THE IMPACT OF GENETIC COUNSELING ON PATIENT ENGAGEMENT AND HEALTH BEHAVIOR

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ABSTRACT

Patient engagement, or active participation and involvement in one's health care, has been beneficially related to health outcomes and lower health care costs. The purpose of this study was to elucidate the relationship between patient engagement, pursuing lifestyle behavior changes (weight loss and tobacco cessation), and the impact of receiving genetic information for hereditary cancer syndromes. We hypothesized that higher baseline engagement scores and receiving a pathogenic variant result would be associated with positive behavior changes. It was also expected that receiving pathogenic variant results would be associated with increased engagement scores. Patients seen in the UPMC Hereditary GI Tumor Program were verbally administered the Altarum Consumer Engagement (ACE) Measure survey to assess patient engagement prior to their initial appointment. Participants were then contacted via phone three to five months after their initial appointment to repeat the ACE measure, as well as a Lifestyle Questionnaire if applicable. A total of 195 participants were included in the analyses, 51 of whom were overweight at their initial appointment and 15 of whom were current smokers at their initial appointment. Two sample T-tests, linear and logistic models, and Fisher's exact test were used to test associations. It was found that having a higher baseline Navigation score within the ACE measure was associated with an individual being less likely to lose weight. Tobacco cessation was not associated with baseline total engagement (ACE). A pathogenic variant result did not make an individual more or less

engaged in their health, lose weight, or quit smoking compared to those with no pathogenic variant. Additionally, participants were found to have significantly greater engagement levels after receiving genetic counseling. Genetic counseling may be an effective healthcare intervention to increase patient engagement, and thus ultimately lead to improved public health, decreased healthcare dollars, and beneficial patient outcomes.

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PREFACE

Special thanks to my committee- Dr. Brand, Beth, Robin, Andrea, and Dr. Shaffer- and the following individuals for their input and support throughout this research project:

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1.0 INTRODUCTION

Patient engagement is a new field of study that strives to understand the implications of being involved in one's health care.[1] Research has found that more highly engaged patients were significantly less likely to be obese, to smoke, and to have an emergency department visit or a hospital stay within the past 12 months.[2] Further, patients with lower engagement levels had health care costs that were up to eight times greater than those with the higher engagement levels.[3]

Two major public health burdens, obesity and tobacco smoking, have been previously associated with patient engagement.[1] It was previously found that individuals who were obese were 25-40% less likely to receive colorectal screening compared to those who were not obese.[4,5] Another study reported that patients who had higher current levels of engagement were 1.62 times more likely to have pursued a tobacco quit attempt over the past year compared to those with lower engagement levels.[6] Genetic counseling is another field that is directly related to patient engagement.[7] Genetic counseling has also previously been found to increase, knowledge about health, satisfaction with health care experiences, and involvement with the health care system, as well as decrease cancer-related worry and perceived risk.[8,9]

The participant population included all patients seen in the Hereditary GI Tumor Program and who consented to participate in the study. At the time of their initial appointment, participants were verbally administered the Altarum Consumer Engagement (ACE) Measure survey to assess individual healthcare engagement. After completing the survey, the participants

next received genetic counseling and a consult with a gastroenterologist who specializes in hereditary GI cancer syndromes. Patients insured by UPMC Health Plan who were overweight (BMI ≥ 30) or were current smokers were given standard lifestyle modification reading material, as well as a Prescription for Wellness to a tobacco cessation or weight loss health coaching program if they were interested. Patients who were overweight or used tobacco and had a different insurer were given only the standard of care reading material for lifestyle changes. All participants were then contacted via phone three to five months after their initial office appointment to repeat the ACE measure survey. Individuals who were overweight (BMI ≥ 30) and individuals who were current tobacco users at the time of their initial visit were also asked to complete the Lifestyle Questionnaires, either the weight loss questionnaire or the smoking cessation questionnaire, as appropriate, during the post follow up phone call.

This study aims to elucidate the relationship between patient engagement, lifestyle behavior changes, and the impact of receiving genetic information for hereditary cancer syndromes after a genetic counseling appointment. This research can serve to help identify effective public health interventions that can be integrated into a clinical setting to identify individuals at risk for poor health outcomes and to further tailor clinical care. Further understanding these associations has the potential to ultimately improve public health and may lead to lower healthcare costs.

The specific aims and hypotheses of this study include:

Aim 1: To investigate the impact of an individual's baseline engagement in their health, as measured by the Altarum Consumer Engagement (ACE Measure), on lifestyle behavior outcomes for tobacco cessation and weight loss before and after genetic counseling.

Hypothesis: Individuals who have higher engagement scores will be more likely to change their behavior (lose weight or stop smoking) after a genetic counseling session compared to individuals who have lower engagement scores.

Aim 2: To compare engagement and behavioral changes between individuals with a pathogenic variant versus those with no pathogenic variant.

Hypothesis 1: Individuals who have a pathogenic variant will be more likely to change their behavior (lose weight or stop smoking) after a genetic counseling session compared to individuals who have no pathogenic variant.

Hypothesis 2: Individuals who have a pathogenic variant will have increased engagement scores after a genetic counseling session compared to individuals who have no pathogenic variant.

1.1 LITERATURE REVIEW

1.2 PATIENT ENGAGEMENT

1.2.1 Definition and Implications

With the growing complexity of the health care system, greater demands are now being placed on patients to navigate, access, and understand health care. A new field of study, called patient engagement, has arisen to understand the implications of being involved in one's health care. The term patient engagement was defined by Gruman et al. (2010) as "actions individuals must take to obtain the greatest benefit from the health care services available to them."[1] Factors that have been found to directly relate to patient engagement include health literacy, values and beliefs, education,

and socioeconomic status.[10] Clinicians can also serve to increase patient engagement. Assessment tools that seek to measure how well clinicians are engaging patients in their health, known as patient-centered outcome measures, have been recently integrated into policy; the Affordable Care Act (ACA) addresses patient engagement and patient-centered outcomes. The ACA created patient-centered medical homes and provided incentives for hospitals to utilize patient portals, thus increasing opportunities for patients to become more engaged in the health care system.[11]

Active participation and involvement in one's health care is an important factor to consider when assessing health outcomes. One research group performed a meta-analysis of 365 studies and conducted 57 key informant interviews with researchers in the field of patient or consumer engagement to create an engagement behavior framework (EBF).[1] The authors then coded 2,433 sessions at seven different professional conferences from 2006-2007 that were related to patient education to quantify specific engaged behaviors of the EBF. It was concluded that engaged patients partake in behaviors ranging from knowledge of navigating health care, involvement in care decisions, and record keeping of medical information.[1] The authors also found that certain disadvantaged groups such as the uninsured, those with low levels of health literacy, those with a lower education status, and older individuals are less likely to engage in health promoting behaviors.[1] These groups of individuals, therefore; may not receive the same benefits as those who are more engaged since the behaviors of those who are active participants in their health may have implications for their well-being.

Increased patient engagement can lead to better health outcomes as well as lower health care costs and thus better utilization of health care resources. Previous studies have found that when patients are more engaged in their own health, they are more likely to follow preventative measures, manage disease, and adhere to health recommendations.[12, 2] In one study assessing the

activation of engaged patients and healthy behavior outcomes, a total of 25,047 patients who had attended a primary care visit within the past six months completed a Patient Activation Measure.[2] Patients with higher levels of engagement were significantly less likely to be obese, to smoke, and to have an emergency department visit or hospital stay within the past 12 months.[2] They were also significantly more likely to have undergone a breast cancer screening, and to have normal lab results (A1c, HDL, and triglyceride levels).[2] The authors concluded that patient engagement was associated with beneficial health behaviors as well as a better utilization of health care services, thus resulting in fewer costs. Another study found that implementing strategies to increase overall patient engagement resulted in beneficial clinical outcomes. A quasi-experimental trial gave a total of 11,797 patient's access to their clinical records at three different hospitals.[13] It was found that 77-87% of the patients reported feeling more in control of their health and 60-78% of patients taking medications reported better adherence to their medications.[13] Although patients reported few concerns, around 1-8% reported feelings of confusion, worry or offense.[13] Overall, both clinicians and patient's positive outcomes of granting patient's access to their records, and thus increasing their engagement in their health.

There are limited studies that have directly analyzed the extent to which patient engagement leads to lower health care costs. A longitudinal cross-sectional study analyzed Patient Activation Measure scores from 33,163 patients of a large health care system in Minnesota in relation to the patient's total cost of non-inpatient care within the first six months of the following year.[3] Adjusting for previous health conditions and risks, demographics, and the use of health care services outside of their system, it was found that higher patient engagement levels were positively associated with lower costs of care. More specifically, those with the lowest engagement levels had health care costs over the six-month period that were eight times higher than those with the

highest engagement levels. A follow up study analyzing data from the same health care system in Minnesota over a longer time period also found that individuals with higher engagement levels had total annual medical charges from their institution that were eight percent lower than those with the lowest engagement levels and had significantly better outcomes, including not smoking or not being obese, two years later.[14] Measuring levels of engagement among patients may provide key information on outcomes that can be integrated into the clinic and reduce health care costs.

1.2.2 The ACE Measure

Given that measuring engagement levels can provide information that can be used to potentially improve patient health, health care systems and providers must consider which specific measurement tool is optimal. Only a small number of validated engagement measures exist, and most do not measure multiple factors of patient engagement.[15] The Altarum Consumer Engagement (ACE) Measure™ (June 2015) is a validated patient measure created to provide a comprehensive, up to date measurement of a patient's engagement in their health.[15] Prior to the creation of the ACE, patient engagement measures only measured certain factors of patient engagement, such as clinical decision-making, patient autonomy, or activation.[15] Additionally, no previous engagement measures factored in patient use of health care ratings and other tools to compare health care providers/services. In order to address the gap in engagement measures, the ACE measure utilized Gruman's patient engagement definition, defined in the patient engagement section of this paper, in order to address all of the factors of engagement. The goal of the ACE is to assess both patient beliefs and actions in order to improve patient care.

The ACE measure is comprised of 12 statements and utilizes a 5-point Likert scale, ranging from “strongly disagree” to “strongly agree”. The tool has three different domains, with four questions comprising each domain. The domains are defined as:

- “Commitment: confidence and ability to maintain a healthy lifestyle and manage one’s health.
- Navigation: confidence and ability to ask about and participate in treatment decisions.
- Informed Choice: Informed patterns of seeking and using information about health and healthcare.”[15]

This measure has previously been found to be associated with health outcomes.[16] A current study that utilized the ACE measure assessed the relationship between engagement levels and diabetes management and showed that the Commitment domain levels were associated with changes in glycated hemoglobin (HbA1c) levels.[16] Those who had higher Commitment scores were significantly more likely to have improved HbA1c levels over time compared to those with lower Commitment scores.[16] Clinicians could utilize this information to target interventions towards those with lower Commitment scores. Therefore, the ACE measure has the potential to be integrated into a clinical setting in order to improve patient care.

1.3 BEHAVIOR MODIFICATION

1.3.1 Weight Loss

Obesity is a major public health problem in the nation; during 2011-2014, around 36.5% of adults in the United States had a BMI of greater than or equal to 30.[17] During the past couple of decades, the rates of this complex, chronic health problem have significantly grown across the nation.[18] In 1980, around 15% of adults in the United States ages 20-74 were obese.[18] Factors that contribute to body size include genetics, physical inactivity, health conditions, and sociodemographic factors.[19] Being overweight is associated with a variety of health problems including breast cancer, colon cancer, pancreatic cancer, type 2 diabetes, and cardiovascular disease.[19] Okabayashi et al. (2012) conducted a meta-analysis of 23 studies that included a total of 105,190 individuals who had a BMI of less than 25 and 42,179 individuals who had a BMI of greater than or equal to 25. It was found that individuals with a BMI of greater than or equal to 25 have a 24% greater incidence of colorectal cancer.[20] Maintaining a healthy weight and being physically active is an integral component of a healthy lifestyle.[21] A prospective cohort study investigating the impact of weight loss on cancer incidence surveyed a total of 21,707 postmenopausal women who initially had never been diagnosed with cancer.[22] After adjusting for age and BMI, the study found that women who had intentionally lost 20 pounds or more had a 14% decrease in obesity-related cancer incidence, a 9% decrease in colorectal cancer incidence, and a 19% decrease in breast cancer incidence compared to women who had never lost 20 pounds or more.[22] In order to reach weight loss goals and subsequently decrease obesity-related health problems, individuals can pursue weight management intervention programs.

A review by Wu et al (2009) found that weight loss interventions that encompass both a physical activity and diet component are more successful in long-term weight loss.[23] When an individual pursues weight loss interventions, there are several factors that can contribute to their success. A study was conducted to determine the predictors of long-term weight loss in participants who had participated in the Sibutramine Trial on Obesity Reduction and Maintenance, a 6-month weight-loss intervention comprised of Sibutramine treatment (an appetite suppressant) and dietary, fitness, and behavior advice.[24] After the initial 6-month weight-loss intervention, a total of 261 participants received advice from a dietician over an 18-month time period. It was found that initial weight loss and being physically active were predictors of long-term weight loss and accounted for 20% of the variation in weight maintenance.[24] However, weight regain after completing a weight loss intervention is a common problem. Weight maintenance can be defined as an initial weight loss that has been sustained for over 6 months.[25] Barte, Ter Bogt, and Bogers (2011) performed a meta-analysis and found that only around 54% of people maintain their weight a year after a weight loss intervention.[25] Considering the factors that may make an individual more likely to lose weight and maintain that weight loss is important to inform the development of interventions.

One such factor that may be associated with body size is patient engagement, as maintaining a recommended body weight is a behavior that is part of the engaged behavioral framework (EBF).[1] Individuals who are obese face barriers to receiving heath care, such as the fear of negative attitudes from physicians and few accommodations for seating in a clinic.[26] These factors have contributed to individuals choosing not to receive screening services such as mammograms and colonoscopies.[4,5] Ferrante et al. (2006) conducted a study to assess the rates of colorectal screening in a primary care setting among individuals who were obese.[4] Retrospective

chart reviews were completed on a total of 1,297 patients. It was found that individuals who were obese were 25% less likely to receive colorectal screening compared to those who were not obese.[4] Similarly, Messina et al. (2012) conducted a study to assess gender differences as well as attitudes towards colorectal cancer screening in individuals who were overweight. A random sample of people aged 50-75 years old who had never been diagnosed with colorectal cancer or colon polyps were surveyed by telephone.[27] The authors reported that women who were overweight and obese were 40% less likely to receive colorectal screening compared to women who were not overweight or obese. Women, but not men, who were overweight and obese were half as likely to know that increased body weight can be associated with colorectal cancer and to report worry about developing colorectal cancer. No differences were found between men and rates of colorectal screening. Therefore, being overweight, especially for women, may hinder an individual's ability to engage in behaviors such as receiving cancer screening that will contribute to their health. As obesity is a risk factor for colorectal cancer and other health conditions, interventions to increase the engagement of individuals who are obese are needed. Weight loss is one health behavior that is important to consider when assessing health outcomes.

1.3.2 Tobacco Cessation

Another health behavior that contributes to poor health, tobacco usage, is one of the most significant causes of cancer-related morbidity and mortality in the United States.[28] In 2015, around 15.1% of adults in the nation were current smokers.[28] Tobacco usage has been associated with a variety of health risks, including cancer.[29] The American Cancer Society estimated that in 2017, around 32% of deaths caused by cancer are directly attributable to tobacco usage.[29] Smoking has been most strongly associated with lung, oropharynx and larynx cancers, but has also been found

to be associated with colorectal cancer.[30] After a cancer diagnosis, tobacco cessation has been associated with better prognosis.[31] A recent meta-analysis analyzed the smoking behavior and survival rates of 12,414 patients recently diagnosed with colorectal cancer.[31] It was found that compared to those who continued to smoke, smoking cessation was associated with both increased overall and colorectal cancer-specific survival rates. Quitting tobacco usage may reduce the associated risk of developing colorectal cancer and the poorer prognosis.

Tobacco status has not only been associated with health outcomes; it has also been related to patient engagement. A study that analyzed health care providers' counseling regarding smoking cessation sampled a total of 8,656 participants who were autoworkers and their spouses through a mail survey.[6] As the autoworkers all received similar health benefits through union rules, the differences in health benefits were largely controlled for. Current levels of patient engagement were measured through a 4-question survey asking how many times participants engaged in specific behaviors during a clinical encounter. Provider counseling on smoking cessation and smoking behavior questions over the past year were included in the same survey. It was found that patients who had higher engagement levels were 1.62 times more likely to have pursued a quit attempt over the previous year compared to those with lower engagement levels.[6] Additionally, current smokers who had higher engagement levels were 1.51 times more likely to receive counseling on smoking cessation from their health care providers compared to those with lower engagement levels.[6] It can be hypothesized that individuals who smoke and have higher engagement scores may be more likely to attempt to quit smoking compared to individuals who smoke and have lower engagement scores.

1.4 CANCER

1.4.1 Prevalence of cancer and health care costs

The growing prevalence of cancer in the United States, more than 15.5 million affected individuals, contributes to a large proportion of health care expenditures.[29] In 2014, it was estimated that $87.8 billion was spent on treating cancer.[29] While cancer is the second most common cause of death in the United States, it has been estimated that around two-thirds of cancer diagnoses could be prevented through health behavior modifications.[29] National guidelines have been established by health organizations, such as American Cancer Society, US Department of Health and Human Services, and the World Research Fund that detail recommendations on weight management, nutrition, and physical activity in order to decrease overall cancer incidence.[32-34] A prospective cohort study conducted by Kabat et al. (2015) analyzed the association between following the ACS lifestyle guidelines and the reduction of the incidence of cancer. A total of 476,396 participants enrolled in the NIH-AARP Diet and Health Study were followed for a median of 10.5 years.[35] It was found that compliance with the lifestyle guidelines was associated with an overall reduction of new cancer diagnoses by 10% in men and 19% in women and a reduction of new colorectal cancer diagnoses by 48% in men and by 35% in women.[35] Designing interventions to encourage behavior modification that, as a result could prevent cancer from developing, could reduce the incidence and mortality of cancer as well as save substantial health care dollars.

1.4.2 Hereditary Predispositions to Cancer

Hereditary predispositions to cancer are associated with increased chances to develop certain cancers over a person's lifetime. Two of the more common hereditary cancer syndromes include Lynch syndrome (caused by mutations in the *MSH1, MSH2, MSH6, PMS2,* and *EPCAM* genes) and Hereditary Breast and Ovarian Cancer syndrome (caused by mutations in the BRCA1 and BRCA2 genes). Lynch syndrome increases the risk of colorectal cancer as well as uterine, stomach, ovarian, small bowel, urinary tract, pancreatic, and brain cancers.[36] Individuals with mutations in the Lynch syndrome-associated genes have a 10-82% chance to develop colon cancer over their lifetime, compared to the general population risk of 4.5%.[36] Hereditary Breast and Ovarian Cancer syndrome increases the risk of breast, ovarian, prostate, and pancreatic cancers, and melanoma.[37] Women with mutations in BRCA1 or BRCA2 genes have a 40-80% chance to develop breast cancer and a 11-24% chance to develop ovarian cancer over their lifetime.[37]

1.4.3 Behavioral modifications and Hereditary Predispositions to Cancer

Risk modifying factors have been suggested to decrease the likelihood of cancer development, even in individuals with hereditary cancer syndromes.[38,39] A previous study found that in individuals with Lynch syndrome, those with higher physical activity levels had lower chances of developing breast cancer.[40] Both body weight and smoking have also been reported to contribute to cancer development in patients with hereditary cancer syndromes.[41,42] Kotsopoulos et al. (2005) performed a matched case-control study of 1,073 pairs of women to assess if changes in body weight were associated with the risk of developing breast cancer in individuals with mutations in the *BRCA1* and *BRCA2* genes. It was concluded that women who lost 10 pounds or more between

ages 18 and 30 were 0.47 times significantly less likely to develop breast cancer compared to controls, which translates to a 34% decrease in the risk of developing breast cancer. Another study analyzed the effect of smoking on breast cancer risk on a matched case-control population that included 2,538 women with mutations in the *BRCA1* and *BRCA2* genes.[43] It was found that being a former smoker was significantly associated with a 1.27% increased risk of developing breast cancer among individuals with mutation in the BRCA1 gene. However, no significant risk was observed among current smokers with mutations in the *BRCA1* and *BRCA2* genes. Similarly, Watson et al. (2004) performed a retrospective cohort study utilizing data from the Hereditary Cancer Institute at Creighton University's registry to assess if tobacco use was associated with risk of developing colorectal cancer in individuals with mutations in the *MLH1* or *MLH2* genes. The authors reported that those who were smokers were 1.43 times significantly more likely to develop colorectal cancer compared to those who did not smoke.[42] The two aforementioned studies demonstrate that behavioral modifications have the power to reduce the cancer risks associated with inherited cancer syndromes.

1.4.4 Health Behavior Models

While behavioral modification can reduce cancer risks, understanding the motivation to pursue behavior changes can help determine interventions. The application of two different psychological theories may explain the behaviors of individuals with positive genetic testing results. The first theory, the Health Belief Model, incorporates the effect of beliefs and perceptions on an individual's ultimate decision on whether or not to adopt a health behavior change (Figure 1).[44] The model specifically addresses perceived susceptibility, perceived severity, perceived benefits, perceived barriers, cues to action, and self-efficacy. A previous study analyzed the association

between an adaptation of the health belief model and the likelihood of pursuing genetic testing for hereditary cancer.[45] The authors found that perceived benefits, perceived barriers, perceived susceptibility, and pessimism of undergoing genetic testing all impacted an individual's decision to pursue testing after accounting for contributing factors such as age, socioeconomic status, and family history of cancer. The application of the Health Belief Model to behavior change after genetic testing may conclude that those who have a genetic mutation that places them at higher risk for cancer might view the information as motivation to pursue healthier lifestyle factors to decrease their risk. It is hypothesized that an individual's perception of their susceptibility to cancer, perception of severity of a cancer diagnosis, as well as perceived benefits of losing weight or quitting smoking would influence a person's decision to pursue the behavior change. The Health Belief model is one model that might explain an individual's likelihood to adopt change.

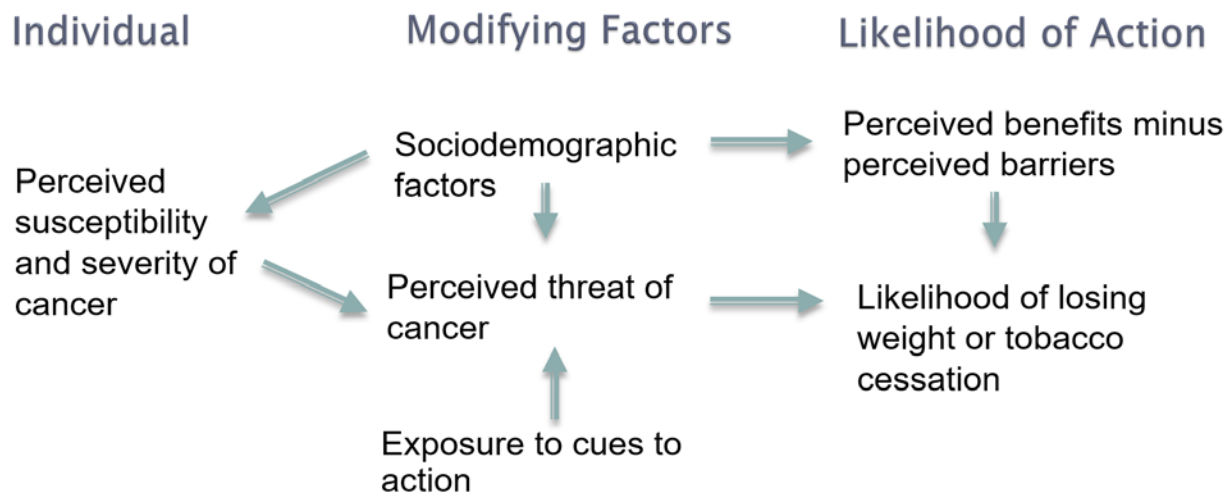


Figure 1. Health Belief Model (adapted from Glanz et al. 2008)[46]

A second theory, the Health Locus of Control, addresses an individual's perception of the extent to which their health is controlled by their own actions or by outside actions.[47] A previous study assessed whether or not an individual's health locus of control was associated with the

likelihood to participate in breast cancer screening.[48] A total of 461 unaffected women who had a family history of cancer were included in the study. Individuals who had a higher internal locus of control were significantly more likely to perform self-breast exams but the locus of control scores were not associated with likelihood of receiving mammograms.[48] In the current study, it is hypothesized that if an individual has a higher external locus of control, then he/she might believe that genetic testing results equate to the development of cancer. Therefore, individuals might not think that a behavioral change will positively affect them. Understanding an individual's perceptions and motivations may help predict their health outcomes.[48]

1.4.5 Impact of Genetic Information on Behavior Change

While understanding the different theories that address behavior change is important, direct measurements of outcomes after receiving genetic information may further elucidate the likelihood of behavior change. A previous study analyzed the responses after individuals received genetic susceptibility information by mail in a population of 199 individuals aged 25-40 years old.[49] After 3-months, it was found that only 1% of participants had discussed their results with a health care provider.[49] A few studies have assessed beliefs towards and compliance with screening and lifestyle recommendations in patients with hereditary diseases. For individuals with Lynch syndrome, there is around a 95.9% compliance rate for receiving the recommended colonoscopies.[50] However, it is unclear if this high compliance with cancer screening recommendations is comparable to a compliance with lifestyle recommendations, such as being physically fit or eating a healthy diet. Palmquist et al. (2011) investigated the beliefs regarding the relationship between diet and cancer prevention in patients at risk for Lynch syndrome. A total of 390 individuals first completed a questionnaire to measure their perceptions on diet and cancer

and then underwent genetic counseling. The authors found that 83% of the participants believed that a healthy diet could lead to cancer prevention.[51] The belief was strongest when an individual had a previous cancer diagnosis, a high perceived controllability, and a high level of genetics knowledge. [51] The strong belief in the ability of lifestyle factors to prevent cancer may translate to a high compliance rate with positive lifestyle behaviors, but more research is needed to draw further conclusions.

While previous studies have reported high compliance rates for cancer screening recommendations, studies regarding compliance with lifestyle recommendations in patients with hereditary diseases have been mixed.[50,52,53,54,55] A study by Ruffin et al. (2011) conducted a cluster-randomized clinical trial to investigate the effect of delivering personalized risk messages to individuals with a strong family history of diseases, including breast and colorectal cancers, on health behavior changes. A total of 3,344 participants were divided into an intervention group and a control group. The intervention group engaged with Family Healthware, which is a web-based tool designed to deliver personalized risk messages based on family history. The control group received age- and sex- related health messages. The authors found that participants who received the risk messages based on family history were significantly more likely to positively change their eating habits as well as increase their physical activity compared to those who received age- and sex-related messages.[52] The positive impact of delivering personalized risk information is consistent with other studies that have directly measured the effect of delivering genetic testing results.[52,56]

A study by Chao et al. (2008) assessed health behavior changes of individuals after undergoing genetic counseling for Alzheimer disease.[56] The randomized controlled trial recruited 162 participants at risk for Alzheimer disease. One year after receiving their results, participants

were asked three health behavior questions related to diet, exercise, and medication. It was found that participants who learned they had the APOE ε4 allele, placing them at higher risk for Alzheimer disease, were significantly more likely to pursue risk-reducing health behavior changes one year after receiving genetic counseling compared to those who did not have the ε4 allele.[56] Receiving positive genetic test results might make an individual more likely to pursue heath behavior changes than receiving negative results will.

Another study assessed the relationship between genetic testing for alpha-1 antitrypsin deficiency and changes in smoking behavior.[53] Alpha-1 antitrypsin deficiency is a genetic condition that increases susceptibility to lung disease, COPD, and emphysema. This susceptibility is further exacerbated when individuals are exposed to cigarette smoke. Participants who were found to be affected received informational pamphlets and the majority underwent phone counseling as well. The authors of the study concluded that those who were discovered to have severe alpha-1 antitrypsin deficiency were 3.3 times more likely to engage in quit attempts, were more likely to pursue treatment options (such as pharmacotherapy and smoking cessation programs, and nicotine replacement) and reported decreased smoking rates after 3 months compared to those who were carriers and those who were unaffected. However, the authors did not find any significant results related to abstinent levels after three months, which highlights the complexity of smoking cessation. These results lead to the conclusion that genetic testing may have an impact on smoking reduction but not total abstinence. While some studies conclude that knowledge of increased health susceptibility does positively impact behavior change, other studies have found the opposite or no impact.

A study investigated the impact of receiving genetic testing results for Lynch syndrome on smoking behaviors and rates of receiving colonoscopies over a 5-year period.[57] It was found that

those who discovered they had a pathogenic variant in the Lynch syndrome-associated genes and who had never been diagnosed with cancer were 13.124 times more likely to receive colonoscopies compared to those who elected to not receive their genetic results but who also had positive genetic testing (pathogenic variants).[57] It was also found that individuals who did not have a genetic mutation and who had never been diagnosed with cancer were 1.213 times less likely to quit smoking compared to those who did not receive their genetic testing results but who also had negative genetic testing.[57] Additionally, a meta-analysis of 18 studies was conducted by Hollands et al. (2016) and examined the impact of communicating tailored genetic risks on an individual's incentive to pursue lifestyle changes that have the potential to reduce disease risk.[54] Genetic information assessed in the studies included mutations associated with diseases such as cardiac conditions, cancers, diabetes, and Alzheimer's disease. It was found that the genetic information did not have an impact on motivation to pursue risk-modifying behaviors, including smoking cessation and physical activity.[54] The authors concluded that genetic testing as an intervention to change health behaviors would not be an effective public health approach. These findings are consistent with a study by Bloss, Schork & Topol (2011) that assessed outcomes of receiving a genomewide risk scan. A total of 2,037 participants were recruited from health and technology companies to partake in the study. The authors reported that the communication of direct-to-consumer genome-wide testing results that indicated increased risks for disease were not associated with behavior change including changes in exercise habits, dietary fat consumption, and anxiety.[55] However, not all of the participants in both studies received genetic counseling. Given the mixed results regarding adherence to lifestyle recommendations, further research into factors related to health behavior changes would be beneficial.

1.5 GENETIC COUNSELING

1.5.1 Genetic Counseling Practice

The epidemiological goal of genetic services is to decrease the burden of genetic diseases on a population.[58] Genetic counseling services include providing education, psychosocial support, resources, and testing options. Genetic counselors aim to help individuals with possible genetic predispositions manage their risks for developing or passing on a genetic disorder. The National Society of Genetic Counselors defines genetic counseling as follows:

> "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."[59]

Genetic counselors serve to guide decision making and, rather than specifically recommend courses of action, work with patients to help determine the best individualized course of action. As part of the shared-decision making model, genetic counselors often educate clients on the national recommended guidelines set forth by organizations such as the American Cancer Society.[32] Additionally, in a genetic counseling session beneficial lifestyle changes are also often discussed in the context of reducing an individual's risk of developing cancer.[7] While genetic

counselors provide unique services, understanding health-related outcomes of genetic counseling is an important consideration in the practice.

1.5.2 Impact of Genetic Counseling

Genetic counselors have a unique skillset that encompasses genetics expertise, education, psychosocial support, patient advocacy, and resource identification. However, there has been limited research related to specific evidence-based patient outcomes of genetic counseling.[7,8] To address this lack of research, Redlinger-Grosse et al. (2015) sought to identify an all-encompassing list of the beneficial outcomes of genetic counseling services utilizing the Reciprocal-Engagement Model (REM) as a practice model for genetic counseling.[7] The REM is comprised of five tenants and 17 patient-centered goals of genetic counseling. In the study, five focus groups, comprised of 27 peer-nominated leaders in the genetic counseling field, identified 194 genetic counseling outcomes related to the REM. The authors identified four major outcomes of genetic counseling− patient knowledge, decision-making, patient satisfaction, and psychological adaptation− which all relate to engagement. One identified goal, "a change in patient's adherence to health behaviors", directly relates to the aim of this paper. Since the outcomes identified by Redlinger-Grosse et al. (2015) were provider reported, further research is needed to establish evidence-based patient outcomes in order to gain knowledge on the clinical effectiveness of genetic counseling.

Several studies have directly measured outcomes related to genetic counseling. Bowen et al. (2004) performed a randomized controlled trial to assess outcomes of breast cancer risk counseling.[9] A total of 354 asymptomatic participants were recruited and were randomly assigned to either receive an individual genetic counseling session, a psychosocial group counseling session, or a control group. It was found that individuals in both counseling groups experienced decreased

cancer-related worry and decreased perceived risks compared to the control group.[9] Similarly, Inglis et al. (2014) evaluated patient outcomes after undergoing psychiatric genetic counseling.[60] A total of 75 clients consented to participate. All participants completed the GC outcomes scale (GCOS), a validated survey that measures patient empowerment, and participants with mental illness completed the GCOS and the Illness Management Self Efficacy scale (IMSES) prior to genetic counseling and at a 1-month follow-up appointment. Paired sample t-tests were utilized to assess changes in pre- and post-genetic counseling outcome measurements. It was found that both mean GCOS, which measured empowerment, ($p < 0.0001$) and IMSES scores, which measured self-efficacy, ($p = 0.011$) significantly increased after genetic counseling.[60] These studies provide evidence that genetic counseling is associated with positive outcomes.

Athens et al. (2017) conducted a review of 58 Randomized Control Trials evaluating patient outcomes across four genetic counseling specialties: Cancer (n = 45), Prenatal (n = 7), Adult (n = 5), and Pediatrics (n = 1).[8] Of the reported patient benefits, 40 studies (69%) identified psychological well-being, 29 studies (50%) identified knowledge, 23 studies (40%) identified perceived risk, 20 studies (35%) identified satisfaction, 15 studies (26%) identified intentions to pursue genetic testing/screening, 11 studies (19%) identified genetic testing uptake, 10 studies (17%) identified decision quality, nine studies (16%) identified medical management/health behavior, five studies (9%) identified sharing information, and two studies (5%) identified informed choice.[8] The majority of the identified patient outcomes will presumably increase patient engagement, as having more knowledge about health, satisfaction with health care experiences, and involvement with the health care system have all been found to be behaviors related to active participation in one's health.[1] However, no studies reported an actual change in behavior of patients after receiving genetic services, aside from pursuing the management recommendations

in hereditary cancer syndromes. In order to measure the goal of achieving "a change in patient's adherence to health behaviors" as identified by Redlinger-Grosssought et al. (2015), additional research on specific changes in health behaviors after genetic counseling will address the gap in the current research.[7]

1.6 PREVIOUS PILOT STUDY

This study serves to expand upon a previous pilot study that found patient engagement (measured with the ACE measure) increased after a genetic counseling visit in a hereditary gastrointestinal (GI) tumor clinic.[61] During the genetic counseling session, patients received education regarding cancer and genetics and were provided with a risk assessment of the likelihood of hereditary predisposition to cancer based on their personal medical history and family history. The patient population for the lifestyle behavior analysis included six participants who were current smokers and seven participants who were currently overweight at the time of their initial appointment. The pilot study found that individuals with a higher ACE score were more likely to undergo lifestyle behavior changes after receiving genetic counseling.[61] The results were stronger when considering baseline ACE scores (mean difference of 4.7 points) compared to post-counseling ACE scores (mean difference of 1.9 points); therefore, indicating that baseline ACE scores may be more indicative of health behavior changes.[61] Based on the results of the pilot study, it can be hypothesized that baseline ACE scores is a better predictor of behavior change than post-counseling ACE scores. It was also found that those who had a family history of cancer were more successful in lifestyle changes (83% success rate) compared to those who had a recent diagnosis

of cancer (17% success rate). Further research can help to identify effective interventions for lifestyle behavioral changes in order to reduce individual cancer risk.

To date, no other studies have investigated the impact of genetic information on engagement and modifiable lifestyle factors of high-risk cancer patients. This research can serve to help identify effective public health interventions that can be integrated into a clinical setting, such as administering the ACE survey to measure a patient's engagement before their appointment. Through identifying individuals who have a low engagement in their health, genetic counselors could use that information to identify individuals at risk for poor health outcomes and to further personalize the session. Ultimately, these findings have the potential to improve public health and may lead to lower healthcare costs.

1.7 STUDY AIMS

The specific aims and hypotheses of this study include:

Aim 1: To investigate the impact of an individual's baseline engagement in their health, as measured by the Altarum Consumer Engagement (ACE Measure), on lifestyle behavior outcomes for tobacco cessation and weight loss before and after genetic counseling.

Hypothesis: Individuals who have higher engagement scores will be more likely to change their behavior (lose weight or stop smoking) after a genetic counseling session compared to individuals who have lower engagement scores.

Aim 2: To compare engagement and behavioral changes between individuals with a pathogenic variant those with no pathogenic variant.

Hypothesis 1: Individuals who have a pathogenic variant will be more likely to change their behavior (lose weight or stop smoking) after a genetic counseling session compared to individuals who have no pathogenic variant.

Hypothesis 2: Individuals who have a pathogenic variant will have increased engagement scores after a genetic counseling session compared to individuals who have no pathogenic variant.

2.0 MANUSCRIPT

2.1 INTRODUCTION

With the growing complexity of the health care system, greater demands are now being placed on patients to navigate, access, and understand health care. A new field of study, called patient engagement, has arisen to understand the implications of being involved in one's health care. The term patient engagement was defined by Gruman et al. (2010) as "actions individuals must take to obtain the greatest benefit from the health care services available to them."[1] Research has found that more highly engaged patients were significantly less likely to be obese, to smoke, and to have an emergency department visit or a hospital stay within the past 12 months.[2] Further, patients with lower engagement levels had health care costs that were up to eight times greater than those with the higher engagement levels.[3] Measuring levels of engagement among patients may provide key information on outcomes that can be integrated into the clinic and reduce healthcare costs.

Given the recent information on the association between patient engagement, health outcomes, and healthcare costs, more health care providers may be interested in measuring the engagement levels of their patients. Only a small number of validated engagement measures exist, and most do not measure multiple factors of patient engagement. The Altarum Consumer Engagement (ACE) Measure™ (June 2015) is one such validated patient measure created to provide a more comprehensive, up-to-date measurement of a patient's engagement in their health (Appendix A.1).[15] The ACE measure utilized Gruman's patient engagement definition in order to address all of the factors of engagement. The tool has three domains, which are defined as:

- "Commitment: confidence and ability to maintain a healthy lifestyle and manage one's health.
- Navigation: confidence and ability to ask about and participate in treatment decisions.
- Informed Choice: Informed patterns of seeking and using information about health and healthcare."[15]

This measure has previously been found to be associated with health outcomes.[16] A current study that utilized the ACE measure assessed engagement levels in a population of patients with diabetes and showed that the Commitment domain levels were associated with changes in glycated hemoglobin (HbA1c) levels.[16] Those who had higher Commitment scores were more likely to have improved HbA1c levels after an 8-month period compared to those with lower Commitment scores.[16] Clinicians could utilize this information to target interventions towards those with lower Commitment scores. Therefore, the ACE measure has the potential to be integrated into a clinical setting in order to improve patient care.

Several behavior-related factors that may be, in part, influenced by patient engagement have been studied extensively. Being obese has been found to be related to poorer engagement; individuals who were obese were 25-40% less likely to receive colorectal screening compared to those who were not obese.[4,5] Therefore, if individuals are successful in weight loss, then they may become more likely to engage in behaviors such as receiving cancer screening that will contribute to their health. Another health behavior that contributes to poor health~~,~~ tobacco status, has also been related to patient engagement. It was found that patients who had higher current levels of engagement were 1.62 times more likely to have pursued a tobacco quit attempt over the past year compared to those with lower engagement levels.[6] It can be hypothesized that individuals who

smoke and have higher engagement scores may be more likely to attempt to quit smoking compared to individuals who smoke and have lower engagement scores.

Health behaviors are just one of the many areas that have been implicated with patient engagement. Genetic counseling is another field that is directly related to patient engagement.[7] Genetic counselors have a unique skillset that encompasses genetics expertise, education, psychosocial support, patient advocacy, and resource identification. While behavioral risk factors like patient weight and tobacco status may not be the focus of many genetic counseling sessions, prior research has shown that these factors may increase the risk for cancer in individuals with hereditary cancer syndromes.[38,39] Furthermore, genetic counseling has previously been found to be associated with increased self-efficacy and empowerment in patients, as well as decreasing cancer-related worry and perceived risk.[9,60] Given the importance of these environmental factors in cancer risk and the ability of genetic counseling to improve elements related to patient engagement, the relationship between receiving genetic information and subsequent health behavior changes is important to consider in a clinical setting. Previous literature assessing health behavior changes of an individual after receiving genetic testing results have been mixed. One study found that participants who learned they had the APOE ε4 allele, placing them at higher risk for Alzheimer disease, were significantly more likely to pursue risk-reducing health behavior changes one year after receiving genetic counseling compared to those who did not have the ε4 allele.[56] Similarly, another study found that patients who were discovered to have severe alpha-1 antitrypsin deficiency were 3.3 times more likely to engage in tobacco quit attempts, were more likely to pursue treatment options and reported decreased smoking rates after 3 months compared to those who were carriers and those who were unaffected.[53] However, the authors did not find

any significant results related to tobacco abstinent levels after three months, which highlights the complexity of smoking cessation.

While the aforementioned studies conclude that knowledge of increased health susceptibility due to a genetic risk does impact behavior change, other studies have found the opposite. A meta-analysis of 18 studies conducted by Hollands et al. (2016) found that genetic information (mutations associated with diseases such as cardiac conditions, cancers, diabetes, and Alzheimer's disease) did not have an impact on motivation to pursue risk-modifying behaviors, including smoking cessation and physical activity.[54] The authors concluded that genetic testing as an intervention to change health behaviors would not be an effective public health approach. These findings are consistent with a study by Bloss, Schork & Topol (2011) that reported that the communication of direct-to-consumer genome-wide testing results that indicated increased risks for disease were not associated with behavior modifications including changes in exercise habits, dietary fat consumption, and anxiety.[55] However, not all of the participants in both studies underwent genetic counseling and the participants did not always receive risk information that would significantly increase their risk of disease. Given the mixed results regarding adherence to lifestyle recommendations, further research into the influence of genetic counseling and genetic test results on health behavior changes would be beneficial.

This study serves to expand upon a previous pilot study that found that patient engagement (measured with the ACE measure) increased after a genetic counseling visit in a hereditary gastroenterology clinic.[61] During the genetic counseling session, patients received education regarding cancer and genetics and were provided with a risk assessment of the likelihood of a hereditary predisposition to cancer based on their personal medical and family history. The patient population for the lifestyle behavior analysis included six participants who were current smokers

and seven participants who were currently overweight at the time of their initial appointment. The pilot study found that individuals with a higher ACE score were more likely to undergo lifestyle behavior changes after receiving genetic counseling.[61] The results of the pilot study were stronger when considering baseline ACE scores (mean difference of 4.7 points) compared to post-counseling ACE scores (mean difference of 1.9 points); suggesting that baseline ACE scores may be more indicative of health behavior changes.[61] It was also found that those who had a family history of cancer were more successful in lifestyle changes (83% success rate) compared to those who had a recent diagnosis of cancer (17% success rate). Further research can help to identify effective interventions for lifestyle behavioral changes in order to reduce individual cancer risk.

To date, no other studies have investigated the impact of genetic information on engagement and modifiable lifestyle factors of high-risk cancer patients. This research can serve to help identify effective public health interventions that can be integrated into a clinical setting, such as administering the ACE survey to measure a patient's engagement before their appointment. Genetic counselors could use this information to identify individuals at risk for poor health outcomes and to further personalize the session. Ultimately, these findings have the potential to improve genetic counseling practice, and public health, and may lead to lower healthcare costs. The following were the specific aims and hypotheses of the study:

Aim 1: To investigate the impact of an individual's baseline engagement in their health, as measured by the Altarum Consumer Engagement (ACE Measure), on lifestyle behavior outcomes for tobacco cessation and weight loss before and after genetic counseling.

Hypothesis: Individuals who have higher engagement scores will be more likely to change their behavior (lose weight or stop smoking) after a genetic counseling session compared to individuals who have lower engagement scores.

Aim 2: To compare engagement and behavioral changes between individuals with a pathogenic variant versus those with no pathogenic variant.

Hypothesis 1: Individuals who have a pathogenic variant will be more likely to change their behavior (lose weight or stop smoking) after a genetic counseling session compared to individuals with no pathogenic variant.

Hypothesis 2: Individuals who have a pathogenic variant will have increased engagement scores after a genetic counseling session compared to individuals with no pathogenic variant.

2.2 METHODS

2.2.1 Participants

Participants were recruited from the University of Pittsburgh Medical Center (UPMC) Hereditary GI Tumor Program's patient population who received an initial genetic counseling session from July, 2016 to December, 2017. Those who were under the age of 18 or unable to give informed consent were excluded from the study. Patients were referred to the program due to a personal history and/or a family history that was suggestive for a hereditary predisposition to cancer. Indications for referral include young ages of cancer diagnoses, multiple primary cancer diagnoses, multiple family members affected with the same or related types of cancers, and/or tumor studies indicative of a possible underlying genetic cause.

2.2.2 Procedure

This study was approved by the University of Pittsburgh IRB (PRO16050209, 07/12/16) (Appendix A.6). The investigators obtained informed consent for participants who met the study criteria and who were interested in participating in the study. Next, the Altarum Consumer Engagement (ACE) Measure was delivered verbally to assess individual healthcare engagement.[15] The ACE measure is comprised of 12 statements and utilizes a 5-point Likert scale, ranging from "strongly disagree" to "strongly agree" (Appendix A.1).[15] It has three different domains, Commitment, Navigation, and Informed Choice, with four questions comprising each domain.[15] An average of the four questions per domain was taken and then multiplied by 6.25 to produce a total score for each domain ranging from 0-25.[15] The final scores for each domain were then summed to calculate an individual's total engagement score ranging from 0-75.[15]

After completing the survey, the participants next received genetic counseling and a consult with a gastroenterologist who specializes in hereditary GI cancer syndromes. Patients insured by UPMC Health Plan who were overweight (BMI $\geq$ 30) or were current smokers were given standard lifestyle modification reading material, as well as a Prescription for Wellness to a tobacco cessation or weight loss health coaching program if they were interested. When participants were both overweight and current smokers, the gastroenterologist and patient discussed which program would be most beneficial. Patients who were overweight or used tobacco and had a different insurer were given only the standard of care reading material for lifestyle changes.

The Prescription for Wellness is a model of health coaching that is physician-prescribed and is available at no cost to any patient insured by UPMC Health Plan. In the current study, once a prescription was given by the gastroenterologist, the patient either called the program, or a health

coach contacted the participant. The program consisted of 6-8 weekly phone calls conducted by health coaches. Sessions addressed the overall goals and concerns for the patient, as well as explored motivations to pursue health behavior changes. Other support resources, such as assigned homework or referrals to other services were also given when appropriate.

The genetic counseling that participants received consisted of a review of cancer and genetics, a personalized cancer and genetic risk assessment, information about hereditary cancer syndromes, cancer preventive measures and psychosocial counseling. When clinically appropriate, genetic testing was discussed and offered. Participants who had genetic testing received the results from a genetic counselor by telephone within a three-month time period after their initial appointment. Possible results included positive (pathogenic or likely pathogenic variant), a variant of unknown significance (VUS) and negative (benign or likely benign variant). All participants were then contacted via phone three to five months after their initial office appointment to repeat the ACE measure survey. Individuals who were overweight (BMI $\geq$ 30) and individuals who were current tobacco users at the time of their initial visit were also asked to complete the Lifestyle Questionnaires, either the weight loss questionnaire or the smoking cessation questionnaire, as appropriate, during the post follow up phone call (Figure 2).

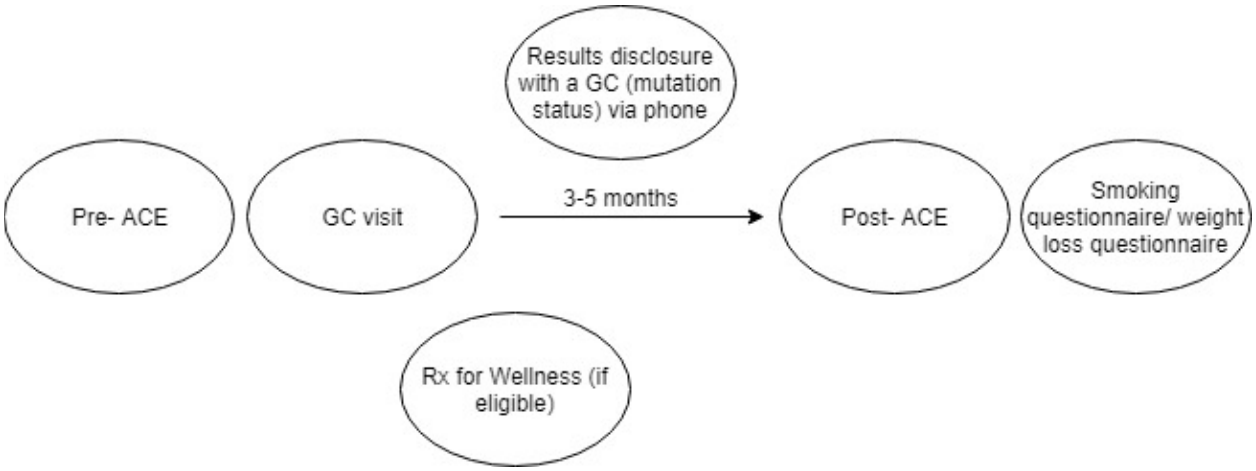


Figure 2. Protocol Flowsheet

2.2.3 Data Analysis

Pre- and post- visit ACE scores were first tested for normality of distribution across individual domains and total engagement scores. To corroborate the previous pilot study, paired sample t-tests were conducted to analyze differences in engagement scores across all participants excluding those who were included in the previous pilot study. In order to analyze the effect of pre-engagement levels on weight loss, univariate and multiple linear regressions to adjust for age, gender, cancer status, and completion status of the Prescription for Wellness were conducted. Paired sample t-tests and multiple logistic regressions were also conducted in order to analyze the effect of pre-engagement levels on smoking cessation. For the variant status analysis, variant of unknown significance and negative results were combined together since participants were told both in pre-counseling and post-counseling that variants of unknown significant (VUS) results should be treated as negative results. Univariate and multiple linear regressions were conducted to test the associations of both changes in engagement scores and weight loss with genetic variant status. Fisher's exact test was computed to test the association of smoking cessation and genetic mutation status. The statistical software STATA (StataCorp 2015) was used for analyses. Two indicators of weight loss were considered in the analysis: quantitative percent change in BMI (ΔBMI) and categorical successful weight loss (SWL)/failure to lose weight, with success defined as a 3-month difference of $\geq 2.5\%$ body weight, 4-month difference of $\geq 3.25\%$ body weight, or 5-month difference of $\geq 4\%$ body weight. Previous literature has concluded that weight loss ranging from 2.5-5% and above is associated with a reduction in obesity-related health risks.[62] Smoking cessation definitions were adapted from Velicer et al. (2002); total smoking cessation was defined as not smoking for 30 days and a quit attempt was defined as not smoking for 7 days.[63] Individuals who were undergoing cancer treatment during

the time of the study were excluded in the health behavior analyses, as active cancer treatment might reduce the likelihood that an individual could pursue health behavior changes.

In order to carry out the weight loss analyses, participants were divided into different categories. The different categories included:

- Participants who were not eligible for the Prescription for Wellness compared to participants who were eligible for the Prescription for Wellness
- Eligible participants who did not accept the referral from the physician compared to participants who accepted the referral from the physician,
- Participants given a Prescription for Wellness who did not complete the health coaching program compared to participants who completed the health coaching program (Figure 3).

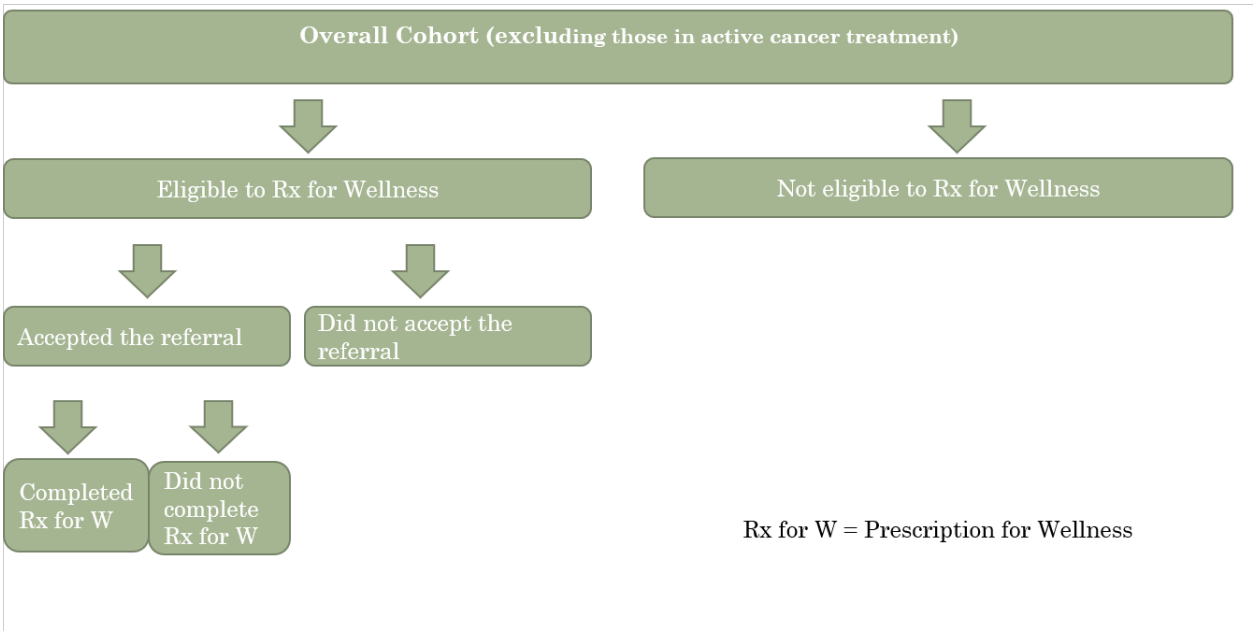


Figure 3. Health Behavior Participant Categories

2.3 RESULTS

Two hundred and thirty-four (234) participants initially consented to be in the study. Of these, two participants elected to withdraw from the study when they were contacted to complete the follow-up ACE survey, thirty-one (31) participants were lost to follow up, three participants passed away during the study, and three participants were excluded due to failing to answer at least two questions in either the pre- or post- ACE survey. A total of 195 participants aged 18-86 years old (mean age of 52 years) were included in the analysis (Table 1). Majority of participants were Caucasians (97%) and female (62%). Almost half (47%) of participants had no personal cancer history, and the most common cancer type was colorectal (32%). Thirteen participants completed a health coaching program, the Prescription for Wellness program, aimed at weight loss (n = 10) or smoking cessation (n = 3) during the study. Of the 195 participants, data from sixty-two participants had been analyzed by the previous pilot study.

Table 1. Characteristics of the sample at baseline

	n	%
Sex		
Female	121	62
Male	74	38
Age		
18-34	32	16
35-51	58	30
52-64	57	29
65 or older	48	25
Mean age = 52		

Table 1 Continued

Ethnicity		
Caucasian	189	97
African American	6	3
Cancer History		
No cancer	95	47
Colorectal	58	32
Pancreatic	8	4
Other cancer	34	14
Total	195	100

Sixty-one participants had a BMI ≥ 30 at the time of their initial appointment. Of the total 61 participants, ten participants were undergoing current cancer treatment and were excluded from the overall cohort. Rates of successful weight loss (SWL) (i.e., 3-month difference of ≥ 2.5% body weight, 4-month difference of ≥ 3.25% body weight, or a 5-month difference of ≥ 4% body weight) across Prescription for Wellness categories is summarized in Figure 4. Participants were then divided into categories based on eligibility, acceptance, and completion status of Prescription for Wellness (Figure 4). Overall, 31% of individuals who received genetic counseling lost weight. Individuals with UPMC Health Plan who were eligible for referral, individuals who accepted the referral, and individuals who completed the program were all more likely to lose weight than their counterparts. For individuals in this study who completed the Prescription for Wellness program demonstrated a 60% weight loss rate, which can be compared to a previous report of individuals who enrolled in the Prescription for Wellness who did not receive genetic counseling demonstrated a 43.9% weight loss rate.[64]

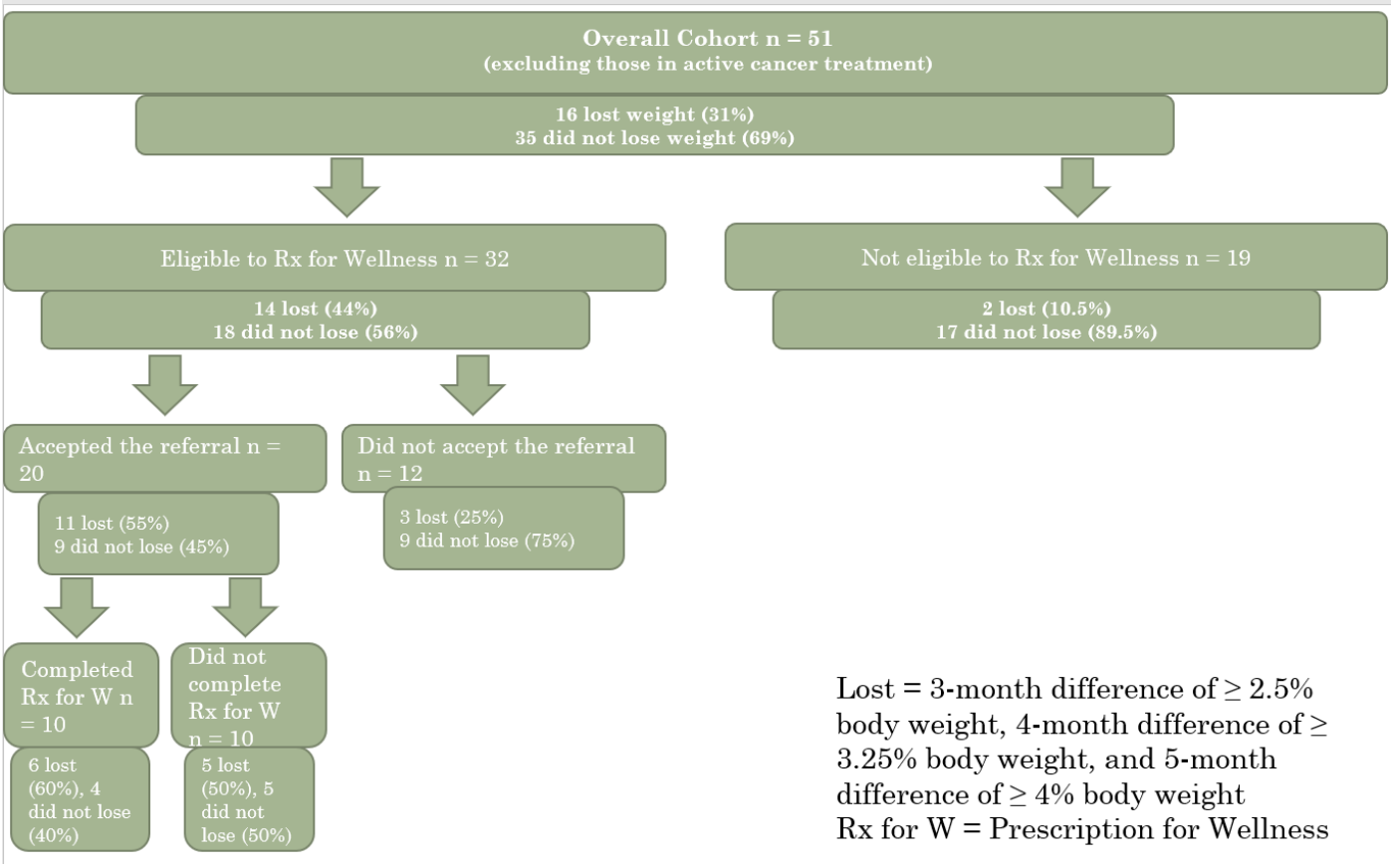


Figure 4. Results of SWL for the Weight Loss Participant Categories

Eighteen participants were current smokers at the time of their initial appointment. Of the 18 participants, three were undergoing current cancer treatment and were excluded from the smoking cessation analysis cohort. Among the remaining 15 participants, 20% of individuals quit smoking and 47% engaged in a quit attempt (Figure 5). Individuals with UPMC Health Plan who were eligible for referral and individuals who accepted the referral were more likely to quit smoking or pursue a quit attempt compared than their counterparts. Among those who accepted the referral, the smoking cessation rates among those who completed the program and those who did not complete the program were equivalent—33% quit smoking and 67% engaged in quit attempt.

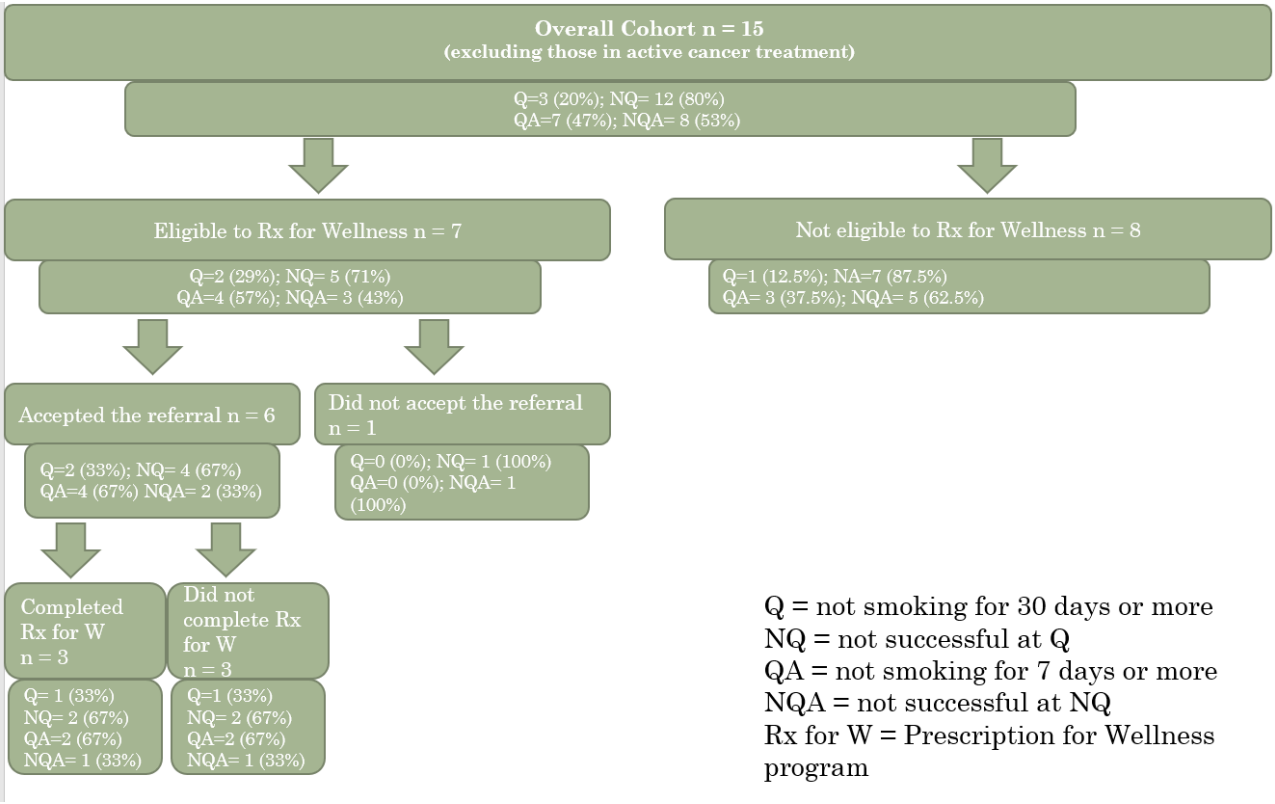


Figure 5. Results for Smoking Cessation Participant Categories

One hundred and forty-six participants had genetic testing; 10 participants had undergone genetic testing and received their results prior to their appointment, 133 individuals received the results prior to the delivery of the post-engagement survey, and 3 had not received their results yet at the time of the delivery of the post-engagement survey. Of the 133 who had received their results within the time period of this study, 34 (26%) had positive testing (pathogenic variants were detected), 14 (10%) were found to have a variant of unknown significance (VUS), and 85 (64%) had negative testing (no pathogenic variants were detected).

2.3.1 ACE Measure across all Participants

Previously we had demonstrated in a pilot study that patient engagement increased after a genetic counseling visit in a hereditary gastroenterology clinic. In this study, which looked at an independent cohort of 120 patients, these results were replicated. Post engagement scores increased after a genetic counseling appointment across all participants. There was a significant difference in total pre- and post-counseling ACE scores (two-sided p-value: $p = 0.0001$) with post-counseling ACE scores approximately 3.2 points greater than pre-counseling scores. All of the domains within the ACE Measure (Navigation, Commitment, and Informed Choice) also were significantly greater after counseling ($p = 0.0038$; $p = 0.0012$; and $p = 0.0268$ respectively) (Table 2).

Table 2. Mean Engagement Score Pre- and Post-Counseling and Differences

Averages of Results (n = 120)				
	Pre-counseling ACE Score	**Post-counseling ACE Score**	**Difference**	**p-value**
Navigation	18.186	19.206	1.02	0.0038
Commitment	17.247	18.347	1.099	0.0012
Informed Choice	13.750	14.688	0.938	0.0184
Total	49.183	52.240	3.057	0.0001

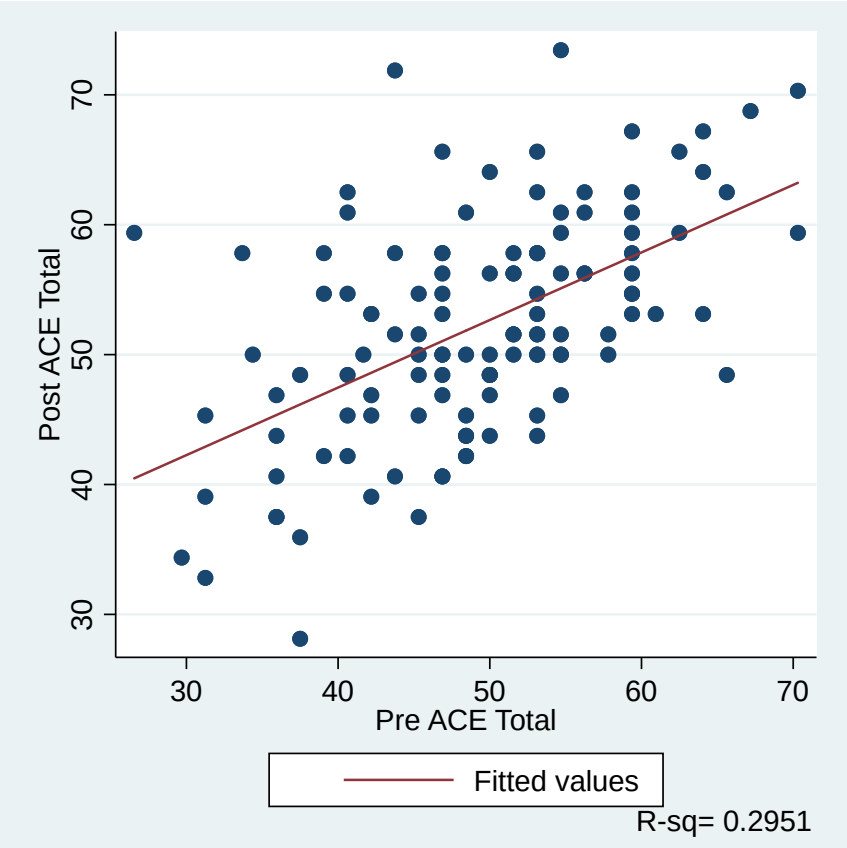


Figure 6. Pre-counseling ACE vs. post-counseling ACE

2.3.2 Behavior Change and Baseline Engagement

For the overall cohort, pre-counseling ACE total scores were not significantly associated with ΔBMI, although there was a slight trend between higher engagement levels and being less likely to lose weight (p = 0.213, R^2 = 0.032, 95% CI = (-0.053, 0.012)) (Figure 7) (Table 3). For the Navigation domain, higher pre-counseling ACE scores were significantly associated with being less likely to lose weight (F(1,49) = 5.45, p = 0.024, R^2 = 0.100, 95% CI = (-0.164, -0.012)). The Commitment and Informed Choice domains were not significantly associated with change in BMI (F(1,49) = 0.01, p = 0.923, R^2 = 0.0002, 95% CI = (-0.068, 0.061; F(1,49) = 0.19, p = 0.662, R^2 =

0.004, 95% CI = (-0.063, 0.040 respectively). A multiple linear regression was conducted to test the association of weight loss and pre-counseling ACE scores (both total engagement scores and the individual domains) while adjusting for age, gender, cancer status, and completion status the Prescription for Wellness (Table 3). The same results were observed in the covariate-adjusted models as the univariate tests. Furthermore, the same analyses were conducted to analyze if change in engagement scores was associated with weight loss and none of the analyses were found to be significant (Appendix B).

For the specific categories of eligibility, acceptance, and completion status of Prescription for Wellness, the total pre-counseling ACE scores, the Commitment domain, and the Informed Choice domain were not significantly associated with ΔBMI in any category. For those who were not eligible for the Prescription for Wellness, the Navigation domain pre-counseling ACE scores were significantly associated with ΔBMI, with higher Navigation engagement scores being associated with being less likely to lose weight ($F(1,17) = 8.00$, $p = 0.012$, $R^2 = 0.320$, 95% CI = (-0.184, -0.027).

As a post-hoc analysis, weight loss was defined as a 3-month difference of ≥ 2.5% body weight, 4-month difference of ≥ 3.25% body weight, or a 5-month difference of ≥ 4% body weight) and two-sample t-tests with equal variances were conducted to predict weight loss from baseline engagement (ACE) scores. For the overall cohort, total pre-counseling ACE scores did not significantly predict weight loss ($p = 0.5025$, 95% CI = (-3.400, 6.843). None of the individual domains were found to be significant. A multiple logistic regression was conducted on the overall cohort, and it was found that higher pre-counseling ACE Navigation scores were significantly associated with a smaller change in BMI, with age being a significant covariate (OR = 0.761, $p = 0.021$, 95% CI = (0.603, 0.960). When assessing the individual categories of participants, it was

found that for those enrolled in the Prescription for Wellness, pre-counseling ACE Navigation scores were significantly associated with weight loss (p= 0.044, 95% CI = (0.138, 8.456). Those who failed to lose weight had higher pre-counseling ACE Navigation scores.

Table 3. Pre-counseling engagement (ACE) scores relationship with weight loss (% change in BMI) in the overall cohort

	Coefficient	Standard Error	p-value	95% Confidence Interval
Univariate Analysis-				
Pre-ACE Total	-0.020	0.016	0.213	-0.053, 0.012
Pre-ACE Commitment	-0.003	0.032	0.923	-0.068, 0.061
Pre-ACE Navigation	-0.088	0.038	0.024*	-0.164, -0.012
Pre-ACE Informed Choice	-0.011	0.026	0.662	-0.063, 0.040
Multivariate Analysis (including covariates of age, gender, cancer status, and completion status of the Prescription for Wellness)-				
Pre-ACE Total	-0.018	0.016	0.281	-0.051, 0.015
Pre-ACE Commitment	-0.006	0.032	0.846	-0.069, 0.057
Pre-ACE Navigation	-0.010	0.038	0.012*	-0.176, -0.023
Pre-ACE Informed Choice	0.005	0.026	0.984	-0.051, 0.052

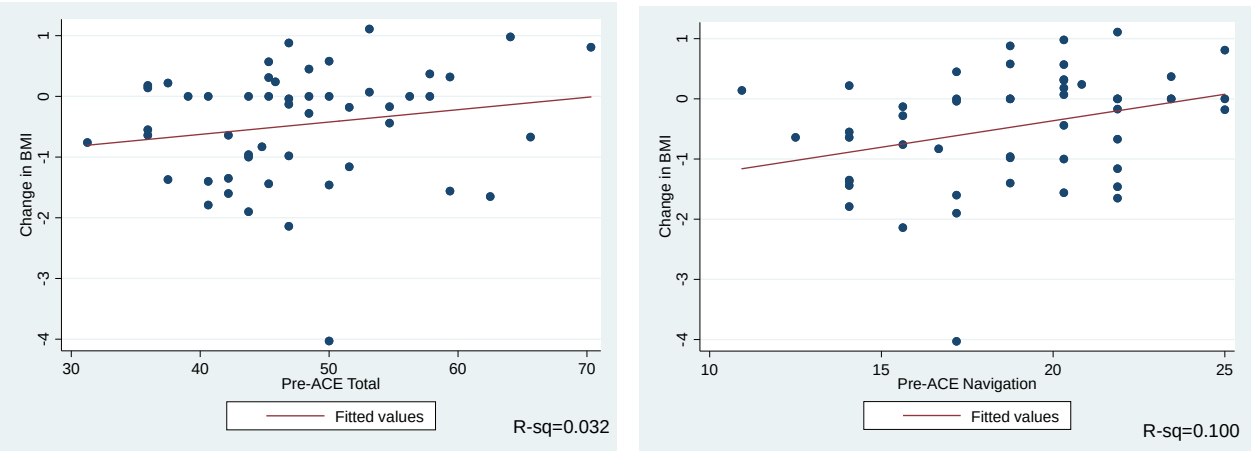


Figure 7. Univariate linear regression on % change in BMI as predicted by pre-engagement levels

For the overall cohort, no statistical differences in pre-counseling ACE total scores were found between participants who ceased smoking and those who did not (p = 0.871), 95% CI =(-24.502, 21.002) (Table 4) (Figure 8). When looking individually at each of the specific domains (Commitment, Navigation and Informed Choices), none were found to be significantly different between participants who ceased smoking and those who did not. NO statistical differences in pre-counseling ACE total scores were found between participants who pursued a quit attempt and those who did not (p = 0.942, 95% CI = (-17.639, 18.886) (Table 4) (Figure 8). None of the analyses for the individual domains were found to be significant. Although there was not an adequate sample size, a multiple logistic regression was run to predict smoking cessation status from pre-engagement (ACE) scores to adjust for the covariates of age, gender, cancer status, and completion status of the Prescription for Wellness program. The overall analysis was not significant.

Table 4. Baseline engagement (ACE) scores relationship with total smoking cessation (>31 days)

Averages of Results (n = 15)				
	Total Cessation (n = 3)	**No Total Cessation (n = 12)**	**Difference**	**p-Value**
Navigation	16.667	17.70833	1.042	0.7853
Commitment	16.667	13.484	3.182	0.451
Informed Choice	14.0625	14.45313	0.391	0.9196
Total	47.396	45.646	1.75	0.871

Table 5. Baseline engagement (ACE) scores relationship with smoking quit attempt (>7 days)

Averages of Results (n = 15)				
	Quit Attempt (n = 7)	**No Quit Attempt (n = 8)**	**Difference**	**p-Value**
Navigation	17.188	17.77344	0.586	0.8486
Commitment	14.063	14.063	0.125	0.971
Informed Choice	14.45313	14.45313	0.167	0.9570
Total	45.661	46.289	0.628	0.942

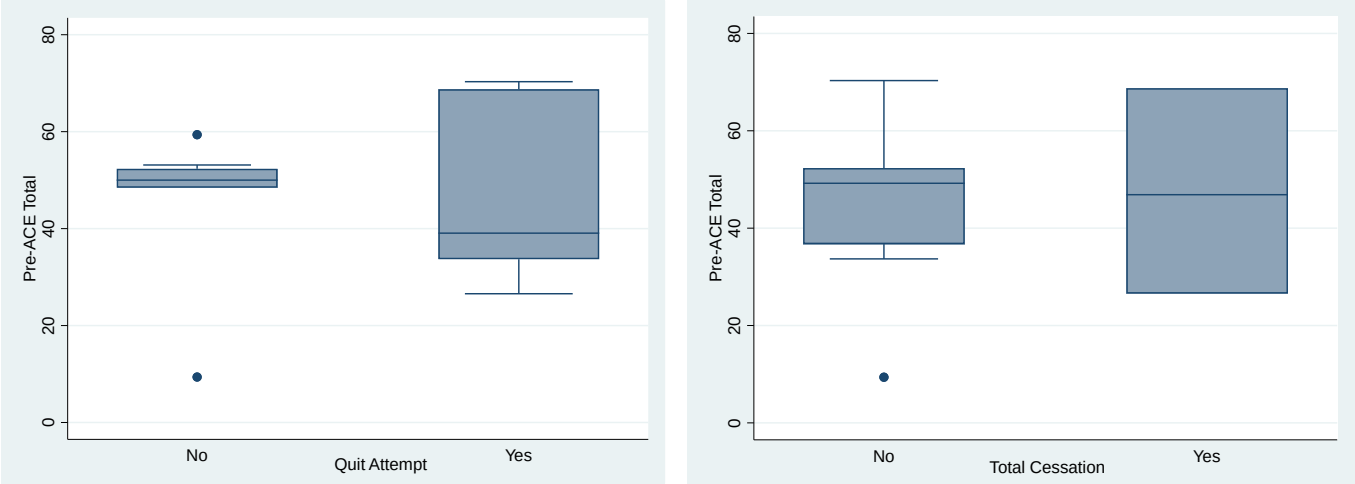


Figure 8. Smoking cessation status as predicted by pre-engagement levels, yes = successful, no = not successful

As a post hoc analysis, successful weight loss and total tobacco cessation outcomes were combined into one category of health behavior changes. A total of 66 participants were included in the analysis. No statistically significant differences in pre-counseling ACE total scores were found between participants who successfully made health behavior changes and those who did not ($p = 0.749$), 95% CI = (44.805, 49.919) (Table 4) (Figure 9). A multiple logistic regression was run to test the association of health behavior change with pre-counseling (ACE) scores to adjust for the covariates of age, gender, cancer status, and completion status of the Prescription for Wellness program. The overall analysis was not significant. When looking individually at each of the specific domains (Commitment, Navigation and Informed Choices), none were found to be significant differences in pre-counseling ACE were observed between those who made behavior change and those who did not.

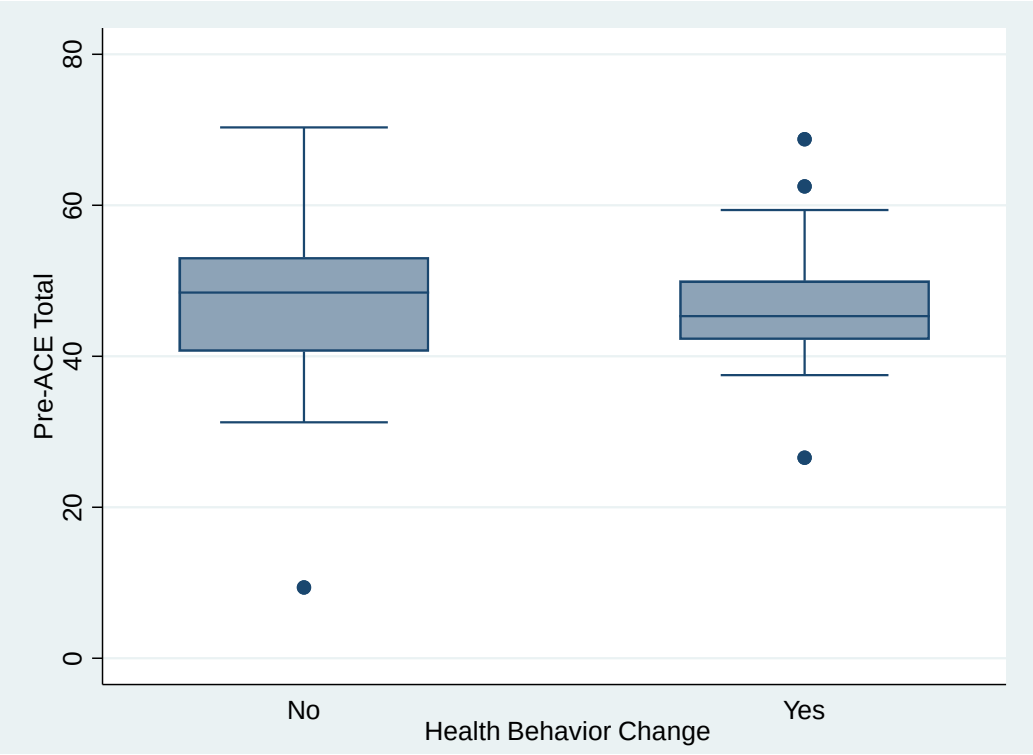
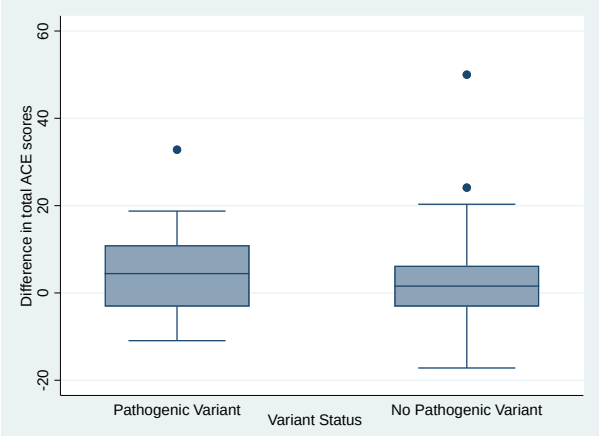


Figure 9. Health Behavior Change as predicted by total pre-engagement levels

2.3.3 Variant Status and ACE Differences

Variant status did not significantly predict changes in total ACE scores, ($F(1,131) = 0.43$, $p = 0.514$, $R2 = 0.003$, 95% CI = (-4.502, 2.262)) (Figure 11). In addition, analyses did not reveal significant differences for the individual domains, although differences in Navigation ACE scores approached significance ($F(1,131) = 3.19$, $p = 0.076$, $R2 = 0.024$, 95% CI = (-2.863, 0.146)) (Figure 11). A multiple linear regression was subsequently conducted to predict differences in ACE scores from variant status to include the covariates of age, gender, cancer status, and

completion status of the Prescription for Wellness program. No significantly statistical differences were observed.



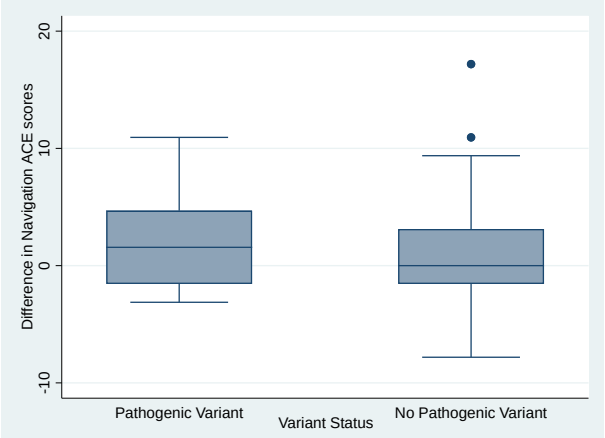


Figure 10. Change in engagement scores as predicted by variant status

2.3.4 Variant Status and Behavior Change

Variant status did not significantly predict weight loss (percent change in BMI), $F(1,44) = 0.295$, $p = 0.295$, $R^2 = 0.025$, 95% CI = (-0.317, 1.018) (Figure 11). A multiple linear regression was conducted to predict weight loss from variant status to include the covariates of age, gender, cancer status, and completion status of the Prescription for Wellness. However, this adjusted model included more covariates than would be recommended for the sample size. The multivariate analysis did not reveal significant findings. Fisher's exact test showed no significant difference between total smoking cessation and genetic variant status, $p = 0.152$ or between quit attempt (>7 days abstinence from smoking) and variant status, $p = 0.545$ (Table 6).

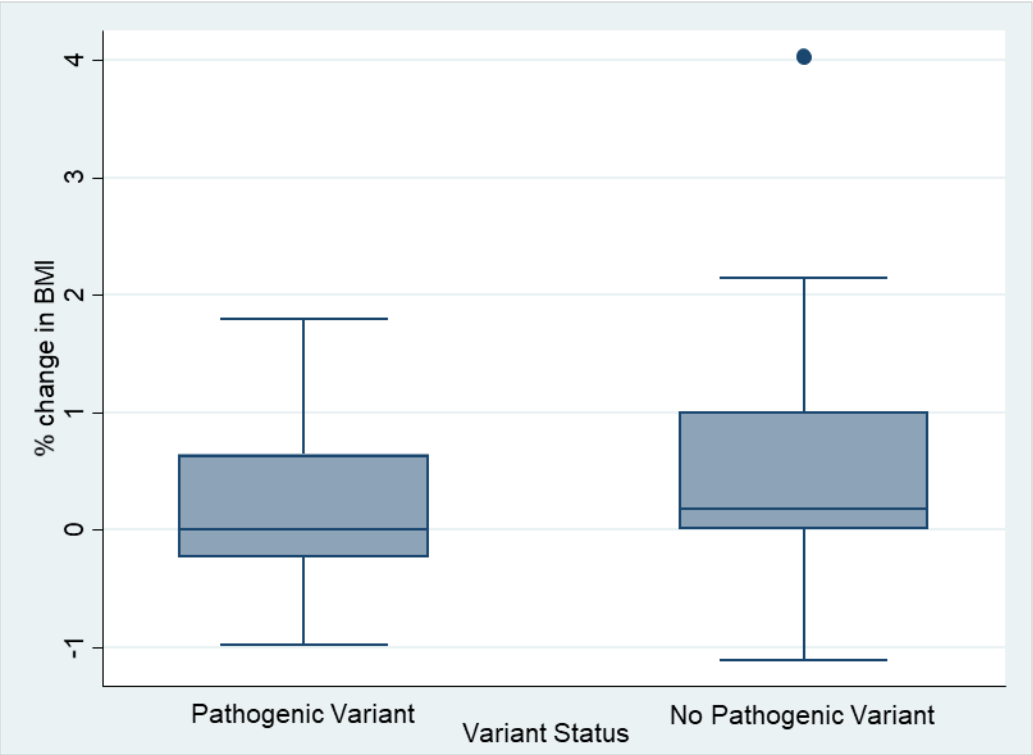


Figure 11. Percent change in BMI as predicted by variant status

Table 6. Summary of total smoking cessation and genetic variant status data

	Pathogenic Variant	No Pathogenic Variant	Total
Total Cessation	1	7	8
No Total Cessation	2	1	3
Total	3	8	11
Quit Attempt	1	5	6
No Quit Attempt	2	3	5
Total	3	8	11

2.4 DISCUSSION

This study aimed to investigate the impact of an individual's baseline engagement in their health on health behavior changes and aimed to compare engagement and behavioral changes between individuals with a pathogenic variant those with no pathogenic variant. Identifying individuals who are less likely to pursue health behavior changes may allow health care providers to target interventions that could lead to improved clinical outcomes. Clinicians could utilize patient engagement measures to target such interventions. Further, understanding how behavior is influenced by receiving genetic information that places an individual at a greater risk to develop cancer would also contribute to patient care through providing additional resources to those who need it. Another component that this study analyzed was the effect of genetic counseling on patient engagement scores. As there has been limited research related to specific evidence-based patient outcomes of genetic counseling, this research significantly contributes to the literature.[7,8]

It was found that genetic counseling significantly increased engagement scores over a 3-5-month time period. This finding validated the previous pilot study in an independent cohort. The total pre-counseling and post-counseling engagement scores were both lower by approximately 1.9 to 1.4 values on the ACE domain scoring respectively, in the current study compared to the pilot study. The current study delivered the pre-counseling ACE survey verbally as opposed to the delivery method in the pilot study where participants completed the survey on their own. Therefore, the delivery method of the ACE measure may not affect the results. Previous research has found similar beneficial outcomes of genetic counseling. Inglis et al. (2014) evaluated patient outcomes after undergoing psychiatric genetic counseling and found empowerment and self-efficacy significantly increased after genetic counseling.[60] Genetic counseling has also previously been found to decrease cancer-related worry and perceived risk.[9] Athens et al. (2017) conducted a

review of 58 Randomized Control Trials evaluating patient outcomes across four genetic counseling specialties: Cancer (n = 45), Prenatal (n = 7), Adult (n = 5), and Pediatrics (n = 1).[8] Of the reported patient benefits, 40 studies (69%) identified psychological well-being, 29 studies (50%) identified knowledge, 23 studies (40%) identified perceived risk, 20 studies (35%) identified satisfaction, 15 studies (26%) identified intentions to pursue genetic testing/screening, 11 studies (19%) identified genetic testing uptake, 10 studies (17%) identified decision quality, nine studies (16%) identified medical management/health behavior, five studies (9%) identified sharing information, and two studies (5%) identified informed choice. The majority of the identified patient outcomes will presumably increase patient engagement, as having more knowledge about health, satisfaction with health care experiences, and involvement with the health care system have all been found to be behaviors related to active participation in one's health.[1] In the current study, it was also found that individuals who received genetic counseling as well as enrolled in Prescription for Wellness health coaching program lost more weight than a previous report of individuals who enrolled in the Prescription for Wellness who did not receive genetic counseling.[64] Therefore, the combined interventions of genetic counseling and a health coaching program may lead to beneficial health outcomes.

The first aim of this study investigated the impact of an individual's engagement in their health on lifestyle behavior outcomes for tobacco cessation and weight loss. Based on the findings, it can be concluded that baseline total engagement scores were not significantly associated with behavior changes in this population. The Navigation domain demonstrated that higher pre-counseling ACE scores were significantly associated with an individual being less likely to lose weight. The Navigation domain is a measure of one's confidence level to engage in a shared-decision model with a health care provider. The findings could be explained by an individual's

comfort level with their ability to address their weight with their health care provider. These results differ from the previous pilot study that had demonstrated that those who were successful in behavior change were more likely to have higher baseline engagement scores. However, only 13 individuals were included in the pilot study. Additionally, the current findings that demonstrated no relationship between behavior change and the Commitment ACE domain are inconsistent with the prior literature, as a study that also utilized the ACE measurement found that individuals with higher baseline Commitment levels were significantly more likely to have improved HbA1c levels, a measurement of diabetes management, after an 8-month period compared to those with lower Commitment scores. However, this study also found that prior to 8-months, no differences in diabetes management were observed. Another study by Cunningham et al. (2014) concluded that current levels of higher engagement predicted smoking quit attempts over the previous year.[6] The current study assessed health behavior changes after a 3 to 5- month time period, which may be too short of a time period to adequately assess change.

The second aim of this study examined differences in engagement levels between individuals with a positive genetic test result and those with no pathogenic variant on a genetic test for hereditary cancer syndromes. This study showed that in this patient population, a positive genetic test (pathogenic variant) result did not make an individual more or less engaged in their health compared to those with a negative or a VUS result (no pathogenic variant). These findings might be explained by the implication that both types of genetic testing results can have large implications. Discovering that one has a hereditary predisposition to cancer or discovering that one has a significantly reduced likelihood of having a hereditary predisposition to cancer may equally empower an individual to become more engaged in their health. While no previous studies have directly measured engagement levels before and after receiving genetic information, a

previous study found that 3-months after receiving genetic susceptibility information by mail, only 1% of participants in a study had discussed their results with a health care provider.[49]

Differences in behavior changes between individuals with a pathogenic variant and those with no pathogenic variant was also assessed. The results indicate that knowledge of genetic variant status does not make an individual more or less likely to lose weight or quit smoking, but additional studies with a larger sample size are needed to draw further conclusions. It should also be noted that all participants received counseling about lifestyle modifications to reduce cancer risk during their initial genetic counseling appointment despite genetic testing results, so the lack of difference in behavior change by variant status may therefore be less impacted by genetic test results. Previous studies have been mixed regarding the impact of receiving genetic information on behavior change. The findings of this study are consistent with Holland et al. (2016) who concluded that receiving genetic information does not change behaviors such as smoking cessation and physical activity.[54] Other studies have found that receiving genetic information led to beneficial health outcomes, such as pursuing risk-reducing health behavior changes and engaging in smoking quit attempts.[53,56]

2.4.1 Limitation and Future Research

These findings are limited by several factors. The study included a population of patients from one Hereditary GI cancer clinic; therefore, the findings may not be generalizable to other populations. Concluding that genetic counseling increases patient engagement is also limited by the lack of a control group. It cannot be certain that genetic counseling was the only contributing factor to the observed increased engagement scores. Another limitation was the small sample size for behavioral data (weight loss and tobacco cessation). Additionally, the findings may be influenced

by social desirability on the survey responses. Participants may have felt that they should respond to the ACE and the Lifestyle Questionnaires on weight loss and tobacco cessation questions in a "socially desirable manner" rather than with the truth, although measures were taken in the procedure to administer the survey in a neutral fashion.

Future directions include conducting the same analyses on different populations, including a larger sample size, a population outside of the Hereditary GI clinic, or a population referred to a different specialty of genetic counseling. Analyzing differences between a control group, such as a patient who only visits with a physician and not a genetic counselor, could provide important information about the impact of genetic counseling on health behavior changes and patient engagement. Additional analyses could also explore the outcomes of combining the interventions of genetic counseling and a health coaching program to expand upon the findings in this study.

2.5 CONCLUSION

The association between genetic counseling and increased patient engagement identified in this study contributes to the current body of knowledge. Genetic counseling as a service may motivate individuals to become more active in their health care. This may, in turn, lead to downstream positive effects such as better health care outcomes and lower health care costs that have been previously associated with patient engagement. In regards to the health behavior findings, having a higher baseline Navigation score within the ACE measure may make one less likely to lose weight. Therefore, individuals who are overweight and have a higher Navigation score may require additional resources in order to lose weight. However, a larger sample size and a longer assessment period may be necessary in order to draw full conclusions. As it was found that a pathogenic variant

result did not make an individual more or less engaged in their health compared to those with no pathogenic variant, factors related to health behavior changes and engagement levels may be complex and might not be influenced solely by receiving genetic information.

3.0 RESEARCH SIGNIFICANCE TO GENETIC COUNSELING AND PUBLIC HEALTH

Cancer is the second leading cause of death and accounts for the largest proportion of potential life years lost in the United States, making it a significant burden on the health of the population.[29] From 1980 to 2014, 1,518 years of potential life lost before age 75 per 100,000 was attributed to cancer.[65] The high mortality and morbidity rates of cancer lead to substantial economic burdens on the nation. In 2014, around $87.8 billion health care dollars were spent on cancer treatment.[29] However, nearly two thirds of cancer diagnoses, are estimated to be preventable through changes in health behavior such as smoking cessation and increased physical fitness.[29] Such health behavior modifications are a promising area of public health interventions aimed at preventing cancer development. Widespread implementation of such interventions could lead to decreased mortality and morbidity of cancer in the nation. This study explored several of the many factors that may influence an individual's likelihood to lose weight or quit smoking. As weight loss and tobacco cessation are health behavior changes that are known to be associated with reducing cancer risk, even amongst a population with a hereditary predisposition to cancer, further understanding of what components make an individual more likely to pursue these behaviors has public health implications.[38,39] If public health interventions are designed to target those who are less likely to pursue health behavior changes, it may increase health outcomes and ultimately lead to decreased cancer incidences. Such a decrease would especially benefit individuals with hereditary cancer syndromes that are associated with high cancer risks. Ultimately, there is the potential to decrease the burden of cancer and save significant health care dollars.

This study addresses the assessment component of the core essentials of public health, the research "analyze[d] the determinants of identified health needs."[66] Genetic counseling was found to be a positive determinant for patient engagement. Additionally, having a higher baseline Navigation score within the ACE measure may make one less likely to lose weight. Therefore, individuals who are overweight and have a higher Navigation score may require additional resources in order to lose weight. We also identified that, in the current sample, having a pathogenic variant does not make one more or less likely to engage with the health care system compared to not having a pathogenic variant. Therefore, genetic variant status was not found to be a determinant of patient engagement in this sample.

In terms of the ten essential public health services, this study fulfills the component of "inform[ing], educat[ing], and empower[ing] people about health issues".[66] An additional analysis in this paper found that genetic counseling increased patient engagement. There is currently a lack of research that examines the influence of genetic counseling on patient engagement. Genetic counseling has previously been found to increase empowerment, self-efficacy, knowledge about health, satisfaction with health care experiences, and involvement with the health care system.[8] These factors are all related to active participation in one's health. Further delineating the outcomes of genetic counseling is imperative in the field in order to demonstrate the value of genetic counseling. If individuals become more active in the health care system after receiving genetic counseling, it may lead to further positive downstream outcomes, such as reducing their cancer risks through receiving services that decrease the risk of cancer, like colonoscopies. As patient engagement has been related to better health outcomes and lower healthcare costs, the service of genetic counseling may, in turn, lead to those outcomes as well. This research can serve to help identify effective public health interventions that can be integrated into a clinical setting, such as

administering the ACE survey to measure a patient's engagement before their appointment. Genetic counselors could use that information to identify individuals at risk for poor health outcomes and to further personalize the session by providing additional resources. Ultimately, these findings have the potential to improve public health and may lead to lower healthcare costs.

4.0 PUBLIC HEALTH ESSAY

4.1 INTRODUCTION

Patient engagement is a new field of study that strives to understand the implications of being involved in one's health care.[1] The term patient engagement was defined by Gruman et al. (2010) as "actions individuals must take to obtain the greatest benefit from the health care services available to them."[1] Increased patient engagement can lead to better health outcomes as well as lower health care costs and thus better utilization of health care resources. Previous research has found that more highly engaged patients were significantly less likely to be obese, to smoke, and to have an emergency department visit or a hospital stay within the past 12 months.[2] Further, patients with lower engagement levels had health care costs that were up to eight times greater than those with the higher engagement levels.[3]

One measure of patient engagement is the Altarum Consumer Engagement (ACE) Measure™ (June 2015), which is a validated patient measure created to provide a comprehensive, up to date measurement of a patient's engagement in their health.[15] The ACE measure utilized Gruman's patient engagement definition in order to address all of the factors of engagement. The tool has three domains, which are defined as:

- "Commitment: confidence and ability to maintain a healthy lifestyle and manage one's health.
- Navigation: confidence and ability to ask about and participate in treatment decisions.

- Informed Choice: Informed patterns of seeking and using information about health and healthcare."[15]

One intervention that has been previously related to increasing patient engagement is health coaching.[64] Personal health coaching is an intervention designed to help individuals pursue behavior changes through creating accountability.[64] The research on clinical outcomes of health coaching has been mixed, although the majority of the research has concluded that health coaching leads to beneficial patient outcomes.[67-69] One study found no reported benefits from a health coaching intervention.[67] Wakefield et al. (2004) examined the differences between a motivational interviewing intervention compared to usual care on smoking cessation outcomes in a cohort of 137 cancer patients in Australia. They found no statistically significant differences between the treatment group and the control group. In contrast, many studies have shown that health coaching is an effective intervention at promoting health behavior change.[68,69] One study assessed the outcomes of a 12-week health coaching program addressing diet, physical fitness, and sleep habits that was conducted by medical assistants over the phone in a primary care setting.[69] A total of 40 participants completed the program, and 33 participants were weighed by the investigators before and after the intervention. It was found that BMI after the intervention was significantly decreased compared to prior to the intervention across all 33 participants.[69] A similar study by Appel et al. (2011) conducted a randomized controlled trial to analyze the outcomes and potential differences between in-person health coaching and remotely-delivered, which included telephone calls, an informational website, and emails, health coaching. Four hundred and fifteen individuals participated in the trial, and it was found that both health coaching delivery models resulted in clinically significant weight loss over a two-year period.[68] There are fewer studies assessing health coaching addressing smoking cessation. A retrospective cohort study compared 241 participants

who received tobacco cessation health coaching to two control groups, one group who did not receive any intervention and one group who completed a tobacco cessation education course.[70] It was found that after 12 months, smoking cessation rates among participants who received health coaching were significantly higher compared to the control group who received no intervention, and were similar compared to the control group who received the education course.[70] Regardless of the outcomes of health coaching, identifying individuals who might be less likely to pursue a health intervention after discussing the option with a health care provider may have implications for their care. Providers could target interventions to address some of the underlying issues that contribute to their lack of engagement, such as providing more resources or identifying other health promoting programs that they may be interested in.

There are a variety of delivery models for health coaching; the intervention can be effectively delivered in person, via telephone, or through online-based programs. Appel et al. (2011) reported no statically significant differences between in-person health coaching and remotely delivered health coaching.[68] Similarly, another study assessed the outcomes of an internet-based health coaching program designed to increase discussion between patient and provider regarding the patient's chronic conditions.[71] A total of 241 participants were randomly assigned to the intervention or to the control group. It was found that participants who completed the Internet-based program were significantly more likely to receive advice about their condition and referrals to specialists from their health care providers compared to participants who did not receive health coaching.

Coaches of such programs include health care professionals, specially trained personnel, and peers. Leahey & Wing (2013) conducted a randomized controlled study to assess differences in outcomes between professional, peer, and mentor (an individual who previously lost weight)-

delivered health coaching for obese patients.[72] Forty-four participants were randomly assigned to a health coaching group.[72] Weight loss rates for individuals who received health coaching from a professional (56% weight loss) or a peer (50% weight loss) were higher than individuals who received health coaching from a mentor (17% weight loss).[72] The difference between professional and mentor- delivered health coaching was significant.[72] This study provided evidence that health coaching from either a professional or a peer may be an effective measure.

In order to integrate additional resources and programs aimed at behavior change, such as health coaching, into a physician's practice, the Agency for Healthcare Research and Quality and the Robert Wood Johnson Foundation conducted a national trial involving 17 practice-based research networks across the nation.[73] The incorporation of additional physician-recommended interventions to address health behavior change in a primary care setting were analyzed. These interventions concentrated on smoking, unhealthy diet, physical inactivity, and alcohol abuse. The project demonstrated a high uptake rate for both provider referrals and patient participation. Ultimately, the UPMC Health Plan chose to model a health coaching program based on the Robert Wood Johnson Foundation's program.

When considering behavior change in the context of public health genetics and genetic counseling, it is hypothesized that genetic test results may have an impact on the pursuit of interventions like health coaching programs. Although no studies have directly assessed the outcome of genetic testing on the likelihood of an individual to pursue a health coaching program, previous literature has assessed the health behavior changes of losing weight and quitting smoking after receiving genetic testing results. One study found that participants who learned they had the APOE ε4 allele, placing them at higher risk for Alzheimer disease, were significantly more likely to pursue risk-reducing health behavior changes one year after receiving genetic counseling

compared to those who did not have the ε4 allele.[56] Similarly, another study found that patients who were discovered to have severe alpha-1 antitrypsin deficiency were 3.3 times more likely to engage in tobacco quit attempts, were more likely to pursue treatment options and reported decreased smoking rates after 3 months compared to those who were carriers and those who were unaffected.[53] However, the authors did not find any significant results related to tobacco abstinent levels after three months, which highlights the complexity of smoking cessation. In contrast, a meta-analysis of 18 studies conducted by Hollands et al. (2016) found that genetic information (mutations associated with diseases such as cardiac conditions, cancers, diabetes, and Alzheimer's disease) did not have an impact on motivation to pursue risk-modifying behaviors, including smoking cessation and physical activity.[54]

The purpose of this essay is to understand the factors, including patient engagement and genetic variant status, that may make an individual more likely to complete a health intervention such as a health coaching program. This essay assessed participant completion of a physician-prescribed health coaching program, UPMC's Prescription for Wellness. The program is available at no cost to any patient insured by UPMC Health Plan. The goal of the wellness program is to help an individual understand and manage their health and navigate the health care system in order to improve their health. The program was adapted from an initiative funded by the Agency for Healthcare Research and Quality and the Robert Wood Johnson Foundation that demonstrated the benefits of a physician partnership with community resources addressing behavior change.[64] In order to be enrolled in UPMC's Prescription for Wellness program, a patient's physician writes them a prescription for the appropriate health coaching program. There are a number of programs available through UPMC's Prescription for Wellness including behavioral health, condition management, maternity, lifestyle improvement, and shared decision making. In the current study,

once a prescription for either a weight loss program or smoking cessation program was given by the gastroenterologist, and the patient accepted the prescription, the patient either called the program, or a health coach contacted the participant. Health coaches consisted of trained and licensed health care professionals. The program consisted of 6-8 weekly phone calls conducted by health coaches that were supplemented by educational materials mailed to the participant. Sessions addressed the overall goals and concerns for the patient, as well as explored motivations to pursue health behavior changes. Other support resources, such as assigned homework or referrals to other services were also given when appropriate.

The first aim of this essay is to evaluate the relationship between an individual's pre-counseling engagement in their health and completion of the UPMC Prescription for Wellness program. It is hypothesized that individuals who have higher pre-counseling health engagement scores will be more likely to complete the UPMC Prescription for Wellness program after given a referral compared to individuals who have lower pre-counseling health engagement scores.

The second aim of this essay is to evaluate the relationship between an individual's variant status and completion of the UPMC Prescription for Wellness program. It is hypothesized that individuals who have a positive genetic test result (pathogenic variant) will be more likely to complete the Prescription for Wellness program after given a referral compared to individuals with no pathogenic variant.

4.2 PARTICIPANTS

Participants were recruited from University of Pittsburgh Medical Center (UPMC) Hereditary GI Tumor Program's patient population who underwent genetic counseling for the first time from

July, 2016 to December, 2017. In order to receive a referral to the UPMC Prescription for Wellness program, participants had to be insured by UPMC Health Plan, and either be overweight (BMI ≥ 30) or current smokers at the time of their initial appointment. Those who were under the age of 18 or unable to give informed consent were excluded from the study. Patients were referred to the clinic due to a personal history and/or a family history that is concerning for a hereditary predisposition to cancer. Indications for referral include young ages of cancer diagnoses, multiple primary cancer diagnoses, multiple family members affected with the same or related types of cancers, and/or tumor studies indicative of a possible underlying genetic cause.

4.3 PROCEDURE

This study was approved by the University of Pittsburgh IRB (PRO16050209, 07/12/16) (Appendix A.6). The investigators obtained informed consent for participants who met the study criteria and who were interested in participating in the study. Next, the Altarum Consumer Engagement (ACE) Measure was delivered verbally to assess individual healthcare engagement.[15] The ACE measure is comprised of 12 statements and utilizes a 5-point Likert scale, ranging from "strongly disagree" to "strongly agree" (Appendix A.1).[15] It has three different domains, Commitment, Navigation, and Informed Choice, with four questions comprising each domain.[15] An average of the four questions per domain was taken and then multiplied by 6.25 to produce a total score for each domain ranging from 0-25.[15] The final scores for each domain were then summed to calculate an individual's total engagement score ranging from 0-75.[15]

After completing the survey, the participants next received genetic counseling and a consult with a gastroenterologist who specializes in hereditary GI cancer syndromes. Patients

insured by UPMC Health Plan who were overweight (BMI ≥ 30) or were current smokers were included in this study and given standard lifestyle modification reading material, as well as a Prescription for Wellness to a tobacco cessation or weight loss health coaching program if they were interested. When participants were both overweight and current smokers, the gastroenterologist and patient discussed which program would be most beneficial. Patients who were overweight or used tobacco and had a different insurer were given only the standard of care reading material for lifestyle changes. For participants who were given a referral to the Prescription for Wellness program, completion status of the program was tracked through the Electronic Medical Record or directly discussed with the UPMC Health Plan team.

The genetic counseling that participants received consisted of a review of cancer and genetics, a personalized cancer and genetic risk assessment, information about hereditary cancer syndromes, cancer preventive measures and psychosocial counseling. When clinically appropriate, genetic testing was discussed and offered. Participants who had genetic testing received the results from a genetic counselor by telephone within a three-month time period after their initial appointment. Possible results that were reported on patient's genetic testing reports included positive (pathogenic or likely pathogenic variant), a variant of unknown significance (VUS) and negative (benign or likely benign variant). All participants were then contacted via phone three to five months after their initial office appointment to repeat the ACE measure survey. Individuals who were overweight (BMI ≥ 30) and individuals who were current tobacco users at the time of their initial visit were also asked to complete the Lifestyle Questionnaires, either the weight loss questionnaire or the smoking cessation questionnaire, as appropriate, during the post follow up phone call (Figure 12). Individuals who were undergoing cancer treatment during the time of the

study were excluded in the health behavior analyses, as active cancer treatment might reduce the likelihood that an individual could pursue health behavior changes.

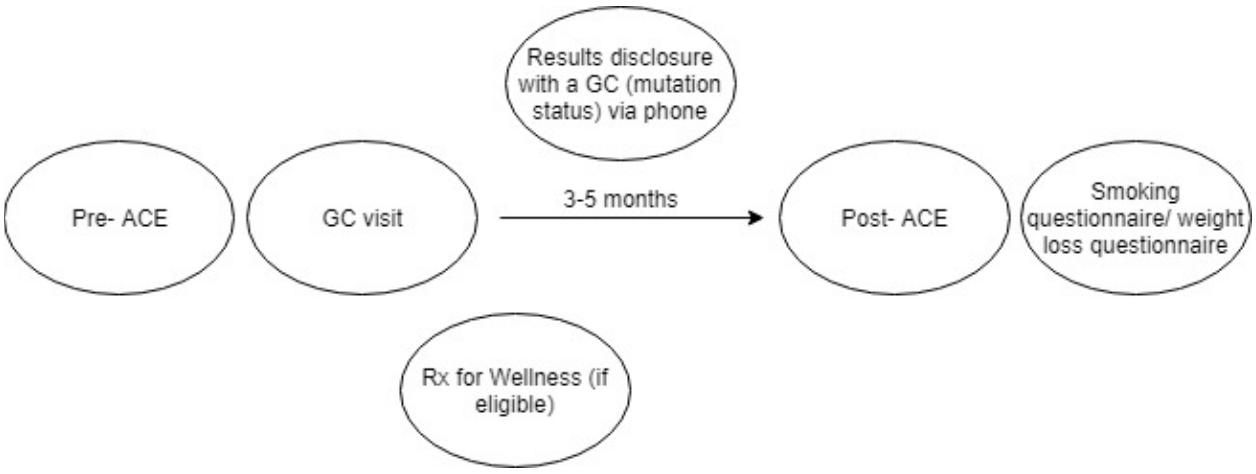


Figure 12. Protocol Flowsheet

4.4 RESULTS

Of the 195 participants who completed the study, 116 were not overweight or current smokers and they were excluded from the analyses (Figure 13). Thirteen participants were undergoing current cancer treatment and were excluded. Twenty-seven participants had a different insurer and did not qualify for a Prescription for Wellness. A total of 39 participants qualified for a referral to the Prescription for Wellness, either for weight loss (n = 32) or smoking cessation (n = 7). Thirteen (13) participants ultimately enrolled and completed the Prescription for Wellness program, either for weight loss (n = 10) or smoking cessation (n = 3). Participants ranged from ages 26-78 years old (mean age of 49 years) (Table 7). Approximately 97% of participants were Caucasians and 3% were African Americans. 56% were females and 44% were males. Their personal cancer history was as follows: no cancer (n = 27), colorectal cancer (n = 4), and other cancer (n = 8). Twenty-nine (29) participants underwent genetic testing.

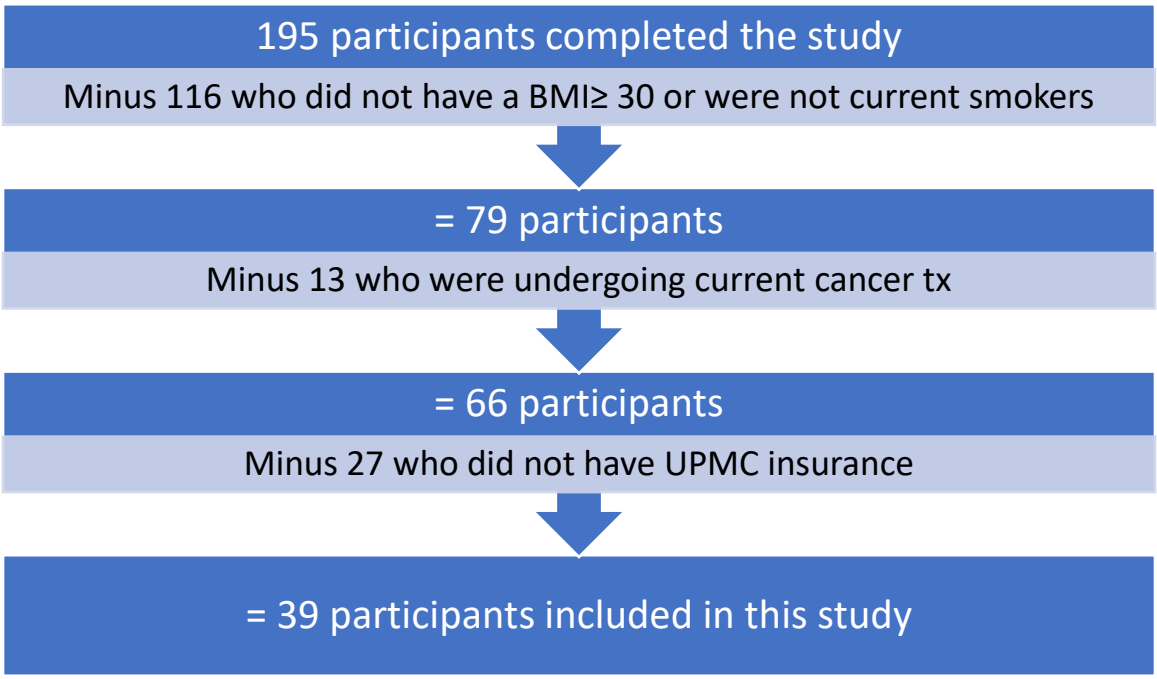


Figure 13. Participant Flowsheet

Table 7. Characteristics of the sample at baseline

	n	%
Sex		
Female	22	56
Male	17	44
Age		
18-34	6	15
35-51	13	33
52-64	15	38
65+	5	13
Mean age = 49		
Ethnicity		

Table 7 Continued

Caucasian	38	97
African American	1	3
Cancer History		
No cancer	27	69
Colorectal	4	10
Pancreatic	1	3
Other cancer	7	18
Total	39	100

Two-sample t-tests with equal variances were conducted in order to analyze the effect that pre-counseling engagement levels had on whether or not participants completed the Prescription for Wellness program. No statistical differences were found between pre-counseling engagement levels in participants who did or did not complete the Prescription for Wellness program ($p = 0.151$), 95% CI = (-2.082, 13.019) (Table 8) (Figure 14). Likewise, none of the individual domains were significantly different between participants who did or did not complete the program (Table 8). Although there was a small sample size, a multiple logistic regression was run to test associations between completion status and pre-counseling engagement (ACE) scores to adjust for the covariates of age, gender, and cancer status. No association between pre-counseling engagement and completion status was observed after adjustment for covariates.

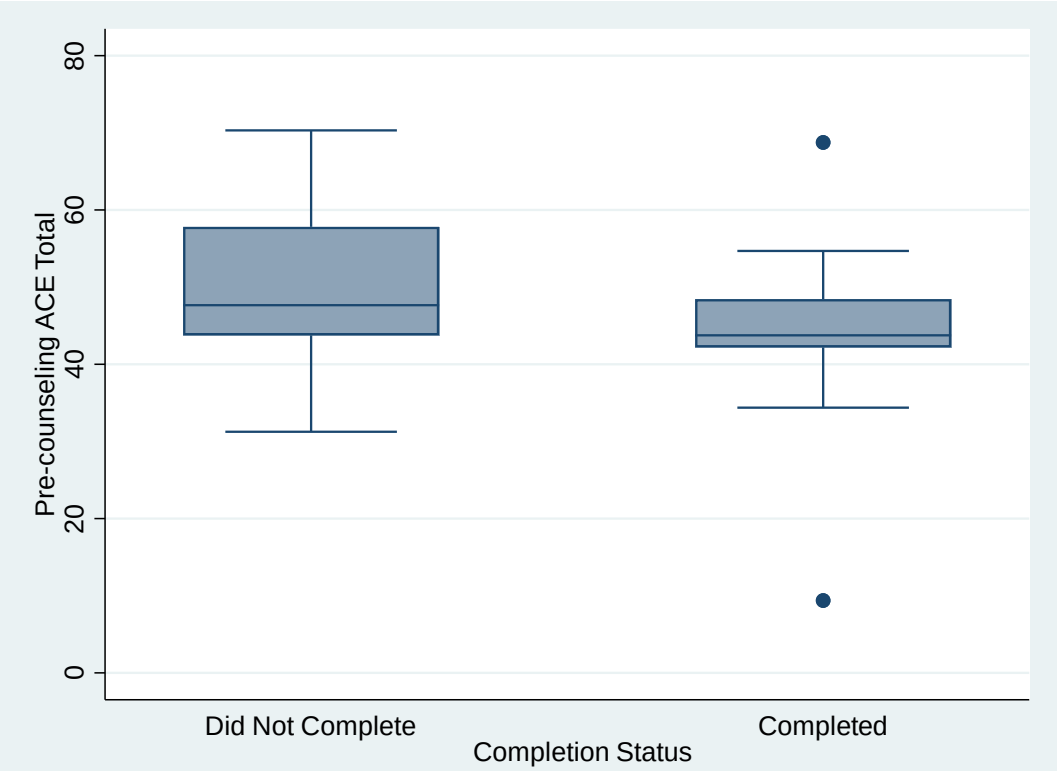


Figure 14. Pre-counseling engagement levels effect on completion of the Prescription for Wellness program

Table 8. Summary statistics of pre-counseling engagement levels effect on completion of the Prescription for Wellness program

Averages of Results (n = 39)				
	Coefficient for the Completed group (n = 12)	**Coefficient for the Did not Complete group (n = 17)**	**Difference**	**p-Value**
Navigation	16.987	18.610	1.428	0.263
Commitment	15.024	16.286	1.262	0.419
Informed Choice	11.899	14.483	2.584	0.171
Total	43.910	49.379	5.469	0.151

Two-sample t-tests with equal variances were conducted in order to analyze the effect that variant status had on completion status in the Prescription for Wellness program. No statistical differences were found between variant status and completion status in the Prescription for Wellness program (p = 0.572), 95% CI = (-0.266, 0.472) (Table 9 & 10). Although there was a small sample size, a multiple logistic regression was run to test the association between completion status of the program and variant status to adjust for the covariates of age, gender, and cancer status. No association between variant status and completion status was observed after adjustment for covariates.

Table 9. Summary statistics of the effect of variant status on completion of the Prescription for Wellness program

Averages of Results (n = 29)				
	Coefficient for the Completed group (n = 12)	**Coefficient for the Did not Complete group (n = 17)**	**Difference**	**p-Value**
Variant Status	0.25	0.353	0.103	0.572

Table 10. Frequencies of variant status and completion of the Prescription for Wellness

	Pathogenic Variant	No Pathogenic Variant	Total
Completed Rx for Wellness	3	9	12
Did Not Complete Rx for Wellness	6	11	17
Total	9	20	29

4.5 DISCUSSION

The aims of this study were to evaluate the relationship between an individual's pre-counseling engagement in their health as well as an individual's genetic variant status and completion status of the UPMC Prescription for Wellness program. Although the data demonstrated a trend towards increased engagement levels leading to someone being less likely to complete the Prescription for Wellness program, this was not statistically significant, and thus no definitive conclusions on an association can be determined with this study. Previous studies have found that higher patient engagement was associated with beneficial health behaviors, including a healthier body weight and lower smoking rates, as well as a better utilization of health care services.[2,14] Patient engagement has also been found to lead to individuals feeling more in control of their health.[13] If the trend seen in this data is found to be significant in future studies, one possible explanation is that this feeling of control could therefore lead an individual to not feel the need to pursue a health coaching program because they may feel they already have all the resources they need to improve their health. However, more research is needed in this area to draw any definitive conclusions.

The analyses between variant status and completion of the Prescription for Wellness demonstrated a trend towards individuals with a negative or a variant of unknown significance genetic testing result leading to someone being more likely to complete the Prescription for Wellness program. However, the results were not significant thus no definitive conclusions can be drawn at this time. The current research on the effect of receiving genetic testing results have been mixed. Previous research has concluded that individuals with positive genetic testing results are more likely to pursue cancer surveillance services such as colonoscopies and self-breast exams but not mammograms.[50,48] Although health coaching and cancer surveillance services are both services that may help in reducing cancer risk, patients may perceive a more immediate benefit to cancer

surveillance services such as colonoscopies when compared to programs like health coaching. This perception of benefit may make an individual more likely to pursue cancer surveillance services compared to health coaching programs. Furthermore, the findings of this research are consistent with another study that found no association between genetic information and pursuing risk-modifying behaviors, and concluded that genetic testing as an intervention to change health behaviors would not be an effective public health approach.[54]

The results of this research are limited by different factors, including the small sample size. Further, the study included a population of patients from one Hereditary GI cancer clinic; therefore, the findings may not be generalizable to other populations. Individual differences outside of patient engagement may play a large role in one's decision on whether or not to pursue a health coaching program. For example, culture and values are two determinants of health that may be related to health outcomes.[74] One study that assessed the relationship between American regional cultures and health outcomes analyzed a dataset of cultural distribution among regions in the nation compared to life-expectancies by state.[75] It was found that certain cultures had lower life expectancies.[75] In the current study, it can be hypothesized that certain cultures might not feel comfortable with a health coach for various reasons. Values can also affect the choice of enrolling in a wellness program; if an individual does not think it is important to stop smoking then they might not choose to enroll. However, there has not been specific research that has addressed the relationship between culture and values and health coaching.

There are three core functions of public health, which include assessment, policy development and assurance.[66] This study addresses the assessment component of the core function of public health, which is defined as "analyz[ing] the determinants of identified health needs."[66] The current study focuses on assessment by assessing factors that may impact an

individual's completion of a prescribed health coaching program, in this case how pre-counseling engagement scores and genetic test results impact participation in the UPMC Prescription for Wellness Program. The results of this study showed that neither an individual's pre-counseling engagement nor genetic variant status was found to be a determinant of whether or not someone completed the Prescription for Wellness. There are most likely other factors that contribute to an individual's likelihood to pursue a health coaching program.

Additionally, health coaching programs like the Prescription for Wellness can serve to fulfill one of the ten essential public health services of, "inform[ing], educate[ing], and empower[ing] people about health issues".[66] Health coaches provide individualized education and support to individuals, which can enhance the evidence-based information that they receive about their health condition and empower them to take action to improve their health. Previous studies on health coaching found that the intervention can lead to significant weight loss and tobacco cessation rates.[68,69] This research found similar findings and also concluded that individuals who received genetic counseling as well as enrolled in the Prescription for Wellness health coaching program lost more weight than a previous report of individuals who enrolled in the Prescription for Wellness who did not receive genetic counseling.[64] Therefore, the combined interventions of genetic counseling and a health coaching program may lead to beneficial health outcomes.

Furthermore, the physician partnership model that the Prescription for Wellness utilizes, as it is a physician-prescribed program, addresses the essential service of "link[ing] people to needed personal health services and assure the provision of health care when otherwise unavailable".[66] The health coaching program provides physicians with an additional resource to provide to their patients as an option in managing health problems such as obesity and tobacco use. While this study found that completion of a health coaching program was not affected by

engagement scores or genetic test results, other factors may be play a role in an individual's likelihood to complete a health coaching program.

This study demonstrates that collecting information on pre-counseling engagement scores and genetic variant status may not be informative as part of an intervention to increase the likelihood of an individual completing a health coaching program. However, based on the limited sample size of this study, more research is needed in this area. Future directions would include sampling a larger population size as well as studying additional factors that may motivate an individual to pursue a health coaching program in the context of a genetic counseling clinic. Additional factors could include socioeconomic status, an individuals' type of locus of control (internal or external), desire to lose weight, and knowledge of obesity-related health conditions. The effect of patient engagement scores on the use of other health interventions commonly recommended in the cancer genetic counseling setting could also be addressed, including cancer screening services and other referrals made by genetic counselors. The effect of patient engagement scores on the extent of cascade testing and cancer screening of relatives that occurs after an individual discovers they have a pathogenic variant that causes an increased cancer risk would provide information on another important aspect of genetic counseling. Additionally, a qualitative research study, utilizing individual interviews or focus groups, would help to gain a deeper understanding of a patient's engagement and willingness to complete a health coaching problem.

4.6 CONCLUSION

Patient engagement levels and genetic variant status was not found to make an individual more or less likely to complete the Prescription for Wellness program. Motivations to pursue health interventions may be complex and multifactorial in nature. Further research to delineate the factors that may make an individual more likely to engage in a health intervention could be helpful in order to guide intervention development.

APPENDIX A: DOCUMENTATION FOR METHODOLOGY

A.1 ACE MEASUREMENT

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.					

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.					

ALTARUM INSTITUTE
SYSTEMS RESEARCH FOR BETTER HEALTH

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 TOBACCO CESSATION QUESTIONNAIRE

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

A.4 WEIGHT LOSS QUESTIONNAIRE

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

A.5 CONSENT FORM

UPMC LIFE CHANGING MEDICINE

CONSENT TO USE MEDICAL RECORDS AND/OR QUESTIONNAIRES FOR RESEARCH IN THE **UPMC Shadyside Division of Gastroenterology**

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:

We are 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 verbally asked a questionnaire at the beginning of your visit to be completed in office. The survey should take about 5- 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: 8/23/2017
Renewal Date: 5/16/2018
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 study 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: 8/23/2017
Renewal Date: 5/16/2018
IRB #: PRO16050209

A.6 IRB APPROVAL LETTER

University of Pittsburgh
Institutional Review Board

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

Memorandum

To: Randall Brand, MD
From: IRB Office
Date: 10/9/2017
IRB#: MOD16050209-03 / 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 requested modifications by the expedited review procedure authorized under 45 CFR 46.110 and 21 CFR 56.110.

Modification Approval Date: 10/9/2017
Expiration Date: 5/16/2018

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: RESULTS

Table 11. Change in engagement (ACE) scores relationship with weight loss (% change in BMI) in the overall cohort

	Coefficient	Standard Error	p-value	95% Confidence Interval
Univariate Analysis-				
Change in ACE Total	-0.032	0.019	0.095	-0.069, 0.006
Change in ACE Commitment	-0.025	0.040	0.528	-0.105, 0.055
Change in ACE Navigation	-0.049	0.040	0.222	-0.130, -0.031
Change in ACE Informed Choice	-0.037	0.030	0.223	-0.096, 0.023
Multivariate Analysis (including covariates of age, gender, cancer status, and completion status of the Prescription for Wellness)-				
Change in ACE Total	-0.030	0.019	0.169	-0.065, 0.012
Change in ACE Commitment	-0.023	0.0397	0.564	-0.103, 0.057
Change in ACE Navigation	-0.040	0.040	0.329	-0.121, 0.042
Change in ACE Informed Choice	-0.029	0.030	0.339	-0.090, 0.032

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