Assessment of a Glossary on Patient Satisfaction and Anxiety Levels in an Oncology Genetic Counseling Clinic

by

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ABSTRACT

Patients who attend genetic counseling appointments report high anxiety and varied satisfaction levels following their appointments. It has been suggested in previous literature that some of the increase in anxiety and reduction in satisfaction is caused by lack of prior information. Here, I investigated whether providing patients with a glossary of genetic terms prior to their counseling appointment improves patient satisfaction and reduces anxiety in an oncology genetic counseling appointment. I surveyed 96 patients attending their first genetic counseling appointment at Banner MD Anderson Cancer Center and analyzed 92 patients for which I had complete data. Patients were randomly selected to receive one of two folders, containing either an educational document or an educational document and a glossary comprised of ten genetic terms. Each patient was given a post-counseling survey at the end of the counseling appointment to assess their anxiety and satisfaction levels. I did not observe a statistically significant difference in levels of anxiety or satisfaction, but the data are consistent with increased satisfaction for patients who received a glossary. Interesting, the data are also consistent with decreased anxiety levels for patients who did not receive a glossary. Furthermore, I did observe differences in reported satisfaction with patients who had college experience and patients that did not have any college experience.

Key words: Anxiety, Satisfaction, Genetic Counselors, Genetic Counseling

DEDICATION

I would like to dedicate this research to my late grandfather Luis Manuel Peon and my family. They love me unconditionally and motivate me each day to pursue my dreams.

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TABLE OF CONTENTS

Page

APPENDIX

LIST OF TABLES

INTRODUCTION

As a field, medical genetics has attracted the attention of the general population; however, the complex topics and scientific jargon make it particularly difficult for the average person to understand. Due to the increasing use of, and interest in, personalized genetics such as 23andMe, Ancestry DNA and patient’s own family histories, individuals who can explain genetic testing results (i.e. genetic counselors) have risen in demand. Genetic counseling helps people to understand their family’s risks to genetic disorders by educating patients about their family history, testing options, and, if needed, prevention, resources and types of management of illnesses (Resta et al., 2006). Oncology genetic counseling is a subspecialty in the genetic counseling field that focuses on the identification and management of inherited cancer risks (Motulsky et al., 1994; Schild, 1979).

Prior research has shown that patients’ satisfaction and anxiety levels in a genetic counseling appointment are impacted by the uncertainty and lack of education (Motulsky et al., 1994). Anecdotal evidence here in Arizona shows that confusion about the counseling appointment, including its purpose and goal, can naturally occur since educational materials are not consistently given to patients prior to a counseling appointment (Phoenix/Tucson Genetic Counselors). Previous studies note that the uncertainty and lack of education can be fixed by providing patients with educational materials prior to a genetic counseling appointment to allow patients to prepare and to know what to expect during their counseling appointment (Motulsky et al., 1994; Hallowell et al., 1997).

Due to the general population’s lack of experience with genetic counseling and genetic terminology, anxiety can often be an unintended consequence of a genetic counseling appointment (Motulsky et al., 1994; Chapple et al., 1997). Specifically, regarding genetics, patients who hear terminology they have not heard before – such as “mutation”, “defect” or “syndrome” – may associate these words with alarming images causing them to view themselves as imperfect or flawed in some way. (Chapple et al., 1997; Motulsky et al., 1994). Hearing words, that have a traditionally negative connotation with no context may cause patients to view themselves as defective or sick, which can in turn increase levels of anxiety (Chapple et al., 1997; Motulsky et al., 1994; Kessler, 1979). Also, studies have shown that increased levels of anxiety during a counseling appointment could lead to limited retention of the genetic information provided (Motulsky et al., 1994; Childs, 1976; Kessler, 1989). Elevated levels of anxiety during a counseling appointment could cause confusion and lead to poor decisions (Motulsky et al., 1994; Chapple et al., 1997). Additionally, people who have not taken a biology class or reached higher levels of education (e.g. high school) may feel vulnerable throughout the counseling appointment due to difficulties communicating with the genetic counselors (Chapple et al., 1997). Although genetic counseling caters to patients of all educational backgrounds, patients experience elevated levels of anxiety during these appointments which may be due to unfamiliarity with the content (Motulsky et al., 1994; Biesecker, 1992). This anxiety can also be attributed to patients having to deal with complex information while also being confronted with issues that can be frightening and sensitive (Motulsky et al., 1994; Chapple et al., 1997).

Patient satisfaction during an oncology consultation may naturally vary when a patient does not receive the news or results they were expecting (Motulsky et al., 1994). However, even amid unwelcome news, the way information is being delivered may impact a patient’s satisfaction (Motulsky et al., 1994; Chapple et al., 1997; Shiloh & Saxe, 1989). One study showed that providing more medical information during a counseling appointment may lead to lower satisfaction – possibly due to the patient being overwhelmed by unwelcome or extraneous information or the need for a patient to ask more questions to get the information they expected to receive (Pieterse et al., 2007). However, the same study found that more information can improve patients knowledge and recollection (Pieterse et al., 2007). Contrasting this study, three other studies stated that receiving more information led to increased levels of satisfaction (Hallowell et al., 1997; Motulsky et al., 1994; Chapple et al., 1997). These conflicting data between too much information, too little information, and the way the information is being delivered can contribute to limited retention and comprehension of information provided during a counseling appointment and overall patient satisfaction (Motulsky et al., 1994; Chapple et al., 1997; Shiloh & Saxe, 1989).

Studies have shown that if patients are not given enough information about a counseling appointment, symptom, or test, they may try to do additional research at home to answer their questions (Sorenson et al., 1981; Motulsky et al., 1994; Chapple et al., 1997; Roche & Skinner, 2009). Unfortunately, individual household web searching does not give patients a boundary as to what information is important for their own case, often leading to information that is irrelevant, confusing, and alarming (Roche & Skinner, 2009). This leads to confusion during a counseling appointment when the patient’s own research differs from what the medical professional tells them (Roche & Skinner, 2009; Chapple et al., 1997; Motulsky et al., 1994). Patients admit that they are likely to develop their own bias toward information given to them in the counseling appointment based on what they themselves have discovered in other resources which can further impact their anxiety or satisfaction levels (Roche & Skinner, 2009; Chapple et al., 1997). Additionally, this internet-based education may persuade more patients to not see a genetic counselor, as they feel fully informed (Sorenson et al., 1981; Motulsky et al., 1994). However, if information was given to these patients in advance, it might curb their desire to perform their own research or guide them to better places of research.

Beyond research looking at how information or lack of information influences patient anxiety and satisfaction levels, previous studies have also shown a general demand for providing patients with educational materials prior to a genetic counseling appointment (Hallowell et al., 1997). Patients prefer to have information before a counseling appointment to better prepare for what to expect (Hallowell et al., 1997). Additionally, one study showed that women felt they were inadequately prepared and did not know what would happen during a counseling appointment (Hallowell et al., 1997). The same study mentions that patients who are unfamiliar with the process of genetic counseling may feel limited and unable to ask questions, making them feel inadequately prepared (Hallowell et al., 1997). The study suggests that providing patients with written information about what will occur during their consultation, possible topics that could be discussed in a consultation, as well as some facts about cancer can help them feel more prepared (Hallowell et al., 1997). Other studies state that receiving written information prior to a consultation can help reduce anxiety and increase patient satisfaction levels (Hallowell et al., 1997; Austoker & Ong, 1994; Gibbs & George, 1990). Previous studies have focused on educational materials in the form of pamphlets and print materials specializing in genetic testing, BRCA1 and BRCA2 (Cho et al., 1997; Schwartz et al., 2001). However, studies focusing on the use of a glossary are limited and hard to find. Therefore, a glossary could be an appropriate solution.

Providing patients with a glossary containing genetics terms will hopefully help offer a preview of terminology typically used during a counseling appointment, giving patients an idea of what to expect during a counseling appointment and causing a decrease in anxiety and an increase in patient satisfaction levels with counseling appointments. Additionally, the introduction of a glossary could be a suitable alternative for providing prior information of generalized terminology that a patient may hear during a counseling appointment. We will explain more in-depth how patient experience affects anxiety and satisfaction levels in genetic counseling, the factors and instances that affect anxiety and satisfaction levels, and what we propose as a solution.

HYPOTHESES

We used a post-counseling survey to assess anxiety and satisfaction levels in patients attending a cancer genetic counseling appointment (DeMarco et al., 2004, Marteau, 1992, Tluczek, et al., 2009, Julian, L. J., 2011). We hypothesize that implementing a glossary prior to a patients’ genetic counseling appointment results in a difference in anxiety or satisfaction levels for the experimental group. We predict that patients in the experimental group will report higher mean Likert responses for the satisfaction survey questions. Additionally, we predict that patients in the experimental group who receive a glossary prior to their counseling appointment will report higher mean Likert responses for the three positive anxiety traits if they are not anxious and lower mean Likert responses for the three negative anxiety traits if they are not anxious. These predictions are founded on the idea that patients who see a genetic counselor do not know what is expected from the counseling appointment, causing patients to feel anxious and dissatisfied (Pieterse et al., 2005; Pieterse et al., 2007; Motulsky et al., 1994). The feeling of being informed could possibly make patients feel less anxious and more satisfied (Hallowell et al., 1997; Pieterse et al., 2005; Motulsky et al., 1994).

METHODS

Patients

We recruited patients from the Oncology Genetic Counseling department at Banner MD Anderson Cancer Center (BMDACC) in Gilbert, Arizona. We included patients who were English speaking, 18 years or older and were attending an initial genetic counseling appointment. There was a total of 96 patient participants in this study, all of which we obtained informed consent (Appendix A). Additionally, this was a single-blind study where the research team collectors knew which patients received a glossary and which patients did not, but the counselors did not. This removed the possibility of subjective bias from counselors. Patients were given a folder that was assigned with either number 1 or 0. Folders assigned number 1 contained a glossary and folders assigned 0 did not contain a glossary.

Intervention

This study implemented a glossary containing genetic terminology as an intervention. We collected terms from materials that cancer genetic counselors in the Phoenix/Tucson area sent to the research team. We chose the terms based on the frequency of use during a standard genetic counseling appointment or by the suggestion of the Phoenix/Tucson genetic counselors. We pulled the definitions from the NHGRI "Talking Glossary" database (National Institutes of Health, 2018). A total of ten terms were implemented in the glossary: Cancer, DNA, Gene, Tumor Suppressor Gene, Mutation, Inherited, Autosomal Dominant, Family History, First Degree Relative, and Pedigree (Appendix B).

Instrument

To assess patient satisfaction and anxiety, we administered a survey by paper to patients after their initial genetic counseling appointment. We based this survey on the Genetic Counseling Satisfaction Scale (GCSS) and the shortened 6-item State-Trait Anxiety Inventory for adults (STAI-6) (DeMarco et al., 2004; Marteau & Bekker, 1992; Tluczek, et al., 2004). Both the GCSS and the STAI-6 are validated Likert scale questionnaires- consisting of six questions each- where the GCSS assesses patient satisfaction and the STAI-6 assesses patient anxiety levels (DeMarco et al., 2004; Marteau & Bekker, 1992; Tluczek, et al., 2004). We chose the GCSS and the STAI-6 based on their routine use in this field of study and their rigorous validation (DeMarco et al., 2004; Marteau & Bekker, 1992; Tluczek, et al., 2004; Julian, 2011). We also included two additional socio-demographic questions (education and income levels) in the survey. This led to a total of 14 questions on the post-counseling survey (Appendix C). We further collected demographic data from patient electronic medical charts: race, ethnicity, age, education level, cancer status, cancer type, income level, marital status and gender (Table 1).

Procedure

Upon arrival, a patient's consent was obtained following a script (Appendix D). Each patient was randomly given one of two folders, based on a computerized random number generator. One group, the experimental group, was given a packet containing a glossary (Appendix B) and an educational document about genetic counseling (Appendix E) to read. The second group, the control group, was given a packet containing only the educational document (Appendix E). Patients were given approximately five minutes to review the packet before it was collected from them. Patients then participated in a standard genetic counseling appointment performed by one of two genetic counselors at BMDACC, Counselor A or Counselor B. While most patients attended counseling appointments with just the genetic counselor, some patients were counseled by a genetic counseling second-year student alongside one of the two above certified genetic counselors. Other patients had students observing the counseling appointments; however, these students did not counsel the patients. At any given time, there was only one extra individual in addition to the genetic counselor, the patient, and the patient's family in the consultation rooms during the counseling appointment. At the end of the counseling appointment, each patient was given a post-counseling survey by one of two students, Collector A or Collector B (Appendix C), both of whom are part of the research team. Patients filled out surveys, without any genetic counseling provider, counseling student or counseling observer being present. Once the post-counseling survey was filled out, there was no further participation required from the patient.

DATA ANALYSIS

Data collection took place over a total of six months (mid-July 2017 through mid-January 2018). We analyzed the satisfaction and anxiety survey responses using the R statistical computing environment, implemented in RStudio (Rstudio Team, 2015; R Core Team, 2013). There was no need to perform a normality test or equal variance test because of the non-normal distribution nature of Likert Scale responses; the Likert scales are bound from 1 to 5 (satisfaction Likert scale) and 1 to 4 (anxiety Likert scale) answer options (Norman, 2010; Kamran, 2018; Mangiafico, 2016; Levene, 1960). For the 1 to 5 satisfaction scale, 1 is associated with, "Strongly Disagree," with the question presented and 5 is associated with, "Strongly Agree," with the question (Appendix C). For the 1 to 4 anxiety scale, 1 is associated with feeling, "Not at all," like the question and 4 is associated with feeling, "Very Much," like the question (Appendix C). The 1 to 5 and 1 to 4 restricted boundaries are discrete (Norman, 2010; Mangiafico, 2016). Since the aim was to compare the groups' means of the experimental and the control group, we used a Welch two-sample t-test, also known as unequal variance test (Lu & Yuan, 2010; Welch, 1947). It has been shown that Likert scale data can be tested with parametric tests (i.e., t-tests) and that parametric tests are more robust than non-parametric tests (e.g., Mann Whitney U test) (Sullivan & Artino, 2013). Parametric tests are further recommended when performing analysis on patient satisfaction (Sullivan & Artino, 2013). Our data met the Welch t-test unequal variance assumption, and even though it did not meet the unequal sample size or normality assumption, this test is preferred over the Mann Whitney U Test that ranks differences as opposed to the group mean differences (Lani, 2013).

RESULTS

Patient Characteristics

Demographic information revealed an underrepresentation of minorities: 8.6% of the patients identified as a race other than White and 9.7% identified as Hispanic (Table

1). The minority data in this study was too small to further analyze. Patient ages ranged from 21 to 87, with a mean age of 55. The data consisted of 80.4% females and 19.5% males.

Patient Characteristic: Annual Household Income Status

Across all six anxiety questions and six satisfaction questions, at a significance level of 0.05, there was no difference between the group of patients who make greater than $75,000 and the group of patients that make less than $75,000 a year (Table 2)

Patient Characteristic: Education Level

At a significance level of 0.05, we found a difference in responses to satisfaction questions S3 and S4 between the group of patients who had college experience and the group of patients who had no college experience (Table 3). For questions S3 and S4, the group of patients who had no college experience reported a higher satisfaction mean Likert response (Table 3). We found no difference in anxiety levels between the group of patients who had college experience and the group of patients who had no college experience.

Patient Characteristic: Cancer Status

Across all six anxieties and six satisfaction questions, at a significance level of 0.05, there was no difference between the group of patients who are affected with cancer and the group of patients who are unaffected with cancer (Table 4).

Anxiety Survey Questions

Across all six anxiety questions, at a significance level of 0.05, there was no difference between the control group that did not receive a glossary and the experimental group that did receive a glossary (Table 5).

Satisfaction Survey Questions

Across all six satisfaction questions, at significance level 0.05, we found a difference for question S1 between the experimental group that received a glossary and the control group that did not receive a glossary (Table 6). The experimental group that received a glossary reported a higher satisfaction mean Likert response (Table 6). We found no difference in satisfaction levels between the control group that did not receive a glossary and the experimental group that did receive a glossary for questions S2-S6 (Table 6).

Table 1. Patient Characteristics. Patient demographics are presented below including all data collected from patients' charts: race, ethnicity, age, education level, cancer status, cancer type, annual household income, marital status and gender.

Characteristics	Total (N=92)
Gender	
Males	18
Females	74
Age Range	21-87
Mean Age	55
Intervention	
Glossary Group	53
No Glossary Group	39
Annual Household Income	
>$75,000	53
<$75,000	39
Cancer Status	
Affected Status	59
Unaffected Status	33
Ethnicity	
Hispanic/ Latino	9
No Hispanic/Latino	83
Education Level	
8th grade	1
High School	11
Partial College	26
College Graduate	27
Professional Degree	27
Marital Status	
Married	63
Divorce	8
Single	16
Widowed	4
Unknown	1
Race	
White	84
Black	1
Asian	3
Middle Eastern	2
Native American	1
Other	1

Table 2. Mean Likert Response for Responses for patient characteristics of annual household income status on patient's anxiety and satisfaction levels. The mean differences between patients who made greater than $75,000 a year and patients who made less than $75,000 based on the 12 satisfaction and anxiety survey questions asked are reported, along with p-values from a Welch's t-test.

	Question	**Mean for <$75,000**	**Mean for >$75,000**	***P-value***
A1	I feel Calm	3.41	3.53	0.4863
A2	I feel Tense	1.56	1.36	0.1689
A3	I feel Upset	1.15	1.19	0.7444
A4	I feel Relaxed	3.15	3.26	0.6165
A5	I feel Content	3.28	3.32	0.8507
A6	I feel worried	1.59	1.60	0.9347
	Question	**Mean for <$75,000**	**Mean for >$75,000**	***P-value***
S1	My genetic counselor seemed to understand the stresses I was facing	4.82	4.85	0.8465
S2	My genetic counselor helped me to identify what I needed to know to make decisions about what would happen to me	4.49	4.40	0.7528
S3	I felt better about my health after meeting with my genetic counselor	4.62	4.30	0.08346
S4	The genetic counseling session was about the right length of time I needed	4.82	4.85	0.8439
S5	My genetic counselor was truly concerned about my well-being	4.82	4.89	0.6252
S6	The genetic counseling session was valuable to me	4.90	4.85	0.35996

Table 3. Mean Likert Response for Responses for patient characteristics of education level on patient's anxiety and satisfaction levels. The mean differences between patients who had college experience and patients who had no college experience based on the 12 satisfaction and anxiety survey questions asked are reported, along with p-values from a Welch's t-test.

	Question	**Mean for College Experience**	**Mean for No College Experience**	***P-value***
A1	I feel Calm	3.50	3.33	0.6124
A2	I feel Tense	1.46	1.33	0.4376
A3	I feel Upset	1.19	1.08	0.325
A4	I feel Relaxed	3.21	3.25	0.9205
A5	I feel Content	3.33	3.17	0.647
A6	I feel worried	1.61	1.50	0.6565
	Question	**Mean for College Experience**	**Mean for No College Experience**	***P-value***
S1	My genetic counselor seemed to understand the stresses I was facing	4.84	4.83	0.9822
S2	My genetic counselor helped me to identify what I needed to know to make decisions about what would happen to me	4.45	4.33	0.8092
S3	I felt better about my health after meeting with my genetic counselor	4.39	4.75	**0.03789**
S4	The genetic counseling session was about the right length of time I needed	4.81	5	**0.0212**
S5	My genetic counselor was truly concerned about my well-being	4.85	4.92	0.5529

Table 4. Mean Likert Response for Responses for patient characteristics of cancer status on patient's anxiety and satisfaction levels. The mean differences between patients who are affected with cancer and patients who are unaffected with cancer based on the 12 satisfaction and anxiety survey questions asked are reported, along with p-values from a Welch's t-test.

	Question	**Mean for Affected**	**Mean for Unaffected**	***P-value***
A1	I feel Calm	3.49	3.45	0.8274
A2	I feel Tense	1.34	1.64	0.07164
A3	I feel Upset	1.17	1.18	0.9149
A4	I feel Relaxed	3.27	3.12	0.5116
A5	I feel Content	3.24	3.42	0.349
A6	I feel worried	1.56	1.67	0.5554
	Question	**Mean for Affected**	**Mean for Unaffected**	***P-value***
S1	My genetic counselor seemed to understand the stresses I was facing	4.85	4.82	0.8532
S2	My genetic counselor helped me to identify what I needed to know to make decisions about what would happen to me	4.36	4.58	0.4331
S3	I felt better about my health after meeting with my genetic counselor	4.41	4.48	0.6663
S4	The genetic counseling session was about the right length of time I needed	4.85	4.82	0.8473
S5	My genetic counselor was truly concerned about my well-being	4.85	4.88	0.8273
S6	The genetic counseling session was valuable to me	4.90	4.82	0.5995

Table 5. Mean Likert Response for Responses to Anxiety Survey Questions. The mean differences for the experimental that received the glossary versus the control group that did not receive a glossary based on the six anxiety survey questions asked are reported, along with p-values from a Welch's t-test.

	Question	**Mean for Terms**	**Mean for No Terms**	***P-value***
A1	I feel Calm	3.47	3.49	0.9258
A2	I feel Tense	1.43	1.46	0.8518
A3	I feel Upset	1.19	1.15	0.7510
A4	I feel Relaxed	3.06	3.44	0.0702
A5	I feel Content	3.16	3.51	0.0551
A6	I feel worried	1.60	1.59	0.9347

Table 6. Mean Likert Responses for Responses to Satisfaction Survey Questions. The mean differences for the experimental group that received a glossary versus the control group that did not receive a glossary based on the six satisfaction survey questions asked and p-values from a Welch's t-test.

	Question	**Mean for Glossary**	**Mean for No Glossary**	***P-value***
S1	My genetic counselor seemed to understand the stresses I was facing	4.98	4.64	**0.0438**
S2	My genetic counselor helped me to identify what I needed to know to make decisions about what would happen to me	4.58	4.23	0.2397
S3	I felt better about my health after meeting with my genetic counselor	4.54	4.28	0.1680
S4	The genetic counseling session was about the right length of time I needed	4.96	4.66	0.0712
S5	My genetic counselor was truly concerned about my well-being	4.96	4.71	0.1090
S6	The genetic counseling session was valuable to me	4.92	4.79	0.3924

DISCUSSION

We did not detect a significant difference in patients' anxiety or satisfaction levels for the experimental group who received a glossary versus the control group that did not receive a glossary. Additionally, we did not detect a difference in patients' anxiety or satisfaction levels for patients' annual household income status, cancer status and patients' levels of education.

Participant Characteristics: Gender, Race and Ethnicity

Our sample was skewed toward patients who were white, married and had post-high school education (Table 1). Also, our sample consisted of patients who were largely not Hispanic or Latino, made greater than $75,000 for their annual household incomes, were diagnosed with cancer and were mainly females (Table 1). There were few non-white individuals in our dataset, and so we did not analyze by reported race; underrepresentation in our sample set could have been a result of barriers related to income, insurance, education, language or community awareness of genetic counseling (Culver et al., 2001; Schwartz et. al, 2001; Cooper, 1990; Allford et al., 2014). We had a higher participation rate of women than men, but as we did not collect the number of people who did not consent to participate, we do not know whether this was a participation bias. Typically, women tend to take more health precautions with cancer screenings and have prior knowledge of mainstream genetic terminology that increases their interest (Brain et al., 2002; Geller et .al 1999; Sach & Whynes, 2009), which could explain the overrepresentation of women in our dataset. We assessed patient satisfaction and anxiety levels for were patients based on annual household income status, levels of education and cancer status.

Patient Characteristic: Annual Household Income Status

Most of the sample consisted of individuals who made greater than $75,000 a year; 57.6% of the patients identified as making greater than $75,000 a year and 42.3% identified as making less than $75,000 a year (Table 1).We found that there were no differences between all six anxiety questions and all six satisfaction questions for the groups of patients that made greater or less than $75,000 a year (Table 2). These results are in the same direction as a previous study that found annual household income has no effect on patient satisfaction levels (DeMarco et al., 2004). Yet, we observed a trend, an observation in which there is a change developing toward a certain direction, in anxiety levels for questions A1, A4, A5, A6 where the group of patients that made less than $75,000 a year was more anxious than patients who made greater than $75,000 a year (Merriam-Webster, 2018; Table 2). Moreover, we found a trend in satisfaction levels, where patients who made greater than $75,000 were more satisfied with how the counselor helped them, felt better about their health, and thought their genetic counseling session was valuable to them (Table 2). However, these same patients reported less satisfaction for questions S1, S4, and S6 (Table 2). We did not a have an observed trend, for questions that had similar mean values for both groups (Table 2). There is no quantitative measure for a trend, therefore, a cutoff cannot be assigned.

Patient Characteristic: Education Level

Additionally, most of our sample consisted of individuals who had some post-high-school education; 86.9% of the patients identified as having had college experience and 13.0% of the patients identified as not having any college experience (Table 1). We tested for differences between patients who had college experience and patients who did not have any college experience. For education level, we found that the mean Likert response for satisfaction was significantly higher for questions S3 and S4 for patients who stated not having any college experience (p-value = 0.03789 and p-value 0.0212, respectively prior to a multiple test correction) (Noble, 2009) (Table 3). Our observations are in contrast with previous research that stated educated patients report higher levels of satisfaction (Hall & Dornan, 1990). Furthermore, our data did not match with the results of previous literature that reported that people who have not taken a biology class or reached higher levels of education (e.g. high school) feel vulnerable throughout a counseling appointment due to having difficulties communicating with genetic counselors (Chapple et al., 1997), increasing patient anxiety levels. In our sample, the analysis showed that patients' education levels did not affect their anxiety levels, though we may have been underpowered to detect such a difference (QFAB, 2018).

Patient Characteristic: Cancer Status

Most of our sample consisted of individuals with cancer, 64.1 % of the patients identified as being affected by cancer and 35.8% of the patients identified as being unaffected by cancer (Table 1). We tested whether there were differences in anxiety and satisfaction levels between patients who had a cancer diagnosis and those who did not have a cancer diagnosis. We found that there was no difference between being affected or unaffected with cancer across all six anxiety questions and all six satisfaction questions (Table 4). But, we did find a trend in increased anxiety, where patients who were affected with cancer were for the most part less anxious than patients who were affected with cancer (Table 4). There was one question, A2 (I feel content), where the group of patients that did have cancer was more anxious. Additionally, we found a trend in increased satisfaction levels for patients who were affected with cancer for questions

S1,

S4, and S6 (Table 4). However, this same group of patients also showed a trend of feeling less satisfaction for questions S2, S3, and S5(Table 4). We did not a have an observed trend, for questions that had similar mean values for both groups (Table 4). Our results were in the same direction as a previous study finding that there is no difference in affected or unaffected cancer status in patient satisfaction levels (DeMarco et al., 2004). However, our observations are in contrast with previous research that states patients who have cancer report higher levels of anxiety (Hamang et al., 2012). Our inability to detect a difference could be due to our studies small sample size and lower statistical power (QFAB, 2018).

Anxiety Survey

In this study, we tested whether the experimental group that received the glossary had less anxiety than the control group that did not receive the glossary. We found that there was no difference between the control and the experimental group across all six anxiety questions (Table 5). But we did find a trend for question A4 (I feel Relaxed) and A5 (I feel Content) where patients who received a glossary were more anxious than patients that did not receive a glossary (A4 p-value= 0.0702 and A5 p-value= 0.0551 respectively) (Table 5). Our results differed from studies that found, the feeling of being informed could possibly make patients feel less anxious and more satisfied (Pieterse et al., 2005; Pieterse et al., 2007; Motulsky et al., 1994). Ultimately, just like annual household income and cancer status, the lack of difference detected in the present study could stem from low statistical power and small sample size (QFAB, 2018).

Satisfaction Survey

We also tested whether individuals in the experimental group that received the glossary were more satisfied compared to those in the control group that did not receive the glossary. We found that the mean Likert response was significantly higher for the experimental group (mean = 4.98; Table 6) compared to the control group (mean = 4.64; Table 6) for question S1, indicating that the experimental group who received the glossary was more satisfied, when only this question was considered (Table 6). The difference for satisfaction question S1 is statistically significant with a p-value of 0.0438, but only prior to multiple test correction (Table 6). Just like education level, we did not perform this multiple test correction and if it had been done, the significant difference would no longer be present (Noble, 2009). This result difference was in the same direction as a previous study finding that being informed increased satisfaction levels (Hallowell et al., 1997; Motulsky et al., 1994; Chapple et al., 1997; Pieterse et al., 2005).

CONCLUSION

This study assessed the use of a glossary containing genetic terminology on patient satisfaction and anxiety levels in an oncology genetic clinic. We did not observe differences in patient satisfaction and anxiety levels. We suggest that future studies attempt similar analyses with a larger sample size, a longer collection period, and in different settings.

LIMITATIONS

There are several limitations of the current study design. First, we had a low sample size that prevented us from having the power to detect small effects of the intervention. Second, additional family members were present at the time the survey was administered, which may have influenced survey responses. Third, it is possible that biases could have unintentionally been introduced if patients indicated that they read the glossary or the educational document to the genetic counselor. Fourth, patients were not monitored while reading their educational materials, it is possible they did not read the entire glossary prior to their counseling appointment and did not gain the full potential benefit of the intervention. We feel that these limitations can be addressed in future studies.

FUTURE RECOMMENDATIONS

We strongly recommend that future studies use a larger sample size to assess the effect of this survey with better statistical power. Additionally, future studies could implement a pre-counseling survey of satisfaction and anxiety levels; this way an assessment could be made on their initial anxiety state as compared to their post-counseling anxiety state. It would also be interesting to analyze patients' understanding of educational material reviewed during a counseling appointment with the aid of the glossary. Lastly, another suggestion would be to further investigate transportation, accessibility, and other demographic factors such as race and ethnicity that could directly or indirectly affect a patient's ability to attend and their attitudes towards a genetic counseling appointment.

REFERENCES

Allford, A., Qureshi, N., Barwell, J., Lewis, C., & Kai, J. (2014). What hinders minority ethnic access to cancer genetics services and what may help?. *European Journal of Human Genetics*, *22*(7), 866.

Austoker, J., & Ong, G. (1994). Written information needs of women who are recalled for further investigation of breast screening: results of a multicentre study. *Journal of Medical Screening, 1*(4), 238-244.

Biesecker, B. 1992. (published in 1994). Issues in genetic counseling for prenatal diagnosis. In Fullarton, J., editor. (ed.) Proceedings of the Committee on Assessing Genetic Risks. Washington, D.C.: National Academy Press.

Brain, K., Norman, P., Gray, J., Rogers, C., Mansel, R., & Harper, P. (2002). A randomized trial of specialist genetic assessment: psychological impact on women at different levels of familial breast cancer risk. *British journal of cancer, 86*(2), 233.

Chapple, A., Campion, P., & May, C. (1997). Clinical terminology: anxiety and confusion amongst families undergoing genetic counseling. *Patient Education and Counseling, 32*(1), 81-91.

Cho, M. K., Arruda, M., & Holtzman, N. A. (1997). Educational material about genetic tests: does it provide key information for patients and practitioners?. *American Journal of Medical Genetics Part A, 73*(3), 314-320.

Childs, B., et al. 1976. Tay-Sachs screening: Motives for participating and knowledge of genetics and probability. American Journal of Human Genetics 28:537-49.

Cooper, P. S. (1990). The effects of ethnocultural background on access to and use of genetic services. Unequal opportunity. *Birth defects original article series, 26*(2), 46-48.

Culver, J., Burke, W., Yasui, Y., Durfy, S., & Press, N. (2001). Participation in breast cancer genetic counseling: the influence of educational level, ethnic background, and risk perception. *Journal of Genetic Counseling, 10*(3), 215-231.

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*(4), 293-304.

Geller, G., Doksum, T., Bernhardt, B. A., & Metz, S. A. (1999). Participation in breast cancer susceptibility testing protocols: influence of recruitment source, altruism, and family involvement on women's decisions. *Cancer Epidemiology and Prevention Biomarkers, 8*(4), 377-383.

Gibbs, S., Waters, W. E., & George, C. F. (1990). Communicating information to patients about medicine. *Journal of the Royal Society of Medicine, 83*(5).

Hall, J. A., & Dornan, M. C. (1990). Patient sociodemographic characteristics as predictors of satisfaction with medical care: a meta-analysis. *Social science & medicine, 30*(7), 811-818.

Hallowell, N., Murton, F., Statham, H., Green, J. M., & Richards, M. P. M. (1997). Women's need for information before attending genetic counselling for familial breast or ovarian cancer: a questionnaire, interview, and observational study. *Bmj, 314*(7076), 281.

Hamang, A., Eide, G. E., Rokne, B., Nordin, K., Bjorvatn, C., & Øyen, N. (2012). Predictors of heart-focused anxiety in patients undergoing genetic investigation and counseling of long QT syndrome or hypertrophic cardiomyopathy: a one year follow-up. *Journal of genetic counseling, 21*(1), 72-84.

Julian, L. J. (2011). Measures of anxiety: State-Trait Anxiety Inventory (STAI), Beck Anxiety Inventory (BAI), and Hospital Anxiety and Depression Scale-Anxiety (HADS-A). *Arthritis care & research, 63*(S11).

Kamran (https://stats.stackexchange.com/users/62167/kamran), How to judge if 5 point Likert scale data are normally distributed?, URL (version: 2014-12-06): https://stats.stackexchange.com/q/126788.

Kessler, S. (1989). Psychological aspects of genetic counseling: VI. A critical review of the literature dealing with education and reproduction. *American Journal of Medical Genetics Part A, 34*(3), 340-353.

Kessler, S., editor. (ed.). 1979. Genetic Counseling: Psychological Dimensions. New York: Academic Press.

Lani, J. (2013). Mann-Whitney U Test.

Levene, Howard (1960). "Robust tests for equality of variances". In Ingram Olkin; Harold Hotelling; et al. *Contributions to Probability and Statistics: Essays in Honor of Harold Hotelling*. Stanford University Press. pp. 278–292.

Lu, Zhenqiu & Yuan, Ke-Hai. (2010). Welch's t test. 1620-1623. 10.13140/RG.2.1.3057.9607.

Mangiafico, S. (2016). Summary and Analysis of Extension Program Evaluation in R. https://www.researchgate.net/post/Why_data_on_5-point_Likert_scales_are_never_normally_distributed.

Marteau, T. M., & Bekker, H. (1992). The development of a six-item short-form of the state scale of the Spielberger State—Trait Anxiety Inventory (STAI). *British Journal of Clinical Psychology, 31*(3), 301-306.

Merriam-Webster. Trend. 2011. In *Merriam-Webster.com*. Retrieved April 19, 2018, from https://www.merriam-webster.com/dictionary/trend

Motulsky, A. G., Holtzman, N. A., Fullarton, J. E., & Andrews, L. B. (Eds.). (1994). *Assessing genetic risks: implications for health and social policy* (Vol. 1). National Academies Press.

National Institutes of Health. National Human Genome Research Institute. "Talking Glossary of Genetic Terms." Retrieved March 19, 2018, from https://www.genome.gov/glossary/

Noble, W. S. (2009). How does multiple testing correction work?. *Nature biotechnology, 27*(12), 1135.

Norman, G. (2010). Likert scales, levels of measurement and the "laws" of statistics. *Advances in Health Sciences Education*, *15*(5), 625–632.

Pieterse, A. H., Ausems, M. G., Van Dulmen, A. M., Beemer, F. A., & Bensing, J. M. (2005). Initial cancer genetic counseling consultation: change in counselees' cognitions and anxiety, and association with addressing their needs and preferences. *American journal of medical genetics Part A, 137*(1), 27-35.

Pieterse, A. H., Van 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*(1), 85-96.

QFAB. (2018). ANZMTG Statistical Decision Tree, Power Calculator (Version 1.0 (Web Application).

R Core Team (2013). R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. URL http://www.R-project.org/.

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*(2), 77-83.

Roche, M. I., & Skinner, D. (2009). How parents search, interpret, and evaluate genetic information obtained from the internet. *Journal of genetic counseling, 18*(2), 119-129.

Sach, T. H., & Whynes, D. K. (2009). Men and women: beliefs about cancer and about screening. *BMC Public Health*, *9*(1), 431.

Shiloh, S., & Saxe, L. (1989). Perception of risk in genetic counseling. *Psychology and Health, 3*(1), 45-61.

Schwartz, M. D., Benkendorf, J., Lerman, C., Isaacs, C., Ryan-Robertson, A., & Johnson, L. (2001). Impact of educational print materials on knowledge, attitudes, and interest in BRCA1/BRCA2. *Cancer*, *92*(4), 932-940.

Sorenson, J. R., Swazey, J. P., Scotch, N. A., Kavanagh, C. M., & Matthews, D. B. (1981). Reproductive pasts, reproductive futures. Genetic counseling and its effectiveness. *Birth defects original article series*, *17*(4), 1-192.

Sullivan, G. M., & Artino Jr, A. R. (2013). Analyzing and interpreting data from Likert-type scales. *Journal of graduate medical education, 5*(4), 541-542.

Tluczek, A., Henriques, J. B., & Brown, R. L. (2009). Support for the reliability and validity of a six-item state anxiety scale derived from the State-Trait Anxiety Inventory. *Journal of nursing measurement*, *17*(1), 19.

Welch, B. L. (1947). The generalization of students' problem when several different population variances are involved. *Biometrika, 34*(1/2), 28-35.

APPENDIX A

CONSENT FORM

Banner Health®

Informed Consent to Participate in Research and HIPAA Authorization

Assessment of patient satisfaction and anxiety level in an oncology genetic counseling clinic

Banner MD Anderson Cancer Center

Rebecca Luiten, MS, CGC

INVITATION TO PARTICIPATE

You are being asked to take part in this study because you are attending a cancer genetic counseling session.

This is a cancer genetic counseling research study. Research studies include only patients who choose to take part. Please take your time to make your decision.

WHY IS THIS STUDY BEING DONE?

To investigate way to improve patient satisfaction and reduce anxiety in oncology genetic counseling.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

About 300 people will take part in this study. All participants will take part in the study at this site.

WHAT IS INVOLVED IN THIS STUDY?

You will receive education documents to review prior to your appointment with the genetic counselor. You will receive a standard genetic counseling session and will be given a survey to fill out after your appointment. This survey will help investigate ways to improve genetic counseling. The genetic counselor will not see the results of the survey. Beyond this, no active participation from you is required.

HOW LONG WILL YOU BE ON THE STUDY?

- Your participation in this study will last the duration of your genetic counseling appointment. After completion of your appointment, no other active participation will be necessary
- This study will analyze data collected from May 1, 2017 through September 30, 2017; however, your active participation will conclude today. There will be no follow-ups conducted for this study.

WHAT ARE THE RISKS?

This project has no anticipated risks.

ARE THERE BENEFITS TO TAKING PART IN THIS STUDY?

There are no direct benefits to you for enrolling in this study, other than the knowledge that you are contributing to scientific inquiry. We hope the information learned from this study will benefit other patients in the future.

WHAT OTHER OPTIONS ARE THERE?

Instead of being in this study, you have these options:

- Other than this study, there are no current ongoing genetic counseling research studies at BMDACC; however, you may always decline participation in this study.

WHAT ABOUT CONFIDENTIALITY?

Efforts will be made to keep your personal information private and confidential; however, we cannot guarantee absolute privacy and confidentiality.

Your private health information may be disclosed if required by law and/or following completion of the authorization at the end of this document from you giving your permission to release select private health information to certain individuals associated with this research. The individuals associated with this study who will receive your private health information include:

- The research team
- Banner Health, including the Banner Health Institutional Review Board
- The sponsor of the study: Melissa Wilson Sayres, PhD
- The contract research organization (CRO): Banner MD Anderson Cancer Center
- The site management organization: Banner MD Anderson Cancer Center
- Data analysis center: Melissa Wilson Sayres' lab at Arizona State University
- A core laboratory for genomics, evolution and bioinformatics.
- A central laboratory for Arizona State University School of Life Sciences
- No other research entities will be given your private health information. Your private health information will be de-identified and seen only by the student coordinator and primary investigator.

WHAT ARE THE COSTS?

There is no cost associated to you as a result of participating in the project. You will be responsible for all co-pays and deductibles associated with routine care billable to insurance.

IS THERE COMPENSATION FOR PARTICIPATING?

No compensation will be given to you for participating.

WHAT ABOUT COMPENSATION FOR MY DOCTOR?

There is no compensation for your physicians or genetic counselors.

WHAT HAPPENS IF YOU ARE INJURED?

In the case of injury or illness resulting from this study, emergency medical treatment is available from Banner Gateway Medical Center, but will be provided at the usual charge. No funds have been set aside to compensate you in the event of injury. You or your insurance company will be charged for continuing medical care and/or hospitalization.

We do not anticipate an injuries as a result of participating in this study.

This does not waive your rights in the event of negligence.

WHAT ARE YOUR RIGHTS AS A PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part or may leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to which you are entitled.

We will tell you about new information developed during the course of the study that may affect your health, welfare, or willingness to stay in this study.

CAN YOU BE REMOVED FROM THE STUDY?

For your safety, your participation may be terminated by your physician at any time without your consent. Your participation would also be terminated if you choose to not take the post-counseling survey. You are free to withdraw from the study at any time. No safety precautions are needed after a withdrawal or termination of participation. You are free to participate in other research projects while enrolled in this project.

WHOM DO YOU CALL IF YOU HAVE QUESTIONS?

For questions about the study or a research-related injury, contact the researcher Melissa Wilson Sayres at 814-321-6416 or Lidia Peon at (760)-585-5214.

If you have any questions about your rights as a research participant, contact the Banner Health Human Subject Protection Administrator at 602-839-4583, Monday through Friday, from 9AM to 5PM. This study has been approved by a panel of the Banner Health Institutional Review Board (IRB).

Informed Consent to Participate in Research
and HIPAA Authorization

Assessment of patient satisfaction and anxiety level in an oncology genetic counseling clinic

Banner MD Anderson Cancer Center
Rebecca Luiten, MS, CGC

Authorization to Use Your Health Information for Research Purposes

WHAT IS THE PURPOSE OF THIS FORM?

The federal medical HIPAA Privacy Rule protects your personal health information (PHI). The purpose of this form is to inform you about how your PHI will be used or disclosed (given out) in this research study. In order for the research team to use and give out your PHI, your written permission, called your "authorization", is needed.

If you sign this form, you give permission to the research team to use and/or disclose your PHI as described in the attached consent form. Please consider the important information in this form prior to making your decision.

If you have any questions or concerns about this authorization you should contact Sue Colvin, Banner Research Regulatory Affairs Program Director at (602) 839-4583 or sue.colvin@bannerhealth.com. You may also request and will be provided a copy of the Notice of Privacy Practices.

WHAT PHI WILL BE OBTAINED, USED OR DISCLOSED?

The following is a description of your PHI you are authorizing to be used and/or disclosed in connection with this research study:

☐ Entire Official Medical/Clinical Record (**including all boxes in this table**)				
☐ Assessments	☐ Discharge Summaries	☐ Interviews	☐ Operative Reports	☐ Primary Care Physician Records
☐ Audiology Records	☐ EEG Reports	☐ Laboratory Reports	☐ Outpatient Clinic Records	☐ Problem List (electronic medical record)
☐ Autopsy Reports	☐ EKG Reports	☐ Medicare Records	☐ Ophthalmology Records	☐ Progress Notes

☐ Consultation Reports	☐ Emergency Medicine Reports	☐ Medication Lists	☐ Pathology Reports	☐ Questionnaire
☐ Demographic Information	☐ Genetic Testing	☐ Neuropsych Test Results	☐ Pathology Slides	☐ Recordings (Audio/Video)/ Photographs
☐ Dental Records	☐ Healthcare Billing Records	☐ Nursing Notes	☐ Pathology Specimens	☐ Survey
☐ Diagnostic Imaging Reports/Films/ CDs/Scans	☐ History & Physical Exams	☐ Occupational Therapy Records	☐ Physical Therapy Records	☐ Vocational Test Results
☐ Other:				

Information related to this research study that identifies you and your PHI will be collected from your past, present, and future hospital and/or other health care provider medical records. The demographic information to be disclosed may include, but is not limited to, your name, address, phone number, or social security number. If you receive compensation for participating in this research study, information identifying you may be used or disclosed as necessary to provide that compensation.

Your existing health records may include information related to the diagnosis or treatment of Sexually Transmitted Disease (STD), Acquired Immunodeficiency Syndrome (AIDS), Human Immunodeficiency Virus (HIV), Other Communicable Diseases (except as described in d. above), Genetic Information (e.g., Genetic Testing), and Treatment of Alcohol and/or Drug Abuse. **The research team may see this information while reviewing your regular health records for this study, but they WILL NOT create, collect, use, or disclose this type of information for the purposes of the research.**

WHO WILL USE AND/OR DISCLOSE YOUR PHI?

The following parties are authorized to use and/or disclose your PHI for the research described in the attached consent form:

a. The primary investigator and the study coordinator
b. Banner Health

WHO MAY RECEIVE YOUR PHI?

The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

a. Melissa Wilson Sayres and her agents or study monitors
b. Banner Health IRB

Your PHI may no longer be protected under the HIPAA privacy rule once it is disclosed by the research team to these other parties.

WHAT PURPOSES ARE YOU AUTHORIZING THE USE AND/OR DISCLOSURE OF YOUR PHI?

a. To conduct the study described earlier in this document
b. Oversight, audit and monitoring of the study

WHEN WILL MY AUTHORIZATION EXPIRE?

There is no expiration date or event for your authorization. Therefore, unless you cancel this authorization (as instructed below) this authorization will continue to be effective.

DO YOU HAVE TO SIGN THIS AUTHORIZATION FORM?

You do not have to sign this authorization. However, if you decide not to sign, you will not be able to participate in this research study. If you do not sign, it will not affect any non-study Banner Health medical treatment or health care, payment, enrollment in any health plans, or benefits.

WHAT DO YOU NEED TO KNOW IF YOU DECIDE TO CANCEL YOUR AUTHORIZATION?

After signing the authorization, you may decide to cancel your permission to use your PHI. If you cancel the authorization, you will no longer be able to stay in the research study.

Any PHI collected before you cancel the authorization may still be used by the research team and recipients described above to maintain the integrity or reliability of the research study. The research team is required by law to report any bad side effect you experience even if you have canceled your authorization.

HOW DO YOU CANCEL YOUR AUTHORIZATION?

To cancel this authorization you must notify the principal investigator in writing at the following address:

Melissa Wilson Sayres
Arizona State University
Po Box 874501
Tempe, Az 85287-4501
melissa.wilsonsayres@asu.edu

WILL ACCESS TO YOUR MEDICAL RECORD BE LIMITED DURING THE STUDY?

To maintain the integrity of this research study, you may not have access to any health information developed as part of this study until it is completed. At that point, you would have access to such health information if it was used to make a medical or billing decision about you (e.g., if included in your official medical record).

WHAT OTHER INFORMATION DO YOU NEED TO KNOW?

If you choose to sign this Authorization, the disclosure or transfer of your PHI will result in payment/compensation to Banner Health. Additionally, the disclosure or transfer of your PHI by any person or entity identified above will also result in payment/compensation to such person or entity.

SIGNING THE CONSENT FORM

I have read (or someone has read to me) this form, and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study **and I**

authorize the use and/or disclosure of my PHI.

I am not giving up any legal rights by signing this form. I will be given a signed copy of this form**.**

Printed name of subject	**Signature of subject**	**Date**
Printed name of person authorized to consent for subject	**Signature of person authorized to consent for subject**	**Date**
Relationship to the subject		

Investigator/Research Staff

I have explained the research to the subject or the subject’s representative before requesting the signature(s) above. There are no blanks in this document. A signed copy of this form has been given to the subject or to the subject’s representative.

Printed name of person obtaining consent	**Signature of person obtaining consent**	**Date**

APPENDIX B

GLOSSARY LIST

Genetics Terms List

DNA: DNA is the chemical name for the molecule that carries genetic instructions in all living things.

Gene: The gene is the basic physical unit of inheritance. Genes are passed from parent to offspring and contain the information needed to specify traits (physical characteristics). Genes are arranged, one after another, on structures called chromosomes.

Mutation: A mutation is a change in the DNA sequence.

Inherited: An inherited trait is one that is genetically determined. Inherited traits are passed from parent to offspring according to the rules of Mendelian genetics. Most traits are not strictly determined by genes, but rather are influenced by both genes and environment.

Cancer: Cancer is a group of diseases characterized by uncontrolled cell growth. Cancer begins when a single cell mutates, resulting in a breakdown of the normal regulatory controls that keep cell division in check. These mutations can be inherited, caused by errors in DNA replication, or result from exposure to harmful chemicals. A cancerous tumor can spread to other parts of the body, which is called a metastasis.

Tumor Suppressor Gene: A tumor suppressor gene directs the production of a protein that is part of the system that regulates cell division. The tumor suppressor protein plays a role in keeping cell division in check. When mutated, a tumor suppressor gene is unable to do its job, and as a result uncontrolled cell growth may occur. This may contribute to the development of cancer.

Autosomal Dominant: Autosomal dominant is a pattern of inheritance characteristic of some genetic diseases. “Autosomal” means that the gene in question is located on one of the numbered, or non-sex, chromosomes. “Dominant” means that a single copy of the disease-associated mutation is enough to cause the disease. This is in contrast to a recessive disorder, where two copies of the mutation are needed to cause the disease.

Family History: A family history is a record of medical information about an individual and their biological family.

First Degree Relative: A first degree relative is a family member who shares about 50 percent of their genes with a particular individual in a family. First degree relatives include parents, offspring, and siblings.

Pedigree: A pedigree is a genetic representation of a family tree that diagrams the inheritance of a trait or disease through several generations. The pedigree shows the relationship between family members and indicates which individuals express or silently carry the trait in question.

APPENDIX C

POST-COUNSELING SURVEY

Instructions. In an effort to continuously monitor and improve the quality of genetic counseling services delivered to patients at this healthcare organization, please take a moment to fill-out this form regarding the appointment you just completed with your genetic counseling professional. Please read each statement below very carefully, and tell us how much you agree or disagree with each statement by circling your response on the scale to the right. Your honest responses will be kept strictly confidential, and they will not be shared with your genetic counseling professional. Thank you for assisting us.

Please circle the answers that best describes your agreement with the statement:

Q		**Strongly Agree**	**Disagree Somewhat**	**Uncertain**	**Agree Somewhat**	**Agree Strongly**
1	**My genetic counselor seemed to understand the stresses I was facing**	1	2	3	4	5
2	**My genetic counselor helped me to identify what I needed to know to make decisions about what would happen to me**	1	2	3	4	5
3	**I felt better about my health after meeting with my genetic counselor**	1	2	3	4	5
4	**The genetic counseling session was about the right length of time I needed**	1	2	3	4	5
5	**My genetic counselor was truly concerned about my well-being**	1	2	3	4	5
6	**The genetic counseling session was valuable to me**	1	2	3	4	5

Please circle the answers that most describes your current state:

Q		**Not at all**	**Somewhat**	**Moderately**	**Very Much**
7	**I feel calm**	1	2	3	4
8	**I feel tense**	1	2	3	4
9	**I feel upset**	1	2	3	4
10	**I feel relaxed**	1	2	3	4
11	**I feel content**	1	2	3	4
12	**I feel worried**	1	2	3	4

Please circle the answer that applies to you:

13	**Highest level of education completed**	High School	Partial College	College graduate	Professional degree
14	**Annual household income**	Less than or equal to $75,000	Greater than $75,000		

APPENDIX D

SCRIPT FOR INTERVENTION

Assessment of genetic terms list on patient satisfaction and anxiety level in an oncology genetic counseling clinic

Melissa Wilson-Sayres, PhD, Lidia Peon, Rebecca Luiten MS CGC, Jennifer Siettmann MS CGC, Ken Buetow, PhD

Scripts for Patient Communication

1. Script for calling patients ahead of the study

Hello, my name is Lidia Peon and I am calling about your genetic counseling appointment at Banner MD Anderson scheduled for DATE at TIME. I am a graduate student at Arizona State University and I'm working on a research project with the genetic counselors at Banner MD Anderson to investigate ways to improve the genetic counseling experience. In order to do that, we were hoping you would be willing to show up 15 minutes early to your appointment to review some information with me prior to seeing the genetic counselor. This is all voluntary, so if you're not able to arrive early, that's completely fine and you'll still receive the same quality of genetic counseling.

1. Patient indicates agreement
    a. Great, thank you for your interest in this project. We will see you at NEW TIME on DATE.
2. Patient says they can't come early
    a. That's fine, I completely understand: I know you probably have a busy schedule right now. We'll see you at your scheduled appointment time on DATE at TIME.
3. Patient asks questions about genetic counseling/cancer/genes
    a. That is a great question: unfortunately, I am not a genetic counselor and can't answer that for you. This would be a great question to ask them when you see them on DATE.
4. Patient asks questions about purpose of appointment or why she even needs to come
    a. Unfortunately, I am not a genetic counselor so I can't answer that for you, but I can let COUNSELOR know that you have this question and they can call you before your appointment.
5. Patient asks questions about billing/cost/coverage
    a. Unfortunately, I don't have the answer to that question, but you can call the main clinic line to get in touch with PFS and they can answer that question for you. The main clinic line is 480-256-6444.
6. Patient wants to cancel/reschedule appointment

    a. I’m sorry to hear that. I can’t cancel that appointment for you, but I’ll let one of the genetic counselors know and they will follow-up with that.

2. Script for handing out the materials and informed consent

Hello, my name is Lidia Peon and I am a graduate student at Arizona State University. I’m working with the genetic counselors here at BMDACC on a research project to investigate ways to improve the genetic counseling experience. I was hoping that you would be able to take a couple minutes to be part of my research project.

ALL PARTICIPANTS
If you agree to participate, your involvement would be pretty minimal. I am going to give you packet to read over before your appointment. After that, you will see your genetic counselor just like usual, but after the appointment, your genetic counselor will step out of the room and I will enter to give you a post-counseling survey about how you feel after the genetic counseling appointment. And that would be all; there’s no additional follow-up needed.

Does this sound like something you would be interested in doing?

NO
Okay, that’s not a problem. I’ll let the genetic counselor know that you’re here and she’ll take you back shortly.

YES
Great, thank you for your interest! I’m going to read through this informed consent with you. Afterwards, please ask any questions that you have about the information in the consent and then sign it.

3. Script for handing out/collecting the survey.
(Handing out survey)
Hi there,

Thank you again for participating in this research. It really means a lot to us. Here is the post-counseling survey. Feel free to answer truthfully: your genetic counselor will not see the results of this survey. On this survey, please circle/select the number that appropriately describes how you feel right now.

(Collect Survey)
Thank you for filling out the survey. I wasn't able to tell you before, but the goal of this study is to can see whether having a glossary handed to patients before a session will help increase patient satisfaction and reduce anxiety. Your participation has helped my research tremendously and will hopefully help influence future policy by demonstrating the benefit of providing patients with the glossary prior to their appointment.

Do you have any additional questions before I tell your genetic counselor she can come back into the room?

APPENDIX E

WHAT IS GENETIC COUNSELING? FORM

Banner MD Anderson Cancer Center
Making Cancer History®

What is Genetic Counseling?

Your doctor may ask you to meet with a genetic counselor. Many people have not heard of this service before. During a genetic counseling session at Banner MD Anderson Cancer Center, the genetic counselor will:

- look at your health record.
- ask you questions about your family history of cancer and sometimes other health issues.
- use these facts to estimate the chance that you could have an inherited condition that causes a higher than usual risk for cancer.
- talk to you about genetic testing if needed.

The genetic counselor will explain how genetics and family history can affect cancer risks. He or she will help you understand your own risk and help you make choices that are best for you. Such as, if you are found to be at a greater risk for cancer, the genetic counselor can tell you about more cancer testing and prevention options that are available.

Who are genetic counselors?

Genetic counselors are health care experts with graduate degrees and experience in the areas of medical genetics and counseling. Most counselors enter the field with a background in biology, genetics, nursing, psychology, public health or social work.

Should I think about having cancer genetic counseling?

You should think about seeing a genetic counselor for a cancer risk assessment if you and/or your family history has any of these risk factors:

- Cancer before age 50
- One person in your family has two or more different cancers
- Two or more close family members have the same or related type of cancer
- Several generations of your family have the same or related type of cancer
- A family member of Ashkenazi Jewish ancestry (Eastern or Central European) who has breast, ovarian or colorectal cancer
- You or your family members have had multiple polyps
- Certain rare cancers, such as male breast cancer, retinoblastoma (eye cancer), medullary thyroid cancer or pheochromocytoma/paraganglioma
- A family member with a genetic test diagnosing a hereditary cancer syndrome
- Fear about getting cancer because of family history

If you are interested in having a cancer risk assessment, please call the Banner MD Anderson Cancer Center at
(480) 256-6444 and ask to speak to the Genetic Counselor.

What is Genetic Counseling? © 2005, 2012 The University of Texas MD Anderson Cancer Center, Revised 08/28/12 Patient Education Office.

Banner MD Anderson Cancer Center, Revised, 08/14/2012, 7/2/2015 .**Banner MD Anderson Cancer Center 2946 E. Banner Gateway Dr. Gilbert, AZ 85234 (480) 256-6444 www.bannermdanderson.com**

APPENDIX F

IRB APPROVAL

Banner Health®
FWA #00002630
IORG #0004299

July 13, 2017

Rebecca Luiten
Attn: Alicja M Ball/Amelia Larsen
Jasmine Neumann/Stephanie Henkel
Banner MD Anderson Cancer Center
2946 E. Banner Gateway Drive Ste.375
Gilbert, AZ 85234

RE: **Project # 14-17-0026** Assessment of genetic terms list on patient satisfaction and anxiety level in an oncology genetic counseling clinic
iRIS Reference # 018409
IRB Expedited Approval – New Protocol (Version 1.1 dated 6/28/17), Informed Consent and HIPAA Authorization (Version 1.2 dated 7/5/17), Master Log (Version 1.0 dated 6/13/17), What is Genetic Counseling Flyer (dated 7/2/15), Genetic Terms List (Version 1.0 dated 6/13/17), Post Counseling Survey (Version 1.0 dated 6/13/17), Scripts for Patient Communication (Version 1.0 dated 6/13/17), Data Collection Form (Version 1.0 dated 6/13/17)

Dear Ms. Luiten:

This letter serves to notify you the above referenced **Protocol, Informed Consent, and HIPAA Authorization** received expedited review and approval by Marc Lee, MD, Chair of the Banner Health Institutional Review Board (Phoenix Panel) on July 13, 2017 for conduction at Banner MD Anderson Cancer Center. This expedited review was performed in accordance with 21CFR56.110 (b) and/or 45CFR46.110(b). This study has received approval for one year. Federal regulations require all studies be reviewed at least annually. The final approved, stamped Informed Consent is available electronically. You must use copies of this Informed Consent exclusively. A copy of the signed Informed Consent document must be placed in the patient's medical records.

The Board's approval to conduct your study will expire on **July 12, 2018**. The IRB requests that you submit a Continuing Review report one month prior to the June 19, 2018 IRB meeting. This allows time for processing and review prior to the IRB expiration date of the study.

Any internal unanticipated problems or unexpected drug/biologic adverse events must be reported to the IRB within 7 working days of the investigator learning of the event.

If you wish to change any aspect of this study, such as the procedures, the consent forms, or the investigators, please communicate your requested changes to the Board. The new procedure is not to be initiated until the IRB approval has been given.

Unusual events, results of the study or any additional information relative to the study must be submitted to the Board. A Closing report is required upon completion of the project. In the event the study results are published, please send a copy to Banner Research so it may be included in the file. A copy of this letter will be retained electronically.

Rebecca Luiten
Project # 14-17-0026
iRIS Reference # 018409
July 13, 2017
Page Two

The Board appreciates your participation in research. If you have any questions, please contact Jane Hoverson, CIP, CIM, CRC, Research Regulatory Specialist, at (480) 412-4083.

Sincerely,

Signature applied by Marc Lee on 07/13/2017 04:22:12 PM MST

Marc Lee, MD
Chair, Banner Health IRB (Phoenix Panel)

ML/jh
cc: Research Director

Banner Health®
FWA #00002630
IORG #0004299

September 20, 2017

Rebecca Luiten
Attn: Alicja M Ball/Amelia Larsen
Jasmine Neumann/Stephanie Henkel
Banner MD Anderson Cancer Center
2946 E. Banner Gateway Drive Ste.375
Gilbert, AZ 85234

RE: **Project # 14-17-0026** Assessment of genetic terms list on patient satisfaction and anxiety level in an oncology genetic counseling clinic
iRIS Reference # 018580
IRB Review and Acknowledgement – Protocol Deviation

- **30 subjects consented with non-approved (unstamped) Informed Consent**

Dear Dr. Luiten:

This letter serves to notify you the **Protocol Deviation** for the above referenced study received review and acknowledgement by the Banner Health Institutional Review Board (Phoenix Panel) on September 19, 2017. No further action is required. This review was performed in accordance with 45CFR46.

A copy of this letter will be retained electronically. If you have any questions, please contact Jane Hoverson, CIP, CIM, CRC, Research Regulatory Specialist, at (480) 412-4083.

Sincerely,

Signature applied by Marc Lee on 09/20/2017 09:20:25 PM MST

Marc Lee, MD
Chair, Banner Health IRB (Phoenix Panel)

ML/jh
cc: Research Director