéticas en el consultorio del médico?	◯ Sí ◯ No
I am able to identify the next steps to take in the genetic testing process	◯ Agree ◯ Unsure ◯ Disagree
ISoy capaz de identificar los próximos pasos a seguir en el proceso de pruebas genéticas.	◯ Aceptar ◯ Inseguro ◯ Discrepar
I am able to identify the implications of a positive result	◯ Agree ◯ Unsure ◯ Disagree
Soy capaz de identificar las implicaciones de un resultado positivo	◯ Aceptar ◯ Inseguro ◯ Discrepar

Thank you for watching!

Please let your doctor know if you have any questions regarding the video you have just watched. As part of genetic testing, a certified Genetic Counselor will be available to discuss more details about your test results and what they mean for you.

Sincerely,

Perlmutter Cancer Center

¡Gracias por ver!

Informe a su médico si tiene alguna pregunta sobre el video que acaba de ver. Como parte de las pruebas genéticas, un consejero genético certificado estará disponible para discutir más detalles sobre los resultados de sus pruebas y lo que significan para usted.

Atentamente,

Centro de Cáncer Perlmutter

Appendix 3.2: Provider satisfaction survey

Genetics Point of Care Testing Feedback Survey

Thank you for participating in this survey. Your feedback is very important to us. The purpose of this survey is to evaluate your experience with the Genetics Point of Care Testing (POCT) service delivery model. As a reminder, the patient watches a 5-minute video about hereditary cancer genetic testing and is consented in the doctor's office prior to getting their blood drawn on site with an Ambry Genetics Kit. We ask you to answer all the questions to the best of your ability and knowledge. If you are involved in more than 1 clinic location, please complete one survey for each clinic location.

If you have any questions or concerns, please do not hesitate to reach out.

Thank you for your time.

The NYU High-Risk Cancer Genetics Program

Department information: Please enter your name, position, and your department information.	
Q1a. Name (Optional)	_____
Q1b. Job role of the employee completing this feedback survey	◯ Nurse ◯ Nurse Practitioner ◯ Practice Manager ◯ Physician ◯ Other
Q1c. If other, please enter your position	_____
Q1d. In which borough(s) is your department located?	☐ Manhattan ☐ Brooklyn ☐ Queens ☐ Long Island
Q1e. What is your disease management group (DMG)?	◯ Breast ◯ Gastrointestinal ◯ Genitourinary ◯ Gynecological ◯ Head and Neck ◯ Melanoma ◯ Neurological ◯ Radiology Oncology ◯ Thoracic
Q2. Have you referred any patients through the Genetics Point of Care Testing workflow?	◯ Yes ◯ No
Q2a. If no, please select all reasons for not doing so:	☐ Do not understand the workflow ☐ Issues implementing ☐ No eligible patients ☐ Other
Q2b. What other reasons have prevented you from referring patients through the workflow?	_____
Q2c. Would you like a genetic counselor to reach out to your team for follow-up?	◯ Yes ◯ No

Q2d. If yes, please provide your email: _____

Implementation: For each of the following questions, we would like you to think about your experience with the implementation of Genetics Point of Care Testing, both in terms of the initial launch and continuation of the workflow.

Q3. As a provider, how long have you been using the genetics point of care testing workflow?

- ◯ Less than/equal to 1 month
- ◯ 1-3 months
- ◯ 3-6 months
- ◯ 6-12 months
- ◯ Greater than/equal to 1 year

Q4a. I am satisfied with the resources and support provided by the genetic counseling team for the initial launch of this workflow
(Ex. level of training, iPads)

Strongly disagree — Strongly agree

(Place a mark on the scale above)

Q4b. How easy is it for you/clinical staff to utilize this workflow?
(Ex. You were able to integrate extra time into the clinic and coordinate with other providers)

- ◯ Very difficult
- ◯ Somewhat difficult
- ◯ Uncertain
- ◯ Somewhat easy
- ◯ Very easy

Q4b.i) What was easy? What was difficult? _____

Q4c. Did you have questions for the genetic counseling team related to ongoing support?

- ◯ Yes
- ◯ No

Q4c.i) If yes, how easy or difficult was it to get the answers to these questions?

- ◯ Very difficult
- ◯ Somewhat difficult
- ◯ Uncertain
- ◯ Somewhat easy
- ◯ Very easy

Q4c.ii) If yes, these questions were regarding...
(Check all that apply)

- ☐ Workflow (in general)
- ☐ Patient eligibility
- ☐ Blood draws
- ☐ Technical (iPad troubleshooting)
- ☐ Test consent form
- ☐ Other

Q4c.iii) Please explain what other questions you had for the genetic counseling team _____

Q5a. I am comfortable identifying patients eligible for genetic testing

- ◯ Strongly disagree
- ◯ Somewhat disagree
- ◯ Uncertain
- ◯ Somewhat agree
- ◯ Strongly agree
- ◯ N/A (I don't identify patients for testing)

Q5b. I am comfortable obtaining informed consent and answering patient questions related to genetic testing	◯ Strongly disagree ◯ Somewhat disagree ◯ Uncertain ◯ Somewhat agree ◯ Strongly agree ◯ N/A I don't consent patients for testing
Q6. Since the introduction of this model, how much time, on average, do you spend discussing genetic testing in each patient appointment?	◯ Up to 3 minutes ◯ 4-5 minutes ◯ 6-10 minutes ◯ 11-20 minutes ◯ Over 20 minutes ◯ N/A (I don't discuss testing with patients)

Maintenance and Sustainability: For the next set of questions, we would like you to think about long term continuation and maintenance of the genetics point of care testing workflow.

Q7a. Compared to the current level of support you are receiving from the genetics team; what level of support is needed for you and your clinic to continue this workflow going forward?	◯ Current level of support ◯ More support
Q7a.i) What type of support do you need?	_____

Q7b. For the below categories, please rank the level of support you would like to receive going forward:

	Current Level of Support	More Support
Billing and Insurance (submission and follow-up)	◯	◯
Blood Draw	◯	◯
Patient Eligibility	◯	◯
Test Ordering	◯	◯
Workflow Questions	◯	◯

Comparison: For the next set of questions, we would like to ask you about how the Cancer Genetics Point of Care Testing (POCT) model compares to the previous workflow of routine genetics referrals.

Q8a. Does this workflow require more or less time to complete as compared to other referral workflows?	◯ Requires more time ◯ About the same ◯ Requires less time
Q8b. How does patient satisfaction in this workflow compare to non-point of care genetics referrals? Satisfaction is...	◯ Significantly increased ◯ Somewhat increased ◯ No change ◯ Somewhat decreased ◯ Significantly decreased

Q9. How comfortable are your patients proceeding with genetic testing after watching the pretest education video?	◯ Very uncomfortable ◯ Somewhat uncomfortable ◯ Uncertain ◯ Somewhat comfortable ◯ Very comfortable
Q10. Around what percent of patients have questions before they consent?	_____

Feedback/Improvements: Please share your feedback about the feasibility of the Cancer Genetics Point of Care Testing (POCT) workflow including facilitators, barriers, and possible improvements.

Q11. What aspects of this workflow work well?	_____
Q12. Are there barriers that prevent this workflow from being efficient?	_____
Q13. What changes could be made to improve the efficiency of this workflow?	_____
Q14. What feedback did you receive from patients about this workflow? (Both positive and negative)	_____
Q15. Is there anything else you would like to tell us about your experience with this workflow?	_____

Appendix 4.1: Description of patient demographics between POCT and Non-POCT arms (n=116)

		POCT *n*=53	Non-POCT *n*=63
Sex	Female	21 (40%)	60 (95%)
	Male	32 (60%)	3 (5%)
Race	American Indian or Alaska Native	0	1 (2%)
	Black or African American	0	3 (5%)
	White	18 (34%)	11 (17%)
	Unknown/Missing	35 (66%)	48 (76%)
Ethnicity	Hispanic or Latino	1 (2%)	2 (3%)
	Not Hispanic or Latino	18 (34%)	14 (22%)
	Unknown/Missing	34 (64%)	47 (75%)
Language	English	53 (100%)	57 (90%)
	Korean	0	1 (2%)
	Polish	0	1 (2%)
	Russian	0	4 (6%)
Age	Median (Range), in years	69 (36-93)	63 (42-81)
	Mean±SD, in years	68.7±12.7	62.7±10.3

Appendix 4.2: Description of provider demographics (n=25)

Job Role	Medical Assistant	2 (8%)
	Nurse	1 (4%)
	Nurse Practitioner	14 (56%)
	Physician	7 (28%)
	Physician Assistant	1 (4%)
Practice Location (could choose more than one)	Manhattan	20 (80%)
	Brooklyn	2 (8%)
	Long Island	4 (16%)
Disease Management Group (DMG)	Breast	19 (76%)
	Gastrointestinal	3 (12%)
	Genitourinary	1 (4%)
	Gynecological	2 (8%)

Appendix 5.1: Patient satisfaction survey responses (POCT vs. Non-POCT)

Question	Score distrib-ution	Non-POCT (n=63)	POCT (n=51)	*p*-value* (POCT vs. Non-POCT)
"Rate the convenience of this visit type."	1 2 3 4 5	0 (0%) 0 (0%) 1 (2%) 5 (8%) 57 (90%)	2 (4%) 1 (2%) 0 (0%) 2 (4%) 46 (90%)	0.26
"I was contacted in a timely manner to schedule this appointment."	1 2 3 4 5	0 (0%) 0 (0%) 1 (3%) 1 (3%) 34 (94%)	0 (0%) 3 (9%) 0 (0%) 0 (0%) 32 (91%)	0.17
"I can explain Hereditary (genetic) Cancer to my friends or family members."	1 2 3 4 5	0 (0%) 0 (0%) 3 (5%) 12 (19%) 47 (76%)	1 (2%) 0 (0%) 7 (14%) 8 (16%) 34 (68%)	0.24
"I am able to understand the limitations of genetic testing."	1 2 3 4 5	0 (0%) 0 (0%) 3 (5%) 11 (18%) 48 (77%)	0 (0%) 1 (2%) 4 (8%) 9 (18%) 36 (72%)	0.62
"I am able to understand the implications of a positive result."	1 2 3 4 5	1 (2%) 0 (0%) 1 (2%) 11 (18%) 47 (78%)	0 (0%) 2 (4%) 2 (4%) 6 (12%) 39 (80%)	0.34
"I would recommend these services to a friend or family member."	1 2 3 4 5	0 (0%) 0 (0%) 1 (2%) 8 (13%) 52 (85%)	0 (0%) 0 (0%) 2 (4%) 8 (17%) 38 (79%)	0.61
"The appointment was about the right length of time."	1 2 3 4 5	0 (0%) 0 (0%) 1 (2%) 4 (7%) 56 (92%)	2 (4%) 0 (0%) 0 (0%) 4 (8%) 42 (88%)	0.32

"How satisfied are you with the resources and support provided by the Genetic Counselor?"	1 2 3 4 5	0 (0%) 0 (0%) 0 (0%) 4 (11%) 32 (89%)	0 (0%) 0 (0%) 2 (6%) 3 (9%) 30 (86%)	0.33
"The genetic counselor was able to address all of my questions."	1 2 3 4 5	0 (0%) 0 (0%) 1 (2%) 3 (5%) 57 (93%)	0 (0%) 0 (0%) 2 (4%) 6 (12%) 42 (84%)	0.28
"The genetic counselor provided me with enough information to make decisions about my care."	1 2 3 4 5	0 (0%) 0 (0%) 0 (0%) 4 (7%) 57 (93%)	0 (0%) 0 (0%) 3 (6%) 7 (14%) 40 (80%)	0.056
"The information discussed in the session was valuable to me."	1 2 3 4 5	0 (0%) 0 (0%) 0 (0%) 4 (7%) 57 (93%)	0 (0%) 0 (0%) 3 (6%) 6 (12%) 40 (82%)	0.077

*significance level of $p < 0.05$

Appendix 5.2: Patient satisfaction survey responses (POCT Breast vs. POCT Non-Breast)

Question	Score distrib-ution	POCT Breast (n=15)	POCT Non-Breast (n=36)	*p*-value* (POCT Breast vs. POCT Non-Breast)
"Rate the convenience of this visit type."	1 2 3 4 5	0 (0%) 0 (0%) 0 (0%) 0 (0%) 15 (100%)	2 (6%) 1 (3%) 0 (0%) 2 (6%) 31 (86%)	0.51
"I was contacted in a timely manner to schedule this appointment."	1 2 3 4 5	0 (0%) 0 (0%) 0 (0%) 0 (0%) 7 (100%)	0 (0%) 3 (11%) 0 (0%) 0 (0%) 25 (89%)	0.37
"I can explain Hereditary (genetic) Cancer to my friends or family members."	1 2 3 4 5	0 (0%) 0 (0%) 1 (7%) 1 (7%) 13 (87%)	1 (3%) 0 (0%) 6 (17%) 7 (20%) 21 (60%)	0.32
"I am able to understand the limitations of genetic testing."	1 2 3 4 5	0 (0%) 0 (0%) 0 (0%) 3 (20%) 12 (80%)	0 (0%) 1 (3%) 4 (11%) 6 (17%) 24 (69%)	0.50
"I am able to understand the implications of a positive result."	1 2 3 4 5	0 (0%) 0 (0%) 0 (0%) 1 (7%) 14 (93%)	0 (0%) 2 (6%) 2 (6%) 5 (15%) 25 (74%)	0.42
"I would recommend these services to a friend or family member."	1 2 3 4 5	0 (0%) 0 (0%) 0 (0%) 1 (7%) 13 (93%)	0 (0%) 0 (0%) 2 (6%) 7 (21%) 25 (74%)	0.31
"The appointment was about the right length of time."	1 2 3 4	0 (0%) 0 (0%) 0 (0%) 0 (0%)	2 (6%) 0 (0%) 0 (0%) 4 (12%)	0.24

	5	14 (100%)	28 (82%)	
"How satisfied are you with the resources and support provided by the Genetic Counselor?"	1 2 3 4 5	0 (0%) 0 (0%) 0 (0%) 0 (0%) 7 (100%)	0 (0%) 0 (0%) 2 (7%) 3 (11%) 23 (82%)	0.48
"The genetic counselor was able to address all of my questions."	1 2 3 4 5	0 (0%) 0 (0%) 0 (0%) 0 (0%) 15 (100%)	0 (0%) 0 (0%) 2 (6%) 6 (17%) 27 (77%)	0.13
"The genetic counselor provided me with enough information to make decisions about my care."	1 2 3 4 5	0 (0%) 0 (0%) 0 (0%) 0 (0%) 15 (100%)	0 (0%) 0 (0%) 3 (9%) 7 (20%) 25 (71%)	0.069
"The information discussed in the session was valuable to me."	1 2 3 4 5	0 (0%) 0 (0%) 0 (0%) 0 (0%) 14 (100%)	0 (0%) 0 (0%) 3 (9%) 6 (17%) 26 (74%)	0.11

*significance level of $p < 0.05$

Appendix 5.3: Provider satisfaction survey responses regarding implementation, usability, support from the HRCGP, and comparison with other workflows

Question	Options/ Score Distribution	Frequency, n (%)
Have you referred patients to the Genetics POCT workflow?	Yes	21/25 (84%)
	No	4/25 (16%)
If no, please select all reasons for not doing so"	Do not understand the workflow	0
	Issues Implementing	3/4 (75%)
	No eligible patients	0
	Other	2/4 (50%)
What other reasons have prevented you from referring patients through the workflow?	Free-text responses: "Do not have tablet with link, nor office space for them to view video" "Lack of time" "Time, language barriers as the video is only available in English"	
How long have you been using the Genetics POCT workflow?	Less than or equal to 1 month	0
	1-3 months	2/21 (10%)
	3-6 months	6/21 (29%)
	6-12 months	9/21 (43%)
	Greater than or equal to 1 year	4/21 (19%)
I am satisfied with the resources and support provided by the genetic counseling team for the initial launch of this workflow (Ex. level of training, iPads)	1 2 3 4 5	2/21 (10%) 6/21 (29%) 4/21(19%) 1/21 (5%) 8/21 (38%)

How easy is it for you/clinical staff to utilize this workflow? (Ex. You were able to integrate extra time into the clinic and coordinate with other providers)	Very difficult	3/21 (14%)
	Somewhat difficult	4/21 (19%)
	Uncertain	2/21 (10%)
	Somewhat easy	7/21 (33%)
	Easy	5/21 (24%)
What was easy?	Free-text responses: “Very responsive team” “Genetic Counseling team is great, difficult to implement due to our high patient volume and workflow leads to slower room turnover/delay in clinic” “Easy to explain to patient why they are watching video and its gives them better understanding” “Takes about 5 min with the video if patients are willing to get testing”	
What was difficult?	Free-text responses: “I don't do it often [...] It's very easy but since I don't do it often it takes me longer to review each step.” “Difficulty is in regard to non-English speaking patients.” “It takes up additional time to office visit” “The additional workload to incorporate into our already busy flow” “Multiple steps and can take more time than allowed to get patient to infusion” “Time is the main issue as we are addressing many other things during oncology visit and do not always have time to properly discuss genetic testing. Language barrier has also been an issue for some patients” “The ipad does not work, unable to load video” “It is helpful to expedite testing for patients and they appreciate it, the steps can take extra time which we don't really have, is there any way to shorten the workflow?” “No space to discuss with patients and No extra clinic time to review consent and video” “No extra clinic time to review the video and consent. Also lack of space for patients to have an area to complete this.”	

Did you have questions for the genetic counseling team related to ongoing support?	Yes	6/21 (29%)
	No	15/21 (71%)
If yes, how easy or difficult was it to get the answers to these questions?	Very difficult	0
	Somewhat difficult	1/11 (9%)
	Uncertain	4/11 (36%)
	Somewhat easy	1/11 (9%)
	Very easy	5/11 (46%)
If yes, these questions were regarding.. (could choose more than one)	Workflow (in general)	9/10 (90%)
	Patient eligibility	4/10 (40%)
	Blood draws	5/10 (50%)
	Technical (iPad troubleshooting)	0
	Test consent form	2/10 (20%)
	Other	1/10 (10%)
Please explain what other questions you had for the genetic counseling team	Free-text responses: “Saliva testing” “Is there a way to have the E consent automatically uploaded to the Ipad that we use for them to watch video?” “Main issue is getting the team to place the order for the lab so it could be done while patient is in the lab, often it takes multiple message” “Patient eligibility” “Regarding the extra email” “Changes to the workflow so that it can be used within our setting” “Non-urgent cases, non-English speaking patients”	
I am comfortable identifying patients eligible for genetic testing	Strongly disagree	0
	Somewhat disagree	1/17 (6%)
	Uncertain	2/17 (12%)
	Somewhat agree	2/17 (12%)

	Strongly agree	12/17 (71%)
	N/A (I don't identify patients for testing)	3 (excluded)
I am comfortable obtaining informed consent and answering patient questions related to genetic testing	Strongly disagree	0
	Somewhat disagree	1/20
	Uncertain	0
	Somewhat agree	7/20 (35%)
	Strongly agree	12/20 (60%)
	N/A (I don't consent patients for testing)	0
Since the introduction of this model, how much time, on average, do you spend discussing genetic testing in each patient appointment?	Up to 3 minutes	0
	4-5 minutes	6/20 (30%)
	6-10 minutes	6/20 (30%)
	11-20 minutes	6/20 (30%)
	Over 20 minutes	2/20 (10%)
	N/A (I don't discuss testing with patients)	0
Compared to the current level of support you are receiving from the genetics team; what level of support is needed for you and your clinic to continue this workflow going forward?	Current level of support	13/20 (65%)
	More support	7/20 (35%)
What type of support do you need?	Billing and insurance (submission and follow-up)	Current level: 16/20 (80%) More support: 4/20 (20%)
	Blood draw	Current level: 18/20 (90%) More support: 2/10 (10%)
	Patient eligibility	Current level: 18/20 (90%) More support: 2/10 (10%)

	Test ordering	Current level: 15/20 (75%) More support: 5/20 (25%)
	Workflow questions	Current level: 14/20 (70%) More support: 6/20 (30%)
Does this workflow require more or less time to complete compared to Non-POCT genetics referrals?	Requires more time	17/20 (85%)
	About the same	3/20 (15%)
	Requires less time	0
How does patient satisfaction in this workflow compare to Non-POCT genetics referrals? Satisfaction is…	Significantly increased	5/20 (25%)
	Somewhat increased	2/20 (10%)
	No change	12/20 (60%)
	Somewhat decreased	1/20 (5%)
	Significantly decreased	0
How comfortable are your patients proceeding with HCGT after watching the pretest education video?	Very uncomfortable	1/20 (5%)
	Somewhat uncomfortable	1/20 (5%)
	Uncertain	3/20 (15%)
	Somewhat comfortable	8/40 (40%)
	Very comfortable	7/20 (35%)
Around what percent of patients have questions before they consent?	Average±SD	52±41%

Appendix 5.4: Thematic analysis of provider free-text responses
Note: 3 one-word free text responses were omitted from analysis due to lack of clarity for interpretation.

What aspects of this workflow work well?	**Frequency n (%)**	**Selected respondent quotes**
Expedited testing	6/10 (60%)	"Collecting blood in office, helps expedite testing results" "Getting the lab test done earlier" "It expedites testing which is always a good thing" "The ability to expedite testing" "Timing of results return" "Expedited results for surgical planning"
Usefulness of educational materials	1/10 (10%)	"Video is great"
Workflow	1/10 (20%)	"Referral is easy"
Communication	1/10 (10%)	"I don't see any barriers between patient/office communication. Everything is handled promptly."
Are there barriers that prevent this workflow from being efficient?	**Frequency n (%)**	**Selected respondent quotes**
Time and/or space constraints	6/12 (50%)	"The extra time it takes" "Time consuming to watch video/consent" "Yes-time" "Time and space constraints, privacy" "Patient volume/limited number of exam rooms to allow for extra to watch the videos/etc." "Yes - lack of space and time which have not been addressed"
Language barriers	3/12 (25%)	"Language barriers" "Language, not available for other languages" "Other languages"

Issues with consent form	2/12 (17%)	"It would be efficient if the consent was also automatically done on the same iPad instead of having to print out consent and then scanning. It would limit the time and back and forth of populating consent and then scanning." "Typing in the consent, emailing"
No barriers	1/12 (8%)	
What changes could be made to improve the efficiency of this workflow?	**Frequency n (%)**	**Selected respondent quotes**
Streamlined consent forms	2/9 (22%)	"Using E- consent for genetic testing" "Pre-filled consent forms since the entered fields do not change, remove email requirement for sending consult as it would be easier to just enter everything in epic"
On-site HRCGP team member in oncology clinics	2/9 (22%)	"Having someone from genetic counseling on the floor or allowing them to view the video at home" "Having genetics team on site to discuss and review with patients"
Other	3/9 (33%)	"Educate RNs who draw blood on infusion about the workflow." "Easy access on genetics medical report" "Expand to non-urgent patients"
No changes	2/9 (22%)	"Nothing to be improved from a genetics team standpoint, just clinic workflow issues" "Nothing really to change unless the genetic counselors go back to doing all of it, but it seems to be getting done to the best of our ability"

What feedback did you receive from patients about this workflow? (Both positive and negative)	Frequency n (%)	Selected respondent quotes
General positive feedback	3/9 (33%)	“Good feedback from patients, they like that they don't need to come in for an extra visit” “Very positive” “Good feedback”
Efficiency	3/9 (33%)	“Good feedback from patients, they like that they don't need to come in for an extra visit” “All patient[s] like the video and they like the efficiency of how and when they are reached out to by genetics staff.” “They were glad they could do the blood draw right away after we discussed with them”
No feedback from patients	2/9 (22%)	
Overwhelmed	1/9 (11%)	“Patient is overwhelmed with too many visits”
Is there anything else you would like to tell us about your experience with this workflow?		
“I do my best to get it done and be through, but I am often rushed in telling patients about it”		
“Genetics 101 in-service?”		
“Workflow is not feasible for our setting, would be best if these challenges could be better addressed”		
“Overall it is effective and quick, but multiple steps sometimes requiring multiple ipads and work outside of epic could be streamlined”		