EVALUATION OF THE GENETIC TESTING STATION, AN ALTERNATIVE VIDEO-BASED MODEL OF CANCER GENETIC COUNSELING AND TESTING

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By
Charlotte Rosenfield
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CERTIFICATION OF APPROVAL

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ABSTRACT

The UCSF Cancer Genetics and Prevention Program (CGPP) has implemented an alternative service delivery model to provide rapid genetic services to a growing number of patients with breast cancer. Dubbed the Genetic Testing Station (GTS), this Genetic Counseling Assistant (GCA) facilitated model gives patients treated at UCSF access to a same-day genetic testing appointment utilizing video genetics education designed by the CGPP. As a first step in evaluating the effectiveness of this model, this study examined patient decision making and genetic counseling satisfaction. Participants seen at UCSF for a new diagnosis of breast cancer were sent to the GTS for genetic testing at clinician discretion. After viewing educational videos and providing informed consent, GCAs administered the SURE decisional conflict scale (DC), a validated measure of assuredness of their decision to proceed with genetic testing. Following completion of genetic testing and results disclosure with a genetic counselor, participants were contacted by phone and/or email to complete the Genetic Counseling Satisfaction Scale (GCSS). Binary and Likert scale responses were scored for the GTS cohort. As a comparison group, individuals with a diagnosis of breast cancer receiving traditional pre- and post-test genetic counseling (traditional model) were also administered DC at the time of informed consent, and GCSS after results disclosure. Mean DC for the GTS group was 3.83 (out of a possible 4.0), and there was no significant difference in scores between the GTS and traditional model (p =

0.845). Mean GCSS of the GTS patients was 5.38 (out of a possible 6.0) and GCSS scores between the models were not significantly different ($p = 0.363$). This study demonstrates that GTS patients have a low level of uncertainty about their decision to undergo genetic testing, are provided enough information and support for decision making, and are ultimately satisfied with the process of genetic testing and counseling. In addition, this study supports the hypothesis that the GTS model does not decrease satisfaction with genetic counseling services when compared to the traditional model. By leveraging video-based education and GCAs, the GTS is a feasible model to increase access to genetic testing that facilitates appropriate decision making and satisfaction with genetic counseling.

INTRODUCTION

Genetic counseling for inherited cancer risk is a well-established specialty in the field of medical genetics. Inherited, or germline, genetic mutations have been established as drivers of cancer development (Chen et al., 2018; Jang & Chung, 2010). As a result, cancer genetic testing has become highly integrated into the field of oncology and cancer treatment through advancements in and application of precision medicine. Today, the identification of somatic and germline alterations can influence treatment recommendations for patients with cancer (Wevers et al., 2012). Because of this, rapid somatic and germline genetic testing results are now commonly requested to inform surgical and systemic treatment decisions. The influence and importance of genetic results have been particularly explored in the field of breast cancer (Manahan et al., 2019), with between 5 to 10% of those diagnosed having some association with a hereditary cancer syndrome (Wevers et al., 2012). Due to expanding research and perspective about the criteria that qualify a patient with breast cancer for germline genetic testing (Beitsch et al., 2019) , the American Society of Breast Surgeons (2019) published new guidelines recommending that "genetic testing should be made available to all patients with a personal history of breast cancer."

BACKGROUND AND SIGNIFICANCE

The University of California San Francisco (UCSF) Helen Diller Family Comprehensive Cancer Center is a high-volume precision medicine cancer treatment center working to treat new diagnoses of cancer of all types. A vital facet of the Cancer Center is the UCSF Cancer Genetics and Prevention Program (CGPP), the largest genetic testing center for cancer in Northern California. This program provides counseling and testing to patients with a family history of cancer as well as those with a new diagnosis of cancer themselves. In order to serve cancer patients and their oncologists within UCSF, the CGPP had previously established an on-call genetic counseling consult service to see patients for genetic testing to inform surgery and treatment decisions.

As the number of patients meeting recommended criteria for cancer genetic testing increase, genetic interpretation and consultation services like genetic counseling should also be offered or requested (Manahan et al., 2019). Research on the growth of the genetic counseling workforce predicts a current shortage of genetic counselors available for direct clinical services (Hoskovec et al., 2018). Given this background and the projected growth of breast cancer referrals, the UCSF CGPP determined that the previous model of rapid consult service was unsustainable and unscalable. Therefore, a new model was developed to meet the specific logistical challenges and needs of the UCSF breast cancer population.

This model leverages standardized video education in place of pre-test genetic counseling for patients with breast cancer requiring genetic testing for surgery and treatment decisions. Dubbed the Genetic Testing Station (GTS), this alternative genetic testing model employs Genetic Counseling Assistants (GCA) (Hnatiuk et al., 2019) to meet with patients scheduled for an appointment on the same day as another UCSF oncology visit (*Figure 1*). A GCA presents the patient with three pre-recorded and animated videos on a laptop computer or iPad device discussing (1) an introduction to genetics and the relationship to cancer risk (1 minute, 42 second in length), (2) details about genetic counseling for a personal or family history of cancer and what to expect at a genetic counseling appointment (1min, 54sec), and (3)

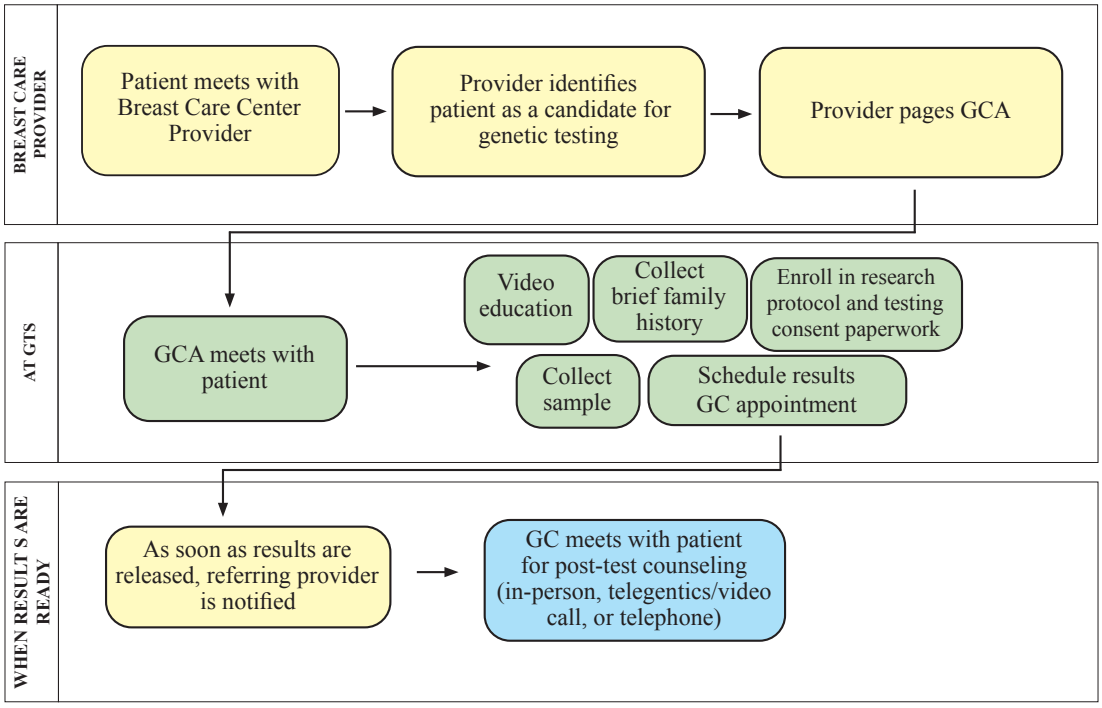

Figure 1. Workflow for genetic testing station (GTS). Boxes in yellow represent when a referring provider is involved, boxes in green represent when a GCA is involved, and boxes in blue represent when a genetic counselor is involved.

possible results of genetic testing for cancer risk and anticipatory guidance regarding possible follow up after results are received (2min, 55sec). These educational videos can be viewed at https://kintalk.org/videos/. These videos were developed in collaboration with the genetic counselors of the UCSF CGPP and have been approved for use by the University of California San Francisco Institutional Review Board (#10-04932).

After viewing all three videos, GTS patients are asked if they would like to continue with genetic testing, decline genetic testing, or if they would like to postpone genetic testing and get more information about its purpose, use, and necessity. These latter patients are then scheduled to meet with the next available genetic counselor for a traditional pre-test cancer genetic counseling appointment, which is typically more exploratory and personalized to an individual's values and decision making process. Those who continue with testing are guided through the consenting process by a GCA. They provide a brief family history, produce a saliva or blood sample for a standardized 133-gene genetic test sent to Invitae Genetics, and are scheduled for a post-test results disclosure appointment with a genetic counselor in approximately 3-4 weeks. GTS patients may request a pre-test genetic counseling appointment at any time and for any reason, and all patients are seen either in-clinic, over telephone, or by telegenetics/video appointment for their results disclosure appointment.

The total time to view all of the required videos for GTS administration significantly reduces the overall time devoted to genetics education as compared to historical pre-test counseling. This could give GCAs the ability to see (and test) more patients than a typical genetic counseling schedule would allow, and may fill the previously unsustainable same-day genetic testing role at UCSF. This relieves genetic counselors to perform other essential tasks and addresses a common clinic issue of GC efficiency. As previously literature has demonstrated, removing GCs from tasks that could be covered by a non-skilled or untrained worker like a GCA has resulted in higher GC efficiency (Pirzadeh-Miller et al., 2016). However, given the recent implementation of this model at UCSF, a number of evaluations are warranted.

With regards to the mode of service delivery, video education and alternative service delivery models in genetic counseling have been oft investigated in the literature. The acknowledgment of the prevalence of alternative service delivery models for genetic counseling and testing has been explored and defined by the National Society of Genetic Counselor (NSGC) Service Delivery Model Task Force (SDMTF) (Cohen et al., 2012). An increasing number of genetic counseling visits are being conducted in alternative ways, including optional pre-test counseling (Sutton, 2018), face-to-face pre-test counseling without face-to-face post-test counseling and post-test counseling only for complex results (Trepanier & Allain, 2013). Alternative genetic counseling and testing workflows have been shown to improve patient access while also fostering collaborative relationships with other healthcare providers (Stoll

et al., 2018). Both patients and non-genetics healthcare providers have been shown to be comparably satisfied with alternative genetic testing models (Colombo et al., 2018; Sie et al., 2013; Sie et al., 2016). Standardized video education in particular has been studied in the prenatal setting (Clayton et al., 1995; Temme et al., 2015), in general and pediatric genetics (Meilleur & Littleton-Kearney, 2009), and within other cancer genetics clinics (Axilbund et al., 2005; Peterson et al., 2006). Previous research has commonly tested knowledge retention of patients exposed to video education (Axilbund et al., 2005; Kalejta et al., 2019), and has established that video or standardized educational materials can measure up in this regard (McCuaig et al., 2018). Of note, patients exposed to video education for whole exome sequencing decision making have reported similar satisfaction when compared to those undergoing routine care (Hernan et al., 2020).

The UCSF CGPP has acknowledged this established research in the process of developing the GTS model and the associated video content, but there is also a recognized gap in study regarding standardized video education and potential harms to patient decision making. While short term knowledge retention has been suggested to facilitate informed decision making (Axilbund et al., 2005), UCSF recognizes that measures related to patient experience and perspective may similarly influence or guide the decision making process. Other alternative service delivery models like telephone and telegenetics/video counseling (Cohen et al., 2012) have been previously evaluated using measures including efficacy, patient knowledge, and

patient satisfaction or acceptance (Coelho et al., 2005; Meropol et al., 2011; Sutphen et al., 2010; Zilliacus et al., 2011).

As a first step in evaluating the GTS, it was determined that this research will focus on measures of harm and overall satisfaction. This study will aim to demonstrate that the GTS model does not cause significant harm to patient confidence in decision making and satisfaction with their genetic counseling services. This study will compare decisional conflict and genetic counseling satisfaction scores between patients who underwent traditional pre-test genetic counseling and those seen through the GTS. Genetic counseling is traditionally a personalized process that incorporates patient preferences and values in decision making. Guiding patients to make the best decisions for themselves is a hallmark of genetic counseling. In contrast, the GTS is instead a "one-size-fits-all" alternative model with regards to genetics education and decision-making tools. We therefore chose to measure decisional conflict (DC) as a means to understand if the GTS model provided enough education and support for patients to feel confident in their decision to undergo genetic testing. This measurement has been shown to be valid and appropriate to gauge decision-making confidence (O'Connor, 1995) when a participants choices "involve risk, loss, regret, or a challenge to personal life values" (Légaré et al., 2010). DC is considered to be a valuable indicator of decision making potential when compared to measurements of knowledge retention (Resta et al., 2006), and DC has been employed in previous hereditary breast and ovarian cancer testing research (Katapodi et al., 2011).

In addition, an evaluation of patient satisfaction with their genetic counseling services is of specific interest for this preliminary evaluation. Satisfaction is an important patient reported outcome of genetic counseling, as it is one of the elements used by professional organizations and health care accrediting bodies to determine the quality of professional work. Perhaps as a result of this value, a standardized measure of genetic counseling satisfaction was developed, the Genetic Counseling Satisfaction Scale (GCSS) (DeMarco et al., 2004). This scale has since been validated and utilized by a variety of cancer genetics literature (DeMarco et al., 2004; Pieterse et al., 2007; Tercyak et al., 2004). As a post-test genetic counseling only model, it is important to demonstrate that the GTS workflow does not significantly harm the satisfaction patients express about their genetic counseling services. Measuring the genetic counseling satisfaction of the GTS cohort in particular is paramount to better understanding the relationship between standardized genetic testing delivery and patient perspective on genetic counseling services.

MATERIALS AND METHODS

Participants for this study were recruited through the UCSF Cancer Genetics and Prevention Program (CGPP) in San Francisco, CA. All participants were recruited and surveyed between October 2019 and March 2020. Data collection was completed prior to the cancellations and closures related to COVID-19 beginning in March 2020.

Eligible patients met a number of inclusion criteria: (1) refereed for genetic testing, (2) current diagnosis of breast cancer, (3) female sex, (4) English as a primary language, and (5) no previous genetic counseling or genetic testing through the UCSF CGPP or through an outside institution. Patients in this eligible pool were offered genetic testing during their appointment, and only those who consented to testing and research were eligible for study participation. The CGPP consent for genetic testing also enrolls the patient in a research registry, which allows them to administer survey measures and study the GTS model. Any patient with concerns about enrolling in the research registry was deferred to the traditional model of pre-test genetic counseling, which is the standard of care at UCSF CGPP.

All GTS patients were referred internally by a UCSF provider or oncologist, as this same-day genetic testing model is designed to meet the UCSF demand for genetic testing of those newly diagnosed with cancer. Appropriate GTS referrals were made based on provider discretion in a similar fashion to the previous UCSF same-day GC consult model. Patients in the traditional genetic counseling control group

were referred either internal UCSF providers or externally from a provider of an outside institution.

This study was conducted by offering and administering study survey measures during or around existing appointment workflow (*Figure 2*). Study participants were attempted to be surveyed at two points in time, regardless of appointment type. Patients who requested a genetic counseling appointment after exposure to GTS educational materials were not eligible for study participation due to their participation in both study groups. Eligible patients were offered initial decisional conflict surveying included within in their consenting paperwork right after making their genetic testing decision. The consent documents and optional survey measure

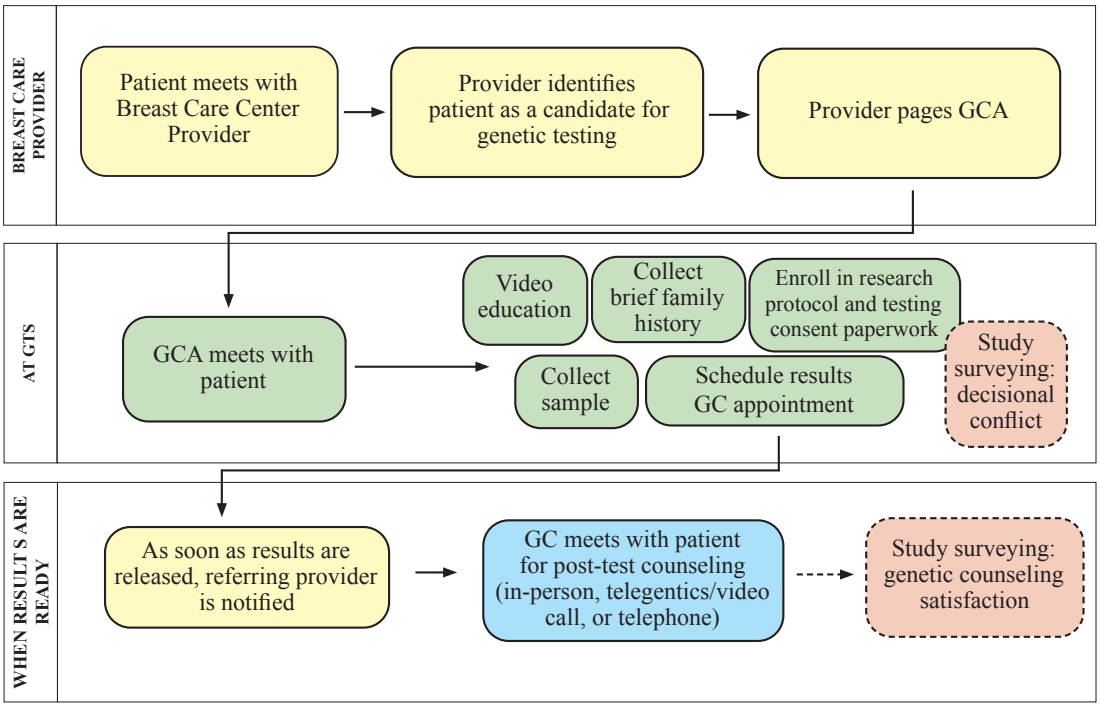

Figure 2. Integration of study survey measures within existing GTS workflow. Boxes in red represent points of study administration.

were administered were administered by a GCA in the GTS workflow or by a genetic counseling in the traditional pre-test appointment model. All patients who completed the first round of surveying were attempted to be contacted for secondary satisfaction surveying at least two weeks after their appointment for results disclosure. Patients were first called by telephone and then emailed to explain the purpose of this contact and request their participation in this study, as they could complete this surveying over the phone or electronically through an online version of the survey questions. All patients were offered an incentive for their completion of post-test surveying through entry into a raffle to receive one of five $25 Visa gift cards. This incentive was funded by the California State University Stanislaus (CSUS) Student Engagement in Research, Scholarship, and Creative Activity (SERCSA) Mini-Grant program. If a patient didn't respond, a telephone voice message was left, an instructional email was sent, and patients were recontacted approximately two weeks after the initial contact attempt. If available, satisfaction surveying was offered and administered. Either study measure could be declined at any time by participants.

SURE Decisional Conflict Scale

Initial surveying during the first GTS or genetic counseling appointment was performed using the four-question SURE decisional conflict (DC) survey (*Figure 3*). The SURE DC scale is a validated measurement of decisional conflict (Légaré et al., 2010) which could be quickly integrated into both appointment workflows.

	Yes (1)	No (0)
Do you feel SURE about the best choice for you?		
Do you know the benefits and risks of each option?		
Are you clear about which benefits and risks matter to you most?		
Do you have enough support and advice to make a choice?		

Figure 3. Four question SURE decisional conflict survey tool.

Genetic Counseling Satisfaction Scale

Participants who had completed DC surveying were contacted for genetic counseling satisfaction surveying after their result disclosure genetic counseling appointment. Post-test surveying was performed using the six-question Genetic Counseling Satisfaction Scale (GCSS) survey (DeMarco et al., 2004) (*Figure 4*). Those in the GTS cohort were asked to base their assessment solely on the results genetic counseling session, while those who had initial genetic counseling were asked to base their assessment on all appointments with their genetic counselor.

Participants first completed the pre-testing DC SURE survey, answering yes or no to four statements describing their confidence in the decision they made to continue with genetic testing. Those who were available for post-test GCSS surveying were given six statements and asked to state if they “Agree”, “Disagree”, or were “Uncertain” about the statement regarding their genetic counseling experience. Demographic information was obtained from the UCSF electronic medical record

	Agree (1)	**Uncertain (0)**	**Disagree (-1)**
My genetic counselor seemed to understand the stress I was facing			
My genetic counselor helped me to identify what I needed to know in order to make decisions about my health care			
I felt better about my health after meeting with my genetic counselor			
The genetic counseling session was about the right length of time I needed			
My genetic counselor was truly concerned about my well-being			
The genetic counseling session was valuable to me			

Figure 4. Six question Genetic Counseling Satisfaction Scale (GCSS) survey tool.

system and documented for all participants who completed both DC and GCSS surveys. These include participant age and race, defined as “White”, “Hispanic”, “Asian”, “Other” referring to those of mixed background, and “Unknown” for individuals whose race and/or ethnicity was not specified or could not be determined. Details on the outcome of participants genetic testing experience were also documented, including genetic testing result outcome (reported as “Negative”, “Positive” or pathogenic, and those with at least one “Variant of Uncertain Significance” or VUS) and post-test genetic counseling appointment type (classified as an “In-person” visit, remote “Video” call, or “Telephone” call).

All consenting paperwork, survey tools, and study protocol were approved by both California State University Stanislaus IRB (#1920-025) and University of California San Francisco Medical Center IRB (#10-04932).

Data Analysis

The individual answers for each survey question were combined and scored to reflect an overall DC and GCSS score for each participant. “Yes” and “Agree” answers (for DC and GCSS respectively) were each scored 1 point for the total participant score. Any “No” answers for DC questions resulted in 0 points. For GCSS, any “Disagree” answers caused 1 point to be subtracted from the total score, while “Uncertain” responses were given 0 points. By this protocol, the maximum DC score possible was a 4.0 and the maximum GCSS score possible was a 6.0. The relationship of these total scores to initial appointment modality was evaluated via independent t-test of significance to determine the effect of GTS vs genetic counseling appointment on the resulting survey score. Additional one-way analysis of variance (ANOVA) tests were performed on demographic and outcome data to determine any relationship between these data points and survey scores. All data were analyzed in the jamovi statistical processing software (https://www.jamovi.org/).

RESULTS

The UCSF CGPP saw 102 patients meeting study inclusion criteria during the study time period, 46 of whom were seen via traditional pre-test genetic counseling and 56 who were referred for the GTS (*Figure 5*). Forty-three of the 46 genetic counseling patients accepted genetic testing (93%), while 3 declined. Similarly, 46 of the 56 GTS group accepted testing (82%), and again 3 declined. Seven patients requested additional information and formal genetic counseling after viewing the GTS video education, thereby making them ineligible for study participation. Of note, 4 of these 7 patients were recommended for additional genetic counseling based on details of their insurance coverage. Of those 7, 5 later accepted genetic testing.

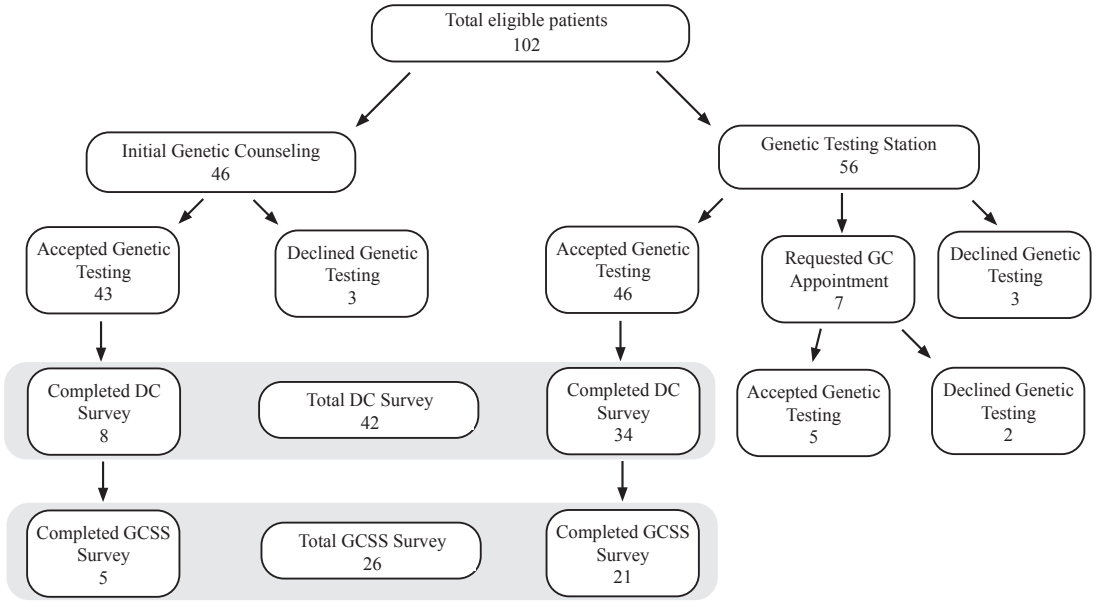

Figure 5. Summary of participant enrollment and survey collection.

Therefore, a total of 91 patients were eligible for study surveying. These patients were offered surveying by their supervising GCA or genetic counselor, resulting in 42 SURE decisional conflict surveys collected (response rate of 46%); 34 from the GTS patients and 8 from the traditional genetic counseling patients. These 42 patients were then recontacted after their results genetic counseling appointment for satisfaction surveying using the GCSS. 26 total participants could be reached for surveying (response rate of 62%), 21 GTS patients and 5 traditional genetic counseling patients.

Demographic and relevant appointment information including age, race, results appointment type, and testing result outcome, was recorded for all 26 participants surveyed on satisfaction (*Table 1*). Of particular interest, a majority of participants scheduled a “video call” for their results genetic counseling appointment (58%), and only 4 participants total were found to have a pathogenic mutation finding (15%).

Table 1

Summary of Participant Information and Demographics

	Genetic Counseling (n = 5)	**GTS (n = 21)**
Age		
31-44	2 (40%)	6 (29%)
45-58	2 (40%)	10 (47%)
59-71	1 (20%)	5 (24%)
Race		
White	1 (20%)	8 (38%)
Hispanic	0 (0%)	1 (5%)
Asian	0 (0%)	2 (9%)
Other	4 (80%)	2 (9%)
Unknown	0 (0%)	8 (38%)
Results Appointment Type		
In-Person	0 (0%)	8 (38%)
Telegenetics/Video	4 (80%)	11 (52%)
Telephone	1 (20%)	2 (9%)
Results Outcome		
Positive or Pathogenic	0 (0%)	4 (19%)
Variant of Uncertain Significance (VUS)	1 (20%)	11 (52%)
Negative	4 (80%)	6 (29%)

Participant SURE DC responses are shown in *Table 2*. GTS and genetic counseling participants overwhelmingly answered "Yes" to all four questions, and the mean aggregate DC score for those in the GTS cohort was 3.83 (out of a possible 4.0). There was no significant difference between the scores of those who had traditional genetic counseling and those at the GTS (*Figure 6*), t(40) = -0.196, p = . 845. The most common statements to which GTS participants responded "No" were

Table 2

Responses to SURE Decisional Conflict Survey Questions

	(Q1) Do you feel SURE about the best choice for you?	**(Q2) Do you know the benefits and risks of each option?**	**(Q3) Are you clear about which benefits and risks matter to you most?**	**(Q4) Do you have enough support and advice to make a choice?**
GTS (n = 34)				
Yes	33	32	32	33
No	1	2	2	1
	M = 0.97 (*SD* = 0.17)	*M* = 0.94 (*SD* = 0.23)	*M* = 0.94 (*SD* = 0.23)	*M* = 0.97 (*SD* = 0.17)
Genetic Counseling (n = 8)				
Yes	7	8	8	8
No	1	0	0	0
	M = 0.88 (*SD* = 0.33)	*M* = 1.00 (*SD* = 0.00)	*M* = 1.00 (*SD* = 0.00)	*M* = 1.00 (*SD* = 0.00)

Note. M = mean; *SD* = standard deviation

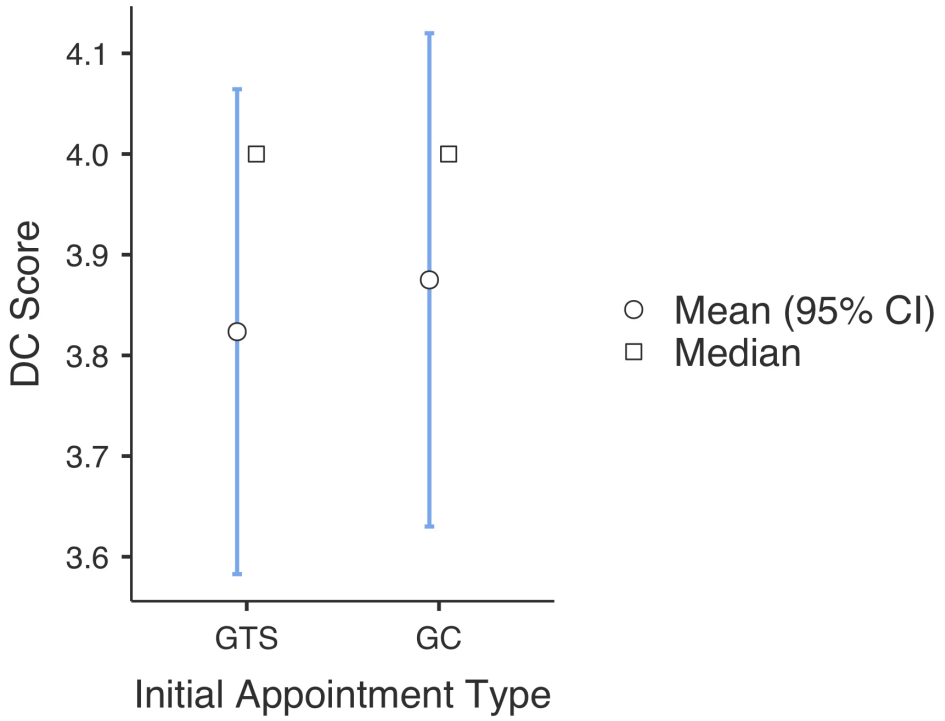

Figure 6. Mean DC score between initial appointment type treatment groups (GTS or genetic counseling). Blue bars indicate the 95% confidence interval.

Q2 ("Do you know the benefits and risks of each option?") and Q3 ("Are you clear about which benefits and risks matter to you most?"), while the only dissenting answer of the genetic counseling group was for Q1 ("Do you feel SURE about the best choice for you?").

Participant GCSS responses are documented in *Table 3*. Similarly, the majority of respondents answered "Agree" to all satisfaction statements, and the mean aggregate GCSS score of GTS participants was high at 5.38 (out of a possible 6.0). There was also no significant difference between GTS and traditional genetic counseling GCSS scores (*Figure 7*), $t(24) = -0.928$, $p = .363$. The most common questions to which GTS participants responded "Uncertain" or "Disagree" were Q1

Table 3

Responses to Genetic Counseling Satisfaction Scale Survey Questions

	(Q1) My genetic counselor seemed to understand the stress I was facing	**(Q2) My genetic counselor helped me to identify what I needed to know in order to make decisions about my health care**	**(Q3) I felt better about my health after meeting with my genetic counselor**	**(Q4) The genetic counseling session was about the right length of time I needed**	**(Q5) My genetic counselor was truly concerned about my well-being**	**(Q6) The genetic counseling session was valuable to me**
GTS (n = 21)						
Agree	18	19	17	21	20	20
Uncertain	3	2	3	0	1	1
Disagree	0	0	1	0	0	0
	M = 0.86 (*SD* =0.35)	*M* = 0.90 (*SD* =0.29)	*M* = 0.76 (*SD* =0.52)	*M* = 1.00 (*SD* =0.00)	*M* = 0.95 (*SD* =0.21)	*M* = 0.95 (*SD* =0.21)
Genetic Counseling (n = 5)						
Agree	5	5	5	5	4	5
Uncertain	0	0	0	0	1	0
Disagree	0	0	0	0	0	0
	M = 1.00 (*SD* =0.00)	*M* = 1.00 (*SD* =0.00)	*M* = 1.00 (*SD* =0.00)	*M* = 1.00 (*SD* =0.00)	*M* = 0.80 (*SD* =0.40)	*M* = 1.00 (*SD* =0.00)

Note. *M* = mean; *SD* = standard deviation

("My genetic counselor seemed to understand the stress I was facing") and Q3 ("I felt better about my health after meeting with my genetic counselor"). Only one

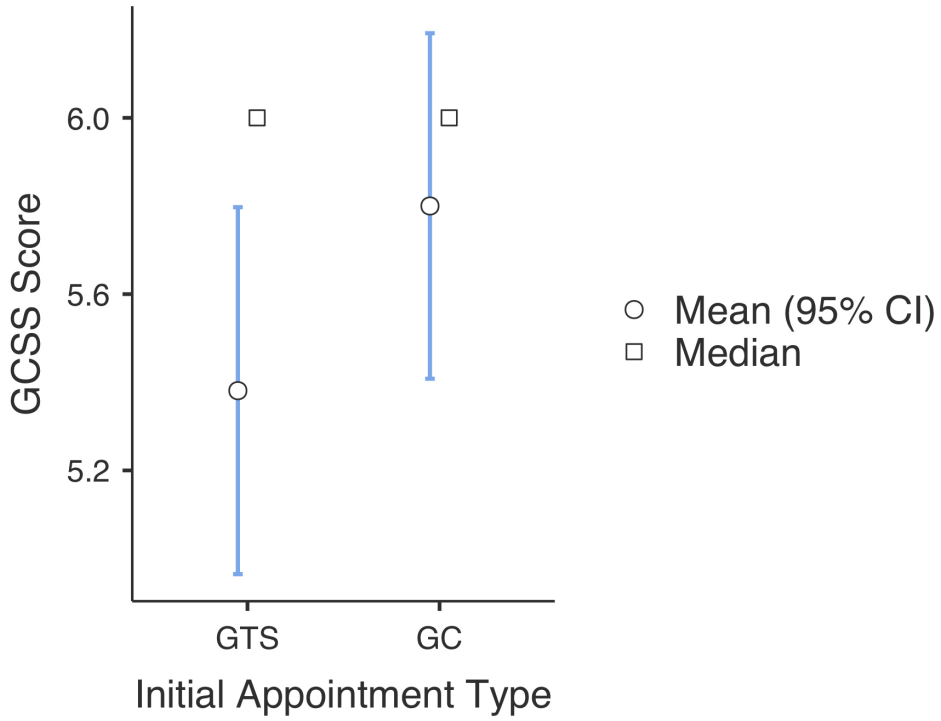

Figure 7. Mean GCSS score between initial appointment type treatment groups (GTS or genetic counseling). Blue bars indicate the 95% confidence interval.

"Uncertain" response was given in the small (n = 5) traditional genetic counseling group to Q5 ("My genetic counselor was truly concerned about my well being"). Of note, all participants, regardless of initial appointment type, responded "Agree" to Q4 ("The genetic counseling session was about the right length of time I needed").

ANOVA analysis did demonstrate a statistically significant relationship between age and response to Q2 ("My genetic counselor helped me to identify what I needed to know in order to make decisions about my healthcare"), $X^2(1) = 19.4$, $p = .014$. This means that there was a trend for those who were older, regardless of initial appointment type, to respond "Uncertain" to this statement. Otherwise, statistical

analysis of demographic factors and results outcomes did not show any significant relationships with regard to GCSS score.

DISCUSSION

This study explores the potential impacts to decisional conflict and genetic counseling satisfaction caused by the GTS, a video-based alternative genetic testing delivery model currently employed by the UCSF CGPP. Utilizing the SURE decisional conflict and GCSS surveys, we determined that the GTS standardized education materials do not appear to significantly reduce decisional confidence or genetic counseling satisfaction scores compared to patients undergoing traditional initial genetic counseling. These results are congruent with previous literature evaluating patient satisfaction and perspective of similar video education and alternative service delivery models. In 2016, Sie and colleagues complied data from a prospective study comparing short and long term outcomes for breast cancer patients who participated in a post-test genetic counseling only model for BRCA-mutation testing. The majority of patients in the abbreviated model reported high satisfaction without increased distress both in the short term and 1 year after conclusion of their genetic testing, and differences between the satisfaction and distress of alternative model and traditional model participants were found to be non-significant (Sie et al., 2016). More recently, data collected over a two-year period by Rana and colleagues for the ProGen study (2020) randomized high risk prostate cancer patients to either video education or in-person genetic counseling. Genetic testing uptake was overall

high among both cohorts, and a vast majority of video education and genetic counseling subjects “agreed that their assigned arm was useful” (Rana et al., 2020).

The average DC and satisfaction scores of GTS participants in this study were considerably high, 3.83 out of a possible 4.0 and 5.38 out of a possible 6.0 respectively. While there may be room for improvement statistically speaking, it is encouraging to see the clear decisional confidence and satisfaction expressed by patients seen through the GTS workflow. Given the statistically similar scores seen in the traditional genetic counseling group, it can be claimed that video education in the GTS workflow does not negatively impact these patient experience measures.

Demographic factors like age and race also did not appear to statistically influence decisional conflict scores, as could be anticipated. For example, it has been suggested that patients of an older age may not be familiar or accepting of video materials and digital communication styles, given that they did not grow up with some of this technology. This could have impacted decisional conflict scores if information was difficult to integrate due to this alternative methodology. However, older GTS patients in this study did not have significantly lower DC scores. This finding can be compared to the statistically significant relationship found between age and an “Uncertain” response for Q2 for satisfaction surveying (“My genetic counselor helped me to identify what I needed to know in order to make decisions about my healthcare”). However, older participants in this study did not demonstrate

cumulatively lower satisfaction scores, so it was only in regard to this specific survey statement that an age-related difference was found.

Similarly, genetic testing results outcome is a factor which could conceivably be related to patient satisfaction. For example, patients who received positive or pathogenic results may be highly anxious or frightened by their results. Or those who tested negative may be left with greater uncertainty as they have no specific germline genetic link or cause for their cancer development. Either of these perspectives could be thought to influence lower satisfaction scores by disagreements with the GCSS statements like Q3 (“I felt better about my health after meeting with my genetic counselor"). However, again, no relationship was found between satisfaction score and results outcome, demonstrating that the outcome of a patient’s genetic testing results are not expected to influence genetic counseling satisfaction.

This data did document that, regardless of initial appointment type, the majority of participants choose to schedule a telegenetics or video call for their post-test results appointment. This data pattern, in addition to the equivalent number of eligible referred patient seen via GTS or by traditional genetic counseling, underscores previous literature documenting patient and provider preference for convenient alternative genetic service delivery models (Colombo et al., 2018; Sie et al., 2013; Sie et al., 2016).

Limitations

There are a number of limitations to discuss in reviewing the conclusions to be drawn from this preliminary evaluation. The GTS and genetic counseling participant sample size (n) was lower than is typically desired for strong statistical analysis and correlation. This is likely due to the multiple rounds of surveying and attempted contact outside of the genetics appointments. While a similar number of eligible GC and GTS patients continued with testing, far fewer GC patients completed initial decisional conflict surveying. This trend could be for a variety of reasons including: patients seen for genetic counseling were more likely to decline study surveying, genetic counselors may have had a more difficult time offering or administering the survey, or the integration of the survey tool was more successful in the GTS workflow. The specific reason for this discrepancy wasn't investigated by this study, though this does provide a unique possible avenue for future research. Overall, the small cohort size limits the statistical power of our conclusions in this study, though the broad take-aways from our data are still a valuable first evaluation of the GTS.

Our study design aimed to integrate data collection into the preexisting GTS and genetic counseling appointment workflows. Enrollment in the UCSF research protocol and review of consent paperwork is only offered to and completed by patients who continue with genetic testing. Our survey administration was thereby limited to patients selecting genetic testing, and excludes those who decline testing or request an additional genetic counseling appointment. Because of this, our study

misses the opportunity to evaluate an important population who were unsure about genetic testing after GTS video education. The decisional conflict scores, satisfaction scores, and feedback of this group could be of particular interest to the UCSF CGPP in their evaluation of the GTS model.

There are a number of contributing factors, unrelated to specific genetics education or availability of genetic counseling services, which may have influenced participant responses for decisional conflict and satisfaction. For example, some patients may have decided prior to their appointment to continue with testing regardless of the information presented to them. Some may have done additional research on the importance of cancer genetics prior to their appointment and felt confident in their understanding of that information. Others may have chosen to mask genuine decisional conflict in order to continue with testing quickly. These individual motivations or perspectives on genetic education were unable to be controlled for in this study. Additionally, because decisional conflict surveying was administered by the genetic counselor or GCA, patients may have felt uncomfortable providing responses of uncertainty in their presence. Ideally, this effect was mitigated for the satisfaction measurement by having a third party administer the survey, though this limitation cannot be discounted entirely.

Future Research

Given the recent implementation of the GTS model, the data and conclusions of this study represent a preliminary investigation of its effects on decisional conflict

and genetic counseling satisfaction. As cancer genetic counselors need to meet the increased demand for cancer genetic testing, the efficacy of standardized models like the GTS must continue to be tested and confirmed. In particular, capturing the perspectives of patients who declined genetic testing would be paramount to better understand the correlation between video information and decision to decline. Future evaluations should include not only additional quantitative research related to the effectiveness and potential harm of video genetics education, but could also involve qualitative components and interviews of participants to explore more nuanced features of the participant experience with standardized education. While both the SURE and GCSS surveys have been validated as appropriate measures of decisional conflict and genetic counseling satisfaction respectively, the response options for these surveys are largely binary. This does not provide the opportunity for patients to express nuanced or detailed perspectives about their experiences. It may also be valuable to study the GCAs responsible for employing this model. Through focus groups or individual interviews, researchers may both document common patient questions or areas for improvement with a GTS model, and better comprehend the realistic scope and scalability of models like this.

CONCLUSION

This study was designed to investigate the GTS, an alternative service delivery model currently employed by the UCSF CGPP. The purpose of this study was to determine if patients exposed to this model demonstrated reductions in decisional confidence or satisfaction of genetic counseling services. The results demonstrate that GTS patients have limited uncertainty about genetic testing, are provided enough information and support for decision making, and are ultimately satisfied with their post-test genetic counseling. In addition, this study supports the hypothesis that the GTS model does not negatively impact satisfaction with genetic counseling services when compared to the traditional model. By leveraging standardized video-based education and GCAs, the GTS is a feasible model to increase access to genetic testing that facilitates appropriate decision making and satisfaction with genetic counseling. Given the expanding landscape of cancer genetics within oncology and precision medicine institutions, this study provides preliminary support for the effectiveness of alternative testing models in maintaining important patient experience and decision making measures.

REFERENCES

REFERENCES

Axilbund, J. E., Hamby, L. A., Thompson, D. B., Olsen, S. J., & Griffin, C. A. (2005). Assessment of the use and feasibility of video to supplement the genetic counseling process: A cancer genetic counseling perspective. *Journal of Genetic Counseling, 14*, 235-243. doi:10.1007/s10897-005-4065-z

Chen, H., Wu, J., Zhang, Z., Tang, Y., Li, X., Liu, S., … Li, X. (2018). Association between BRCA status and triple-negative breast cancer: A meta-analysis. *Frontiers in Pharmacology*, *9*. doi: 10.3389/fphar.2018.00909

Clayton, E. W., Hannig, V. L., Pfotenhauer, J. P., Parker, R. A., Campbell, P. W. 3rd, & Phillips, J. A. 3rd. (1995). Teaching about cystic fibrosis carrier screening by using written and video information. *American Journal of Human Genetics, 57*, 171-181.

Coelho, J. J., Arnold, A., Nayler, J., Tischkowitz, M., & Mackay, J. (2005). An assessment of the efficacy of cancer genetic counseling using real-time videoconferencing technology (telemedicine) compared to face-to-face consultations. *European Journal of Cancer*, *41*, 2257–2261. doi: 10.1016/ j.ejca.2005.06.020

Cohen, S. A., Gustafson, S. L., Marvin, M. L., Riley, B. D., Uhlmann, W. R., Liebers, S. B., & Rousseau, J. A. (2012). Report from the National Society of Genetic Counselors service delivery model task force: A proposal to define models,

components, and modes of referral. *Journal of Genetic Counseling*, *21*, 645–651. doi: 10.1007/s10897-012-9505-y

Colombo, N., Huang, G., Scambia, G., Chalas, E., Pignata, S., Fiorica, J., … Blakeley, C. (2018). Evaluation of a streamlined oncologist-led BRCA mutation testing and counseling model for patients with ovarian cancer. *Journal of Clinical Oncology*, *36*, 1300–1307. doi: 10.1200/jco.2017.76.2781

DeMarco, T. A., Peshkin, B. N., Mars, B. D., & Tercyak, K. P. (2004). Patient satisfaction with cancer genetic counseling: A psychometric analysis of the genetic counseling satisfaction scale. *Journal of Genetic Counseling*, *13*, 293–304. doi: 10.1023/b:jogc.0000035523.96133.bc

Hnatiuk, M. J., Noss, R., Mitchell, A. L., & Matthews, A. L. (2019). The current state of genetic counseling assistants in the United States. *Journal of Genetic Counseling*, *28*, 962–973. doi: 10.1002/jgc4.1148

Hernan, R., Cho, M. T., Wilson, A. L., Ahimaz, P., Au, C., Berger, S. M., … Wynn, J. (2020). Impact of patient education videos on genetic counseling outcomes after exome sequencing. *Patient Education and Counseling*, *103*, 127–135. doi: 10.1016/j.pec.2019.08.018

Hoskovec, J. M., Bennett, R. L., Carey, M. E., Davanzo, J. E., Dougherty, M., Hahn, S. E., … Wicklund, C. A. (2017). Projecting the supply and demand for certified genetic counselors: A workforce study. *Journal of Genetic Counseling*, *27*, 16–20. doi: 10.1007/s10897-017-0158-8

Jang, E., & Chung, D. C. (2010). Hereditary colon cancer: Lynch syndrome. *Gut and Liver*, *4*, 151–160. doi: 10.5009/gnl.2010.4.2.151

Kalejta, C. D., Higgins, S., Kershberg, H., Greenberg, J., Alvarado, M., Cooke, K., … Elms, A. (2019). Evaluation of an automated process for disclosure of negative noninvasive prenatal test results. *Journal of Genetic Counseling*. doi: 10.1002/jgc4.1127

Katapodi, M. C., Munro, M. L., Pierce, P. F., & Williams, R. A. (2011). Psychometric testing of the decisional conflict scale. *Nursing Research, 60*, 368-377. doi: 10.1097/nnr.0b013e3182337dad

Légaré, F., Kearing, S., Clay, K., Gagnon, S., D'Amours, D., Rousseau, M., & O'Connor, A. (2010) Are you SURE?: Assessing patient decisional conflict with a 4-item screening test. *Canadian Family Physician*, *56*, 308-14. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2920798/

Manahan, E. R., Kuerer, H. M., Sebastian, M., Hughes, K. S., Boughey, J. C., Euhus, D. M., … Taylor, W. A. (2019). Consensus guidelines on genetic` testing for hereditary breast cancer from the American Society of Breast Surgeons. *Annals of Surgical Oncology*, *26*, 3025–3031. doi: 10.1245/s10434-019-07549-8

Manne, S., Smith, B., Mitarotondo, A., Frederick, S., Toppmeyer, D., & Kirstein, L. (2019). Decisional conflict among breast cancer patients considering contralateral prophylactic mastectomy. *Patient Education and Counseling, 102*, 902-908. doi:10.1016/j.pec.2018.12.008

McCuaig, J. M., Stockley, T. L., Shaw, P., Fung-Kee-Fung, M., Altman, A. D., Bentley, J., … Kim, R. H. (2018). Evolution of genetic assessment for BRCA-associated gynaecologic malignancies: A Canadian multisociety roadmap. *Journal of Medical Genetics*, *55*, 571–577. doi: 10.1136/jmedgenet-2018-105472

Meilleur, K. G., & Littleton-Kearney, M. T. (2009). Interventions to improve patient education regarding multifactorial genetic conditions: A systematic review. *American Journal of Medical Genetics Part A*, *149A*, 819–830. doi: 10.1002/ajmg.a.32723

Meropol, N. J., Daly, M. B., Vig, H. S., Manion, F. J., Manne, S. L., Mazar, C., … Zubarev, V. (2011). Delivery of internet-based cancer genetic counseling services to patients homes: a feasibility study. *Journal of Telemedicine and Telecare*, *17*, 36–40. doi: 10.1258/jtt.2010.100116

O'Connor, A. M. (1995). Validation of a decisional conflict scale. *Medical Decision Making, 15*, 25-30. doi:10.1177/0272989x9501500105

Peterson, S. K., Pentz, R. D., Blanco, A. M., Ward, P. A., Watts, B. G., Marani, S. K., … Strong, L. C. (2006). Evaluation of a decision aid for families considering p53 genetic counseling and testing. *Genetics in Medicine*, *8*, 226–233. doi: 10.1097/01.gim.0000214632.52958.01

Pieterse, A. H., Dulmen, A. M., Beemer, F. A., Bensing, J. M., & Ausems, M. G. (2007). Cancer genetic counseling: Communication and counselees' post-visit

satisfaction, cognitions, anxiety, and needs fulfillment. *Journal of Genetic Counseling, 16*, 85-96. doi:10.1007/s10897-006-9048-1

Pirzadeh-Miller, S., Robinson, L. S., Read, P., & Ross, T. S. (2016). Genetic counseling assistants: An integral piece of the evolving genetic counseling service delivery model. *Journal of Genetic Counseling*, *26*, 716–727. doi: 10.1007/s10897-016-0039-6

Resta, R., Biesecker, B. B., Bennett, R. L., Blum, S., Hahn, S. E., Strecker, M. N., & Williams, J. L. (2006). A new definition of genetic counseling: National Society of Genetic Counselors' task force report. *Journal of Genetic Counseling*, *15*, 77–83. doi: 10.1007/s10897-005-9014-3

Sie, A. S., Zelst-Stams, W. A. G. V., Spruijt, L., Mensenkamp, A. R., Ligtenberg, M. J. L., Brunner, H. G., … Hoogerbrugge, N. (2013). More breast cancer patients prefer BRCA-mutation testing without prior face-to-face genetic counseling. *Familial Cancer*. doi: 10.1007/s10689-013-9686-z

Sie, A. S., Spruijt, L., Zelst-Stams, W. A. G. V., Mensenkamp, A. R., Ligtenberg, M. J. L., Brunner, H. G., … Hoogerbrugge, N. (2016). High satisfaction and low distress in breast cancer patients one year after BRCA-mutation testing without prior face-to-face genetic counseling. *Journal of Genetic Counseling*, *25*, 504–514. doi: 10.1007/s10897-015-9899-4

Stoll, K., Kubendran, S., & Cohen, S. A. (2018). The past, present and future of service delivery in genetic counseling: Keeping up in the era of precision medicine. *American Journal of Medical Genetics Part C: Seminars in*

Medical Genetics, *178*, 24–37. doi: 10.1002/ajmg.c.31602

Sutphen, R., Davila, B., Shappell, H., Holtje, T., Vadaparampil, S., Friedman, S., … Armstrong, J. (2010). Real world experience with cancer genetic counseling via telephone. *Familial Cancer*, *9*, 681–689. doi: 10.1007/s10689-010-9369-y

Temme, R., Gruber, A., Johnson, M., Read, L., Lu, Y., & Mcnamara, J. (2014). Assessment of parental understanding of positive newborn screening results and carrier status for cystic fibrosis with the use of a short educational video. *Journal of Genetic Counseling*, *24*, 473–481. doi: 10.1007/s10897-014-9767-7

Tercyak, K. P., DeMarco, T. A., Mars, B. D., Peshkin, B. N. (2004). Women's satisfaction with genetic counseling for hereditary breast-ovarian cancer: Psychological aspects. *American Journal of Medical Genetics Part A, 15;131*, 36-41. doi: 10.1002/ajmg.a.30317

Trepanier, A. M., & Allain, D. C. (2013). Models of service delivery for cancer genetic risk assessment and counseling. *Journal of Genetic Counseling*, *23*, 239–253. doi: 10.1007/s10897-013-9655-6

Wevers, M. R., Hahn, D. E., Verhoef, S., Bolhaar, M. D., Ausems, M. G., Aaronson, N. K., & Bleiker, E. M. (2012). Breast cancer genetic counseling after diagnosis but before treatment: A pilot study on treatment consequences and psychological impact. *Patient Education and Counseling*, *89*, 89–95. doi: 10.1016/j.pec.2012.03.019

Zilliacus, E. M., Meiser, B., Lobb, E. A., Kelly, P. J., Barlow-Stewart, K., Kirk, J. A., … Tucker, K. M. (2011). Are videoconference consultations as effective as face-to-face consultations for hereditary breast and ovarian cancer genetic counseling? *Genetics in Medicine*, *13*, 933–941. doi: 10.1097/gim.0b013e3182217a19