THE IMPACT OF GENETIC COUNSELING ON PATIENT ENGAGEMENT

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ABSTRACT

Recent healthcare efforts have targeted patient engagement as a means to improve medical outcomes and reduce the healthcare costs of chronic conditions. This pilot study analyzed engagement levels among patients who underwent genetic counseling for Gastrointestinal (GI) cancer risk assessment, and examined the feasibility of implementing engagement measures in an outpatient specialty clinic. We hypothesized that undergoing genetic counseling would empower patients and result in increased engagement scores. Patients seen at the UPMC Hereditary GI Tumor Program were asked to complete a patient engagement measure, the Altarum Consumer Engagement (ACE), prior to undergoing genetic counseling. Post-appointment ACE measures were completed for each participant three months after enrollment via telephone. Paired t-test analysis was conducted to assess changes in the ACE scores before and after genetic counseling. In the sample of 38 participants, the ACE Measure scores were found to increase significantly after having genetic counseling ($p = 0.0342$). No statistically significant differences were found in ACE scores between participants recently diagnosed with cancer and those with a past personal history or a family history of cancer ($p = 0.2042$). The implementation of engagement measures in the clinical setting is feasible, and may assess the impact of genetic counseling on healthcare efficacy in patients suspected to have a genetic cancer susceptibility. Identifying novel approaches for patient activation is of public health significance,

both in improving patient outcomes and lowering healthcare cost. Future research is ongoing to investigate whether improved patient engagement correlates to lifestyle modifications that reduce cancer risk.

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PREFACE

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1.0 STUDY OVERVIEW

This study aims to analyze patient engagement outcomes in individuals who are suspected to have a genetic cancer susceptibility and who have undergone genetic counseling. This pilot study is valuable in furthering the understanding of patient engagement in their health and in the healthcare system. Studying the outcomes of individuals with and without a cancer diagnosis who have some genetic susceptibility, can help to identify improved means of engaging patients, promoting lifestyle modifications, and ultimately, improve both cost effectiveness and patient satisfaction. Better understanding of such associations will have particular influence on stakeholders including patients, medical professionals, and healthcare systems.

This study examined the level of patient engagement in individuals who were referred for genetic counseling because they have a personal cancer diagnosis or have a family history of cancers, and are thereby suspected to have some genetic cancer susceptibility.

The **hypothesis** tested in this study is that genetic counseling will empower patients and result in increased engagement scores (ACE Measure) over time.

The **specific aims** of this study included:

1. To analyze changes in individuals' engagement in their health (ACE Measure) before and after undergoing genetic counseling.
2. To compare the pre and post ACE Measures between patients who have a current diagnosis of cancer and those patients who have a past personal history of cancer or a family history of cancer.

This pilot study also assessed the feasibility of implementing patient engagement measures in the clinic and evaluated patient recruitment methods, retention, and data analysis approaches for future research studies.

2.0 LITERATURE REVIEW

2.1 CANCER

2.1.1 Acquired Cancer

Cancer is a leading cause of death worldwide, accounting for one in eight deaths globally.[1] In the United States alone, more than 1.7 million new cancers are estimated to be diagnosed in 2017.[2] Recent epidemiological evidence however, suggests that up to 50% of all cancers could potentially be prevented through lifestyle modifications.[3] In more than 20% of cancer cases, unhealthy body weight is a primary contributor to the diagnosis. Smoking is also thought to contribute to two thirds of cancer deaths in the US, and could be prevented with lifestyle modifications.[4] Numerous organizations including the US Department of Health and Human Services, the American Cancer Society, the World Research Fund, the Centers for Disease Control, and the American Institute for Cancer Research have developed several recommendations for lifestyle behaviors. Such lifestyle behaviors include avoidance of tobacco products, restriction of alcohol intake, maintaining a healthy weight, exercising regularly, and eating ample servings of fruits and vegetables.[1,5–9] Adherence to such guidelines have been shown to reduce an individual's breast cancer risk by 22%, colon cancer risk by 52%, and reduce overall cancer risk by at least 17%.[5,4] Further research on the empowerment of patients in their

own health behaviors and in the utilization of the healthcare system to support a healthy lifestyle is important to the improvement of public health as a whole.

2.1.2 Cancer Risk Factors

Today, approximately two thirds of individuals survive at least five years after a cancer diagnosis. Many factors can account for this increase in survival, including improved cancer treatments and the availability of effective screening/early detection strategies for many cancers. Additional factors such as personal lifestyles can also be taken into consideration.[10]

Physical inactivity and its association with obesity, and tobacco usage are two of the major risk factors known to be associated with cancer.[11] In fact, individuals with a body mass index (BMI) of over 25kg/m2 have a 24% increased prevalence of colorectal cancers.[12] Over 25% of all cancer deaths in the United States are estimated to be caused by smoking. Tobacco is traditionally associated with lung cancer, but also has been linked to colorectal, bladder, and esophageal adenocarinomas.[13]

2.1.3 Adherence to Lifestyle Recommendations

Recent National Comprehensive Cancer Network (NCCN) Guidelines for Smoking Cessation suggest that the most effective approach in aiding patients to quit smoking is the combination of pharmacologic therapy, such as nicotine patches, in addition to counseling. The NCCN guidelines also encourage healthcare providers' support and call for an increased discussion about the risks of smoking to decrease relapse rates and further engage patients in their own health.[13] Yet, despite growing evidence surrounding the impact of behaviors on health and cancer risk, studies have found that the majority of patients tend to attribute increased risk with uncontrollable and broad factors including stress, bad luck, and genetics.[3,6]

Various studies have determined that adherence to the recommended guidelines put forth by organizations such as the American Cancer Society and World Cancer Research Fund is associated with statistically significant reduction in cancer incidence and mortality. A systematic review (2016)[14] performed meta-analysis of twelve studies that analyzed patience adherence to recommended guidelines and their cancer outcomes over time. The twelve studies reviewed were international and comprised of large sample cohorts with ample statistical power, and a timeframe of 7-14 years. Compliance with nutritional and physical activity guidelines alone was found to decrease up to 61% of overall cancer and mortality incidence. Participants with high adherence were also found to have lower risk for some site-specific cancers including breast cancer, endometrial cancer, and colorectal cancer by an average of 27 – 57%.[14]

2.1.4 Lifestyle Behaviors on Hereditary Cancers

While lifestyle behaviors have been shown to reduce cancer risk in the general population, fewer studies are available that analyze the effect of behavior on hereditary cancers. Hereditary cancer syndromes, such as hereditary breast and ovarian cancer (*BRCA1* and *BRCA2* genes) and Lynch syndrome (*MLH1, MSH2, MSH6, PMS2, EPCAM* genes) confer an increased risk for the development of specific cancers. For the hereditary breast and ovarian cancer genes, the risk for breast cancer in a woman's lifetime can be up to 70%, and up to 40% for ovarian cancer.[15] Lynch-related genes mutations result in a risk for colorectal cancer that can be as high as 69%.[16] While these risks are significantly increased compared the general population, they are not 100%. Due to the difference in penetrance and cancer incidence between individuals, even within the same family, it is likely that risk-modifying factors contribute to cancer development.[16–18]

Previous research has found that such lifestyle factors can include obesity and tobacco usage. The incidence of breast cancer has been found to be lower in *BRCA1/2* mutation carriers who report high levels of physical activity, while a diet high in fruit and vegetables has been shown to reduce cancer risk in individuals with Lynch syndrome.[20–22] Likewise, smoking has been associated with higher cancer development rates in individuals with hereditary cancer predispositions.[23]

One study observed lifestyle behaviors among individuals at risk for Lynch syndrome. The study of 429 participants looked both at individuals who had a colorectal cancer diagnosis and unaffected, at-risk relatives. The study found that despite all participants being at risk for a hereditary cancer predisposition, individuals who had not had a previous cancer diagnosis were more likely to have poor lifestyle behaviors compared to individuals who had previously been diagnosed with cancer.[24] While all patients in this study were at increased risk for hereditary cancer, the majority of lifestyle modifications took place only after a cancer diagnosis. The impact of lifestyle behaviors on hereditary cancer compared to sporadic cancers, therefore, can be complicated by patient risk perceptions. Furthermore, the need for additional research surrounding risk-reducing behaviors specific to hereditary cancers has led to several clinical trials currently underway (clinicaltrails.gov).

2.2 ENGAGEMENT

2.2.1 Patient Engagement

Engagement of individuals within the healthcare system is of particular importance for understanding and improving the patient experience. The definition of engagement however, varies widely in terms of the behaviors, knowledge base, skills, and attitudes that it is thought to

encompass.[25] Mahmud (2004)[26] for instance, describes engagement as an organizational method that incorporates patient input into the decision making process. Dearing and colleagues (2005)[27] consider engagement to describe a client-therapist relationship, in which treatment and management options are reached through joint effort. Other definitions incorporate the idea of informal discussion, self-care capability, and the utilization of tools such as the web-based patient portals in order to describe engagement.[26,28] A more comprehensive definition for engagement, which will be used for the purpose of this study, is described by Gruman et al.[28] as the "actions individuals must take to obtain the greatest benefit from the health care services available to them." The Gruman definition encompasses the various ways that engagement can be considered, from personalized action and communication, to utilization of various resources both within and outside of the healthcare system.

2.2.2 Benefits of Engaged Patients

The measurement of patient engagement can have multiple effects on a health care organization. Determining a patient's involvement in their health can allow for identification of targeted populations, segmentation, and evaluation of existing interventions. Participation rates can also provide key information about risk stratification for targeted interventions, and help to facilitate customized care pathways, and provide enhanced care both at an individual and community level.[25]

Patient engagement has been linked to a range of beneficial outcomes not only for patients, but for healthcare organizations as well. Patients who had high engagement levels reported higher satisfaction with their healthcare, and recover faster from illnesses. High levels of engagement were also correlated with improved medical adherence, shorter lengths of stay in hospitals, and better long term quality of life. Additionally, patients who are considered to be

highly engaged in their health and in the medical system have half the rate of medical errors compared to those with low-levels of participation.[29]

From the provider's perspective, patient engagement has been shown to afford significant cost reduction in healthcare. When patients are engaged in their health and in the healthcare system finances and resources are preserved through the avoidance of unnecessary surgeries, better adherence to medical management, and the prevention of medical errors. Patient participation can also reduce healthcare costs by choosing options based on an individual's preference, rather than simply being provided with the standard of care approach.[25] High levels of patient involvement lead to safer, more effective, and less expensive healthcare overall. As such, the active role of patients in managing their health is important to increase satisfaction, successful outcomes, and developing economically sustainable healthcare systems.

2.2.3 Changing Role of Patients and Healthcare

Patient engagement is seen to have a positive effect on both the patient experience and on the health care systems. Now more than ever, patients have a diverse and expanding role within the medical field. No longer are patients simply passive recipients of care, but rather patients are encouraged to participate in their own health as empowered consumers.[25] Today, patients often act as advocates for new treatments, management, and personalized decision making. Patient involvement is also essential in traversing interdisciplinary collaboration among healthcare professionals and specialty facilities.

The role of patients in their health is not the only change occurring within the healthcare system. As medical advancements, treatments, and technology continue to develop, so too have the settings and expectations of the medical practice. Patients can now utilize online resources, comparative tools, and rating systems to determine the best care for their personal needs. The

medical field has become a highly competitive domain under constant scrutiny of patients and healthcare professionals are under pressure to provide services tailored to individuals, and not merely offer generalized treatments.[30] The changing role of the patient and the environment of the medical field also influences the ways in which patients interact with the healthcare system and in their opportunities for engagement in their own health.[25,29]

The role that healthcare plays in an individual's lifestyle; however, is limited by the interactions providers have with their patients. For many Americans, the healthcare system is viewed as a reactive model, in which help is sought only after becoming ill. Thus, patients may spend only a few hours a year with healthcare providers to treat the symptoms of significant underlying behavioral concerns such as obesity or smoking. The other five thousand waking hours each year, however, are left to individual choices, surrounding behaviors that can profoundly affect their health.[31] The ability to engage patients in their own health therefore, is essential to the reduction of healthcare spending and to the improvement of public health and healthcare overall.

2.3 ENGAGEMENT MEASURES

2.3.1 Overview of Engagement Measures

The changing role of patients and the evolving expectations of the healthcare system allow for different ways to become more involved in patient well-being. However, not all patients are able to take advantage of such changes. As the role of the patient expands, so too do the skills and knowledge base required to navigate the system. When considering patients' participation in their own health, it is important to note the differences in socio-demographics, individual experiences, and social norms. The ability to acquire up-to-date health information, to participate

in healthy behaviors, to afford medical management, to follow treatment prescription, or to interact with healthcare professionals, are all factors that can affect a patient's engagement.[29] Recognizing these differences is vital to better serve individuals with unique perspectives and abilities. To understand patient engagement therefore, demands consideration of a comprehensive outlook on a variety of factors such as a patient's personal awareness, skill set, confidence, and experience within the healthcare system.[29] Patient engagement measures are valuable to improving patient experiences through identifying problematic aspects of health care disparities in order to develop improved delivery of care and to meet patient expectations.

While engagement is important to the improvement of patient experience and healthcare services, there are few validated methods to assess the role of patients in their health and the health system. It is especially difficult to create valid assessment measures in the rapidly changing healthcare environment and incorporation of developing technology. Most measurement tools that are available are specific to one aspect of patient involvement, typically measuring only autonomy, information preferences, or decision making. Other tools cover multiple domains of engagement, but are specific to management of a particular disease.[25] The current tools are often inadequate in addressing the factors of engagement that encompass the skills patients need today in order to take advantage of technology and information sources, such as online patient portal engagement, or comparison tools for healthcare systems.[25,29,32] Current measures are mainly unidimensional, highly specific, or meant for disease management and do not incorporate technological health care involvement.

2.3.2 The ACE Measure

A new measure, called the Altarum Consumer Engagement (ACE) Measure™ (June 2015), was created to address some of the limitations in the current engagement measurement tools. The

purpose of the ACE measure is to improve the health care experience through understanding the engagement of patients. The ACE strives to consider patient lifestyle behaviors, decision process, and the use of technology and resources in education and involvement of individuals.[29,32]

The ACE measure is a tool designed to evaluate the engagement of individuals in their healthcare. The ACE measure used for this study involves 12 questions, which evaluate three domains of health, including: Commitment, Informed Choice, and Navigation.[32]

- The Commitment domain reviews an individual's proactive behaviors and self-care habits. Commitment scores reflect the level of consistency in health habits and health practices for an individual over time.

- The Informed Choice domain encompasses the types of resources an individual may reference when making health decisions. The Informed Choice score refers to the actions taken to evaluate the medical system when making choices about available providers or services.

- The Navigation domain summarizes an individual's ability to communicate within the healthcare system. Navigation scores refer to the individual experiences, and reflects personal views and impressions about the healthcare system.[32]

The ACE measure was created with the purpose of expanding the way in which patient engagement is measured and understood, as well as to incorporate modern information sources and technology available to patients. ACE can provide valuable information about necessary improvements within the system, but also can enable medical professionals to help patients become more confident and involved in their own health through the identification of strengths and weaknesses in their Commitment, Informed Choice, and Navigation scores. As such, ACE

can also be useful for medical professionals to evaluate the abilities of patients in making decisions, and the type and quantity of support that may be needed for each patient.[32]

The ACE measure can be used not only on an individual scale, but also on a population and community level. Within the population at large, the ACE tool can measure a population's overall engagement, which can provide insight for designing more efficient strategies for community outreach and advocacy. The measure can also be used as a metric to monitor changes and assess the impact of interventions over time in a given population, which can offer valuable information for evaluations and revisions. The ACE can then identify subpopulations at the community level, and target health interventions based on specific population involvement for more efficient and satisfying management.[32] The ACE measure therefore, has a variety of functions and potential uses for bettering both patient experience as well as healthcare systems at larger population levels.

2.4 GENETICS

2.4.1 High-Risk Cancer Individuals

Approximately 10% of all cancer diagnoses are due to a genetic predisposition.[33] These cancers are mainly caused by a single genetic change which can be passed through the generations of a family. These genetic changes can significantly increase the risk for developing cancer. For example, colorectal cancer is the third most common cancer in the United States, and approximately 5-10% of all diagnoses are caused by a hereditary syndrome. While the general population lifetime risk for developing colorectal cancer is about 5-6%, an individual with a genetic predisposition may have an increased lifetime risk as high as 100% if untreated.[34,35] Individuals with an extensive family history of certain cancer types, or an identified genetic

predisposition therefore, are considered to be at a higher risk for cancer development compared to the general population.

Genetic testing is often offered to individuals who are thought to have increased risk in order to better address management and screening options. Patients considered to be at high-risk are typically identified through their personal cancer history, or through identification of multiple family members with cancer. Genetic counselors can help facilitate the process of risk education and genetic testing for hereditary conditions.

2.4.2 Genetic Counseling

Genetic counseling is a specialized medical profession which aims to promote patient understanding of the complex genetic and genomic components of disease, as well as to provide psychosocial support for each patient. The most recent definition of genetic counseling was developed by the Genetic Counseling Definition Task Force of the National Society of Genetic Counselors in 2006:

> "Genetic counseling is the process of helping people understand and adapt to the medical, psychological and familial implications of genetic contributions to disease. This process integrates the following:
>
> • Interpretation of family and medical histories to assess the chance of disease occurrence or recurrence.
>
> • Education about inheritance, testing, management, prevention, resources and research.
>
> • Counseling to promote informed choices and adaptation to the risk or condition."[36]

Since its inception over 40 years ago, genetic counseling has evolved to serve multiple roles including that of an educator, supporter, medical liaison, resource provider, and interdisciplinary team member. Genetic counselors work in an assortment of specialty services specific to the genetics and genomics involved in each discipline. Such fields can include oncology, cardiovascular, neurology, pediatric, prenatal, research, and diagnostic laboratory services.[37]

2.5 OUTCOMES

2.5.1 Patient Outcomes

In healthcare research, an "outcome" can be defined as what happens to a patient, or an end result, as a direct consequence of their encounters with the healthcare system.[37] In order to measure outcomes, a valid and reliable assessment tool can be utilized to track end results or changes over time. Tracking patient outcomes is important for quality assurance purposes and improvement.

Since the Patient Protection and Affordable Care Act of 2010[38], patient outcomes have become even more important to assess within the healthcare system. The Affordable Care Act (aka: Obamacare) has implemented several new considerations revolving around patient centered outcome research. For example, Title I, Subtitle A: Sec. 1001 (as modified by Sec. 10101) requires the Secretary of Health and Human Services to develop reporting requirements to track patient improved health outcomes, prevention of hospital readmissions, reduction of medical errors, and the promotion of patient wellness and health. Furthermore, healthcare systems including the Centers for Medicare and Medicaid Services (CMS) have established a mandatory reporting system, the Physician Quality Reporting System (PQRS), for the identification of a comprehensive set of patient outcome measures.

In order to receive full reimbursement of healthcare services, the PQRS requires professionals and group practices to report patient outcomes such as patient perceptions and timeliness of care for quality assurance purposes. In 2015, the program initiated a negative payment adjustment to those professionals who failed to report satisfactory outcome measures, resulting in a 2% decrease in all reimbursements through CMS.[39]

As a result of the Affordable Care Act, patient outcomes are now emphasized measures of quality institutions and are being rapidly integrated into clinical and medical research. Soon, many more private and public practices may be asked to demonstrate improved patient outcomes as well.[37] This establishment drives the need for both valid measure tools, as well as defined expected outcome values in a variety of professional fields.

2.5.2 Genetic Counseling Outcomes

Genetic counselors are considered valuable members to many clinical and research teams as a means of enhancing patient care as well as improving time management and patient satisfaction, while concurrently decreasing liability and overall cost through reduction of repetitive or inappropriate testing.[40] To date, however; there is limited information concerning the impact of genetic counseling on patient outcomes. Furthermore, despite recent laws toward defined patient outcome measures, genetic counseling lacks research and establishment of a set of evidence-based outcomes expected from the profession.[37]

The identification of outcome measures unique to genetic counseling services has since become a priority for the profession. In one of the first studies to address the growing need for defined expectations in the genetic counseling profession, Redlinger-Grosse, et al.[37] analyzed the results of five focus groups aimed at developing a comprehensive list of outcomes based upon the Reciprocal-Engagement Model (REM). The REM is a specific practice model that outlines

the mutual participation of patients and genetic counselors in the education process and in the understanding and application of new information.

Four major outcomes were described, including:

1. Patient Knowledge
2. Decision-Making
3. Patient Satisfaction
4. Psychological Adaptation

While no defined patient outcomes are universally tracked for genetic counselors, the four major themes addressed in the Redlinger-Grosse, et al.[37] study provide a framework of anticipated benefits. Ensuring patient knowledge is the foundation of genetic counseling training, both through translation of patient's results and information into clear, practical material, and in being able to convey specific, complex genetic information in understandable ways. One of the aims of genetic counseling is likewise to enable patients to make informed decisions.[37]

Through individualized counseling, patients are supported to choose the medical and health decisions that are best for them. Consequently, patient satisfaction can also be expected to improve with genetic counseling, as patients may feel more informed and in control of their decisions and health management than standard healthcare practices alone can offer. Finally, the counseling component inherent in genetic counseling is a vital aspect of the profession, which encourages further exploration of the emotional effect genetic information may create in the patient. The failure to address the emotional consequences of genetic information for an individual may even ultimately act as a barrier in an individual's capacity to process the information.[41] It could be anticipated then, that genetic counseling can benefit the emotional wellbeing of the patient through reducing anxiety, and enabling adaption and open communication for the individual and their families.[37]

Studies that analyze the impact of genetic counseling suggest that patients do have a better understanding of cancer risks and in some cases, may be more likely to participate in cancer screenings. In one study, genetic counseling outcomes and patient empowerment were measured in patients with complex, multifactorial conditions. The study determined that there were statistically significant increased levels of empowerment in patients one month after their genetic counseling appointment. The changes observed however, were not influenced by the provision of genetic test results, as no genetic testing was provided for the participants. The results of the study were statistically significant and had a large effect size observed, with clinically meaningful differences.[41,42] Similarly, a 2016 study reviewed outcomes in 120 individuals with serious mental health illnesses and found that genetic counseling improved both patient knowledge of the genetic components of disease, as well as improved accuracy in risk perception when compared to the provision of only an educational booklet.[43]

In another study, genetic counseling involvement in pediatric care was measured for medical adherence in a study population of approximately 200 participants. The study found that the inclusion of a genetic counselor in pediatric appointments resulted in improved adherence to medical management in a statistically significant manner.[44]

Furthermore, the psychological impact of genetic counseling for familial cancer was analyzed through meta-analysis. This study, published in 2006[45], performed a systematic review of the literature to examine the effect of genetic counseling on patient knowledge and psychological adaptation in 21 studies. The study concluded that genetic counseling did improve patient knowledge of cancer genetics, but had no impact, positive or negative, on the anxiety, distress, depression, or cancer-specific worry examined in the trials. Further investigation was strongly recommended in order to validate such findings and to analyze additional outcomes measures.[45]

In addition, a 2016 study of Australian patients looked at changes in screening and management choices made by individuals specific to genetic testing results. The study found that genetic information provided through genetic counselors impacted individual behavior in those individuals who were identified with a genetic predisposition to colorectal cancer. Those individuals with a genetic predisposition who were seen by a genetic counselor were more likely to undergo colonoscopy screening and were also more likely not to smoke.[46]

Such conclusions indicate the need for more extensive research on the effects of not only genetic information, but of the entire genetic counseling process for the purpose of identifying improved methods of patient engagement.

2.5.3 Impact of Genetic Test Results

The association between genetic predispositions and disease has been an exciting new approach to health and management for patients. Genetic risk information is an exciting tool for healthcare providers to help individuals to change lifestyle behaviors. For some patients, genetic information may influence individuals to increase their screening for cancer, while for others, it may provoke behavior changes such as weight lost or diet modifications. In practice, however, research has found that the use of genetic information alone has little to no impact on patient behavior change.[41]

Several literature reviews have reported on the impact genetic information can have on individual lifestyle and psychological state. One extensive literature review published in 2008 examined the effect of genetic information on patient's perceived risk, psychological, and behavioral changes. A total of 35 articles and 30 studies were analyzed and the review concluded that the genetic information had no significant impact on psychological adjustment regardless of genetic test results, and that only a minor improvement of cancer-reducing behavior modification

was observed.[35] Another recent meta-analysis by Hollands et al.[47] also reviewed 18 studies concerning smoking cessation, diet, and physical activity changes in patients provided with genetic predisposition information. The analysis demonstrated that genetic risk information had little to no effect on lifestyle modifications for patients with genetic predispositions. Genetic information alone therefore, appears to have little to no effect on patient behavior.

3.0 MANUSCRIPT

3.1 INTRODUCTION

In healthcare, an "outcome" can be defined as what happens to a patient as a direct consequence of their encounters with the healthcare system.[37] Patient outcomes are now emphasized measures of quality institutions, and are being rapidly integrated into clinical and medical research. Since the Patient Protection and Affordable Care Act (ACA) of 2010, the assessment of patient outcomes has become even more important, with mandatory reporting of health outcomes including prevention of hospital readmissions, reduction of medical errors, and the promotion of patient wellness efforts.[38] Additional private and public practices may soon be required to demonstrate improved patient outcomes as well.[37] Such legislation drives the need for defined outcome measures across a variety of healthcare fields.

The identification of outcome measures unique to the field of genetic counseling has likewise become a priority of the profession.[37] Previous research on the impact of genetic counseling suggests that patients have an improved understanding of cancer risk and increased patient empowerment. In one study, outcomes in over one hundred individuals with serious mental health illnesses found that genetic counseling improved both patient knowledge of the

genetic components of disease, as well as improved accuracy in risk perception compared to an educational booklet.[43] Genetic counseling outcomes have also been measured in patients with complex, multifactorial conditions in the absence of genetic testing. Over 140 subjects were assessed by psychological state and self-efficacy measures before and after genetic counseling, and found statistically significant increases in empowerment levels one month after undergoing genetic counseling.[41,42] Further genetic counseling outcomes identified through previous research suggest improved medical adherence in both pediatric and cancer settings, and increased patient knowledge of cancer genetics.[44,45] While the impact of genetic counseling has shown to have beneficial patient outcomes, further research on expectations unique to genetic counseling and defined, measurable outcomes is critical in the evolving setting of healthcare.

The ability to measure and define evidence-based outcomes is significant not only to assure quality, but also to obtain key information about risk stratification for customized care pathways.[25] In particular, patient engagement as an outcome has become an attractive new measure for clinicians and healthcare providers to evaluate their patient population. Patient engagement is defined as the actions an individual must take in order to elicit the greatest possible health benefit from the resources available to them.[28] Within the healthcare system, patient engagement outcomes can be seen to influence both individual outcomes, as well as healthcare costs at a community level. Patients with higher engagement levels reported not only having higher satisfaction, but also had improved medical outcomes, faster recoveries, and overall better quality of life. In addition, engaged patients were found to reduce healthcare cost through avoidance of unnecessary surgeries, decreased medical errors, and increased adherence to medical management.[25,29]

Genetic counselors have been shown to be capable of improving patient knowledge and empowerment, however we could not identify any reported research on the impact of genetic counseling on patient engagement. In this study, it was hypothesized that genetic counseling

activates patients in their health and results in increased patient engagement scores. In order to measure patient engagement, the Altarum Consumer Engagement (ACE) Measure™ was utilized. The ACE Measure is a new, validated tool designed to quantify patient engagement levels through the consideration of an individual's lifestyle, decision process, and technology utilization.[29,32]

In this study, the ACE Measure was used to measure engagement levels in participants before and after undergoing a genetic counseling appointment. Participants were comprised of patients referred to the UPMC Hereditary Gastrointestinal (GI) Tumor Program for hereditary cancer risk assessment based on personal cancer diagnoses, and/or on having a family history of cancer. In addition, this pilot study aimed to assess the feasibility of implementing the ACE as a patient engagement measure in the clinic, as well as to evaluate patient recruitment methods, retention, and data analysis approaches for future research studies.

3.2 METHODS

3.2.1 Participants

Participants were comprised of individuals seen at the University of Pittsburgh Medical Center (UPMC) Hereditary GI Tumor Program for genetic counseling. Participants were considered to be at an increased risk for a genetic cancer susceptibility based on an individual cancer history, or on a family history of cancer. Approval for the analysis was obtained from the University of Pittsburgh Institutional Review Boards (PRO16050209, 07/12/16) (Appendix C).

3.2.2 Eligibility Criteria

Participants with a young age of cancer diagnosis, a rare cancer, multiple cancers, or suggestive tumor studies were all candidates for genetic counseling. Additionally, participants who reported several family members with cancer, especially first-degree relatives, rare or multiple cancers, and correlated cancers, were also candidates for genetic counseling and were evaluated for a genetic cancer susceptibility.

3.2.3 Recruitment

Participants were approached about the study at the beginning of their genetics appointment. For those participants who expressed interest in enrolling in the study, a research investigator provided informed consent, reviewed the consent form, and answered any questions prior to the genetic counseling appointment.

3.2.4 Instrument

Valid assessment measures are difficult to maintain in the rapidly advancing technology and changing standards of healthcare, and understanding patient engagement requires a comprehensive examination of factors such as a patient's risk perception, skill set, confidence, and experience within the healthcare system.[29] The majority of engagement measurement tools however, typically measure only one aspect of engagement, such as autonomy, resource preferences, or the decision making process. Other tools cover multiple domains of engagement, but are specific to management of a particular disease. [25,29,32]

The Altarum Consumer Engagement (ACE) Measure™ was created to address some of the limitations in current engagement measurement tools. The validity of the ACE Measure was

established in a study in which over 2,000 participant results were compared between the novel ACE Measure and the Patient Activation Measure (PAM), a tool used for patient activation analysis since 2006. The ACE Measure was confirmed to have significant statistical relevance and validity across three independent domains of health, as a holistic measure of patient engagement.[29]

The ACE measure was created with the purpose of expanding the way in which patient engagement is measured and understood, as well as to incorporate modern information sources and technology available to patients. ACE can provide valuable information about necessary improvements within the system, but also can enable medical professionals to help patients become more confident and involved in their own health through the identification of strengths and weaknesses in their Commitment, Informed Choice, and Navigation scores. As such, the ACE can also be useful for medical professionals to evaluate the abilities of patients in making decisions, and the type and quantity of support that may be needed for each patient.[32]

The ACE measure is a tool designed to evaluate the engagement of individuals in their healthcare. The ACE measure used for this study involves 12 questions, which evaluate three domains of health: Commitment, Navigation, and Informed Choice. The Commitment domain refers to an individual's consistency and self-care habits. The Navigation domain captures an individual's ability to communicate with healthcare providers. The Informed Choice domain addresses the decision-making process and resources used by an individual (Figure 1).

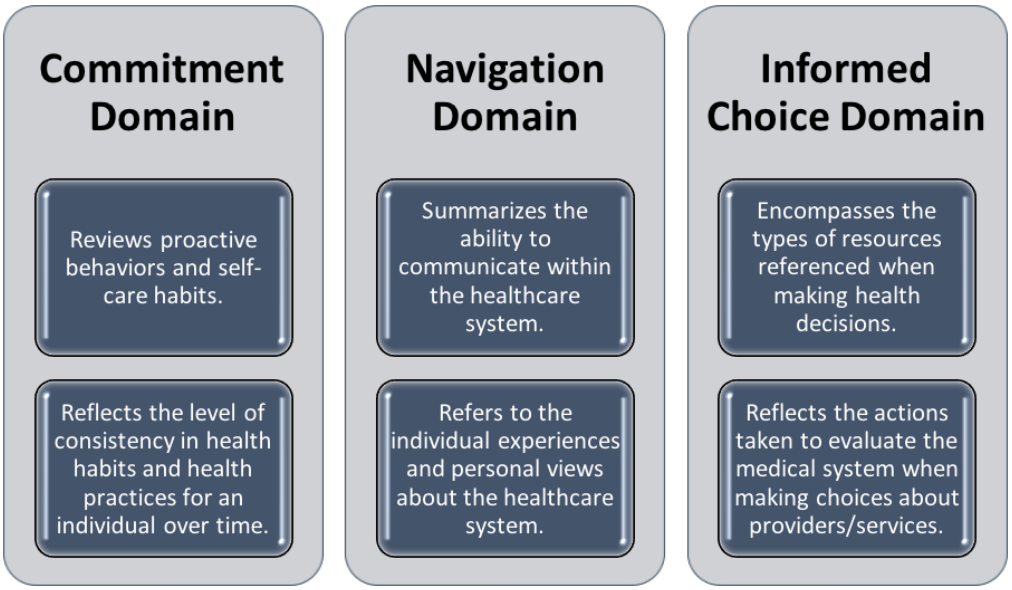


Figure 1. ACE Measure Domains

In addition, the combination of the three domains, the total ACE score, reflects an individual's average engagement in their health and general participation in the healthcare system. While the total ACE score acts as a reflection of a patient's overall engagement level, the three domains provide more specific strengths and weaknesses for targeted interventions.

3.2.5 ACE Measure Scoring

The ACE Measure is composed of 12 questions across three health domains. For each of the domains (Commitment, Navigation, and Informed Choice) there are four related questions which are ranked on a Likert scale of "strongly disagree" to "strongly agree" (Appendix A). The answers were scored with "strongly disagree" being marked as zero points, and "strongly agree" being marked as four points. The four scores within each domain were then averaged and multiplied by 6.25 to provide a final score from 0 to 25 for each domain and ranked (Figure 2).[32]

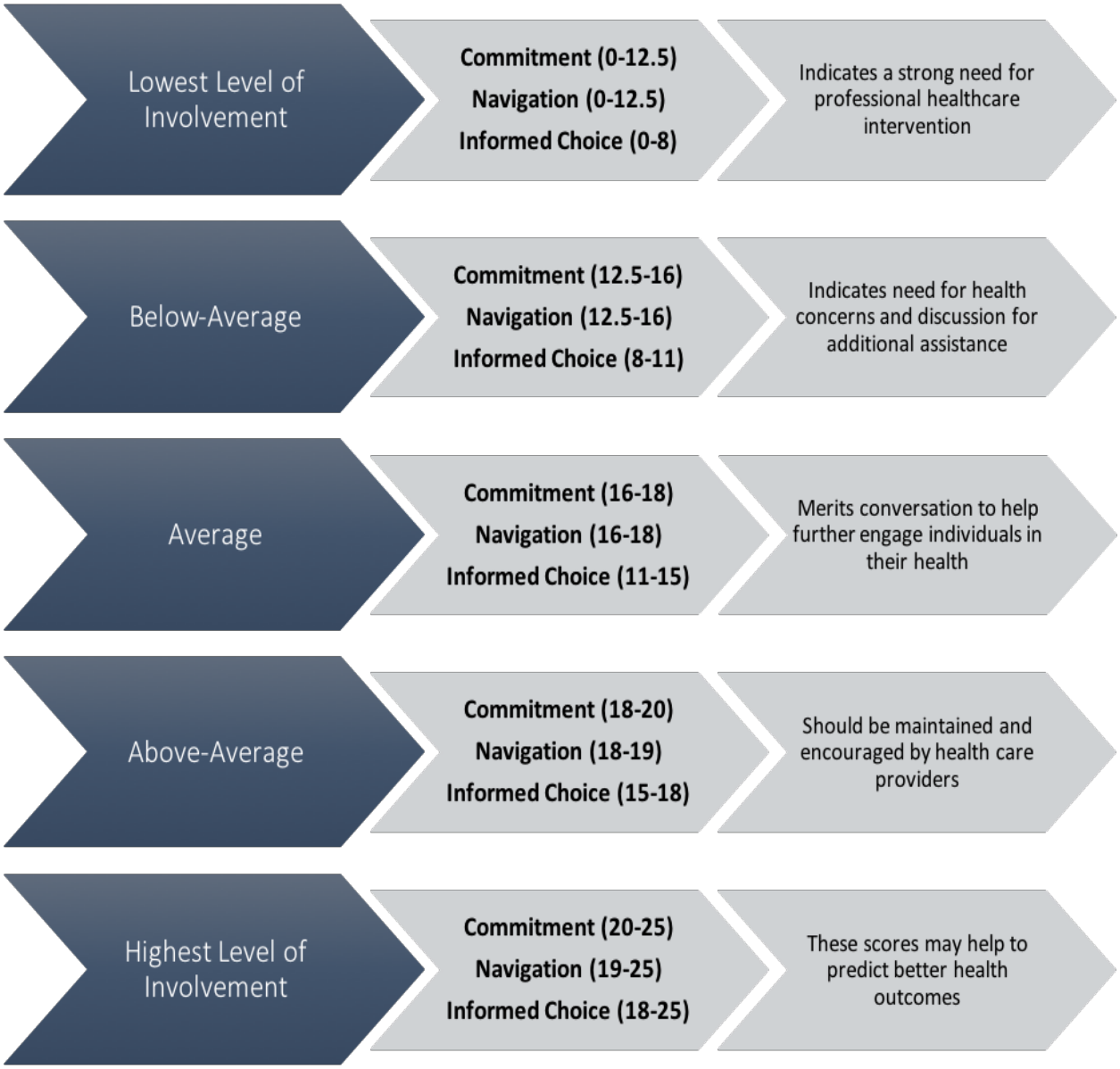


Figure 2. ACE Measure Score Interpretation

These three final scores for each domain can be summed to determine a person's overall engagement score out of a total possible 75 points, which reflects a person's average activation level in their health and within the healthcare system overall.

3.2.6 Procedures

The research investigators overseeing the study included a gastroenterologist, genetic counselors, and a genetic counseling student who facilitated the study enrollment and follow-up questionnaire (Figure 3).

Patients who provided informed consent were provided with the Altarum Consumer Engagement (ACE) Measure to assess their engagement level. The ACE was provided in written format, and completed by the participant in private. The form was collected by a research investigator prior to the genetic counseling session and the physician consult. During the appointment, participants underwent individualized genetic counseling, as well as a physician consult to review overall health.

The genetic counseling intervention comprised a one-hour appointment in which patients received genetic education and information pertaining to hereditary cancer syndromes, and were engaged in personalized cancer risk assessment and psychosocial counseling. Visual aids were utilized to support patient comprehension. Participants were also provided with a written letter of summary after the appointment. Individuals who underwent genetic testing received a phone call for result disclosure and follow-up.

Participants were then contacted three to five months after their office appointment via telephone and were asked the original 12 ACE Measure questions again.

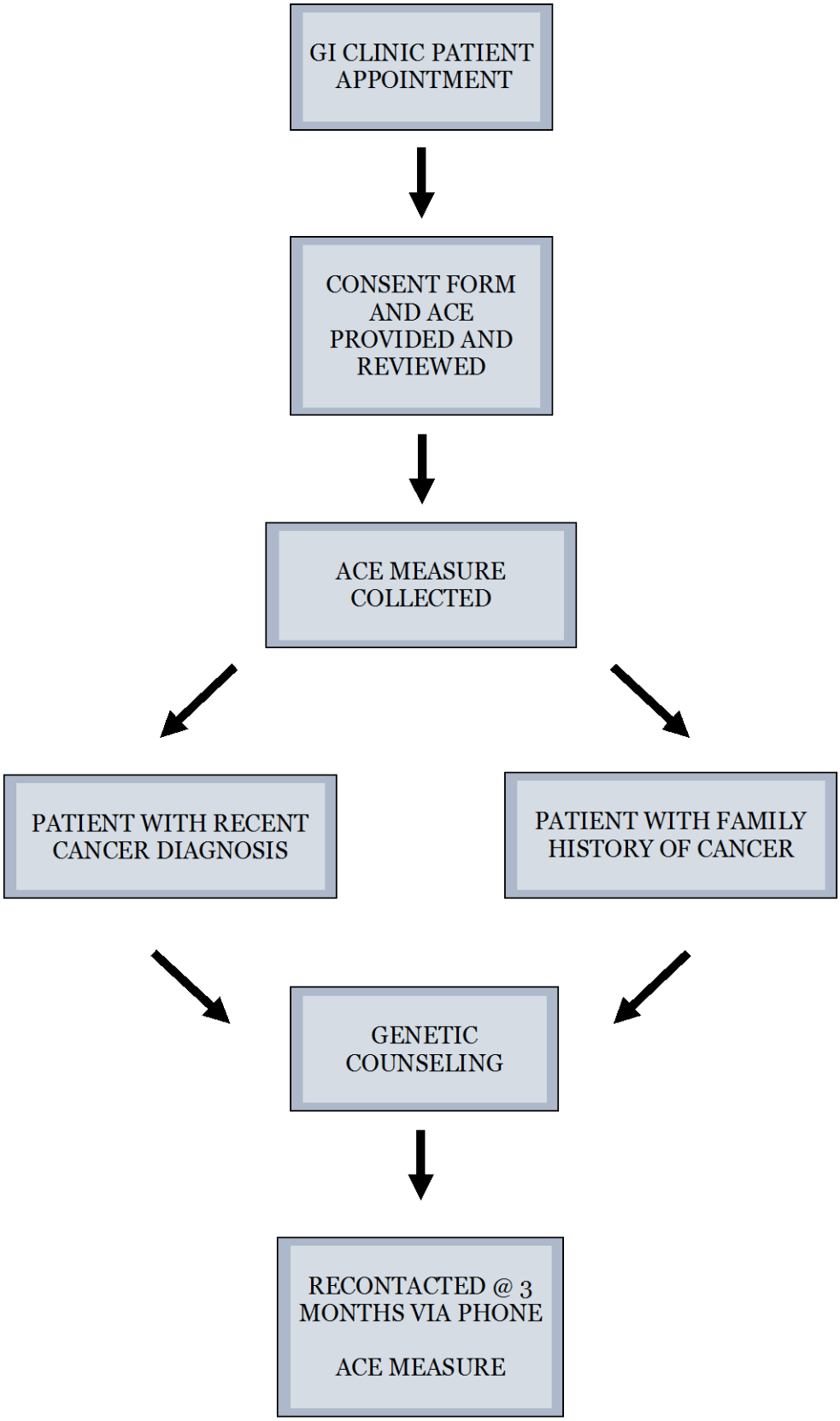


Figure 3. Protocol Flowsheet

3.2.7 Data Analysis

The ACE data were assessed for normality of distribution within each domain of health, and across the total ACE score (summation of domain scores). Data were assessed for distribution between patients recently diagnosed with cancer and those with a past personal or family history of cancer. Paired sample t-tests were utilized to determine mean differences in scores between pre and post genetic counseling across all participants (Appendix B). The statistical computer program STATA (StataCorp 2015)[48] was used for the purpose of analysis and a significance threshold of $p<0.05$ was applied (95% Confidence Interval).

3.3 RESULTS

A total of 46 participants were recruited between July 2016 and October 2016, and each was followed for a period of at least three months after enrollment. Five participants were lost-to-follow up, and two individuals passed away prior to the collection of the post-engagement level. Additionally, participants who failed to answer at least two questions in either of the Pre or Post ACE Measures were not included in the data analysis (1 individual). A final group of 38 participants was included for analysis (Table 1). Nineteen participants had a recent diagnosis of cancer, with the majority of individuals undergoing treatment for colorectal cancer. A total of nineteen participants were referred for past personal history or a family history of cancer. Of these, twelve participants had never been diagnosed with cancer, while seven had a past personal cancer diagnosed greater than three years prior to enrollment and/or were no longer undergoing treatment (Appendix A).

3.3.1 Demographics

Of the participants enrolled, 66% were female, and the majority were Caucasian (89%, n=34). Participant ranged in age from 18 years to 81 years (mean age of 53 years) and the majority of patients were in their 60s at the time of enrollment. Patients recently diagnosed with cancer comprised 50% of the sample population, with colorectal cancer being the most common diagnosis (Table 1).

Table 1. Participant Demographic Data

	Gender	Age	Ethnicity	Cancer Type (Age at Diagnosis)	Current Cancer	Family History of Cancer
1	F	77	Caucasian	Colon (dx. 77)	Yes	Yes
2	M	61	Caucasian	Colon (dx. 61)	Yes	Yes
3	F	42	Caucasian	Colon (dx. 42)	Yes	Yes
4	F	77	Caucasian	Colon (dx. 77)	Yes	Yes
5	F	49	Caucasian	Colon (dx. 49), Soft tissue sarcoma (dx. 34)	Yes	Yes
6	F	33	Caucasian	Colon (dx. 33)	Yes	Yes
7	M	48	Caucasian	Colon (dx. 47)	Yes	Yes
8	M	55	African American	Colon (dx. 55)	Yes	Yes (Polyposis)
9	F	42	Caucasian	Colon (dx. 40)	In treatment	Yes
10	F	81	Caucasian	Colon (dx. 80)	Yes	Yes
11	F	49	Caucasian	Rectal (dx. 48)	Yes	Yes
12	F	64	Caucasian	Pancreatic (dx. 62 mets)	In treatment	Yes
13	M	65	Caucasian	Pancreatic (dx. 63), Prostate (dx. 55)	Yes	Yes
14	F	60	African American	Pancreatic (dx. 58)	In treatment	Yes
15	F	60	Caucasian	Bladder (dx. 60), Thyroid (dx. 39)	Yes	Yes
16	F	39	African American	Gastric (dx. 38)	Yes	Yes
17	F	55	Caucasian	Bile Duct (dx. 54)	Yes	Yes
18	F	74	Caucasian	Endometrial (dx. 71)	In treatment	Yes
19	F	55	Caucasian	Breast (dx. 52)	In treatment	Yes (*ATM* mutation)
20	F	67	Caucasian	Colon (dx. 49)	No	Yes (HNPCC)*
21	F	50	Caucasian	Colon (dx. 46)	No	Yes
22	F	41	Caucasian	Thyroid (dx. 28)	No	Yes
23	M	71	Caucasian	Rectal (dx. 61)	No	Yes
24	F	38	Caucasian	Colon (dx.35)	No	Yes
25	M	58	Caucasian	Colon (dx. 38)	No	Yes
26	M	71	Caucasian	BCC	No	Yes
27	M	18	African American	None	N/A	Yes (Lynch Syndrome)
28	M	50	Caucasian	None	N/A	Yes (Lynch Syndrome)
29	F	60	Caucasian	None	N/A	Yes (Lynch Syndrome)
30	M	47	Caucasian	None	N/A	Yes (*BRCA2* mutation*)
31	F	64	Caucasian	None	N/A	Yes (FAMMM*)
32	F	49	Caucasian	None	N/A	Yes
33	F	32	Caucasian	None	N/A	Yes
34	M	61	Caucasian	None	N/A	Yes
35	F	31	Caucasian	None	N/A	Yes
36	M	30	Caucasian	None	N/A	Yes
37	M	30	Caucasian	None	N/A	Yes
38	F	75	Caucasian	None	N/A	Yes

*HNPCC: Hereditary Non-Polyposis Colorectal Cancer/ FAMMM: Familial Atypical Multiple Mole Melanoma

3.3.2 ACE Measure across all Participants

Across all 38 participants, post ACE scores were higher following genetic counseling, indicating an increase in patient engagement after undergoing genetic counseling. The difference between pre and post ACE scores was statistically significant (two-sided p-value: $Pr(|T| > |t|) = 0.0342$) with a mean difference of approximately three points. The individual categories within the ACE Measure (Commitment, Navigation, and Informed Choice) were not found to have statistically significant changes ($Pr(|T| > |t|) = 0.2049$; $Pr(|T| > |t|) = 0.0635$; $Pr(|T| > |t|) = 0.3025$ respectively). The Navigation domain however, was the domain with the largest change seen between pre and post scores overall. Navigation scores were seen to increase in the post ACE Measure by approximately one point on average (one-sided p-value: $Pr(T < t) = 0.0318$) (Appendix B).

The majority of participants had either improved or maintained scores. For the data analysis, scores were analyzed based on the difference of the raw value scores (Table 2).

Table 2. Participants Raw Data Scores

Result Summary (n= 38)				
	Pre-ACE Score	Post-ACE Score	Difference	Two-sided P-value
Commitment	18.832	19.572	0.740	0.2049
Navigation	18.448	19.572	1.124	0.0635
Informed Choice	13.816	14.515	0.699	0.3025
Total	51.096	53.660	2.563	0.0342
	# Improved	# Maintained	# Worse	
Commitment	17	7	14	
Navigation	17	10	11	
Informed Choice	16	10	12	
Total	22	3	13	

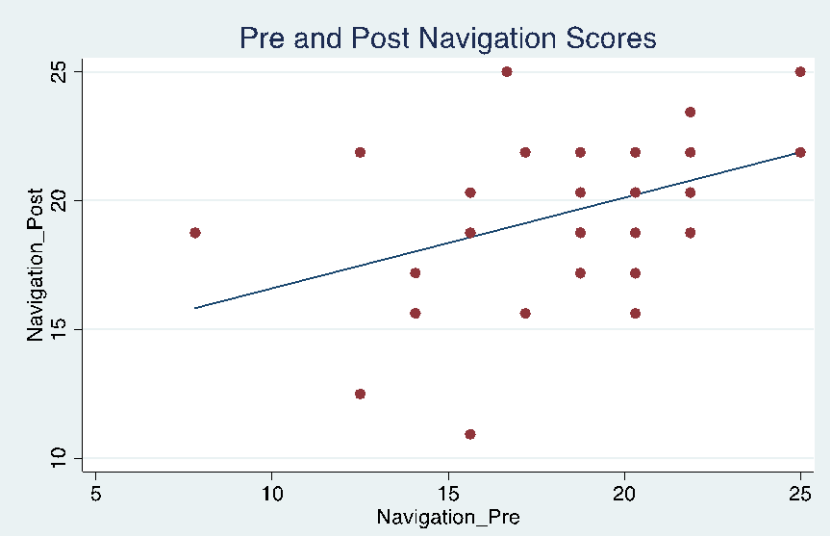
Further data analysis showed a moderately strong, positive correlation between pre and post scores across all three domains and in the total ACE scores (Tables 4-7). The pre and post scores for each domain were analyzed and the statistical relationship was described by the coefficient of determination (r-squared value). The Commitment domain was found to have a r-squared value of 0.3385 (correlation coefficient r =0.5818). The Navigation domain's r-squared value was 0.1606 (correlation coefficient r =0.4007), and the Informed Choice domain was 0.4866 (correlation coefficient r =0.6976). The total ACE score coefficient of determination was r-squared= 0.4770 (correlation coefficient r =0.6907).

In addition, the ACE Measure clusters scores into categories (lowest, below average, average, above average, or highest engagement scores) to better account for natural variation in scores over time. This means that while an individual's overall score can change by one or two points, they may still be within range of their original category (Appendix B.1.1). For the purposes of this study, we looked at the differences in the raw scores independent of the categories to determine overall change and total engagement score differences. Analysis of both the raw score changes and category ranges however, support that the majority of participants either maintained or increased their scores, while the fewest number of participants had worse scores across all three domains.

Table 3. Pre-Commitment vs. Post-Commitment ACE Scores

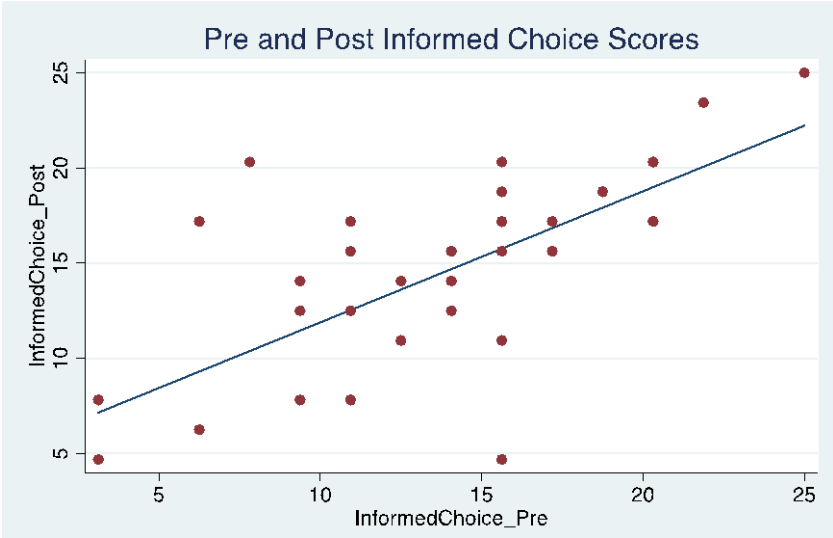
r-squared value: 0.3385

Table 4. Pre-Navigation vs. Post-Navigation ACE Scores



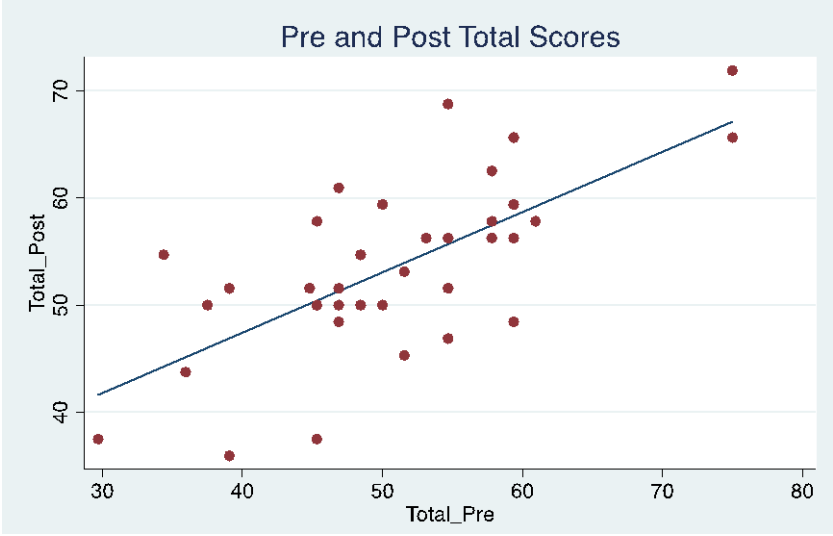
r-squared value: 0.1606

Table 5. Pre-Informed Choice vs. Post-Informed Choice ACE Scores



r-squared value: 0.4866

Table 6. Pre-Total vs. Post-Total ACE Scores



r-squared value: 0.4770

3.3.3 ACE Measure between Recent Cancer Diagnosis and Family History

There were no statistically significant differences found between patients who had recent cancer diagnoses and those who were primarily referred for past personal history or family history of cancers in any categories of the ACE Measure. The total pre and post ACE scores were determined by two-sample, unpaired t test with equal variance, and no difference was found between the two groups ($Pr(|T| > |t|) = 0.2042$). The three categories within the ACE Measures did not indicate statistically significant differences between the two populations (Commitment $Pr(|T| > |t|) = 0.6732$; Navigation $Pr(|T| > |t|) = 0.1795$; Informed Choice $Pr(|T| > |t|) = 0.5062$). The Navigation domain however, was found to have the largest difference between populations. Participants with a past personal history or family history of cancer had a larger change in the Navigation Domain than those with a recent cancer diagnosis (one-sided p-value: $Pr(T < t) = 0.0897$) (Appendix B).

3.3.4 ACE Measure between Male and Female Participants

The ACE Measure scores observed between male and female participants were also analyzed. Across each of the ACE Measure domains, there was no statistically significant differences in the commitment levels observed in either gender (Commitment $Pr(|T| > |t|) = 0.1851$; Navigation $Pr(|T| > |t|) = 0.3094$; Informed Choice $Pr(|T| > |t|) = 0.7813$). The combined total scores for the ACE Measure in both women and men were not statistically significant for differences in patient engagement changes between the sexes (($Pr(|T| > |t|) = 0.1842$) (Appendix B).

3.3.5 Pre and Post ACE Measure Changes by Participant Age

The majority of participants were between the ages of 30s and 70s years of age. However, there was one participant who was 18 years of age and one who was 81 years of age. The mean value of pre and post ACE score changes were analyzed by age in decades. Those patients in their 40s were observed to have the most significant change from pre to post score, with a mean increase of 6.055 points. Those in their 60s were closest to the overall average difference in scores, with a mean change of 3.530 points. Those in their 30s and 70s were seen to have the lowest overall changes in scores, with an increase in scores by approximately 0.24 points. Interestingly, the youngest participant was seen to have the largest change in engagement scores (difference of 7.813), while the oldest participant had an overall decrease in engagement score (difference of -3.125) (Appendix B).

3.4 DISCUSSION

In response to the Affordable Care Act (ACA 2010), patient outcomes are now required quality measures for specific healthcare institutions.[38] Such practices underscore the need for both valid measure tools, as well as improved means of engaging patients in their health.[37]

In this study, genetic counseling was found to have a positive impact on patient engagement over time. Previous research on genetic counseling outcomes has identified several patient benefits. Meta-analysis reviews of the literature found that genetic counseling can lead to improved patient understanding of cancer risks, complex disease, and are also more likely to adhere to medical management, such as participation in cancer screening.[45,46] Additionally, previous research in genetic counseling outcomes described enhanced psychological adaptation to genetic information, as well as increased patient empowerment.[41,42,44–46]

Genetic counseling was associated with increased total ACE scores, indicating that genetic counseling may also contribute to increased patient engagement. Changes in scores across all participants, regardless of cancer diagnosis, were statistically significant, and may suggest a clinically meaningful intervention.

The ability to measure patient engagement outcomes is essential, yet measurement tools are limited. The ACE Measure (2015) was developed with the intention to better capture patient engagement in a holistic manner, and has since been used to determine engagement levels over time and to predict outcomes in diabetic patients at the University of California, Los Angles (UCLA). When measured in six month intervals, ACE scores have been observed to have fairly stable consistency, with moderate positive correlation over time (correlation coefficient r =0.6) (unpublished data, UCLA). The data reported in ACE scores among cancer patients for this study also found a correlation coefficient of approximately r =0.6 across the Commitment, Informed Choice, and total ACE scores as well in the observed three months.

The individual ACE domains were also used to correlate patient outcomes in diabetic individuals. In the diabetic population, the Commitment Domain was able to predict improvement or decline in glycated hemoglobin (HbA1c) levels over time (unpublished data, UCLA). While individual ACE domains were not found to have statistically significant changes in cancer patients for this study, the Navigation Domain was observed to have the largest difference amongst all participants. The Navigation Domain is associated with an individual's comfort level in asking questions of their healthcare providers, as well as providing feedback about their experiences and expectations for the type of care they will receive. The near-significant increase in Navigation scores may reflect the success of genetic counseling in empowering patients to engage in discussion about their health, and in establishing an environment that allowed for patients to reflect and provide feedback about their healthcare management, ultimately driving increased patient empowerment.[37]

In addition, participants who underwent genetic counseling based on a family history of cancers had a larger change in their Navigation score than those patients with a recent cancer diagnosis, although the observation was not statistically significant. A possible explanation for this observed difference could be as a result of each group's goal in undergoing genetic counseling. While a cancer patient may be most interested in next steps and treatment options, an individual referred on the basis of family history may have a broader agenda, leading to more questions and interest in generalized knowledge seeking related to hereditary cancer. Genetic counselors are specialists trained in engaging patients in bi-directional, active communication, with a focus on building rapport.[41] The difference in perspective of these two groups of participants, their current immersion in the healthcare system, as well as the focus of the genetic counseling discussion, could explain the observed changes in the Navigation scores between these two groups.

Scores for the three ACE domains are independently validated, but the ability to measure the total score change and to assign statistical significance was restricted by the classification of engagement levels. Paired sample t-test analysis of the mean difference in total scores therefore, was an approach that was better able to determine statistically significant changes in patient engagement levels both across domains, and in overall scores.

The classification of scores into engagement levels (below average, average, above average, etc.) also limited interpretation as a result of the range variation between categories. The ACE classification category ranges may be as wide as 12 points (Lowest score (0-12.5); Commitment and Navigation Domains) or as narrow as one point (Above Average score (18-19); Navigation Domain), which can significantly influence a participants' status as "changed" vs. "maintained" engagement. Due to this score classification range the t-test analysis determined that more participants improved, rather than maintained, engagement scores based on the mean difference of the scores. The classification of scores by range and the analysis performed by

mean score difference however, both support the conclusion that there were more participants with improved scores than with worsened scores, and that the Navigation Domain reflected the largest score changes across all participants.

Difference in engagement across genders and ages were also analyzed. No changes were found between engagement levels in males and females. Previous research has found that men have worse health seeking behaviors than women, and are less likely to engage in screening and health management.[49–52] Such results could be a consequence of an insufficient sample size, a biased sample population, or may reflect the personalized approach of trained genetic counselors to target information to patient needs.[52]

With regards to age, the greatest changes in pre and post scores on average, were observed in individuals in their 40s, followed by individuals in their 60s. The lowest observed changes were reported in participants in their 30s and 70s. However, no statistically significant analysis was determined for age related engagement.

To our knowledge, this is the first utilization of the ACE Measure to determine changes in patient engagement outcomes for genetic counseling in a specialty cancer clinic setting. The purpose of this pilot study was to analyze how patient engagement levels changed after undergoing genetic counseling and to determine the feasibility of long-term implementation of the ACE Measure in a specialty clinic. The results observed in this study support the utility of the described methodology for measuring patient engagement and defining a genetic counseling outcome. In addition, the data suggests preliminary trends, such as increased engagement post genetic counseling, and age related engagement levels that merit further evaluation.

3.4.1 Research Recommendations and Limitations

The preliminary results discussed in this study merit further investigation. Additional research on large populations in the clinical setting may provide more evidence regarding the impact of genetic counseling on patient engagement, as well as determine risk stratification and personalized approaches to individuals identified at lower levels of engagement. As an observational pilot study, this research also lacked a control group, so changes in engagement cannot be definitely attribute to genetic counseling alone.

One limitation in this research is the difference in data collection methods through an in-person written survey, and a three-month thereafter telephone survey. The "social desirability" bias refers to the phenomenon that participants may report perceived desirable traits rather than true, but socially undesirable, traits.[53] While there is some evidence to suggest that such bias is more frequent during person-based interactions, such as telephone interviews, the total impact of the bias is uncertain.[53] While this study strove to minimize bias through inclusion of normalizing dialect, such bias cannot be disregarded.

Further investigation of patient engagement on additional health outcomes may also be an avenue of research. The role of patient engagement on lifestyle factors, such as weight loss and tobacco cessation, which are factors established in reducing cancer risk, may indicate larger public health interventions to reduce long-term healthcare costs. Although the data are not shown, additional analysis of the correlation between engagement and short term success in weight loss and tobacco cessation has been performed, and determined that initial ACE scores can be predictive of successful behavior modifications over time. Identification of successful interventions, such as genetic counseling or personal health coaching, that increase patient engagement should be studied for their impact on lifestyle changes and on public health.

3.5 CONCLUSION

Patient engagement within the healthcare system can have major implications for individual health outcomes, as well as on reduced healthcare costs. This study is the first known report of patient engagement levels in individuals undergoing genetic counseling in a specialty cancer clinic. The differences seen in levels of engagement were found to be statistically significant regardless of an individual diagnosis of cancer, suggesting that genetic counseling may empower patients to have lasting involvement in their health and in the health care system. Preliminary results reflect the value of the services provided by genetic counselors, and the significance of their availability in the clinic setting. Additional investigation of patient empowerment over time and across specialty settings has been confirmed to be both feasible and warranted through this pilot study.

4.0 RESEARCH SIGNIFICANCE TO GENETIC COUNSELING AND PUBLIC HEALTH

The purpose of this pilot study was to analyze the impact of genetic counseling on patient engagement and to determine the feasibility of implementation in healthcare practice. This research is of particular importance to the field of genetic counseling and public health. Patient engagement has long been a suspected outcome of genetic counseling, as genetic counselors are trained in psychosocial interventions, bi-directional communication, and personalized information delivery.[42] Previous research has found that genetic counseling can increase patient satisfaction and understanding, as well as promote patient empowerment over time.[42,45,54]

Research on the impact of patient engagement in their health and genetic counseling however, is limited. Such research is fundamental in underscoring the value of genetic counselors in the clinic, and in targeting approach modifications and areas of improvement. The

preliminary results of this study suggest that genetic counseling is not only a valuable component of the healthcare system because of increased patient understanding and satisfaction, but also in improving patient engagement in their health. This has implications for public health on a whole, as improved engagement in populations can lead to overall better quality of life.

Patient engagement has been linked to a range of beneficial outcomes not only for patients, but for healthcare organizations as well. Patients who were found to have high engagement levels reported higher satisfaction with their healthcare, and are even seen to recover faster from illnesses. High levels of engagement were also correlated with improved medical adherence, shorter lengths of stay in hospitals, and better long term quality of life. Additionally, patients who are considered to be highly engaged in their health and in the medical system have half the rate of medical errors compared to those with low-levels of participation.[29]

From the provider's perspective, patient engagement has been shown to afford significant cost reduction in healthcare. When patients are engaged in their health, finances and resources are preserved through the avoidance of unnecessary surgeries, better adherence to medical management, and the prevention medical errors. Patient participation can also reduce healthcare costs by choosing options based on an individual's preference, rather than simply being provided with the standard of care approach.[25] High levels of patient involvement lead to safer, more effective, and less expensive healthcare overall. As such, the active role of patients in managing their health is important to increase satisfaction and successful outcomes, and to develop economically sustainable healthcare systems.

Patient engagement research is also important to the field of public health, as it can allow for the identification of targeted populations, segmentation, and evaluation of existing interventions. Participation rates can also provide key information about risk stratification for targeted interventions, help to facilitate customized care pathways, and provide enhanced care both at an individual and community level.[25] Patient engagement measures can provide

information to guide physician intervention through the identification of patient strengths and weaknesses, and providing appropriate support and referrals for customized care. Additionally, engagement measures can identify subsets of patients that could benefit from targeted interventions to facilitate increased engagement at a population level.

Although this pilot study has identified statistically significant correlations, the small study size and short timeframe indicate the data may not yet imply clinical changes, but rather suggest initial trends for additional research. The preliminary results discussed in this study merit further investigation. One such avenue of research may be on the association between patient engagement and health outcomes. The role of patient engagement on lifestyle factors, such as weight loss and tobacco cessation, may be able to identify larger public health interventions, with the potential to reduce long-term healthcare costs. Preliminary data on such associations are included in the Public Health Chapter of this thesis, and found that initial ACE scores can be predictive of successful and unsuccessful behavior modifications over time. Identification of successful interventions, such as genetic counseling or personal health coaching, that increase patient engagement should be studied for their impact on lifestyle changes and on public health, both in a larger sample population and over an extended period of time to determine novel interventions for the benefit of patients and public health endeavors.

5.0 PUBLIC HEALTH ESSAY

5.1 INTRODUCTION

Public Health is defined as the actions taken to protect and improve the health of communities through the detection and control of disease, research for disease prevention, and the promotion

of healthy lifestyles.[55] Patient engagement is imperative to public health as it captures the abilities and activities of individuals in the community in regards to their health management. Patients with higher levels of engagement are less likely to require multiple hospital visits for chronic illnesses, recover faster from illness, and have higher satisfaction in the healthcare system.[25] While patient engagement is targeted at the individual level, the impact of increased healthcare engagement has population effects and the potential to influence public health on a larger scale.

This pilot study addressed the question of whether genetic counseling can empower patients to become more involved in their health and the healthcare system. While preliminary trends found that patient engagement does increase following genetic counseling, more research about behavior changes is needed. Therefore, in addition to tracking the ACE Measure for participants over a period of three months, this study also analyzed additional lifestyle factors through phone questionnaires that tracked behavior change in patients post-genetic counseling.

5.2 PARTICIPANTS

The total number of participants in this pilot study included 38 individuals. In order to analyze lifestyle changes, a subset of these participants were asked additional questions regarding their health and habits. Participants seen for genetic counseling who were also current smokers, or whose BMI was greater than 30 kg/m^2, completed a lifestyle questionnaire (Appendix A) via telephone three months post-genetic counseling at the same time as they were called for the ACE Measure post-survey (Figure 4). If an individual was both a current smoker and had a BMI greater than 30 kg/m^2, the physician and patient worked together to determine the lifestyle change that was most important to them (in both cases, each participant selected to address tobacco cessation). Of the 38 individuals, 13 participants met criteria for weight loss or tobacco usage. Seven of the thirteen participants were recently diagnosed with cancer, and the remaining six participants were seen for a family history of cancer.

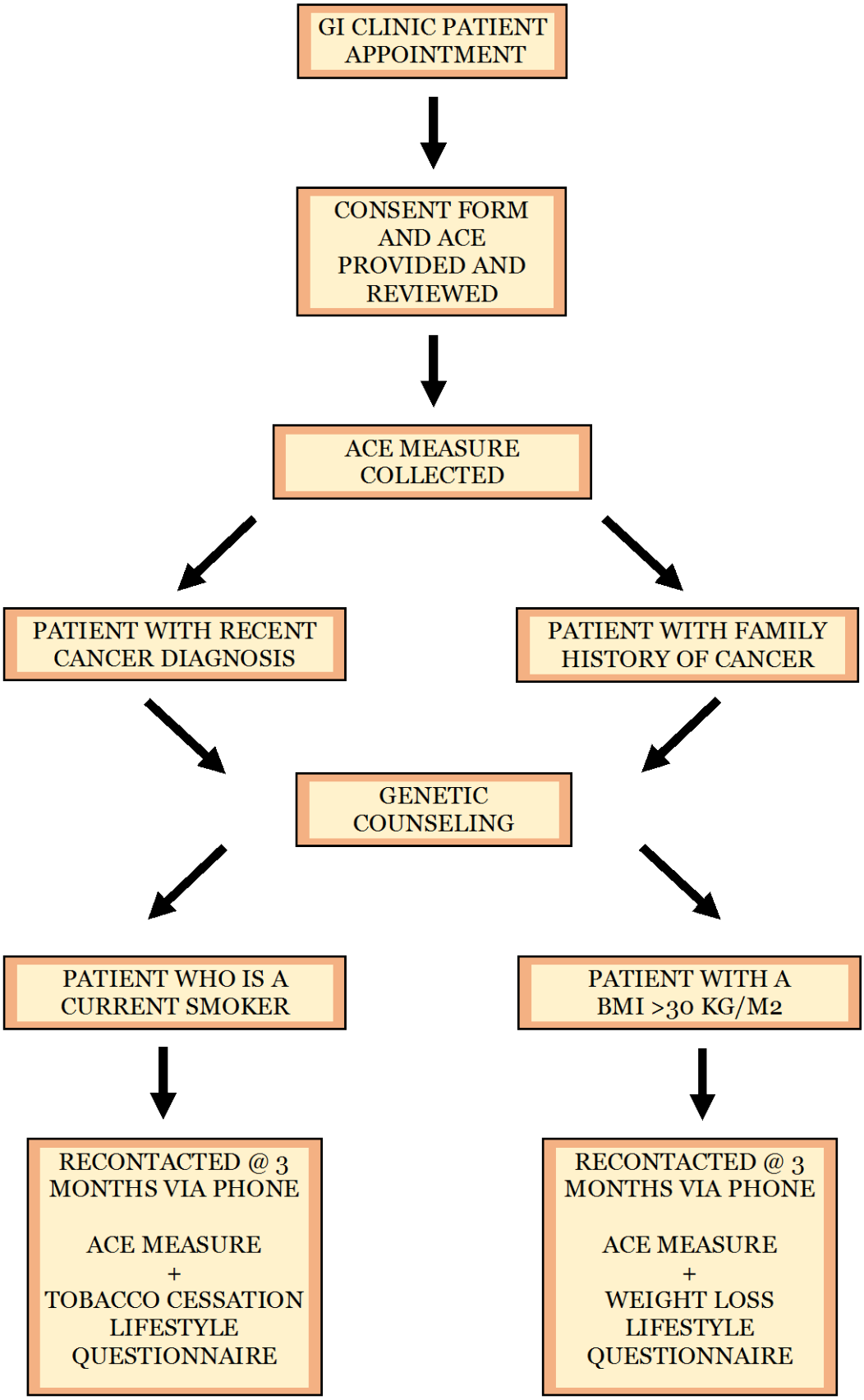


Figure 4. Lifestyle Behavior Protocol Flowsheet

5.3 RESULTS

Participants were asked several questions concerning their perceived ability to maintain a healthy lifestyle, as well as asked to report on their most recent weight and smoking status. Participants who reported a higher weight or no change in weight were categorized as “failure to change.” Likewise, those participants who were not in a current quit attempt were considered as “failure to change” behavior status. Participants who either reported a lower weight, or were currently in a quit-attempt, were noted as “successful in change” status.

Seven participants were recently diagnosed with cancer, of which 86% (n=6) failed to change their lifestyle behaviors. However, of those participants who were seen for family history of cancer, 83% (n=5) were successful in changing their lifestyle behaviors. The majority of successful changes took place in individuals who were not recently diagnosed with cancer, demonstrating a potential target group for intervention.

Table 7. Participant Cancer Status and Lifestyle Behavior Changes

	FAILURE TO CHANGE	SUCCESSFUL CHANGE	TOTAL (N)
Recent Cancer Diagnosis	6	1	7
Family History of Cancer	1	5	6
Tobacco Lifestyle	3	3	6
Weight Loss Lifestyle	4	3	7

A total of six participants were observed for tobacco cessation, and a total of seven participants were observed for weight loss behaviors. The average weight loss observed was approximately three pounds. Of the participants who reported being in a current quit-attempt, one had not smoked in over two months, while the other two participants reported utilization of medication for the quit attempt and a period of non-smoking average of five days. In each group, the ratio of

participants who failed to change versus participants who succeed in change was approximately 50:50. (Table 4)

Table 8. Failed to Change and Succeeded to Change Total ACE Score Comparison

	FAILURE TO CHANGE	SUCCESSFUL CHANGE	DIFFERENCE
Mean Pre-ACE Total score	46.7	51.3	4.7
Mean Post-ACE Total score	51.2	53.1	1.9
DIFFERENCE	4.6	1.8	

Participants who failed to change their behavior had an overall lower Pre-ACE Measure score compared to those who were successful in change (mean difference of 4.7 points). The average total Post-ACE scores for both groups however, were similar, indicating a larger positive change in those who failed to change their lifestyle behaviors (mean difference of 1.9 points). (Table 5). This trend may indicate that the initial pre-ACE engagement score is more informative regarding whether an individual will change lifestyle factors.

Table 9. Failed Change and Successful Change ACE Domains Summary

FAILURE TO CHANGE			
	Pre-ACE Score	Post-ACE Score	Difference
Commitment	17.19	19.64	+ 2.46
Navigation	18.30	17.86	- 0.45
Informed Choice	11.16	13.84	+ 2.68
Total	46.65	51.34	+ 4.69
SUCESSFUL CHANGE			
	Pre-ACE Score	Post-ACE Score	Difference
Commitment	17.45	17.71	+ 0.26
Navigation	18.92	21.09	+ 2.17
Informed Choice	14.84	14.32	- 0.52
Total	51.22	53.13	+ 1.91

Participants who failed to change their lifestyle had a greater overall increase in their commitment scores (mean difference of +2.46 points) compared to those who were successful in

change (mean difference of +0.26 points). The Navigation domain was observed to have a larger change among those who were successful in change (mean difference of +2.17 points) as compared to those who failed to change (mean difference of -0.45) (Table 6). The differences observed in the Navigation scores observed however, were not statistically significant (one-sided p-value: $Pr(T < t) = 0.0914$). (Appendix D)

In the Informed Choice domain however, statistically significant differences were observed. Patients who failed to change their weight or smoking habits had an overall increased score in the Informed Choice domain than those who were successful (two-sided p-value: $Pr(|T| > |t|) = 0.0058$). Among participants who were successful in change, the mean difference in Informed Choice score was decreased (mean difference of -0.52 points), compared to those who failed to change (mean difference of +2.68 points). However, both the mean pre and post ACE scores in successful change individuals were higher than mean post ACE score among failure to change participants. The difference in the informed choice domain was the most significantly increase change observed across all domains in both participants who failed to change and those who were successful in change.

5.4 DISCUSSION

While lifestyle behaviors have been shown to reduce cancer risk in the general population, fewer studies are available that analyze the effect of behavior on hereditary cancers. Hereditary cancers, such as Hereditary Breast and Ovarian (HBOC) and Lynch syndrome, have an increased risk for the development of specific cancers. For the HBOC genes, the risk for breast cancer in a woman's lifetime may be as high as 70%, whereas Lynch-related gene mutations confer a risk for colorectal cancer that may be as high as 69%.[14,16] While these risks are significantly

increased compared the general population, they are not 100%. Due to the difference in penetrance and cancer incidence between individuals, even within the same family, researchers suggested that risk-modifying factors contribute to cancer development.[16–18]

Previous investigators have reported that such lifestyle factors can include obesity and tobacco usage. The incidence of hereditary breast cancer was lower among individuals who report high levels of physical activity, while a diet high in fruit and vegetables has been shown to reduce cancer risk in individuals with Lynch syndrome.[20–22] Similarly, smoking has been associated with higher overall cancer development rates in both the general population, as well as in individuals with hereditary cancer predispositions.[23]

While studies suggest that behavior can influence cancer development even in individuals with a hereditary predisposition, the likelihood of lifestyle mediation can be dependent on cancer status. One study observed lifestyle behaviors among individuals at risk for Lynch syndrome. The study of over four hundred participants looked at both individuals who had a colorectal cancer diagnosis and unaffected, at-risk relatives. The investigators reported that individuals who had not had a previous cancer diagnosis were more likely to have poor lifestyle behaviors, such as poor diet and/or smoking, compared to individuals previously been diagnosed with cancer, despite all participants being at risk for a hereditary cancer predisposition.[24]

In our research however, we found that the majority of successful lifestyle changes took place among individuals who were referred on the basis of family history, and that those with a recent cancer diagnosis were less likely to change lifestyle. Of note however, two of the participants seen for family history had a previous colon cancer diagnosis (diagnosed over three years prior to enrollment with completion of treatment) (Appendix A). One possible explanation for this observed difference may be due to an individual's goal in undergoing genetic counseling. While a cancer patient may be most interested in next steps and treatment options, an individual referred on the basis of family history may have a broader agenda, leading to more questions and

seeking generalized knowledge. Also, it is reasonable to speculate that participants recently diagnosed with cancer would prioritize completing treatment and getting well before undergoing lifestyle modifications to reduce future, secondary cancer risk.

Another possible explanation for the observed results regards the constraints of the study timeline. Participants were followed for a period of three months. While this time frame allows for lifestyle changes to be made, it may not be sufficient time for commitment scores to adjust to new lifestyle habits and consistent, improved levels. The structure of this research as a pilot study limits both the sample size and the ability to follow participants for an extended period of time, however, the trends observed in analysis lay the foundation for further research.[56]

In the design of the ACE Measure, the domain most suited to determine changes in lifestyle in individuals is the Commitment Domain. This domain reflects participants' habits and self-care consistency over time. There were however, no significant differences observed in those who failed to change and those who were successful in change for the Commitment Domain. In fact, the data interpretation determined that the Informed Choice domain had statistically significant differences between participants who were successful and those who were not. The Informed Choice domain encompasses the types of resources that are used when an individual makes health decisions (i.e.: online resources, official medical rankings, etc.). While the Informed Choice domain aims to capture resources used to select healthcare providers, it does not uncover types of resources patients seek when making lifestyle changes. The statistically significant change in the Informed Choice scores between these populations (in which those who do not change their lifestyles had a larger change) may suggest that the use of online resources to select healthcare providers has little contribution to the ability to modify lifestyle behaviors. However, the mean pre and post Informed Choice Score was higher overall in those individuals who were successful in change, which may suggest a threshold value for change.

For the Navigation domain however, the difference in mean scores for those who failed to change decreased, while those who were successful in change had the greatest increase in scores, and also had higher pre and post ACE mean scores. The Navigation Domain is correlated with the comfort of an individual to engage their health care providers, in asking questions, and in relaying their experiences in the healthcare system. The increase in Navigation scores observed among those who were successful in change due to having a successful experience (losing weight/quitting smoking) and were therefore more empowered and engaged in their own health at the time of the questionnaire. The empowerment of success is an important aspect of the feedback loop that drives the patient engagement as a healthcare endeavor.[57] This result could suggest that having a successful experience in changing behaviors may result in higher comfort in communication with healthcare providers.

Furthermore, our study determined that individuals with a higher initial ACE score were more likely to be successful in their lifestyle change. Another, current study has also used the ACE Measure to correlated patient outcomes with improved or declined glycated hemoglobin (HbA1c) levels in diabetic patients over time (unpublished data). The study found that the Commitment Domain score was correlated with patient outcomes in diabetic patients. In this study however, the commitment domain by itself was not informative with regards to patient outcome. Rather, the total pre-ACE score was more informative in that lower scores were associated with failure to change, while higher scores were seen in those who were successful. At the time of the follow-up questionnaire however, the gap between the total ACE scores had decreased. Successful participants had a mean total ACE score difference of approximately +2 points, whereas participants who failed to change had a difference in ACE scores by almost +5 points. As a result, the post-ACE score of those participants who failed to change was similar to the pre-ACE score of those participants who were successful. This result may suggest that if the

participants were observed for a longer period of time, more participants may have had positive lifestyle changes.

Also, the observed data indicate that tobacco cessation and weight loss may be comparable lifestyles, and that the failure or success of an individual was not dependent on the lifestyle behavior they were asked to change. In the literature, long-term weight loss and tobacco cessation have about the same success rate as well (5% success in traditional weight loss method, and 4.5% success in cold turkey quit attempts).[58,59] Successful change for both lifestyles is thought to increase with the usage of accredited program and support groups, as both lifestyle behaviors have similar addictive and psychological aspects that make change difficult. In this study, six participants were analyzed for smoking cessation, while seven were observed for weight loss. In each lifestyle group, approximately half failed to change and half succeeded in change. Considering the low success rate of both lifestyle factors, our report is significant in that despite low numbers, approximately half of participants were able to successfully change over a three-month period. This result may be due to a limited sample size, short time frame, and definition of success long-term, or it may indicate additional benefits of genetic counseling, but certainly merits further research consideration.

5.5 CONCLUSION

The participants in this study have either a family history of cancer or a personal diagnosis that may indicate a higher risk for cancer, and thus would benefit from lifestyle modifications to reduce risk. To our knowledge, this study is the first utilization of the ACE Measure to determine correlations between engagement scores and lifestyle behavior changes in a specialty cancer clinic setting. The results observed in this study support the feasibility of long-term

implementation of the ACE Measure for measuring patient engagement, as well as correlation to patient outcomes in lifestyle modification for tobacco cessation and weight loss. In addition, the data suggest preliminary trends, such as the possibility that increased engagement scores may predict successful lifestyle behavior change, that merit further evaluation.

APPENDIX A: DOCUMENTATION FOR METHODOLOGY

A.1 ACE MEASURE

ACE Measure

We are interested in knowing more about your personal opinions and experiences about your health and health care. This survey consists of 12 items covering three domains of engagement with healthcare: commitment to health; confidence with navigating the healthcare system; and making informed choices. This survey takes 2 or 3 minutes to complete. There are no right or wrong answers.

Please rate how much you agree or disagree with each statement below.

	Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree
1. I spend a lot of time learning about health.	○	○	○	○	○
2. Even when life is stressful, I know I can continue to do the things that keep me healthy.	○	○	○	○	○
3. I feel comfortable talking to my doctor about my health.	○	○	○	○	○
4. When I work to improve my health, I succeed.	○	○	○	○	○
5. I have brought my own information about my health to show my doctor.	○	○	○	○	○
6. When choosing a new doctor, I look for information online.	○	○	○	○	○
7. I can stick with plans to exercise and eat a healthy diet.	○	○	○	○	○
8. I compare doctors using official ratings about how well their patients are doing.	○	○	○	○	○
9. I have lots of experience using the health care system.	○	○	○	○	○
10. When choosing a new doctor, I look for official ratings based on patient health.	○	○	○	○	○
11. Different doctors give different advice, it's up to me to choose what's right for me.	○	○	○	○	○
12. I handle my health well.	○	○	○	○	○

A.2 ACE LICENSURE LETTER

ACE License #_____

CENTER FOR CONSUMER CHOICE IN HEALTH CARE

NON-EXCLUSIVE RESEARCH USE LICENSE AGREEMENT
ACE MEASURE™

Upon submission of this Agreement by the party identified below ("Licensee"), Altarum Institute, a Michigan nonprofit corporation ("Altarum"), will, if the Agreement is accepted by Altarum, provide the Altarum Consumer Engagement Measure ("ACE Measure" or "Measure") to Licensee, subject to the following terms and conditions.

1. ACCEPTANCE; DELIVERY; GRANT

1.1 Submission of this Agreement by Licensee to Altarum at the email address designated for Altarum in Section 6 hereof is a license request by Licensee, which Altarum may accept or reject, in its sole discretion. Rejection of the license request may be made with or without notice to the Licensee.

1.2 If the request is accepted, then this Agreement will become binding upon the parties by Altarum providing the Measure tool and materials in electronic format via email to the email address of Licensee designated in Section 6 hereof, which such delivery will occur within five (5) business days of submission of this Agreement by Licensee. The Effective Date of this Agreement will be the date that Altarum transmits the Measure tool and materials to Licensee.

1.3 Subject to the terms and conditions of this Agreement, Altarum will grant to Licensee, and Licensee hereby accepts, a restricted, non-exclusive, non-transferable license to use the Ace Measure, including the survey questions provided in Exhibit A, which is attached hereto and incorporated herein, for academic, research and internal business purposes only, i.e., not for commercial use. The Measure tools and materials will be provided by Altarum in the English language; however, the license granted herein includes use of the Measure in any language as may be translated by the Licensee. The Measure is owned exclusively by Altarum. The grant is provided to Licensee only. Licensee may not transfer or sublicense the Measure to any other entity or person, in whole or in part, in any form, whether modified or unmodified, without Altarum's prior written consent, which such consent shall be at Altarum's sole discretion. Except for the license rights granted herein, no right, title or interest in the Measure is granted to Licensee. Licensee will not, directly or indirectly, reproduce, distribute, modify, translate, decompile, disassemble, reverse engineer or transmit in any form or by any means any part of the Measure. Licensee agrees to reproduce any and all copyright notices and other proprietary markings on the Measure.

2. CONSIDERATION; DATA

Subject to the terms and conditions of this Agreement, Altarum will provide Ace Measure to Licensee for the term hereof, without compensation or other remuneration, in exchange for the De-Identified Data obtained from Licensee's use of the Measure, which De-Identified Data to be provided to Altarum is more particularly described in and limited to that information provided in Exhibit B hereto ("Data"). For the purposes of this Agreement "De-Identified Data" has the meaning as set forth in 45 CFR §164.514. Altarum will include with the delivery of the Measure tool and materials described in Section 1.2 above, suggested formats (in electronic version) for gathering, and more particularly, submission of the Data as required in the immediately preceding sentence. Licensee will provide the Data in the English language in a format specified in Exhibit B to Altarum (i) in the case of an ongoing use of Ace Measure, on a quarterly basis with a final report and Data extraction and submission completed within thirty (30) days of the termination or expiration of this Agreement, or (ii) in the case of a one-time use, within 30 days of the conclusion of such one-time use. Licensee hereby grants to Altarum a royalty-free, world-wide, perpetual license to use any and all Data, whether individually or in the aggregate, or otherwise, in any format or

language, and for any purpose and reason, including, but not limited to, for research, promotion, marketing, and service offering efforts. In addition, by signing this Agreement, Licensee hereby consents and agrees to Altarum listing and publishing Licensee's name and the contents of Exhibit B in connection with Altarum's reporting on use and results of use of the Measure. Licensee may exclude use of its name by providing written notice to Altarum.

3. USE; OWNERSHIP; PROPRIETARY INFORMATION

3.1 The Measure and associated Proprietary Information (hereinafter defined) is furnished to Licensee on a non-exclusive basis solely for the purpose provided in Section 1.3, and specifically for the intended use described below, and for no other purpose or use. Licensee may request to expand the intended use by submitting a new Agreement.

3.2 Licensee acknowledges that all intellectual property rights relating to the Measure are solely and exclusively owned by Altarum. All modifications, enhancements or changes to the Measure are and shall remain the property of Altarum without regard to the origin of such modifications, enhancements or changes. No ownership rights in the Measure are granted. Use of the Measure by Licensee does not grant Licensee a license to Altarum intellectual property or other rights of Altarum, whether express, implied, by estoppel or otherwise, or grant Licensee the right to make or have made any Measure or to use the Measure beyond the scope of this Agreement. Licensee will not challenge the ownership or rights in and to the Measure, including, without limitation, all copyrights and other proprietary rights. Nothing in this Agreement limits Altarum's ability to enforce its intellectual property rights.

3.3 The Measure and information disclosed or provided by Altarum relating thereto contain Proprietary Information of Altarum. All Proprietary Information has been entrusted to Licensee for use only as expressly authorized under this Agreement. Licensee will use its best efforts, consistent with the practices and procedures under which it protects its own most valuable proprietary information and materials, but no less than a reasonable standard of care, to protect the Measure and associated Proprietary Information against any unauthorized use or disclosure. Consistent with the foregoing, Licensee shall maintain in confidence and shall not disclose to any third party nor shall Licensee use or exploit in any way for its benefit or for the benefit of any third party, any Proprietary Information for a period of five (5) years following termination of this Agreement, unless such information ceases to be Proprietary Information prior to the end of such five (5) year period through no fault of Licensee, or Licensee and Altarum enter into a written agreement authorizing same. Licensee recognizes that Altarum regards the Measure as its proprietary information and as confidential trade secrets of great value. Licensee agrees not to provide or to otherwise make available in any form the Measure or Proprietary Information, or any portion thereof, to any person other than individuals completing the Measure's survey for the purposes provided in Section 1.3 hereof, without the prior written consent of Altarum.

3.4 For purposes of this Agreement, "Proprietary Information" means any information relating to the Measure, including know-how, methodologies, copyrights, trademarks, designs, data, algorithms, and code relating to the Measure, and information not relating to the Measure that is disclosed to Licensee in the manner set forth hereinafter. With respect to any information not relating to the Measure which is sought by Altarum to be Proprietary Information subject to this Agreement, Altarum shall mark such information as "Confidential" prior to disclosing it to Licensee; provided, with respect to any oral communication not relating to the Measure which is deemed by Altarum to be Proprietary Information subject to this Agreement, Altarum shall notify Licensee of such fact and within thirty (30) days thereafter Altarum shall send a memorandum to Licensee outlining the information deemed to be Proprietary Information.

3.5 Licensee agrees that the Measure and Proprietary Information shall not be used as the basis of a commercial product or service or otherwise adapted to circumvent the need for obtaining a license from Altarum (if one is then available) for the use of the Measure and Proprietary Information other than as specified by this Agreement. Notwithstanding the foregoing, incorporation of the Measure, in whole or in part, is permitted into an expanded service offering or product; provided that the Measure is an incorporation versus the actual or substantive portion of the offering. Any incorporation or other use of Ace Measure will require compliance with the terms of this Agreement, as well as providing any and all Data deriving from the use of any or all of the Measure (i.e., Data is not required to be provided from other pieces of a product or service offering that the Measure is incorporated into).

3.6 By using the Measure, Licensee agrees to abide by copyright law and all other applicable laws of the United States. Licensee further agrees to adhere to all applicable export control laws and regulations and will not export or re-export the Measure, in whole or in part, directly or indirectly, to any country to which such export or re-export is restricted by any laws or regulations of the United States, or unless properly authorized by the U.S. Government or other applicable regulatory authority as provided by law or regulation.

3.7 This Agreement conveys to Licensee only a limited right to use, fully terminable in accordance with the provisions of this Agreement. Licensee shall not assert any right, title, or interest in or to the Measure or Proprietary Information. Title to the Measure (including copyright) and Proprietary Information shall remain with Altarum. Altarum claims and reserves to itself all rights and benefits afforded under U.S. copyright law and all international copyright conventions in the Measure (and any associated Proprietary Information).

3.8 Notwithstanding anything to the contrary in the foregoing, but subject to Section 1.3, and any and all applicable laws and regulations, Altarum hereby permits Licensee to report and publish final scores received in connection solely with Licensee's permitted use of Ace Measure, individually or in the aggregate; provided that the content of the Measure, scoring algorithms and other Proprietary Information is not disclosed in violation of this Section 3. Reporting and publishing of scores and other information pertaining to or deriving from the Measure outside the Licensee's permitted use of the Measure is strictly prohibited. Any reporting or publishing of scores and information resulting from use of the Measure (as permitted hereunder) must include an appropriate acknowledgment of the Measure and Altarum, and will be made as follows: "This information derives from use of ACE Measure™, a scale of questions representing four distinct subscales of patient engagement with their health and healthcare (Commitment, Informed Choice, Navigation, and Ownership) that is a good predictor of current health status, lifestyle health behaviors, and medication adherence, developed and owned by Altarum Institute, a nonprofit health systems research and consulting organization that integrates independent research and client-centered consulting to create comprehensive, systems-based solutions that improve health. Any opinions, findings and conclusions or recommendations expressed in this material are those of the author(s) and do not necessarily reflect the views of Alarum Institute."

4. TERM OF AGREEMENT; TERMINATION

4.1 The term of this Agreement shall commence on the Effective Date and shall continue until the earlier of (i) one (1) year thereafter, or (ii) immediately following Licensee's receipt from Altarum of written notice of Licensee's breach of this Agreement or at the convenience of Altarum.

4.2 Upon termination, Licensee will immediately discontinue use of the Measure and Proprietary Information. Within thirty (30) days after termination of this Agreement, Licensee will furnish to Altarum the final Data extraction and reporting in accordance with Section 2 hereof, as well as a certificate providing (i) the total number of individuals that received, as well as completed, a survey

during the term of this Agreement, and (ii) that, through its best effort and to the best of its knowledge, the Measure and Proprietary Information have been discontinued and destroyed, as applicable.

4.3 Any rights or obligations under this Agreement that by their nature survive following termination of this Agreement will continue to remain binding upon the parties.

5. NO WARRANTIES; LIMITATIONS ON TYPES OF DAMAGES

5.1. ANY AND ALL INFORMATION, MATERIALS, SERVICES, INTELLECTUAL PROPERTY AND OTHER PROPERTY AND RIGHTS GRANTED AND/OR PROVIDED BY ALTARUM PURSUANT TO THIS AGREEMENT, INCLUDING THE MEASURE AND/OR THE PROPRIETARY INFORMATION ARE GRANTED AND/OR PROVIDED ON AN "AS IS, AS PROVIDED" BASIS. ALTARUM MAKES NO WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, AS TO ANY MATTER, AND ALL SUCH WARRANTIES, INCLUDING WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, ARE EXPRESSLY DISCLAIMED. WITHOUT LIMITING THE GENERALITY OF THE FOREGOING, ALTARUM DOES NOT MAKE ANY WARRANTY OF ANY KIND RELATING TO EXCLUSIVITY, INFORMATIONAL CONTENT, ERROR-FREE OPERATION, RESULTS TO BE OBTAINED FROM USE, FREEDOM FROM PATENT, TRADEMARK AND COPYRIGHT INFRINGEMENT AND/OR FREEDOM FROM THEFT OF TRADE SECRETS. LICENSEE IS PROHIBITED FROM MAKING ANY EXPRESS OR IMPLIED WARRANTY TO ANY THIRD PARTY ON BEHALF OF ALTARUM RELATING TO ANY MATTER, INCLUDING THE APPLICATION OF OR THE RESULTS TO BE OBTAINED FROM THE INFORMATION, MATERIALS, SERVICES, INTELLECTUAL PROPERTY OR OTHER PROPERTY OR RIGHTS, INCLUDING THE MEASURE AND/OR THE PROPRIETARY INFORMATION GRANTED AND/OR PROVIDED BY ALTARUM PURSUANT TO THIS AGREEMENT.

LICENSEE AGREES THAT ALTARUM SHALL HAVE NO LIABILITY ARISING OUT OF THE USE OR OPERATION OF THE MEASURE AND/OR ANY INFORMATION GENERATED THEREBY. FURTHER, IN NO EVENT SHALL ALTARUM BE LIABLE FOR INDIRECT, INCIDENTAL, SPECIAL, OR CONSEQUENTIAL DAMAGES, INCLUDING LOSS OF USE, LOSS OF PROFITS OR INTERRUPTION OF BUSINESS, HOWEVER CAUSED OR ON ANY THEORY OF LIABILITY.

5.2 Licensee shall defend, indemnify and hold harmless Altarum, its trustees, officers, employees, attorneys and agents from and against any liability, damage, loss or expense (including attorneys' fees and expenses) incurred by or imposed upon any of Altarum and/or its trustees, officers, employees, attorneys and agents in connection with any claim, suit, action or demand arising out of or relating to any exercise of any right or license granted or provided to Licensee under this Agreement under any theory of liability (including without limitation, actions in the form of tort, warranty, or strict liability, or violation of any law, and regardless of whether such action has any factual basis).

Altarum agrees to indemnify, defend and hold harmless Licensee from and against any liability, damage, loss or expense (including attorneys' fees and expenses) resulting from any claim by any third party that the ACE Measure infringes or misappropriates the intellectual property rights of such third party. If the ACE Measure (or any component thereof) becomes, or in Altarum's opinion is likely to become, the subject of an infringement claim, Altarum may, at its option and expense, either (a) procure for Licensee the right to continue exercising the rights licensed to Licensee in this Agreement, (b) replace or modify the relevant service, product or technology so that it becomes non-infringing and remains functionally equivalent, or (c) terminate the Agreement. Notwithstanding anything in this section to the contrary, Altarum is not obligated to indemnify Licensee under this section if the claim results from the use of ACE Measure with other items not furnished by Altarum or modifications to the item are not made by Altarum.

6. NOTICES

All notices required or permitted to be given under this Agreement shall be in writing and shall be either: (i) personally delivered; or (ii) sent by nationally recognized overnight courier; or (iii) transmitted by postage prepaid registered or certified mail; or (iv) transmitted by facsimile; or (v) sent by email, as elected by the party giving notice. Such notice shall be addressed to the party to receive notice at the address and number set forth below or at such other address or number as may be provided in writing by said party for the receipt of notices.

If to Licensee:	If to Altarum:
UPMC Health Plan, Inc.	Director, Legal Affairs
600 Grant Street, 55th Floor	Altarum Institute
Pittsburgh, PA 15219	3520 Green Court, Suite 300
Attn: Chief Legal Officer	Ann Arbor, MI 48105
Fax - (412) 454-2900	Fax: (734) 302-4996
Email:	Email: Legal@altarum.org

Any notice given hereunder shall be deemed effective on the date of delivery. The date of delivery shall be: (i) the date of receipt if delivered personally; or (ii) the date three (3) days after the date of posting if delivered by mail; (iii) the date one (1) day after submitting to an overnight courier; or (iv) the date of confirmed transmission if delivered by facsimile or email.

7. MISCELLANEOUS

7.1 This Agreement and the licenses granted by it may not be assigned, sublicensed, or otherwise transferred by Licensee without the prior written consent of Altarum.

7.2 This Agreement shall be governed and interpreted by the laws of the State of Michigan, except its choice of law rules.

7.3 All remedies available to a party for one or more breaches by the other party shall be cumulative and may be exercised separately or concurrently without waiver of any other remedies. The failure of either party to act on a breach of this Agreement shall not be deemed a waiver of said breach or a waiver of future breaches, unless such a waiver is in writing and is signed by the party against whom enforcement is sought.

7.4 This Agreement sets forth the entire understanding with respect to the subject matter hereof, and merges and supersedes all prior agreements, discussions and understandings, express or implied, concerning such matters. This Agreement may be modified only by a writing signed by a duly authorized representative of the party against whom enforcement thereof is sought.

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ALTARUM INSTITUTE
SYSTEMS RESEARCH FOR BETTER HEALTH

CENTER FOR CONSUMER CHOICE IN HEALTH CARE

NON-EXCLUSIVE RESEARCH USE LICENSE AGREEMENT
ACE MEASURE™

Exhibit A

Altarum Consumer Engagement (ACE) Measure™

Please rate how much you agree or disagree with the following statements below.

Question	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
I can help prevent or reduce problems with my health.					
I spend a lot of time learning about health.					
Even when life is stressful, I know I can continue to do the things that keep me healthy.					
I feel comfortable talking to my doctor about my health.					
When I work to improve my health, I succeed.					
I have brought my own information about my health to show my doctor.					
When I have a question about my health, I find the answer.					
When choosing a new doctor, I look for information online.					
I take an active role in my own health care.					
I often read special health or medical magazines or newsletters to get health information.					

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Question	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
The most important thing that affects my health is my own actions.					
I can stick with plans to exercise and eat a healthy diet.					
I am confident I would know what to do if I had a problem with my health.					
I compare doctors using official ratings about how well their patients are doing.					
My health is my responsibility, not someone else's.					
I have lots of experience using the health care system.					
I take responsibility for managing my health.					
I can follow through on home medical treatments.					
When choosing a new doctor, I look for official ratings based on patient health.					
Different doctors give different advice, it's up to me to choose what's right for me.					
I handle my health well.					

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CENTER FOR CONSUMER CHOICE IN HEALTH CARE

NON-EXCLUSIVE RESEARCH USE LICENSE AGREEMENT
ACE MEASURE™

Exhibit B

ACE Measure™ Survey Response Data Submission Specifications

Please adhere to the following specifications when sending your population's responses to the ACE Measure.

The file should be in one of the following formats: CSV, XLS, XLSX, Tab-delimited, or XML. *(If you would like to send an XML file please send an email to ace.measure@altarum.org for an XML example.)*

There should only be one record per person.

Export File Layout

Element Number	Element ID	Description	Responses	Length	Required
1	ID	An alpha-numeric ID that must be unique for each person		10	Yes
2	Female	Gender of participant	0 = Male 1 = Female	1	Yes
3	Age	Age of participant	1 = 18-24 2 = 25-34 3 = 35-44 4 = 45-54 5 = 55-64 6 = 65-74 7 = 75-84 8 = 85+	1	Yes
4	Zip Code	Participant's first 2 digits of home zip code	Two integers with leading zeros if applicable	2	Yes
5	O3	I can help prevent or reduce problems with my health.	0 = "Strongly Disagree" 1 = "Disagree" 2 = "Neither Agree/Disagree" 3 = "Agree" 4 = "Strongly Agree"	1	Yes
6	I4	I spend a lot of time learning about health.	0 = "Strongly Disagree" 1 = "Disagree" 2 = "Neither Agree/Disagree" 3 = "Agree" 4 = "Strongly Agree"	1	Yes

Element Number	Element ID	Description	Responses	Length	Required
7	C2	Even when life is stressful, I know I can continue to do the things that keep me healthy.	0 = "Strongly Disagree" 1 = "Disagree" 2 = "Neither Agree/Disagree" 3 = "Agree" 4 = "Strongly Agree"	1	Yes
8	N2	I feel comfortable talking to my doctor about my health.	0 = "Strongly Disagree" 1 = "Disagree" 2 = "Neither Agree/Disagree" 3 = "Agree" 4 = "Strongly Agree"	1	Yes
9	C3	When I work to improve my health, I succeed.	0 = "Strongly Disagree" 1 = "Disagree" 2 = "Neither Agree/Disagree" 3 = "Agree" 4 = "Strongly Agree"	1	Yes
10	N5	I have brought my own information about my health to show my doctor.	0 = "Strongly Disagree" 1 = "Disagree" 2 = "Neither Agree/Disagree" 3 = "Agree" 4 = "Strongly Agree"	1	Yes
11	O5	When I have a question about my health, I find the answer.	0 = "Strongly Disagree" 1 = "Disagree" 2 = "Neither Agree/Disagree" 3 = "Agree" 4 = "Strongly Agree"	1	Yes
12	I3	When choosing a new doctor, I look for information online.	0 = "Strongly Disagree" 1 = "Disagree" 2 = "Neither Agree/Disagree" 3 = "Agree" 4 = "Strongly Agree"	1	Yes
13	C6	I take an active role in my own health care.	0 = "Strongly Disagree" 1 = "Disagree" 2 = "Neither Agree/Disagree" 3 = "Agree" 4 = "Strongly Agree"	1	Yes
14	I5	I often read special health or medical magazines or newsletters to get health information.	0 = "Strongly Disagree" 1 = "Disagree" 2 = "Neither Agree/Disagree" 3 = "Agree" 4 = "Strongly Agree"	1	Yes
15	O2	The most important thing that affects my health is my own actions.	0 = "Strongly Disagree" 1 = "Disagree" 2 = "Neither Agree/Disagree" 3 = "Agree" 4 = "Strongly Agree"	1	Yes
16	C1	I can stick with plans to exercise and eat a healthy diet.	0 = "Strongly Disagree" 1 = "Disagree" 2 = "Neither Agree/Disagree" 3 = "Agree" 4 = "Strongly Agree"	1	Yes

Element Number	Element ID	Description	Responses	Length	Required
17	N3	I am confident I would know what to do if I had a problem with my health.	0 = "Strongly Disagree" 1 = "Disagree" 2 = "Neither Agree/Disagree" 3 = "Agree" 4 = "Strongly Agree"	1	Yes
18	I2	I compare doctors using official ratings about how well their patients are doing.	0 = "Strongly Disagree" 1 = "Disagree" 2 = "Neither Agree/Disagree" 3 = "Agree" 4 = "Strongly Agree"	1	Yes
19	O1	My health is my responsibility, not someone else's.	0 = "Strongly Disagree" 1 = "Disagree" 2 = "Neither Agree/Disagree" 3 = "Agree" 4 = "Strongly Agree"	1	Yes
20	N1	I have lots of experience using the health care system.	0 = "Strongly Disagree" 1 = "Disagree" 2 = "Neither Agree/Disagree" 3 = "Agree" 4 = "Strongly Agree"	1	Yes
21	C5	I take responsibility for managing my health.	0 = "Strongly Disagree" 1 = "Disagree" 2 = "Neither Agree/Disagree" 3 = "Agree" 4 = "Strongly Agree"	1	Yes
22	O4	I can follow through on home medical treatments.	0 = "Strongly Disagree" 1 = "Disagree" 2 = "Neither Agree/Disagree" 3 = "Agree" 4 = "Strongly Agree"	1	Yes
23	I1	When choosing a new doctor, I look for official ratings based on patient health.	0 = "Strongly Disagree" 1 = "Disagree" 2 = "Neither Agree/Disagree" 3 = "Agree" 4 = "Strongly Agree"	1	Yes
24	N4	Different doctors give different advice, it's up to me to choose what's right for me.	0 = "Strongly Disagree" 1 = "Disagree" 2 = "Neither Agree/Disagree" 3 = "Agree" 4 = "Strongly Agree"	1	Yes
25	C4	I handle my health well.	0 = "Strongly Disagree" 1 = "Disagree" 2 = "Neither Agree/Disagree" 3 = "Agree" 4 = "Strongly Agree"	1	Yes

Element Number	Element ID	Description	Responses	Length	Required
26	Education	Participant's level of education	1 = 8th grade or less 2 = Some high school, did not graduate 3 = High school graduate/GED 4 = Some college or 2-year degree 5 = 4-year college graduate 6 = More than 4-year college degree	1	No
27	FT/PT	Participant's work status	1= Full Time (30+ hours/week) 2= Part Time (< 30 hours/week)	1	No
28	Primary Health Insurance Coverage	Participant's source of health insurance	1 = Sponsoring company plan 2 = Spouse's plan 3 = State Exchange plan 4 = Medicare/Medicaid 5 = Tricare 6 = Other	1	No
29	Income	Participant's income	1 = Less than $20,000 2 = $20,000-$29,999 3 = $30,000-$39,999 4 = $40,000-$49,999 5 = $50,000-$59,999 6 = $60,000-$74,999 7 = $75,000-$99,999 8 = $100,000-$149,999 9 = $150,000+	1	No
30	Health	Participant's self-reported health status	1 = Poor 2 = Fair 3 = Good 4 = Very good 5 = Excellent	1	No

Data Submission Instructions:

1. Submit the data to this email address: ace.measure@altarum.org
2. Provide the License Number in the subject line of the email
3. Include the following Licensee contact information in the body of the email:
   Name
   Email Address
   Telephone Number

A.3 PARTICIPANT DATA AND LIFESTYLE BEHAVIOR DOCUMENTS

	Patient ID	Age	Gender	Ethnicity	BMI (kg/m2)	Tobacco Use	Cancer Type	Current Cancer	Family History
1	**RXW006**	77	F	Caucasian	22.27	Never	Colon (dx. 77)	Yes	Yes
2	**RXW010**	61	M	Caucasian	23.24	Current	Colon (dx. 61)	Yes	Yes
3	**RXW016**	42	F	Caucasian	24.63	Never	Colon (dx. 42)	Yes	Yes
4	**RXW026**	77	F	Caucasian	31.32	Never	Colon (dx. 77)	Yes	Yes
5	**RXW033**	49	F	Caucasian	23.33	Former	Colon (dx. 49), soft tissue sarcoma (dx. 34)	Yes	Yes
6	**RXW035**	33	F	Caucasian	32.61	Never	Colon (dx. 33)	Yes	Yes
7	**RXW041**	48	M	Caucasian	26.05	Never	Colon (dx. 47)	Yes	Yes
8	**RXW043**	55	M	African American	27.8	Current	Colon (dx. 55)	Yes	Yes (Polyposis)
9	**RXW045**	42	F	Caucasian	28.25	Never	Colon (dx. 40)	Undergoing treatment	Yes
10	**RXW051**	81	F	Caucasian	24.06	Never	Colon (dx. 80)	Yes	Yes
11	**RXW037**	49	F	Caucasian	31.95	Current	Rectal (dx. 48)	Yes	Yes
12	**RXW012**	64	F	Caucasian	22.67	Current	Pancreatic (dx. 62 mets)	Undergoing treatment	Yes
13	**RXW036**	65	M	Caucasian	21.84	Former	Pancreatic (dx. 63), Prostate (dx. 55)	Yes	Yes
14	**RXW044**	60	F	African American	26.43	Former	Pancreatic (dx. 58)	Undergoing treatment	Yes
15	**RXW001**	60	F	Caucasian	21.56	Never	Bladder (dx. 60), Thyroid (dx. 39)	Yes	Yes
16	**RXW015**	39	F	African American	18.3	Never	Gastric (dx. 38)	Yes	Yes
17	**RXW019**	55	F	Caucasian	30.99	Never	Bile Duct (dx. 54)	Yes	Yes
18	**RXW022**	74	F	Caucasian	22.94	Former	Endometrial (dx. 71)	Undergoing treatment	Yes
19	**RXW031**	55	F	Caucasian	26.95	Never	Breast (dx. 52)	Undergoing treatment	Yes (*ATM*)
20	**RXW047**	67	F	Caucasian	24.51	Never	Colon (dx. 49)	No	Yes (HNPCC)
21	**RXW005**	50	F	Caucasian	29.76	Former	Colon (dx. 46)	No	Yes
22	**RXW014**	41	F	Caucasian	28.25	Former	Thyroid (dx. 28)	No	Yes
23	**RXW017**	71	M	Caucasian	29.7	Former	Rectal (dx. 61)	No	Yes
24	**RXW020**	38	F	Caucasian	33.64	Never	Colon (dx.35)	No	Yes
25	**RXW021**	58	M	Caucasian	32.58	Never	Colon (dx. 38)	No	Yes
26	**RXW038**	71	M	Caucasian	34.06	Former	BCC	No	Yes
27	**RXW004**	18	M	African American	22.26	Never	None	.	Yes (Lynch)
28	**RXW029**	50	M	Caucasian	22.96	Former	None	.	Yes (Lynch)
29	**RXW052**	60	F	Caucasian	21.28	Former	None	.	Yes (Lynch)
30	**RXW028**	47	M	Caucasian	22.78	Current	None	.	Yes (*BRCA2*)
31	**RXW048**	64	F	Caucasian	25.54	Never	None	.	Yes (FAMMM)
32	**RXW002**	49	F	Caucasian	20.47	Never	None	.	Yes
33	**RXW003**	32	F	Caucasian	26.89	Never	None	.	Yes
34	**RXW007**	61	M	Caucasian	37.93	Never	None	.	Yes
35	**RXW011**	31	F	Caucasian	29.41	Never	None	.	Yes
36	**RXW023**	30	M	Caucasian	28.37	Former	None	.	Yes
37	**RXW024**	30	M	Caucasian	30.67	Current	None	.	Yes
38	**RXW040**	75	F	Caucasian	19.01	Never	None	.	Yes

A.4 CONSENT FORM

UPMC LIFE CHANGING MEDICINE

CONSENT TO USE MEDICAL RECORDS AND/OR QUESTIONNAIRES FOR RESEARCH IN THE **Hereditary GI Tumor Program**

PRINCIPAL INVESTIGATOR:

Randall Brand, MD. University of Pittsburgh.
Shadyside Medical Office Building 5200 Centre Avenue, Suite 409 Pittsburgh PA 15232 (412) 623-3105

ABOUT THE STUDY:

The Hereditary GI Tumor Clinic is interested in patient opinions and experiences regarding health and healthcare. In order to learn more, we would like to invite you to participate in a research study. The goal of this study is to collect information that will help doctors to better understand patient wellbeing and their engagement in healthcare.
Participation in the study would involve the following three components:

1. Your completion of a survey
2. Permission to possibly re-contact you over the phone at a later date
3. Permission to review your medical records

YOUR PARTICIPATION:

If you choose to participate you will be given a questionnaire during your visit to be completed in office. The survey should take about 2-3 minutes to complete and consists of 12 questions about healthcare involvement and personal opinions. You may also be contacted again over the phone in 3-4 months and asked questions about your health management. We are also requesting your permission to review your medical records. We will collect information about personal and/or family history of cancers, and other basic health information such as height, weight, etc. We will use this information to learn more about the influence of cancer predisposition on individuals. Information may be obtained from your medical records and used by this research team for an indefinite period of time.

Participation is completely voluntary and will not affect your care or management with UPMC or any affiliated organizations. Your doctor may also be involved as an investigator in this research study, but you are not under any obligation to participate in any research study offered by your doctor. Before agreeing to participate in this research study, or at any time thereafter, you may wish to discuss participation in this study with another health professional, to obtain a 'second opinion' about study participation. You are free to withdraw from the study at any time, for any reason, without any penalty or change of care. However, any identifiable information obtained from you before you withdraw from this study will continue to be used by the investigators, as described above. You are also free to withdraw authorization for the research team to access your medical records, while still participating in the study. To formally withdraw your consent for participation in the study you should provide a written and dated notice to the primary investigator at the address above.

CONFIDENTIALITY:

If you choose to participate in the study, your confidentiality will be protected and your personal identifying information will be coded with limited access. Your information will only be available to the research team, and possibly to auditors from the University of Pittsburgh Research Conduct and Compliance Office. There is always the small chance of a breach in confidentiality, but strong precautions and the federal confidentiality guidelines are followed to protect your information to the best of our abilities. Authorized representatives of UPMC hospitals, health plans, or other affiliated health care providers may have access to identifiable information (which may include your identifiable medical information) related to your participation in this research study for the purpose of: (1) fulfilling orders, made by the investigators, for hospital and health care services associated with research study participation; (2) addressing correct payment for tests and procedures ordered by the investigators; and/or (3) for internal hospital operations (i.e. quality assurance). If the researchers learn that you or someone with whom you are involved is in serious danger of harm, they will need to inform the appropriate agencies as required by Pennsylvania law. The research data collected may also be used for future unspecified research and shared in a de-identified manner with investigators both inside and outside of the University.

University Of Pittsburgh Institutional Review Board
Approval Date: 7/12/2016
Renewal Date: 7/11/2017
IRB #: PRO16050209

RISKS AND BENEFITS

There are no direct risks nor direct benefits to you involved in this study, although there is always the possible risk of breach of confidentiality. There is no cost associated with this study, and neither you nor your insurance will be billed if you choose to participate. However, you will be responsible for standard clinical charges regardless of your participation in the study.

VOLUNTARY CONSENT:

This study has been explained to me, and all of my questions have been answered. Additional questions will be answered by the **Hereditary GI Tumor Program** team. The Human Research Subject Advocate of the University Institutional Review Board (1.866.212.2668) can answer any questions about my rights as a research subject. By signing this form, I give my authorization to share my medical records with the research team and answer their questions.

Patient/Subject Signature _____ Date _____

Printed Name of Patient/Subject
(*or* Patient Identification Sticker)

****

I certify that I have explained the nature and purpose of this research study to the above-named individual, and I have discussed the potential benefits and possible risks of study participation. Any questions the individual has about this study have been answered, and we will always be available to address future questions, concerns or complaints as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

Signature of individual obtaining consent _____ Date _____

University Of Pittsburgh
Institutional Review Board
Approval Date: 7/12/2016
Renewal Date: 7/11/2017
IRB #: PRO16050209

A.5 IRB APPROVAL LETTER

University of Pittsburgh
Institutional Review Board

3500 Fifth Avenue
Pittsburgh, PA 15213
(412) 383-1480
(412) 383-1508 (fax)
http://www.irb.pitt.edu

Memorandum

To: Randall Brand , MD
From: IRB Office
Date: 7/12/2016
IRB#: PRO16050209
Subject: GI Hereditary Tumor Program and Prescription for Wellness Study

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The University of Pittsburgh Institutional Review Board reviewed and approved the above referenced study by the expedited review procedure authorized under 45 CFR 46.110 and 21 CFR 56.110. Your research study was approved under:

45 CFR 46.110.(5)
45 CFR 46.110.(7)

The risk level designation is Minimal Risk.

Approval Date: 7/12/2016
Expiration Date: 7/11/2017

For studies being conducted in UPMC facilities, no clinical activities can be undertaken by investigators until they have received approval from the UPMC Fiscal Review Office.

Please note that it is the investigator's responsibility to report to the IRB any unanticipated problems involving risks to subjects or others [see 45 CFR 46.103(b)(5) and 21 CFR 56.108(b)]. Refer to the IRB Policy and Procedure Manual regarding the reporting requirements for unanticipated problems which include, but are not limited to, adverse events. If you have any questions about this process, please contact the Adverse Events Coordinator at 412-383-1480.

The protocol and consent forms, along with a brief progress report must be resubmitted at least one month prior to the renewal date noted above as required by FWA00006790 (University of Pittsburgh), FWA00006735 (University of Pittsburgh Medical Center), FWA00000600 (Children's Hospital of Pittsburgh), FWA00003567 (Magee-Womens Health Corporation), FWA00003338 (University of Pittsburgh Medical Center Cancer Institute).

Please be advised that your research study may be audited periodically by the University of Pittsburgh Research Conduct and Compliance Office.

APPENDIX B: DATA DISTRIBUTION AND STATA OUTPUT

This appendix includes histogram graphs of data subsections and STATA program output analysis for T-test.

B.1 DATA ACROSS ALL PARTICIPANTS

B.1.1 ACE Summary of Pre and Post Scores in Each Domain

Commitment Domain (n=38)						
		Post-ACE Score				
		Lowest Score (0-12.5)	Below Average (12.5-16)	Average (16-18)	Above Average (18-20)	Highest Score (20-25)
Pre-ACE Score	Lowest Score (0-12.5)		2			
	Below Average (12.5-16)	2	3			3
	Average (16-18)				1	2
	Above Average (18-20)		1	1	4	6
	Highest Score (20-25)				2	11

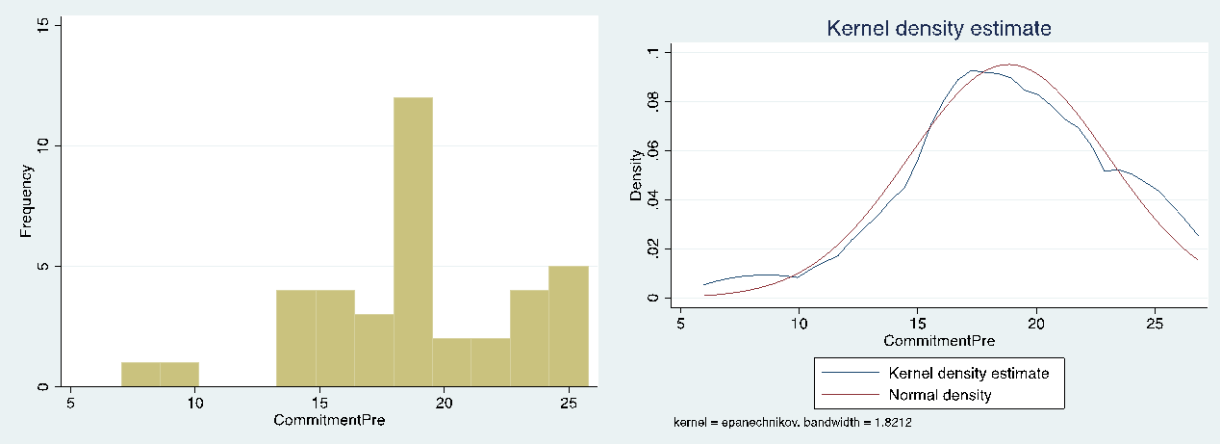
Navigation Domain (n=38)						
		Post-ACE Score				
		Lowest Score (0-12.5)	Below Average (12.5-16)	Average (16-18)	Above Average (18-19)	Highest Score (19-25)
Pre-ACE Score	Lowest Score (0-12.5)	1			1	1
	Below Average (12.5-16)	1	1	1	1	3
	Average (16-18)		2			3
	Above Average (18-19)			1	1	3
	Highest Score (19-25)		1	2	2	13

Informed Choice Domain (n=38)						
		Post-ACE Score				
		Lowest Score (0-8)	Below Average (8-11)	Average (11-15)	Above Average (15-18)	Highest Score (18-25)
Pre-ACE Score	Lowest Score (0-8)	4			1	1
	Below Average (8-11)	2		3	2	
	Average (11-15)		2	4	1	
	Above Average (15-18)	1	2		6	2
	Highest Score (18-25)				2	5

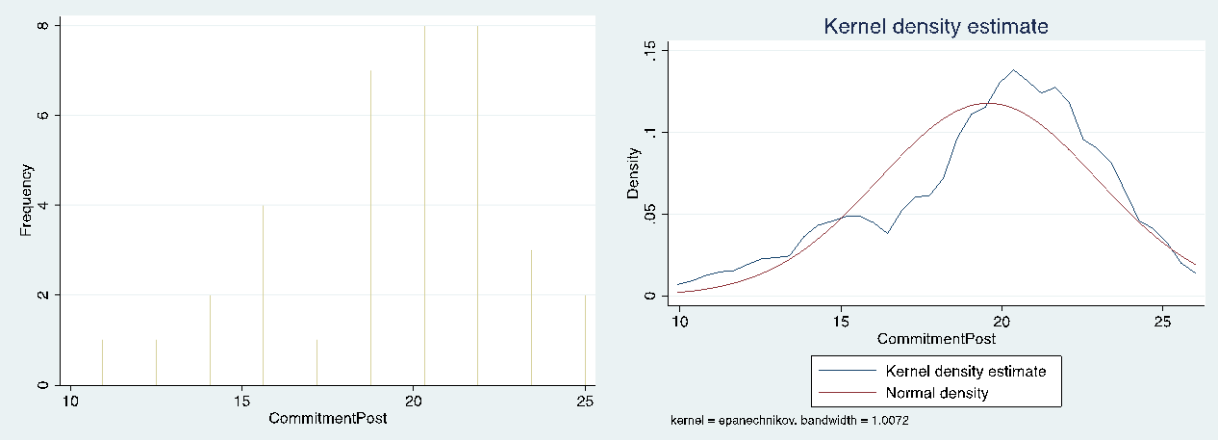
**Used with permission from UPMC Health Plan and Work Partners 2017*

B.1.2 Commitment Pre and Post ACE Scores

COMMITMENT PRE-ACE SCORES



COMMITMENT POST-ACE SCORES

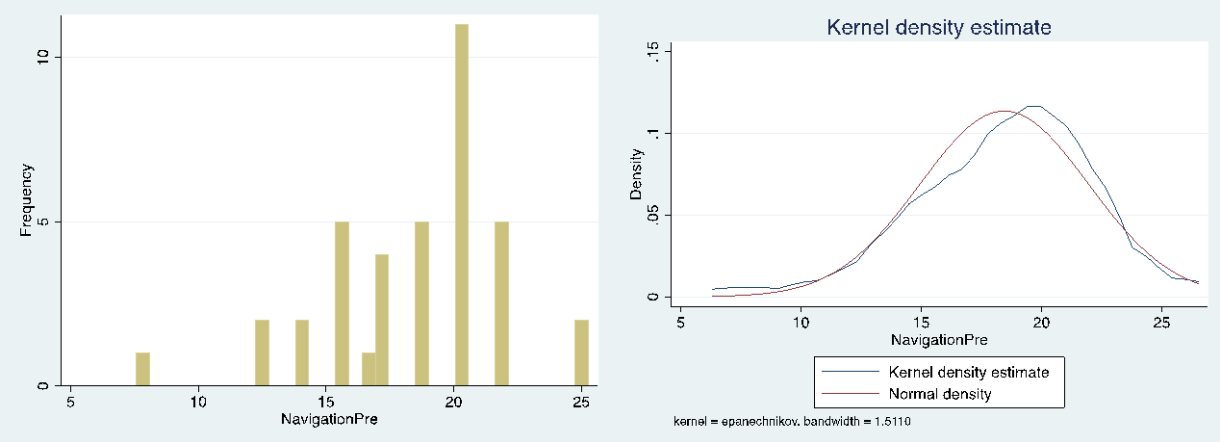


STATA COMMITMENT PRE AND POST ACE SCORES OUTPUT

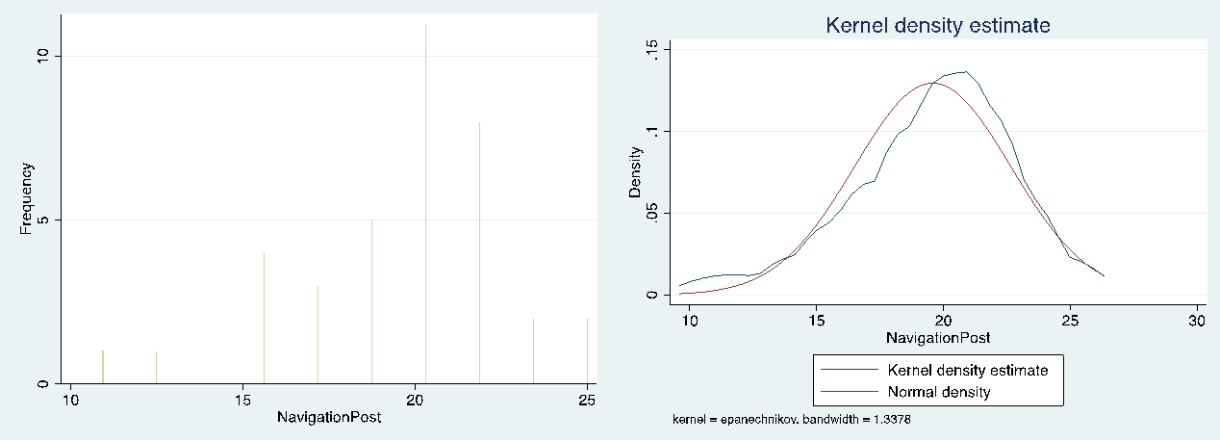
```
Paired t test
------------------------------------------------------------------------------
Variable |     Obs        Mean    Std. Err.   Std. Dev.   [95% Conf. Interval]
---------+--------------------------------------------------------------------
Commit~e |      38    18.83242    .6794816    4.188606    17.45566    20.20918
Commit~t |      38    19.57257    .5488351    3.383247    18.46052    20.68461
---------+--------------------------------------------------------------------
    diff |      38   -.7401447     .573585    3.535816   -1.902338    .4220489
------------------------------------------------------------------------------
     mean(diff) = mean(CommitmentPre - CommitmentPost)           t =  -1.2904
 Ho: mean(diff) = 0                               degrees of freedom =       37

 Ha: mean(diff) < 0           Ha: mean(diff) != 0           Ha: mean(diff) > 0
 Pr(T < t) = 0.1025         Pr(|T| > |t|) = 0.2049          Pr(T > t) = 0.8975
```

B.1.3 Navigation Pre and Post ACE Scores

NAVIGATION PRE-ACE SCORES



NAVIGATION POST-ACE SCORES

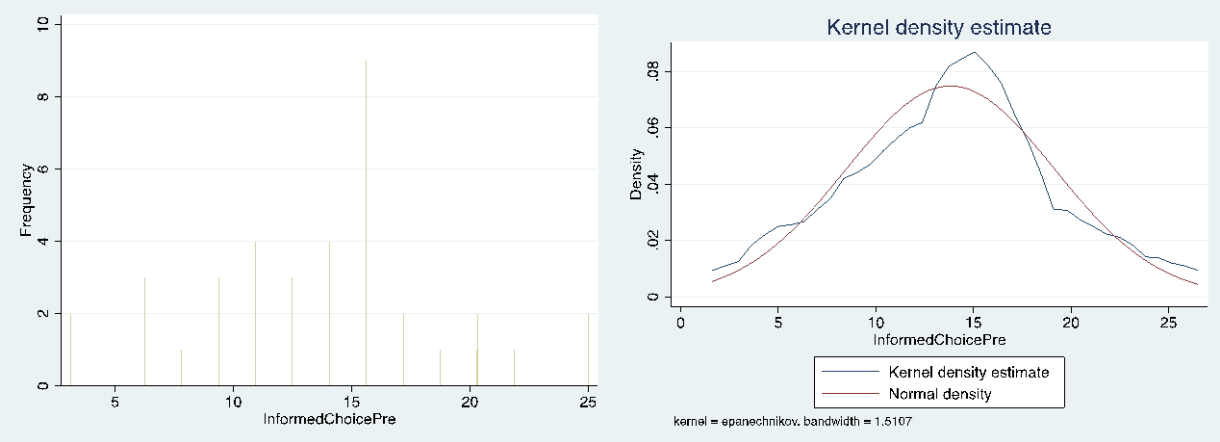


STATA NAVIGATION PRE AND POST ACE SCORES OUTPUT

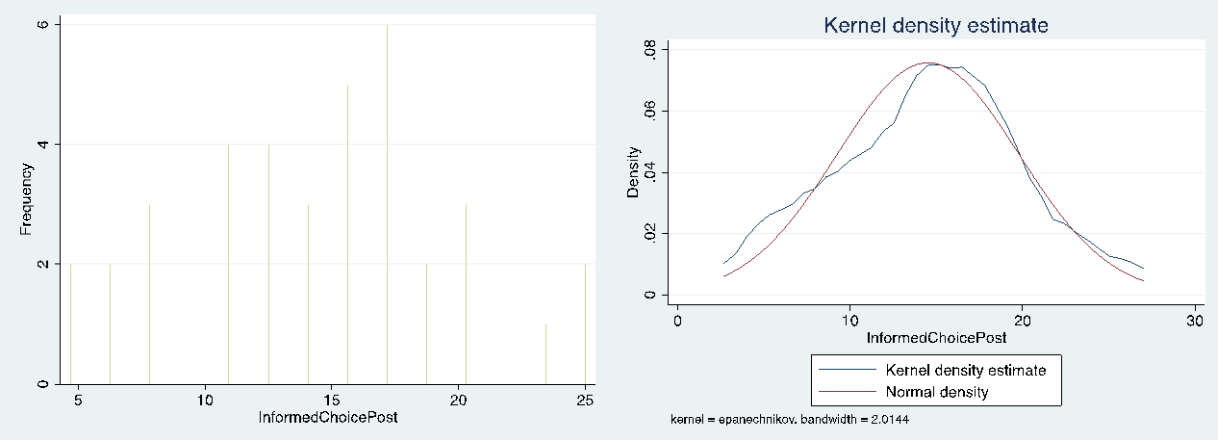
```
Paired t test
------------------------------------------------------------------------------
Variable |     Obs        Mean    Std. Err.   Std. Dev.   [95% Conf. Interval]
---------+--------------------------------------------------------------------
Naviga~e |      38    18.44871    .5688585    3.506679    17.29609    19.60133
Naviga~t |      38    19.57259    .4991299    3.076843    18.56126    20.58393
---------+--------------------------------------------------------------------
    diff |      38   -1.123882    .5875101    3.621655    -2.31429    .0665269
------------------------------------------------------------------------------
     mean(diff) = mean(NavigationPre - NavigationPost)            t =  -1.9130
 Ho: mean(diff) = 0                                     degrees of freedom =       37

 Ha: mean(diff) < 0           Ha: mean(diff) != 0           Ha: mean(diff) > 0
 Pr(T < t) = 0.0318         Pr(|T| > |t|) = 0.0635          Pr(T > t) = 0.9682
```

B.1.4 Informed Choice Pre and Post ACE Scores

INFORMED CHOICE PRE-ACE SCORES



INFORMED CHOICE POST-ACE SCORES

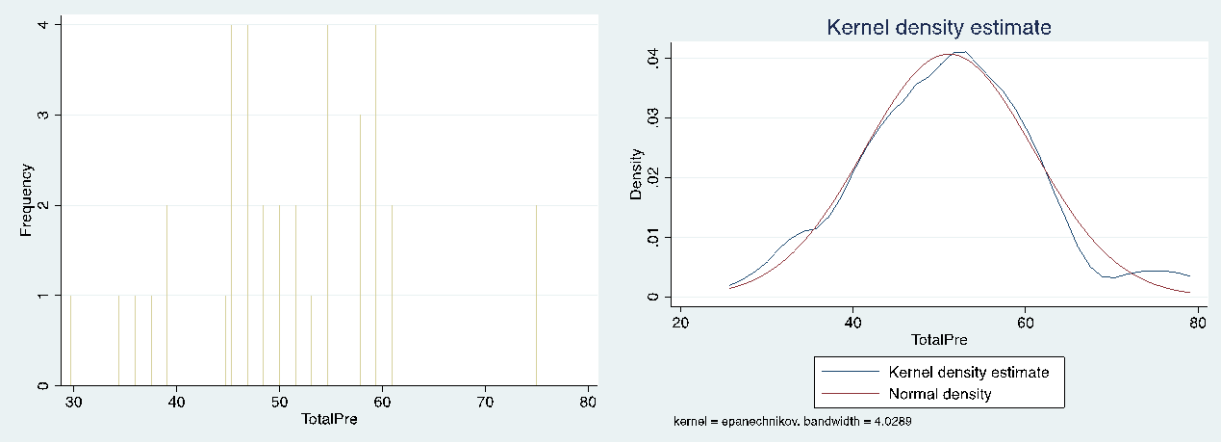


STATA INFORMED CHOICE PRE AND POST ACE SCORES OUTPUT

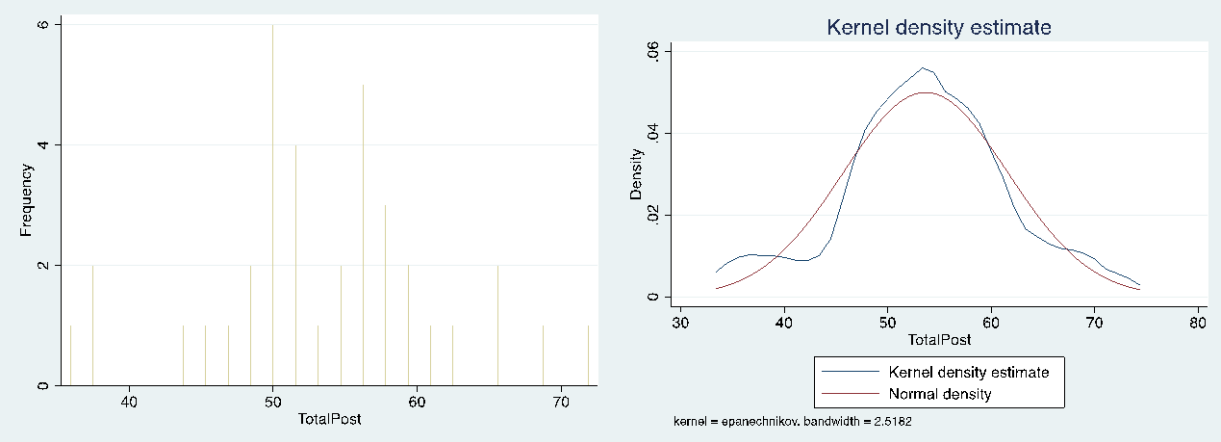
```
Paired t test
------------------------------------------------------------------------------
Variable |     Obs        Mean    Std. Err.   Std. Dev.   [95% Conf. Interval]
---------+--------------------------------------------------------------------
Inform~e |      38    13.81596    .8651535    5.333164    12.06299    15.56893
Inform~t |      38    14.51509    .8537957     5.26315    12.78514    16.24505
---------+--------------------------------------------------------------------
    diff |      38   -.6991316    .6685388     4.12115    -2.05372    .6554568
------------------------------------------------------------------------------
     mean(diff) = mean(InformedChoice~e - InformedChoice~t)       t =  -1.0458
 Ho: mean(diff) = 0                                     degrees of freedom =       37

 Ha: mean(diff) < 0           Ha: mean(diff) != 0           Ha: mean(diff) > 0
 Pr(T < t) = 0.1512         Pr(|T| > |t|) = 0.3025          Pr(T > t) = 0.8488
```

B.1.5 Total Pre and Post ACE Scores

TOTAL PRE-ACE SCORES



TOTAL POST-ACE SCORES



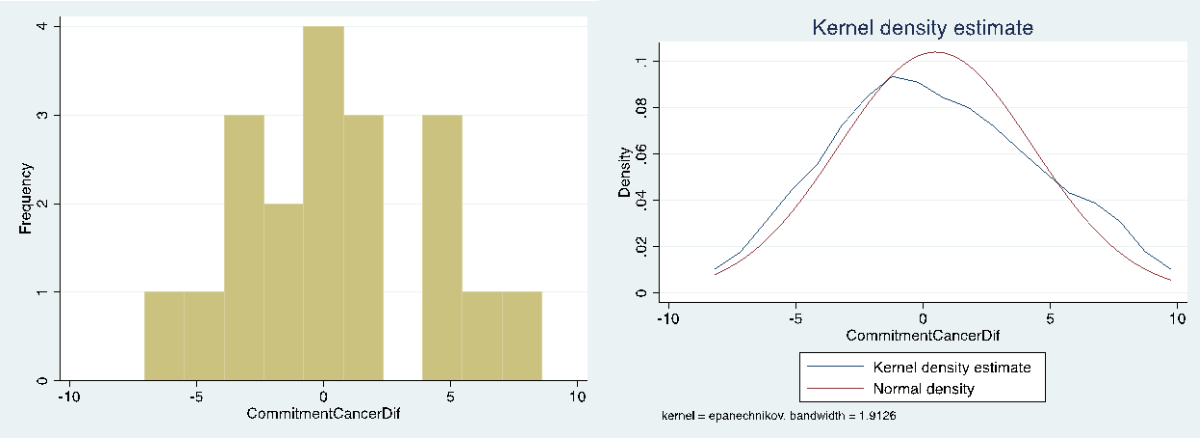
STATA TOTAL PRE AND POST ACE SCORES OUTPUT

```
Paired t test
------------------------------------------------------------------------------
Variable |     Obs        Mean    Std. Err.   Std. Dev.   [95% Conf. Interval]
---------+--------------------------------------------------------------------
TotalPre |      38    51.09678    1.589156    9.796217    47.87684    54.31671
TotalP~t |      38    53.65972    1.292818    7.969467    51.04022    56.27922
---------+--------------------------------------------------------------------
    diff |      38   -2.562947    1.165682    7.185747   -4.924844   -.2010511
------------------------------------------------------------------------------
     mean(diff) = mean(TotalPre - TotalPost)                      t =  -2.1987
 Ho: mean(diff) = 0                                     degrees of freedom =       37

 Ha: mean(diff) < 0           Ha: mean(diff) != 0           Ha: mean(diff) > 0
 Pr(T < t) = 0.0171         Pr(|T| > |t|) = 0.0342          Pr(T > t) = 0.9829
```

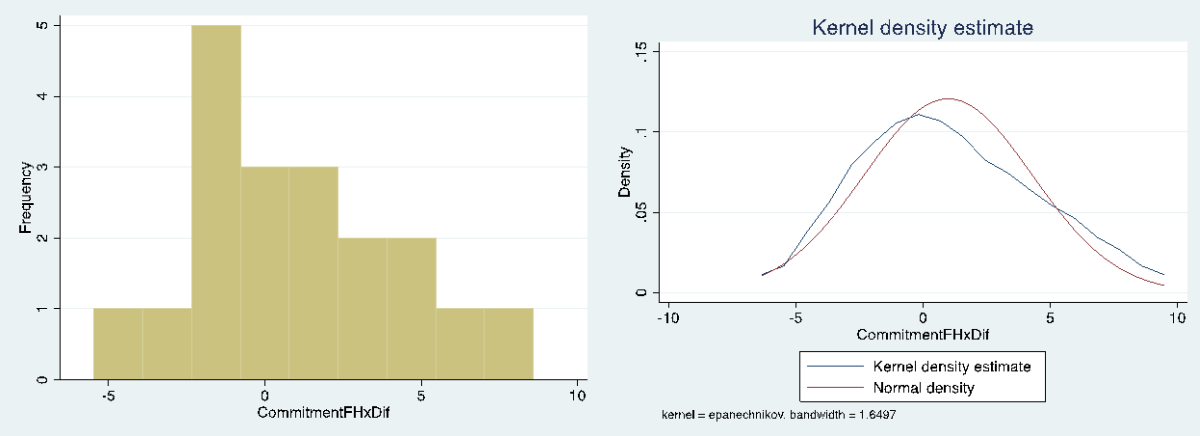
B.2 DATA BETWEEN PARTICIPANTS WITH RECENT CANCER DIAGNOSIS AND PARTICIPANTS WITH FAMILY HISTORY

B.2.1 Commitment Pre and Post ACE Scores

COMMITMENT SCORE CHANGES IN PATIENTS WITH RECENT CANCER DIAGNOSIS



COMMITMENT SCORE CHANGES IN PATIENTS WITH FAMILY HISTORIES OF CANCER

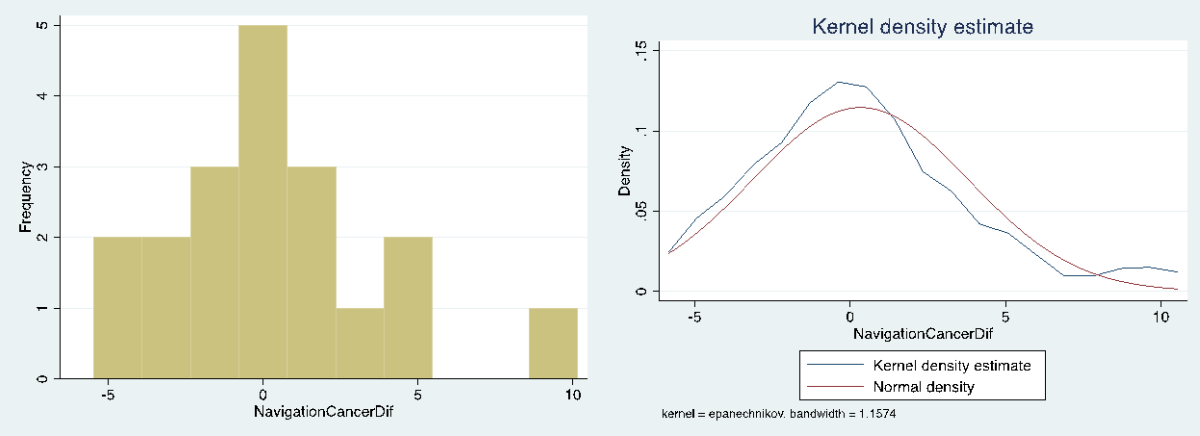


STATA DIFFERENCES IN COMMITMENT SCORES BETWEEN PARTICIPANTS WITH CANCER AND PARTICIPANTS WITH FAMILY HISTORY OF CANCER OUTPUT

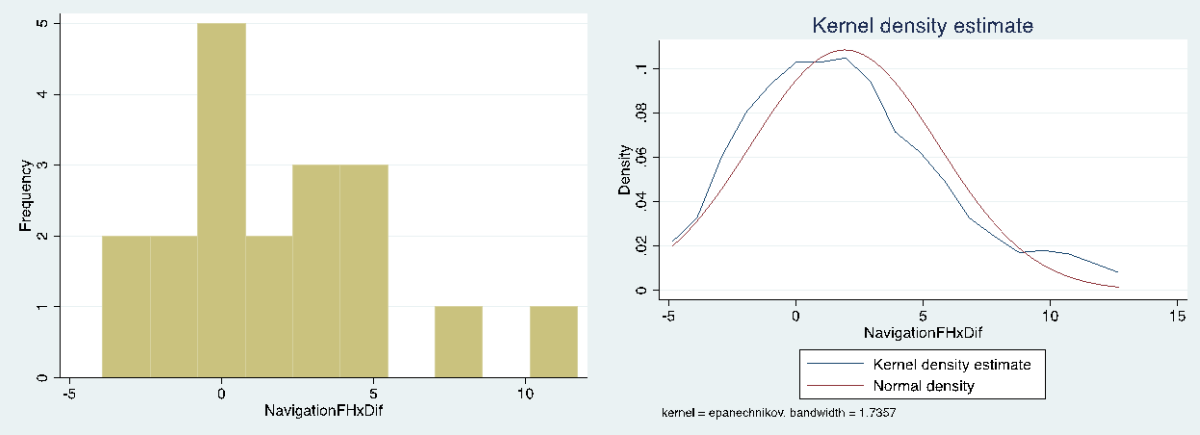
```
Two-sample t test with equal variances
------------------------------------------------------------------------------
Variable |     Obs        Mean    Std. Err.   Std. Dev.   [95% Conf. Interval]
---------+--------------------------------------------------------------------
Com~rDif |      19    .4935263    .8785309    3.829428   -1.352199    2.339251
Com~xDif |      19    .9868421    .7577569    3.302986    -.605146     2.57883
---------+--------------------------------------------------------------------
combined |      38    .7401842    .5736311      3.5361   -.4221028    1.902471
---------+--------------------------------------------------------------------
    diff |           -.4933158    1.160178               -2.846265    1.859633
------------------------------------------------------------------------------
    diff = mean(CommitmentCanc~f) - mean(CommitmentFHxDif)        t =  -0.4252
Ho: diff = 0                                     degrees of freedom =       36

    Ha: diff < 0                 Ha: diff != 0                 Ha: diff > 0
 Pr(T < t) = 0.3366         Pr(|T| > |t|) = 0.6732          Pr(T > t) = 0.6634
```

B.2.2 Navigation Pre and Post ACE Scores

NAVIGATION SCORE CHANGES IN PATIENTS WITH RECENT CANCER DIAGNOSIS



NAVIGATION SCORE CHANGES IN PATIENTS WITH FAMILY HISTORIES OF CANCER

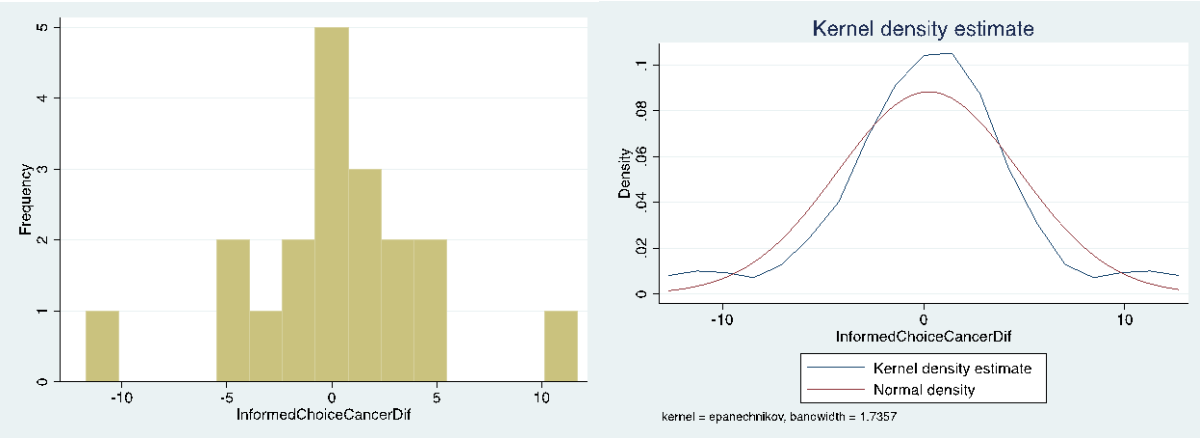


STATA DIFFERENCES IN NAVIGATION SCORES BETWEEN PARTICIPANTS WITH CANCER AND PARTICIPANTS WITH FAMILY HISTORY OF CANCER OUTPUT

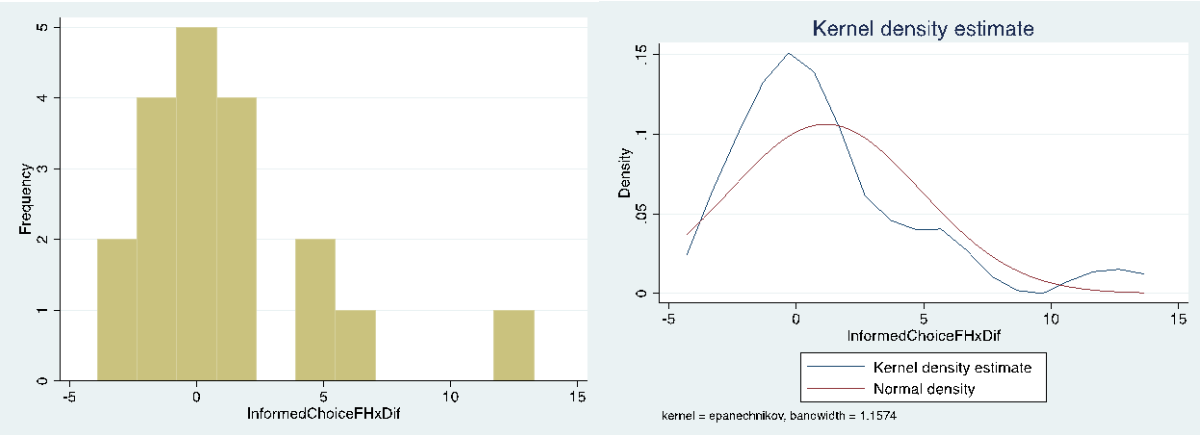
```
Two-sample t test with equal variances
------------------------------------------------------------------------------
Variable |     Obs        Mean    Std. Err.   Std. Dev.   [95% Conf. Interval]
---------+--------------------------------------------------------------------
Nav~rDif |      19    .3289474    .7978384    3.477697   -1.347249    2.005144
Nav~xDif |      19    1.918947    .8440468    3.679115    .1456708    3.692224
---------+--------------------------------------------------------------------
combined |      38    1.123947    .5875436    3.621862    -.066529    2.314424
---------+--------------------------------------------------------------------
    diff |              -1.59    1.161448               -3.945526    .7655254
------------------------------------------------------------------------------
    diff = mean(NavigationCanc~f) - mean(NavigationFHxDif)        t =  -1.3690
Ho: diff = 0                                     degrees of freedom =       36

    Ha: diff < 0                 Ha: diff != 0                 Ha: diff > 0
 Pr(T < t) = 0.0897         Pr(|T| > |t|) = 0.1795          Pr(T > t) = 0.9103
```

B.2.3 Informed Choice Pre and Post ACE Scores

INFORMED CHOICE SCORE CHANGES IN PATIENTS WITH RECENET CANCER DIAGNOSIS



INFORMED CHOICE SCORE CHANGES IN PATIENTS WITH FAMILY HISTORY OF CANCER



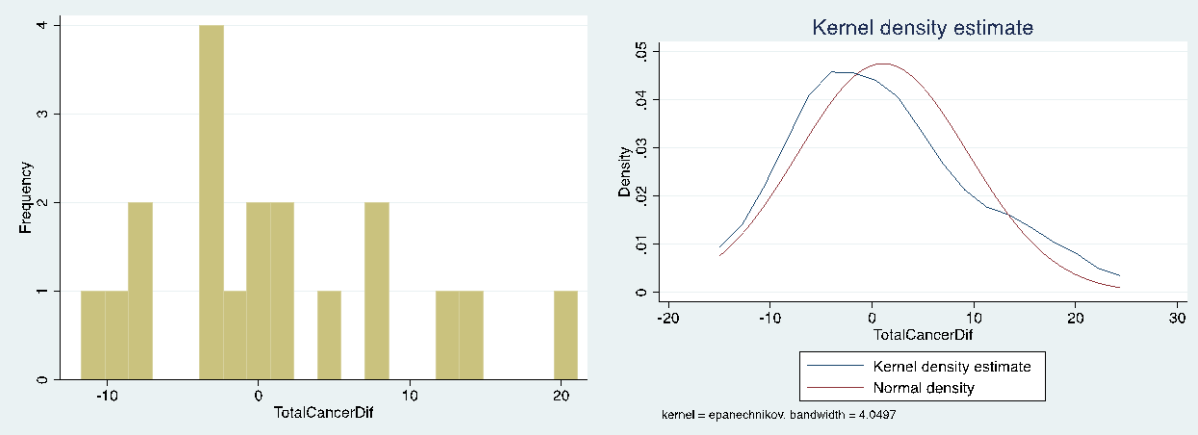
STATA DIFFERENCES IN INFORMED CHOICE SCORES BETWEEN PARTICIPANTS WITH CANCER AND PARTICIPANTS WITH FAMILY HISTORY OF CANCER OUTPUT

```
Two-sample t test with equal variances
------------------------------------------------------------------------------
Variable |     Obs        Mean    Std. Err.   Std. Dev.   [95% Conf. Interval]
---------+--------------------------------------------------------------------
Inf~rDif |      19    .2467368    1.036673    4.518752   -1.931232    2.424705
Inf~xDif |      19    1.151368    .8603597    3.750221   -.6561803    2.958917
---------+--------------------------------------------------------------------
combined |      38    .6990526     .668576    4.121379    -.655611    2.053716
---------+--------------------------------------------------------------------
    diff |           -.9046316    1.347186               -3.636851    1.827588
------------------------------------------------------------------------------
    diff = mean(InformedCho~rDif) - mean(InformedCho~xDif)        t =  -0.6715
Ho: diff = 0                                     degrees of freedom =       36
```

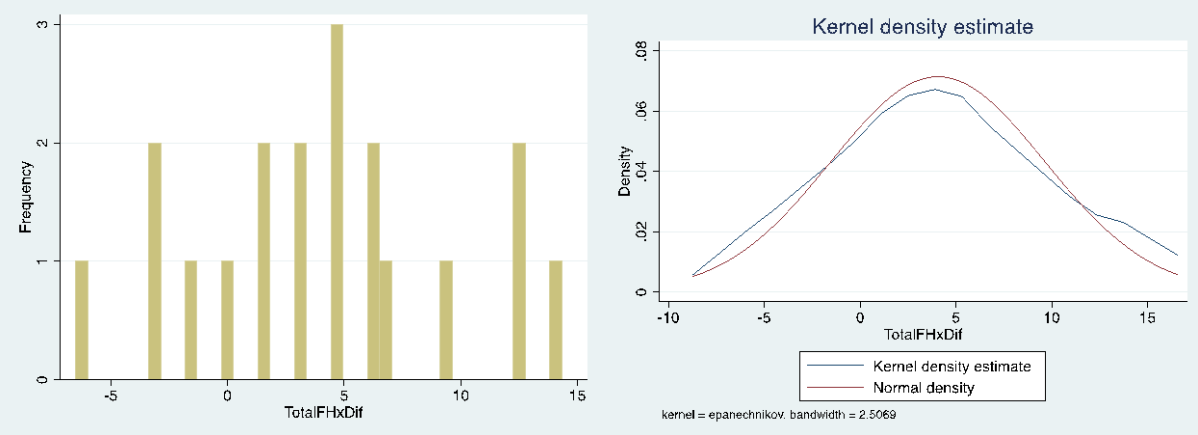
```
    Ha: diff < 0                 Ha: diff != 0                 Ha: diff > 0
 Pr(T < t) = 0.2531         Pr(|T| > |t|) = 0.5062          Pr(T > t) = 0.7469
```

B.2.4 Total Pre and Post ACE Scores

TOTAL SCORE CHANGES IN PATIENTS WITH RECENT CANCER DIAGNOSIS



TOTAL SCORE CHANGES IN PATIENTS WITH FAMILY HISTOTY OF CANCER



STATA DIFFERENCES IN TOTAL SCORES BETWEEN PARTICIPANTS WITH CANCER AND PARTICIPANTS WITH FAMILY HISTORY OF CANCER OUTPUT

```
Two-sample t test with equal variances
------------------------------------------------------------------------------
Variable |     Obs        Mean    Std. Err.   Std. Dev.   [95% Conf. Interval]
---------+--------------------------------------------------------------------
TotalC~f |      19    1.069158    1.923225    8.383145   -2.971389    5.109704
TotalF~f |      19    4.057158    1.280495    5.581546    1.366939    6.747377
---------+--------------------------------------------------------------------
combined |      38    2.563158    1.165706    7.185893    .2012135    4.925102
---------+--------------------------------------------------------------------
    diff |              -2.988    2.310511               -7.673934    1.697934
------------------------------------------------------------------------------
    diff = mean(TotalCancerDif) - mean(TotalFHxDif)               t =  -1.2932
```

```
Ho: diff = 0                                     degrees of freedom =       36

    Ha: diff < 0                 Ha: diff != 0                 Ha: diff > 0
 Pr(T < t) = 0.1021         Pr(|T| > |t|) = 0.2042          Pr(T > t) = 0.8979
```

B.3 DATA BETWEEN MALES AND FEMALES

B.3.1 Commitment Pre and Post ACE Scores

STATA DIFFERENCES IN COMMITMENT SCORES BETWEEN MALE AND FEMALE PARTICPANTS

```
Two-sample t test with equal variances
------------------------------------------------------------------------------
Variable |     Obs        Mean    Std. Err.   Std. Dev.   [95% Conf. Interval]
---------+--------------------------------------------------------------------
MCommi~t |      13    1.803077    1.059321    3.819435   -.5049844    4.111138
FCommi~t |      25      .18748    .6649153    3.324576   -1.184838    1.559798
---------+--------------------------------------------------------------------
combined |      38    .7401842    .5736311      3.5361   -.4221028    1.902471
---------+--------------------------------------------------------------------
    diff |            1.615597    1.195873               -.8097468    4.040941
------------------------------------------------------------------------------
    diff = mean(MCommitment) - mean(FCommitment)                  t =   1.3510
Ho: diff = 0                                     degrees of freedom =       36

    Ha: diff < 0                 Ha: diff != 0                 Ha: diff > 0
 Pr(T < t) = 0.9074         Pr(|T| > |t|) = 0.1851          Pr(T > t) = 0.0926
```

B.3.2 Navigation Pre and Post ACE Scores

STATA DIFFERENCES IN NAVIGATION SCORES BETWEEN MALE AND FEMALE PARTICPANTS

```
Two-sample t test with equal variances
------------------------------------------------------------------------------
Variable |     Obs        Mean    Std. Err.   Std. Dev.   [95% Conf. Interval]
---------+--------------------------------------------------------------------
MNavig~n |      13    1.963231    1.023452    3.690109   -.2666797    4.193141
FNavig~n |      25      .68752    .7165193    3.582596   -.7913031    2.166343
---------+--------------------------------------------------------------------
combined |      38    1.123947    .5875436    3.621862    -.066529    2.314424
---------+--------------------------------------------------------------------
    diff |            1.275711    1.237409               -1.233871    3.785293
------------------------------------------------------------------------------
    diff = mean(MNavigation) - mean(FNavigation)                  t =   1.0310
Ho: diff = 0                                     degrees of freedom =       36

    Ha: diff < 0                 Ha: diff != 0                 Ha: diff > 0
 Pr(T < t) = 0.8453         Pr(|T| > |t|) = 0.3094          Pr(T > t) = 0.1547
```

B.3.3 Informed Choice Pre and Post ACE Scores

STATA DIFFERENCES IN INFORMED CHOICE SCORES BETWEEN MALE AND FEMALE PARTICPANTS

```
Two-sample t test with equal variances
------------------------------------------------------------------------------
Variable |     Obs        Mean    Std. Err.   Std. Dev.   [95% Conf. Interval]
---------+--------------------------------------------------------------------
MInfor~e |      13    .9616924    .6974745     2.51478   -.5579741    2.481359
FInfor~e |      25      .56248    .9584892    4.792446   -1.415744    2.540704
---------+--------------------------------------------------------------------
combined |      38    .6990526     .668576    4.121379    -.655611    2.053716
---------+--------------------------------------------------------------------
    diff |            .3992124    1.427154               -2.49519    3.293615
------------------------------------------------------------------------------
    diff = mean(MInformedChoice) - mean(FInformedChoice)          t =   0.2797
Ho: diff = 0                                     degrees of freedom =       36

    Ha: diff < 0                 Ha: diff != 0                 Ha: diff > 0
 Pr(T < t) = 0.6094         Pr(|T| > |t|) = 0.7813          Pr(T > t) = 0.3906
```

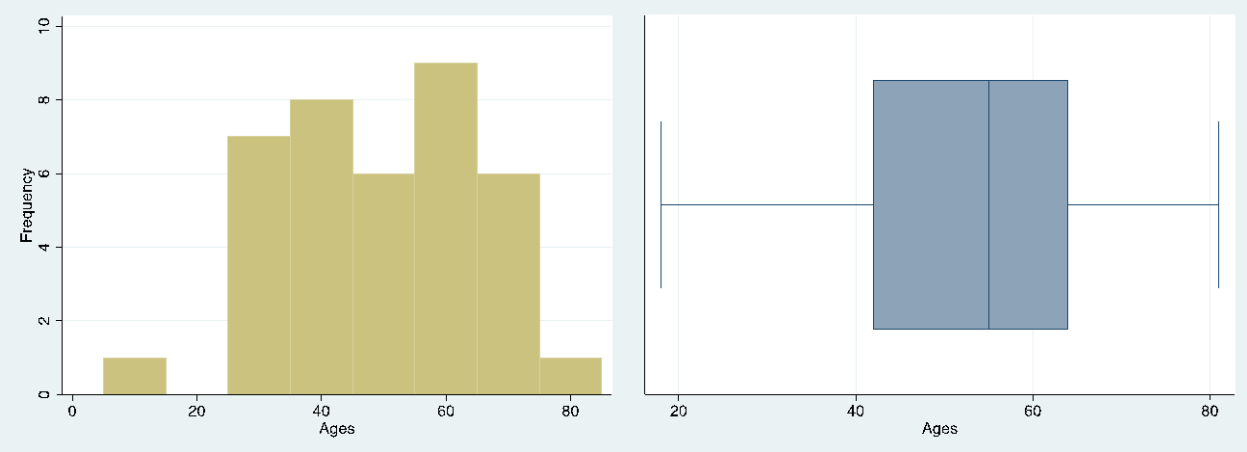
B.3.4 Total Pre and Post ACE Scores

STATA DIFFERENCES IN TOTAL SCORES BETWEEN MALE AND FEMALE PARTICPANTS

```
Two-sample t test with equal variances
------------------------------------------------------------------------------
Variable |     Obs        Mean    Std. Err.   Std. Dev.   [95% Conf. Interval]
---------+--------------------------------------------------------------------
  MTotal |      13    4.727769     1.46304    5.275067    1.540078     7.91546
  FTotal |      25     1.43756     1.57272    7.863601   -1.808375    4.683495
---------+--------------------------------------------------------------------
combined |      38    2.563158    1.165706    7.185893    .2012135    4.925102
---------+--------------------------------------------------------------------
    diff |            3.290209    2.429931               -1.63792    8.218339
------------------------------------------------------------------------------
    diff = mean(MTotal) - mean(FTotal)                            t =   1.3540
Ho: diff = 0                                     degrees of freedom =       36

    Ha: diff < 0                 Ha: diff != 0                 Ha: diff > 0
 Pr(T < t) = 0.9079         Pr(|T| > |t|) = 0.1842          Pr(T > t) = 0.0921
```

B.4 PARTICIPANT AGE DATA

B.4.1 SUMMARY DATA




```
. summarize Ages

    Variable |        Obs        Mean    Std. Dev.       Min        Max
-------------+---------------------------------------------------------
        Ages |         38    53.39474    15.54338         18         81
```

AGE RANGE	N= NUMBER OF PARTICIPANTS	MEAN DIFFERENCE IN PRE/POST TOTAL SCORES
10s	1	+7.813
30s	7	+0.223
40s	8	+6.055
50s	6	+1.823
60s	9	+3.530
70s	6	+0.260
80s	1	-3.125

APPENDIX C: PUBLIC HEALTH CHAPTER DOCUMENTATION

C.1 LIFESTYLE QUESTIONNAIRE, TOBACCO CESSATION

Tobacco Cessation

3 Month Follow-Up Lifestyle Questionnaire

If you used a medication for this quit attempt, are you still using it?

- o Yes
- o No
- o N/A

What is your longest period of continued abstinence (Days in a row without tobacco) since your appointment with Dr. Brand at the GI Clinic? _____

Have you smoked any cigarettes, even a puff, in the last 7 days?

- o Yes
- o No
- o N/A

On the days that you smoke cigarettes, on average, how many do you smoke? _____

Do you currently use any forms of tobacco other than cigarettes?

- o Cigars
- o Pipes
- o Chew/snuff
- o E-cig
- o No

Frequency/amount of other tobacco forms? _____

Importance/Confidence Scales

On a scale of **1** (not at all important) to **10** (extremely important), how important do you feel it is to quit smoking? 1 2 3 4 5 6 7 8 9 10

On a scale of **1** (not at all confident) to **10** (extremely confident), how confident are you that you can quit smoking? 1 2 3 4 5 6 7 8 9 10

C.2 LIFESTYLE QUESTIONNAIRE, WEIGHT LOSS

Weight Management

3 Month Follow-Up Lifestyle Questionnaire

In the past 7 days, have you used an app, tool, program, log, and/or tracker to monitor your physical activity and/or steps?

- o Yes
- o No

In the past 7 days, have you used an app, tool, program, log, and/or tracker to monitor your calorie and/or food intake?

- o Yes
- o No

Module: BMI

What is your height (in)? _____

What is your most recent weight (lbs)? _____

Members current BMI: _____

I am confident that I can use information and tools (such as food labels, apps, or books) to make health food choices

- o Strongly Agree
- o Somewhat Agree
- o Uncertain
- o Somewhat Disagree
- o Strongly Disagree

I am confident that I can manage my weight when I encounter problems, special events, or new situations.

- o Strongly Agree
- o Somewhat Agree
- o Uncertain
- o Somewhat Disagree
- o Strongly Disagree

Importance/Confidence Scales

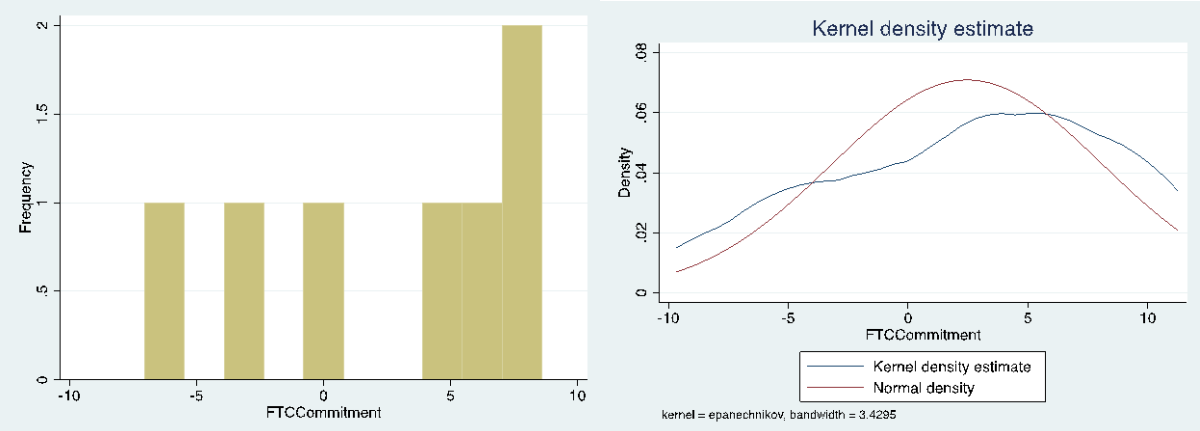
On a scale of **1** (not at all important) to **10** (extremely important), how important do you feel it is to manage your weight? 1 2 3 4 5 6 7 8 9 10

On a scale of **1** (not at all confident) to **10** (extremely confident), how confident are you that you can manage your weight? 1 2 3 4 5 6 7 8 9 10

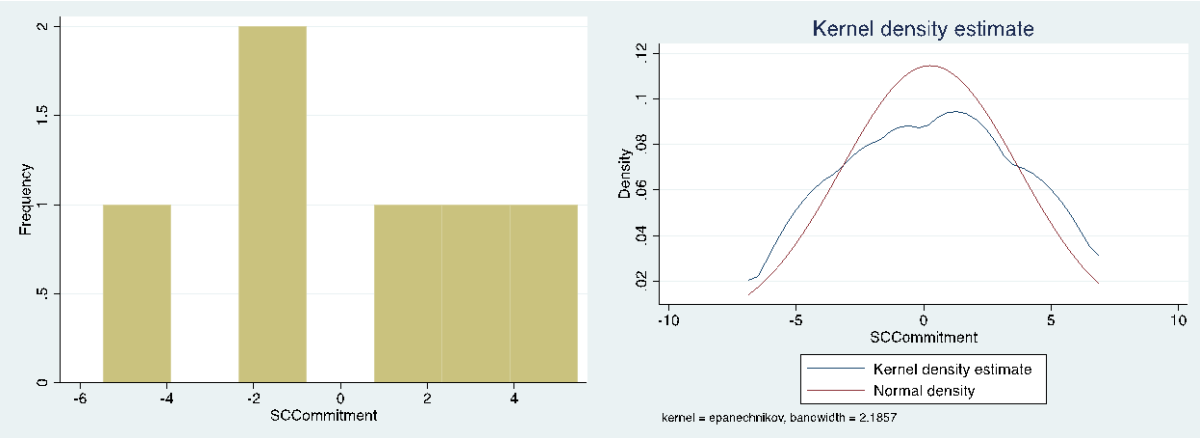
C.3 DATA ACROSS LIFESTYLE PARTICIPANTS

C.3.1 Commitment Scores in Participants who Failed to Change and Participants who were Successful in Change

COMMITMENT SCORE CHANGES IN PARTICIPANTS WHO FAILED TO CHANGE LIFESTYLE BEHAVIORS



COMMITMENT SCORE CHANGES IN PARTICIPANTS WHO SUCCESSFULLY CHANGED LIFESTYLE BEHAVIORS

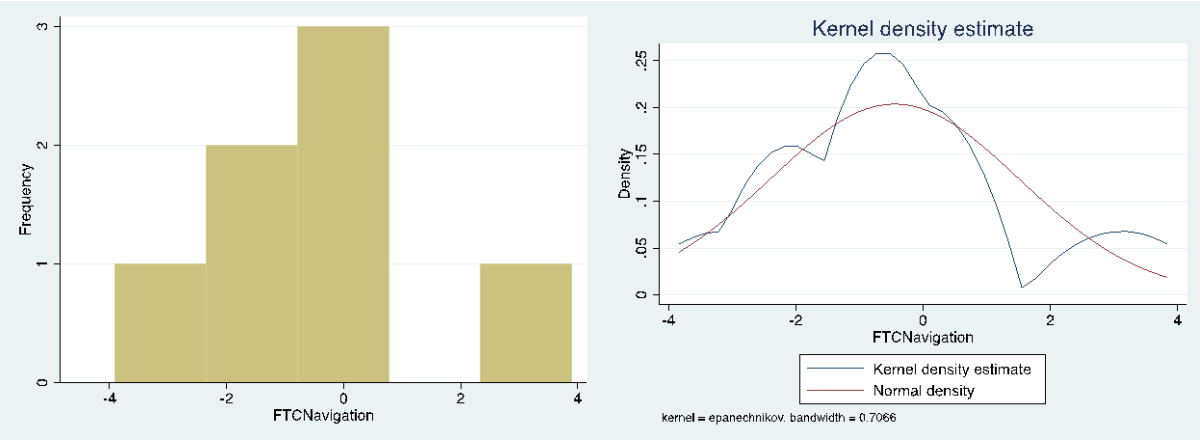


Difference in Commitment Scores between Participants who Failed to Change and Participants who were Successful in Change of Lifestyle Behaviors

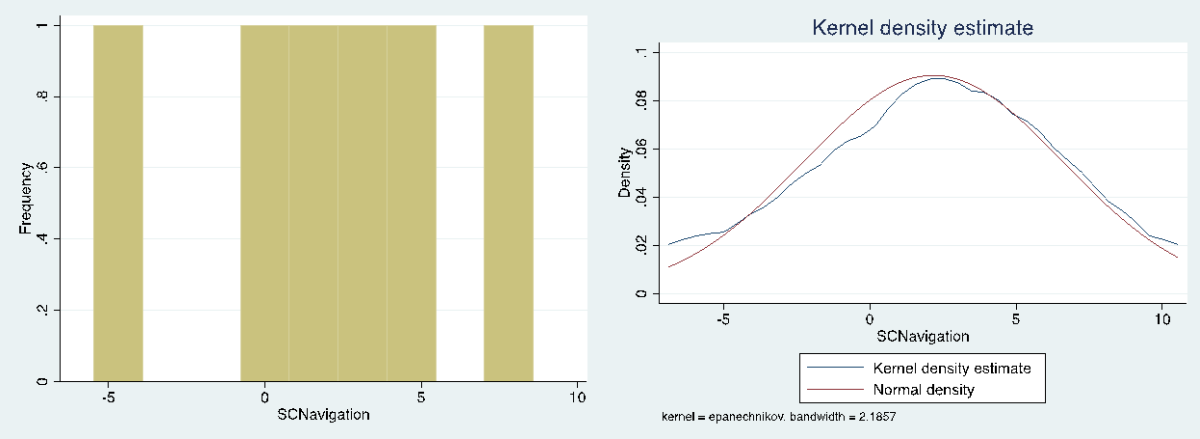
```
Two-sample t test with equal variances
------------------------------------------------------------------------------
Variable |     Obs        Mean    Std. Err.   Std. Dev.   [95% Conf. Interval]
---------+--------------------------------------------------------------------
FTCCom~t |       7    2.455572    2.125498    5.623538   -2.745334    7.656477
SCComm~t |       6    .2603333    1.421766    3.482602   -3.394433      3.9151
---------+--------------------------------------------------------------------
combined |      13    1.442385      1.3057    4.707768   -1.402491    4.287261
---------+--------------------------------------------------------------------
    diff |            2.195238    2.654344               -3.646933    8.037409
------------------------------------------------------------------------------
    diff = mean(FTCCommitment) - mean(SCCommitment)               t =   0.8270
Ho: diff = 0                                     degrees of freedom =       11
    Ha: diff < 0                 Ha: diff != 0                 Ha: diff > 0
 Pr(T < t) = 0.7871         Pr(|T| > |t|) = 0.4258          Pr(T > t) = 0.2129
```

C.3.2 Navigation Scores in Participants who Failed to Change and Participants who were Successful in Change

NAVIGATION SCORE CHANGES IN PARTICIPANTS WHO FAILED TO CHANGE LIFESTYLE BEHAVIORS



NAVIGATION SCORE CHANGES IN PARTICIPANTS WHO SUCCESSFULLY CHANGED LIFESTYLE BEHAVIORS

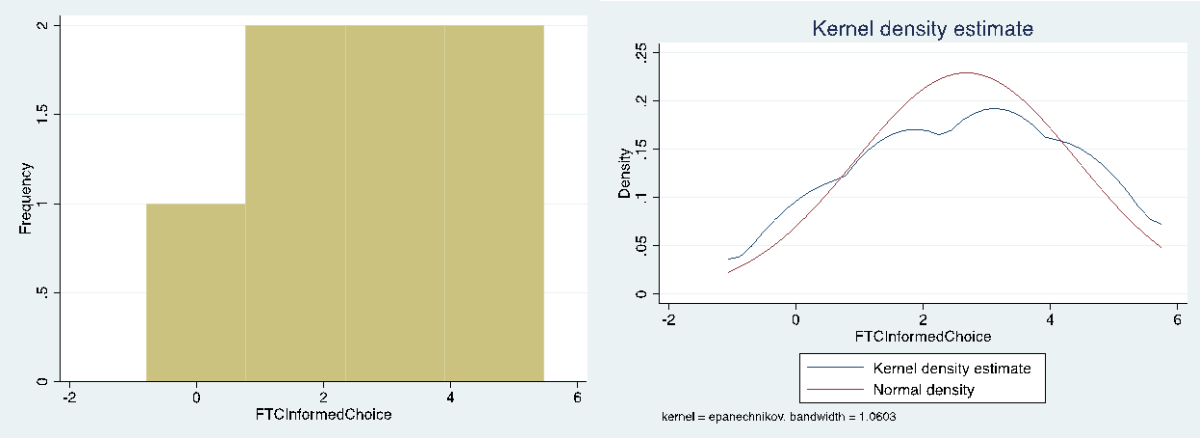


Difference in Navigation Scores between Participants who Failed to Change and Participants who were Successful in Change of Lifestyle Behaviors

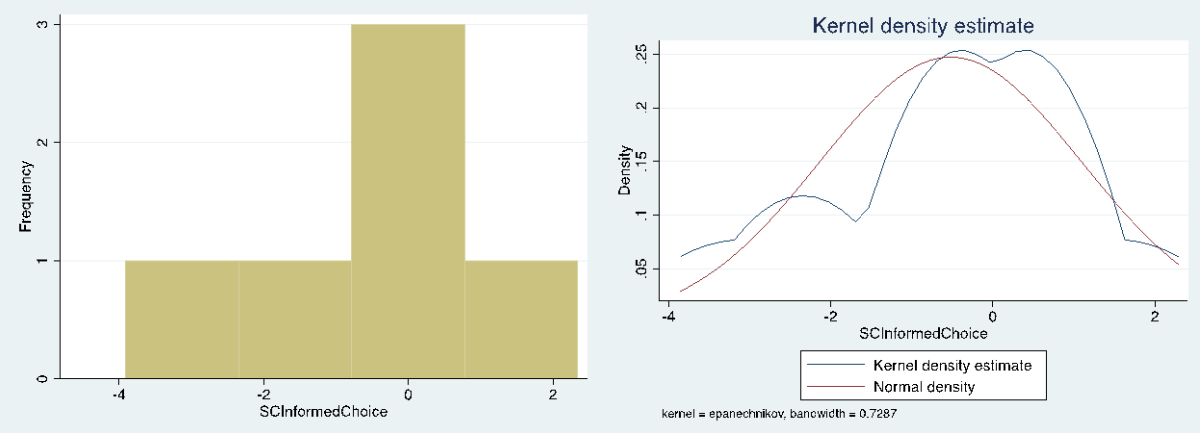
```
Two-sample t test with equal variances
------------------------------------------------------------------------------
Variable |     Obs        Mean    Std. Err.   Std. Dev.   [95% Conf. Interval]
---------+--------------------------------------------------------------------
FTCNav~n |       7   -.4465714    .7403539    1.958792   -2.258152    1.365009
SCNavi~n |       6    2.170167    1.801337    4.412356   -2.460317    6.800651
---------+--------------------------------------------------------------------
combined |      13    .7611539    .9557107    3.445864   -1.321161    2.843469
---------+--------------------------------------------------------------------
    diff |           -2.616738    1.840356               -6.667335    1.433859
------------------------------------------------------------------------------
    diff = mean(FTCNavigation) - mean(SCNavigation)                t =  -1.4219
Ho: diff = 0                                     degrees of freedom =       11

    Ha: diff < 0                 Ha: diff != 0                 Ha: diff > 0
 Pr(T < t) = 0.0914         Pr(|T| > |t|) = 0.1828          Pr(T > t) = 0.9086
```

C.3.3 Informed Choice Scores in Participants who Failed to Change and Participants who were Successful in Change

INFORMED CHOICE SCORE CHANGES IN PARTICIPANTS WHO FAILED TO CHANGE LIFESTYLE BEHAVIORS



INFORMED CHOICE SCORE CHANGES IN PARTICIPANTS WHO SUCCESSFULLY CHANGED LIFESTYLE BEHAVIORS

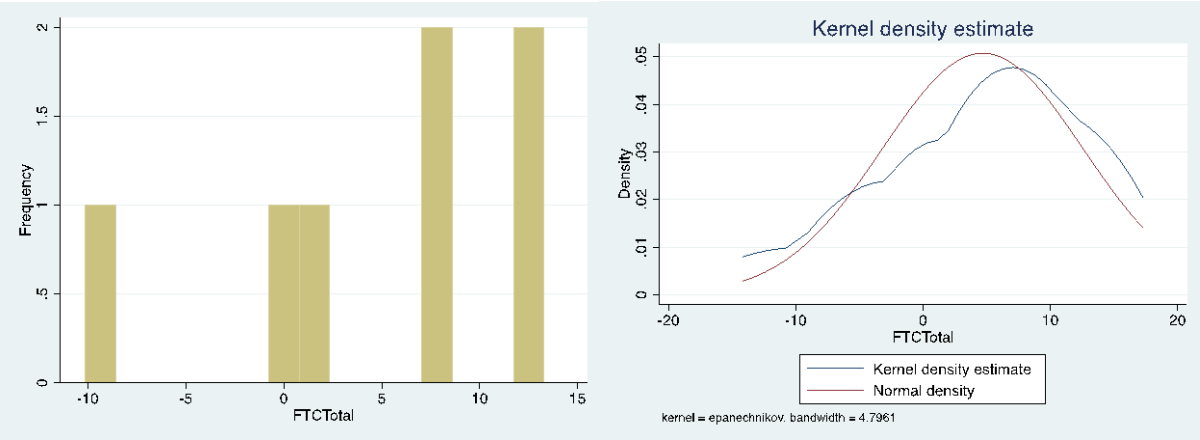


Participants who were Successful in Change of Lifestyle Behaviors

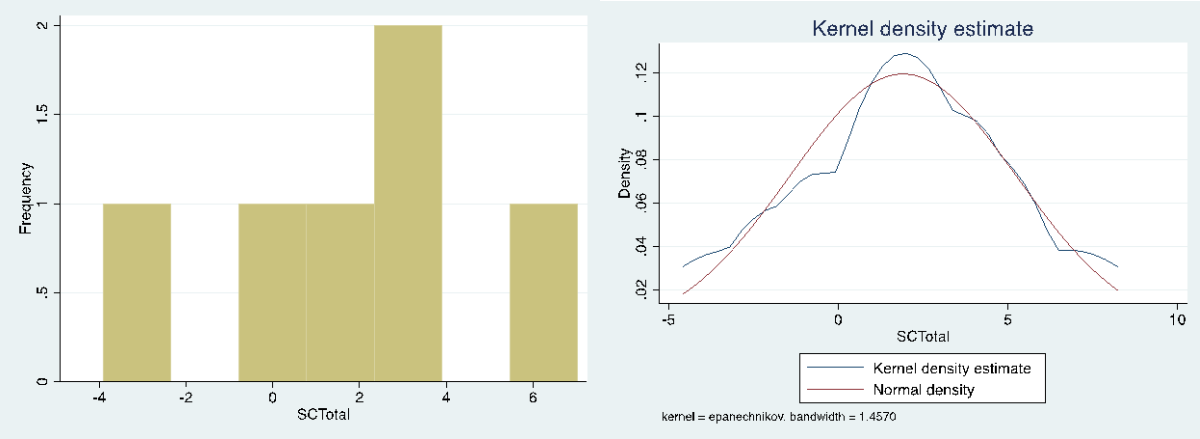
```
Two-sample t test with equal variances
------------------------------------------------------------------------------
Variable |     Obs        Mean    Std. Err.   Std. Dev.   [95% Conf. Interval]
---------+--------------------------------------------------------------------
FTCInf~e |       7    2.678857    .6571575    1.738675    1.070851    4.286864
SCInfo~e |       6   -.5208333    .6588869    1.613937   -2.214556    1.172889
---------+--------------------------------------------------------------------
combined |      13    1.202077    .6417054    2.313702    -.196079    2.600233
---------+--------------------------------------------------------------------
    diff |            3.199691    .9364028                1.138682    5.260699
------------------------------------------------------------------------------
    diff = mean(FTCInformedCho~e) - mean(SCInformedChoice)        t =   3.4170
Ho: diff = 0                                     degrees of freedom =       11

    Ha: diff < 0                 Ha: diff != 0                 Ha: diff > 0
 Pr(T < t) = 0.9971         Pr(|T| > |t|) = 0.0058          Pr(T > t) = 0.0029
```

C.3.4 Total Scores in Participants who Failed to Change and Participants who were Successful in Change

TOTAL SCORE CHANGES IN PARTICIPANTS WHO FAILED TO CHANGE LIFESTYLE BEHAVIORS



TOTAL SCORE CHANGES IN PARTICIPANTS WHO SUCCESSFULLY CHANGED LIFESTYLE BEHAVIORS



Difference in Total Scores between Participants who Failed to Change and Participants who were Successful in Change Lifestyle Behaviors

```
Two-sample t test with equal variances
------------------------------------------------------------------------------
Variable |     Obs        Mean    Std. Err.   Std. Dev.   [95% Conf. Interval]
---------+--------------------------------------------------------------------
FTCTotal |       7    4.687714     2.97248    7.864444   -2.585683    11.96111
 SCTotal |       6    1.909833    1.362614    3.337709   -1.592877    5.412544
---------+--------------------------------------------------------------------
combined |      13    3.405615    1.701675    6.135478   -.3020165    7.113247
---------+--------------------------------------------------------------------
    diff |            2.777881    3.465469               -4.849566    10.40533
------------------------------------------------------------------------------
    diff = mean(FTCTotal) - mean(SCTotal)                         t =   0.8016
Ho: diff = 0                                     degrees of freedom =       11

    Ha: diff < 0                 Ha: diff != 0                 Ha: diff > 0
 Pr(T < t) = 0.7801         Pr(|T| > |t|) = 0.4398          Pr(T > t) = 0.2199
```

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