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Evaluating Effects of Cancer Genetic Counseling on Several Brief Patient Impact Measures

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Evaluating Effects of Cancer Genetic Counseling on Several Brief Patient Impact Measures

by

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TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

ABSTRACT

Many outcomes for assessing cancer genetic counseling (GC) utility have been proposed, with few studies evaluating multiple, theory-based, brief patient-reported experience and outcome measures simultaneously as part of a single study. We conducted a pilot study in which patients seen for pre-test cancer GC took a survey before and after their GC session to evaluate the session's impact on multiple patient impact measures and assess the relationship between these measures. Measures based on the self-determination theory (SDT) assessed three basic needs including: 1) perceived autonomy support, 2) relatedness to the provider, and 3) competence to make a decision. SDT posits that when these three basic needs are met, patient-reported outcomes should improve. Thus, we also assessed the following patient-reported outcomes: 1) knowledge specific to informed consent for panel testing, 2) decisional empowerment/decisional conflict (using the SURE checklist) and 3) general 'empowerment' (using the Genomic Outcomes Scale). Following GC, significant improvements were found in patient competence, knowledge, and both measures of empowerment. Post session competence and perceived autonomy support were significantly correlated to decisional empowerment, while relatedness to the provider was not. The two empowerment measures were not significantly correlated with one another. These findings confirm previous findings of pre-test GC service utility and provide evidence that a patient experience measure (autonomy support from the GC) is positively related to patient-reported outcomes. Findings also confirm that general empowerment and empowerment to make a decision are different and unique constructs.

INTRODUCTION

Data on the impact of genetic counseling (GC) could help in supporting GC licensure, insurance coverage of services, and service delivery optimization (Adam et al., 2018; *H.R. 7083—"Access to Genetic Counselor Services Act" and Medicare*, 2019; R. G. Resta, 2018; Zierhut et al., 2016). Studies have found that GC can improve various short-term patient reported measures such as knowledge, empowerment, and decisional conflict (Adam et al., 2018; Athens et al., 2017; Berkenstadt et al., 1999; Ferron Parayre et al., 2014; Gremigni et al., 2008; Madlensky et al., 2017; M. McAllister et al., 2011; M. McAllister & Dearing, 2015; Yuen et al., 2020).

Most prior studies of GC outcomes have focused on a small number of measures and each is often too lengthy to be routinely implemented into practice (Grant et al., 2018; M. McAllister et al., 2011). One recent study assessed the impact of cardiovascular GC on knowledge and general empowerment (measured by the GC Outcomes Scale)(Ison et al., 2019) and studies have evaluated the impact of psychiatric GC using the GC Outcomes Scale and a measure of self-efficacy (Illness Management Self Efficacy Scale – IMSES) (Inglis et al., 2015; Morris et al., 2019; Slomp et al., 2018). However, the GC Outcomes Scale is still relatively lengthy (24 questions) and challenging to use alongside multiple other measures in a fast-paced clinical setting. A short version of the GC Outcomes Scale (i.e., Genomic Outcomes Scale) was developed to measure overall empowerment related to genetic risk (Grant et al., 2018). However, it is not known whether scores on this measure relate to other measures.

A recent study of patients referred for cancer GC showed significant gains in knowledge and feeling fully informed and empowered to make a decision after viewing an online educational tool prior to counseling (Cragun et al., In press). Additional research is needed to differentiate between the relative

impacts of alternative educational interventions and in person cancer GC and to better understand how the experience patients have with GC may relate to multiple patient-reported outcomes.

The application of theory may help in evaluating relationships between the patient experience and patient-reported outcomes. Self-determination theory (SDT) posits that three constructs (autonomy support, relatedness to the provider, and competence) are needed to empower individuals with intrinsic motivation to take action (Ryan & Deci, 2000; *The Theory – selfdeterminationtheory.org*, 2020). This theory encompasses how both intrinsic and extrinsic factors interplay to influence an individual's motivation to pursue a behavior or a change. It has been previously used in a variety of studies in the healthcare setting to understand and promote factors leading to health behavior change (Gillison et al., 2019). It has specifically been used in the cancer setting to in order to better understand factors relating to support for cancer survivors (Leow et al., 2019).

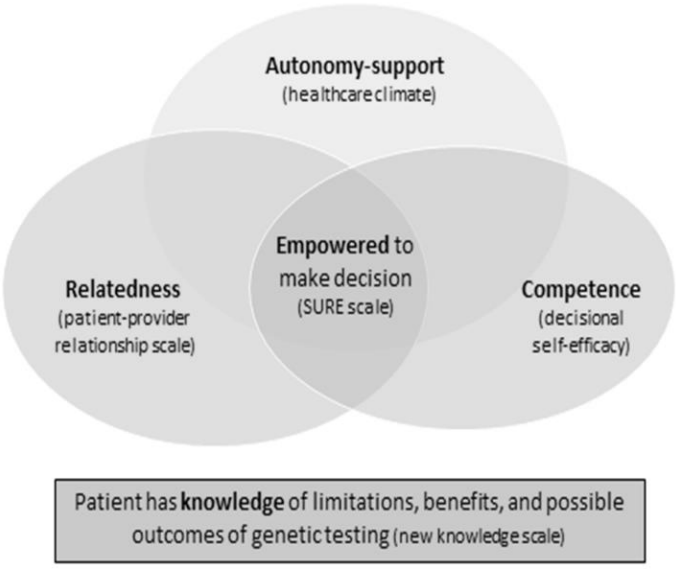

Figure 1. Proposed model for Self Determination Theory based selection of survey measures

In a cancer GC setting, we propose that the GC develops a working relationship with the patient and through shared decision making, they can influence the patient's feeling of autonomy support and competence (figure 1). Applying this theory to a GC session allows for theory-based selection of measures and development of a hypothesis for projected relationships between the measures. According

to this theory, we expect to see correlations between measures of relatedness, autonomy support, competence, and patient-reported outcomes.

The goals of this research are to evaluate multiple, theory-based, brief patient-reported experience and outcome measures simultaneously as part of a single study. For the purposes of this study, knowledge is defined as information related to informed decision making about hereditary cancer panel genetic testing, including the potential utility and limitations/risks of genetic testing. Perceived autonomy support is defined as whether the patient felt the provider included them in the decision-making process and supported their genetic testing decision. Relatedness to the provider refers to how well the patient felt that the provider understood them and their decision. Decisional competency was defined as the patient's self-confidence in their ability to make a genetic testing decision.

Empowerment has been defined by the creators of the GC Outcomes Scale as perceived or actual control and autonomy by an individual with regards to their life direction, including their decision making, knowledge and understanding, instrumentality (ability to identify and utilize resources), and future orientation (M. McAllister & Dearing, 2015; Marion McAllister et al., 2008). The general empowerment measured by the genomics outcomes scale is proposed to represent the patient's empowerment "state" and incorporates constructs proposed to comprise general empowerment such as perceived personal control, decisional conflict, and hope (Grant et al., 2018; M. McAllister et al., 2011). A more specific measure of empowerment used in this study is "decisional empowerment" as defined by a complete absence of decisional conflict (Cragun et al., In press). This information could help to promote development of a short measure that could be used as a tool to demonstrate quality of GC services.

METHODS

Participant Recruitment and Data Collection

Following IRB approval through the University of South Florida, we conducted a pre-post pilot study to measure several short-term GC outcomes. Participants were asked to take an anonymous 5-minute survey before and after a pre-test GC session. Potential participants (18 years or older and scheduled for their first GC appointment at a single academic cancer center) were identified, approached (just prior to their appointment), and given the opportunity to complete the pre-session survey. Instructions were given to retain the post-session survey and complete it either when the genetic counselor left the room to complete paperwork at the end of the appointment (if they chose to have testing) or immediately after the end of their session (if they did not elect to have testing). Participants were given instructions to place and seal the surveys in the provided privacy envelopes, and surveys were stored in a locked cabinet following collection.

Survey Development and Measures

Participants were asked on the pre-session survey to provide demographic information including age range, cancer status, ethnicity, education, and gender. Whether they chose to have genetic testing was also assessed on the post-session survey. The following short-term outcome measures and patient experience measures were selected based on Self-Determination Theory.

Applied Knowledge to Make a Decision (pre/post)

The desired knowledge was operationalized using a 10-question knowledge scale with questions about potential results as well as psychosocial, legal, and management implications of panel cancer genetic testing. This knowledge scale was previously used to evaluate an inherited cancer educational tool, though wording for a few items were simplified or altered slightly based on clinical GC feedback (Cragun et al., In press). Specifically, the word “most” was changed to “nearly all” (question 1) and the

word “usually” was removed from question 7, regarding 50% risk for inheritance among brothers and sisters. Given that the majority of patients are not international, the clarification of “in the United States” in the question regarding health insurance was removed as GCs felt the qualifying statement “in most cases” already included at the end of the question was sufficient (question 4). Finally, one question which talked about potential results was removed due to length and replaced with a more general statement addressing the potential for uncertainty with some genetic testing results.

Decisional Conflict/Decisional Empowerment (pre/post)

The 4 item SURE checklist has been previously validated in a healthcare setting (Ferron Parayre et al., 2014) and used here as it was in a recent study to assess whether or not patients lack decisional conflict (i.e., whether they felt fully informed and empowered to make a decision about cancer genetic testing) (Cragun et al., In press). The SURE checklist contains potential responses of “yes”, “no”, and “unsure”. Only individuals who selected “yes” for all four questions were counted as fully informed and empowered, other scores were interpreted as having relative degrees of decisional conflict about genetic testing.

Decisional Competency (pre/post)

Competency to make a genetic testing decision was assessed via a 4-item scale with acceptable to good inter-item reliability (Cronbach alpha = 0.731-0.883). Questions were modified based on the Center for Self Determination Theory Perceived Competence Scale, which has previously been adapted for use in other healthcare settings (Gremigni et al., 2008; *Health-Care Self-Determination Theory Questionnaire – selfdeterminationtheory.org*, 2020; *Perceived Competence Scales – selfdeterminationtheory.org*, 2020). The primary structure of each of the four questions was maintained but adapted to be appropriate to competence about making a genetic testing decision. Of note, the initial Likert scale ranged from 1 to 7, while the adapted version ranges from 1 to 5.

Perceived Autonomy Support (post)

An abbreviated 6 question Likert scale with good inter-item reliability (Cronbach alpha = 0.827) was created from the healthcare climate control questionnaire (*PAS – Health Care Climate –*

selfdeterminationtheory.org, 2020). This was adapted from the available 6-item version with the structure maintained but the subject adjusted to fit a GC provider in a pre-test scenario. Of note, the initial Likert scale ranged from 1 to 7, while the adapted version ranges from 1 to 5.

Relatedness to the Provider (post)

This was a 4 item scale with acceptable inter-item reliability (Cronbach alpha = 0.716) derived from an 8-item Patient-Doctor Depth of Relationship Measure (Ridd et al., 2011). Questions were adapted by substituting "doctor" for "provider" and making the 5-point response options consistent with the other Likert-scale questions in the survey.

General Empowerment (pre/post)

The Genomic Outcomes Scale has been proposed as a standardized method by which to measure empowerment related to genetic risk. It is a 6 question Likert scale with questionable to acceptable inter-item reliability (Cronbach alpha = 0.633-0.716). This measure was developed to be a short version of the GC Outcomes Scale (Grant et al., 2018) and the sole modification made for this study was to clarify that "condition" in this scenario refers to being born at an increased risk to develop cancer.

Data Analysis

Scale measures for each participant were calculated by averaging scores for the respective items measuring the SDT constructs of relatedness, autonomy support, and competence, as well as general empowerment (Genomic Outcomes Scale). Knowledge scores were calculated by assigning 1 point for each correct response with a maximum of 10 total points. Data were determined to be non-normally distributed if the skewedness value was >±2 or exact kurtosis was >±4 based on SPSS output (Byrne, 2010; George & Mallery, 2010; Hair et al., 2010). Post-session competency and perceived autonomy support were non-normally distributed and thus medians and ranges were calculated. For all other measures, means and standard deviations were calculated.

Paired sample t-tests were used to assess changes in pre versus post-session scores for general empowerment and knowledge. Effect sizes were calculated as Cohen's d (pooled) for repeated sample t

test. Wilcoxon Signed Rank Test was used to assess changes in median pre-post session scores for competency to make a genetic testing decision. Effect sizes were calculated by dividing the test statistic z by the number of individuals with pre and post session survey completion for that measure.

For SURE checklist data, frequencies of individuals who were fully informed and empowered to make a decision about genetic testing (scored 4 out of 4) were calculated. A McNemar test was used to assess for pre-post changes in the percentage fully informed and empowered to make a decision.

Spearman correlations were used to assess relations between SDT construct scores (post-session competency, perceived autonomy support, and relatedness) and outcome measures (post-test knowledge, general empowerment, and decisional conflict/empowerment as indicated by the raw scores on the SURE checklist). An additional Spearman correlation was conducted to assess for relationship between general empowerment and decisional conflict/empowerment as indicated by the raw scores on the SURE checklist. Data analyses were carried out in SPSS 25 and a p-value of 0.05 or below was used to delineate significance for all statistical analyses. Correlation size was interpreted based on standards for the field of psychology (Akoglu, 2018). Open-ended responses were collected, reviewed by the first author, and, grouped according to theme. Frequencies of themes were calculated.

RESULTS

During a 3-week period from January to February of 2020, a total of 68 individuals were approached for the study, 57 consented, and 53 completed at least a majority of both the pre and post session surveys (figure 2). The majority of participants fell between 50-70 years of age (56.6%), were female (66.0%), identified as white (84.9%), and had a current or previous cancer diagnosis (69.8%) with breast cancer being the most common (table 1). The participants saw one of six GC providers and 86.5% elected to proceed with genetic testing following their session.

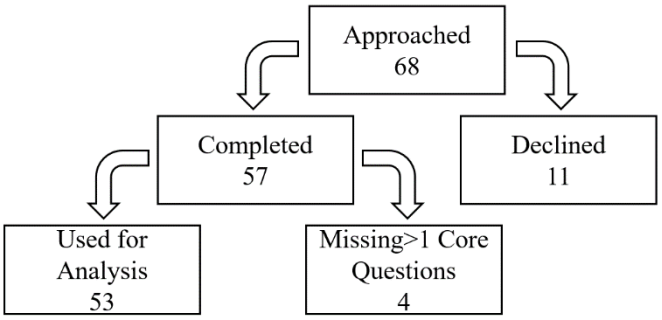

Figure 2. Flow diagram of participant completion of survey items

The median value for perceived autonomy support was 5.00 (N=52, range 3.38-5.00). The mean value for relatedness to the provider was 4.84 (N=53, SD=0.31).

Table 1. Patient Demographics

Gender (N=53)	n (%)
Male	18 (34.0%)
Female	35 (66.0%)
Age (N=53)	n(%)
18-29	2 (3.8%)
30-39	4 (7.5%)
40-49	5 (9.4%)
50-59	11 (20.8%)
60-69	19 (35.8%)
70-79	10 (18.9%)
80-89	2 (3.8%)
Race (N=53)	n(%)
White or Caucasian	45 (84.9%)
Black or African American	1 (1.9%)
Hispanic, Latino, or Spanish	5 (9.4%)
Prefer not to answer	2 (3.8%)
Educational Background (N=53)[1]	n(%)
High school or GED	7 (13.2%)
Some college	14 (26.4%)
Graduated college	20 (37.7%)
Completed postgraduate degree	11 (20.8%)
Other - Trade school 5 years	1 (1.9%)
Cancer Status (N=53)	n(%)
Never diagnosed with cancer	10 (18.9%)
Currently in remission	14 (26.4%)
Currently diagnosed with cancer	23 (43.4%)
Unclear or discrepant response	6 (11.3%)
Type of Cancer (N=60)[2]	n(%)
None	9 (15.0%)
Breast	17 (28.3%)
Ovarian	1 (1.7%)
Colorectal	4 (6.7%)
Prostate	2 (3.3%)
Pancreatic	10 (16.7%)
Other (Kidney, Melanoma, etc)	17 (28.3%)
Genetic testing choice (N=52)	n(%)
Testing ordered	45 (86.5%)

[1] One person indicated some college and other for education

[2] Some individuals indicated they had multiple cancers

There was a significant improvement in performance on the knowledge score from a mean of 3.86 to 6.74 out of a total of 10 with a large effect size ($t(49) = 7.584$, $p<0.001$, effect size =1.077) (table 2). Scores on the Genomic Outcomes Scale (to measure general empowerment) showed significant improvement from a mean of 3.68 to 4.04 out of 5 with a medium effect size ($t(52) = 3.114$, $p=0.003$, effect size = 0.428). Competency to make a decision about genetic testing also showed significant improvement with a medium effect size from a median of 5 to 5 from pre to post session surveys, respectively ($p=0.013$, effect size 0.422). Prior to the session, only 20.8% of participants indicated they felt fully informed and empowered to make a decision about genetic testing (table 3). This rose to 86.8% following the GC session ($p<0.001$).

Table 2. Significance testing for pre-post measures

Repeated Samples t Test

Variable	N	M_{pre}	SD_{pre}	M_{post}	SD_{post}	t	p
Knowledge	50	3.86	2.36	6.74	1.80	7.584	0.000
GOS	53	3.68	0.63	4.04	0.59	3.114	0.003

Wilcoxon Signed Ranks Test

Variable	N	$Median_{pre}$	$Range_{pre}$	$Median_{post}$	$Range_{post}$	Z	p
Competence	52	5	3.5-5.0	5	4.0-5.0	3.016	0.003

Table 3. McNemar test for frequency of decisional empowerment/decisional conflict

	Decisional conflict $present_{post}$	Decisional $empowerment_{post}$
Decisional conflict $present_{pre}$	7	35
Decisional $empowerment_{pre}$	0	11

Perceived autonomy support and post-session competence both showed moderate correlations with post-session performance on the SURE checklist (see table 4). Perceived autonomy support and post-session competency both showed weak correlations with post-session performance on the Genomic Outcomes Scale (see table 4). Relatedness was not significantly correlated with either post-session performance on the SURE checklist or Genomic Outcomes Scale (see table 4). None of the self determination theory constructs (perceived autonomy support, post-session competence, or relatedness) were significantly correlated with post-session knowledge scores. There was no significant correlation

between performance on the Genomic Outcomes Scale (to measure general empowerment) and post session SURE checklist performance (to measure empowerment to make a genetic testing decision).

Table 4. Spearman correlations for Self Determination Theory constructs with outcomes measures

Construct	Outcome	N	r_s	p
Post session competency	Post session SURE Checklist	52	0.404	0.003
Perceived autonomy support	Post session SURE Checklist	52	0.379	0.006
Post session competency	Post session Genomic Outcomes Scale	52	0.313	0.024
Perceived autonomy support	Post session Genomic Outcomes Scale	52	0.290	0.037
Relatedness	Post session SURE Checklist	53	0.221	0.112
Relatedness	Post session Genomic Outcomes Scale	53	0.186	0.182
Post session competency	Post session Knowledge Scale	51	0.140	0.327
Relatedness	Post session Knowledge Scale	52	0.087	0.541
Perceived autonomy support	Post session Knowledge Scale	51	0.026	0.857
Post session SURE Checklist	Post session Genomic Outcomes Scale	53	0.061	0.663

Response rate to the two open ended questions was 90.6 and 71.7%, respectively. The most frequent response themes for question 1 (which asked what they found helpful about their visit) included comments about the information/education provided, testing options and cost, implications for family, and appreciation for the clarity of the communication (including body language, eye contact, and verbal clarity). Frequent response themes for question 2 (which asked about things that could be improved) were that no changes needed, everything was sufficient (or better), or "N/A". Of note, some individuals indicated that being available (or continuing to be available) to answer questions and ensuring that more services like this one were provided would be the best way to be more helpful in the future (table 5).

Table 5. Common themes for open ended questions (by frequency of theme)

Question 1: What about your visit did you find most helpful?		
Theme	**% of total study participants**	**% of those who provided a response**
Information/education provided	52.8	58.3
Testing options and cost	29.2	26.4
Implications for family	17	18.8
Clear communication	17	18.8
Medical implications	9.4	10.4
Related to provider/provider support	9.4	10.4
Unclear response (illegable or didn't address question)	7.5	8.3
No response (missing)	9.4	N/A
Question 2: What could we do to be even more helpful in the future?		
Theme	**% of total study participants**	**% of those who provided a response**
Nothing, no changes, couldn't think of anything	24.5	34.2
Everything was sufficient (or better)	22.6	31.6
"N/A"	11.3	15.8
Be or continue to be available to answer questions	5.7	7.9
Make sure everyone receives this service	5.7	7.9
Unclear response (illegable or didn't address question)	3.8	5.3
No response (missing)	28.3	N/A

CONCLUSION

This pilot study identified multiple positive and significant impacts of GC services on short-term, patient-reported outcome measures including increases in knowledge, decisional empowerment, general empowerment, and decisional competency. The large significant impact that cancer GC showed on patient knowledge suggests that these cancer genetic counselors are effective at increasing knowledge that is important for making informed decisions about cancer panel testing.

A recently published study developed a 24 item knowledge scale (KnowGene) specific to cancer genetic panel testing, with questions similar to the knowledge scale utilized in this study (Underhill-Blazey et al., 2019). The KnowGene scale was validated in a general population of individuals but not applied to pre/post cancer GC sessions. Given the similarities in these two scales, it would be beneficial to test them both in the same patient population, though the length of the KnowGene scale is less pragmatic.

Other studies have found improvements in decisional conflict about genetic testing following GC (Christie et al., 2012; Green et al., 2004; Hunter et al., 2005; Madlensky et al., 2017). However, to our knowledge, this is the first time the SURE checklist has been used to assess the impact of pre-test GC. The percent who felt fully informed and empowered about whether to have genetic testing (i.e., lacked decisional conflict) after the GC session increased by 66%. The SURE checklist proved to be an easy to incorporate a 4-item measure that demonstrated sensitivity to change in a GC setting.

With regard to general or overall feelings of empowerment in the context of genetic service delivery, the GC Outcomes Scale (GCOS-24) has shown significant improvement in a variety of GC settings, (Inglis et al., 2015; Ison et al., 2019; M. McAllister et al., 2011; Morris et al., 2019; Slomp et al., 2018; Yuen et al., 2020), but none appeared to be limited to pretest cancer GC settings. Large effect sizes were reported ranging from 1 to 1.35 (Inglis et al., 2015; Morris et al., 2019; Slomp et al., 2018). The

GCOS-24 was designed to capture multiple empowerment related constructs such as perceived personal control, decisional conflict, and hope (M. McAllister et al., 2011). The 6 question Genomic Outcomes Scale was derived from the initial larger scale, with the creators drawing questions from each of the five sub-dimensions (cognitive, decisional and behavioral control, emotional regulation and hope) of the original scale (Grant et al., 2018). This multi-dimensionality is evident in the lower inter-item reliability (Cronbach alpha) reported in the current study. To our knowledge, this is the first time the Genomic Outcomes scale has been tested in a study focused on cancer pretest GC sessions with moderate changes identified in overall empowerment following GC.

As far as we are aware, perceived competency to make a genetic testing decision has not been previously assessed in a cancer GC setting. Although this study identified a significant improvement in competence following GC, many individuals scored high on perceived competency in both the pre and post settings and thus there was limited room for improvement and a possible ceiling effect for this measure. Variability on this scale may be improved in future studies by expanding the Likert scale options from 1 to 7 rather than 1 to 5.

Scores on perceived autonomy support and relatedness to the provider were also very high and demonstrated a likely ceiling effect with minimal variation (none scoring below a 4 on a 5-point scale). The prior study from which the relatedness scale was adapted also recognized that there could be a lack of sensitivity to change at the higher end of the spectrum (Ridd et al., 2011). Perceived autonomy support showed a slightly greater range of variability than relatedness to the provider, which may be due to the inclusion of 6 items in this autonomy support scale compared to 4 items in the relatedness measure. The initial scale to measure perceived autonomy support was developed on a Likert scale of 1 to 7 rather than 1 to 5 (*PAS – Health Care Climate – selfdeterminationtheory.org*, 2020). The high scores on relatedness and autonomy support suggests these genetic counselors are successful at key tenets in GC such as building rapport and supporting patient autonomy (Veach et al., 2007). The high frequency of responses showing connection to the provider on the open-ended questions further reinforces the high relatedness

scores. Regardless, future work might consider whether increasing the range of the Likert scale SDT constructs from 1-7 rather than 1-5 to results in more variability or whether there is more variability across other genetics providers.

This study also found evidence of a possible relationship between certain patient experience measures from SDT and specific outcomes (figure 3). Results showed that competency to make a decision and perceived autonomy support were correlated to decisional conflict/empowerment while relatedness was not significantly associated with decisional empowerment (as measured by the SURE checklist). The most likely reason for this finding was insufficient variability on the relatedness measure, but findings were also limited by the relatively small sample size and a lack of sensitivity at the upper end of the relatedness scale. Alternatively, it may be that while the need for relatedness was met, relatedness is not the construct making a difference in whether the patient is empowered to make a decision.

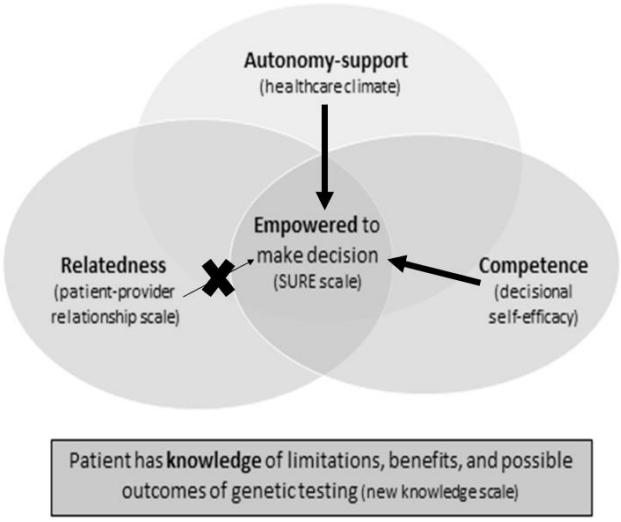

Figure 3. Implications of results for potential relationships in proposed Self Determination Theory model

When the relationship between the SDT constructs and general empowerment (measured by the Genomic Outcomes Scale) were assessed, a similar pattern was found. Perceived autonomy support and post-session competence were significantly correlated (albeit more weakly) than with decisional conflict/empowerment, and relatedness was not significantly correlated. Again, this could be due to the same limitations cited above. No significant correlations were identified between the self determination

theory constructs and patient knowledge after GC. This could be because these constructs are not directly making the difference in whether the patient is able to acquire knowledge.

The findings of this study align with the FOCUS-framework, in which certain patient care experiences (i.e., autonomy support) influences certain outcomes (i.e., decisional conflict/empowerment and general empowerment, but not knowledge) (Cragun & Zierhut, 2018).

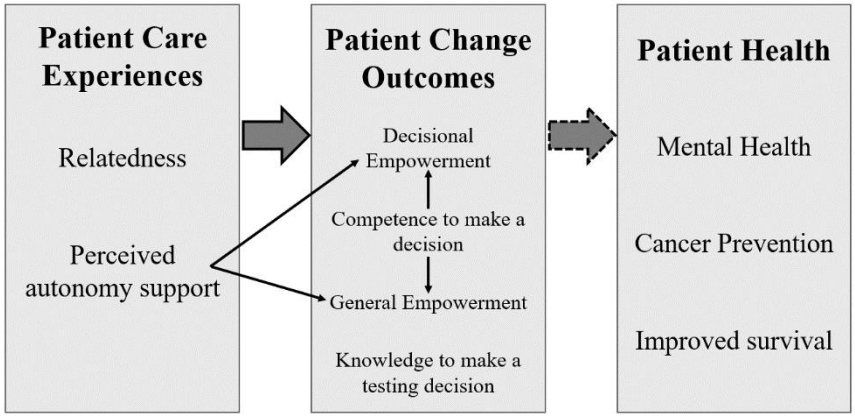

Figure 4. Synthesis of findings of the Self Determination Theory constructs with the FOCUS Framework

The lack of correlation between the SURE checklist and Genomic Outcomes Scale suggests what we anticipated, which is that they do not measure the same type of empowerment and are different constructs. The questions included in the Genomic Outcomes Scale focus on a patient who knows about a specific condition in their family, and their empowerment regarding how to adapt to that condition. The definition of GC specifies that it should help people both understand and adapt to genetic disease (R. Resta et al., 2006) but in the case of pre-test counseling the genetic risk is uncertain and thus the Genomic Outcomes Scale may be more useful in a post-results disclosure session once the genetic risks have been clarified. The SURE checklist assesses empowerment related to the genetic testing decision, which may explain it was more highly correlated with the patient experience measure of autonomy support.

Although the knowledge and SURE checklist have not previously been applied to a GC setting, a recent study assessed how an online educational tool impacted cancer patient's knowledge and decisional empowerment using the original knowledge scale from which this study's scale was derived as well as the

SURE checklist (Cragun et al., In press). Both that study and this study identified a significant increase in patient knowledge, with end knowledge of the educational intervention vs in person GC equal to medians of 8 and 7 respectively. The slightly higher knowledge score with the educational intervention could be attributed to the fact that the educational intervention was designed to match the knowledge questions while the counselors did not receive additional training to cover the material assessed by the questions and they may tailor a session differently for each patient. Alternatively, the changes in wording could have impacted the results, though this is less likely because pre-intervention scores were similar in both studies (median of 4 in Cragun et al and the current study).

Both studies also identified a significant improvement in decisional conflict/empowerment, although the proportion who felt fully informed and empowered to make a decision reached 86.8% in the current study as opposed to only 70% for the educational tool. Notably, patient empowerment scores also started lower for this study as opposed to Cragun et al (20.8% versus 25%, respectively), demonstrating a greater overall improvement. This suggests that the use of educational interventions could be beneficial in providing patients with knowledge, but that in person GC may be preferential and perhaps necessary for some patients to feel fully informed and empowered to make a genetic testing decision and the autonomy support that GCs provide may be contributing to decisional conflict/empowerment (although correlation between these measures may not be causal).

In addition to the inability to conclude causal relationships between the measures in our study, there were several other limitations including standard limitations of a pre-post design with no control group. However, there are unlikely to be significant confounding factors that would influence the post-session results given the short interval between the pre and post surveys. Furthermore, we do not have reason to believe that the pre-session survey had substantial influence on post-session knowledge because the study by Cragun et al found no significant differences in post-test knowledge when randomizing some to a post-test only arm. Results may not be generalizable to all patients, especially given that the providers opted not to approach a few patients with end stage disease, who could have theoretically performed

differently on the surveys. Furthermore, many participants had post-graduate education with little racial/ethnic diversity. Finally, the small sample size inherent to a pilot study may have limited the statistical power available for some correlations. Due to the limited sample size, corrections for multiple statistical tests and for variability due to inclusion of multiple counselors was not considered.

To our knowledge, this is one of few studies that has assessed multiple pragmatic impact measures selected based on theory and our completion rate was high with 77.9% of those approached completing most the survey (those missing only 1 core question were included). The ability to incorporate multiple brief measures into a 5-minute survey with high completion rates will be crucial moving forward to measure GC utility. We were able to incorporate this survey into the clinical flow without significant limitation to clinical functioning, demonstrating feasibility of this approach. This offers a unique perspective on which impact measures are correlated with one another, allowing us to better understand the pattern of impacts GC services may have on patients. By basing the selection of measures on the SDT, we were able to evaluate whether the pattern of impacts genetic counselors align with the theory-based expectations.

Future research should focus on a larger scale study in order to allow for additional analyses and verification of the patterns of relationships between impact measures and assess variability across genetic counselors. Other potential areas for analysis include translation of the survey materials into other languages to capture a broader population as well as the application of the surveys to compare relative impact by a variety of other providers (GC assistants, oncologists, etc). Ultimately the field of GC could benefit from a brief pragmatic survey to measure the quality and utility of GC services as well as capture a variety of impacts GC may have on patients.

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