ABSTRACT

Title of dissertation: THE RELATIONSHIP BETWEEN HEALTH LITERACY

AND INDICATORS OF DECISION MAKING FOR

COLORECTAL CANCER SCREENING AMONG AFRICAN

AMERICANS

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African Americans are disproportionately affected by colorectal cancer (CRC) incidence and mortality. CRC early detection leads to better treatment outcomes and, depending on the screening test, can prevent the development of CRC. African Americans, however, are screened less often than Whites. Aspects of decision making (e.g., decisional conflict, decision self-efficacy) can impact decision making outcomes and may be influenced by social determinants of health, including health literacy. However the relationship between social determinants of health and indicators of decision making in this population is not fully understood. Additionally, individuals have a choice between different CRC screening tests and an individual's desire to use a particular screening test may be associated with social determinants of health such as health literacy.

This study aimed to examine the relationship between social determinants of health and indicators of decision making for CRC screening among African Americans. A total of 111 participants completed a baseline and 14-month follow-up survey assessing decisional conflict, decision self-efficacy, decisional preference (shared versus informed decision making), and CRC test preference. Health literacy was negatively associated with decisional conflict and positively associated with decision self-efficacy (ps < .05). Individuals who were unemployed or working part-time had significantly greater decisional conflict than

individuals working full-time (ps < .05). Individuals with a first-degree family history of CRC had significantly lower decision self-efficacy than individuals without a family history (p < .05). Women were significantly more likely to prefer making a shared decision rather than an informed decision compared to men (p < .05). Lastly, previous CRC screening behavior was significantly associated with CRC test preference (e.g., individuals previously screened using colonoscopy were significantly more likely to prefer colonoscopy for their next screening test; ps < .05). These findings begin to identify social determinants of health (e.g., health literacy, employment) that are related to indicators of decision making for CRC among African Americans. Furthermore, these findings suggest further research is needed to better understand these relationships to help with the future development and improvement of interventions targeting decision making outcomes for CRC screening in this population.

THE RELATIONSHIP BETWEEN HEALTH LITERACY AND INDICATORS OF DECISION MAKING FOR COLORECTAL CANCER SCREENING AMONG AFRICAN AMERICANS

By

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Chapter 1: Introduction

Background of the Problem

Colorectal cancer (CRC) is the third most common cancer in the United States and the third leading cause of cancer-related deaths (American Cancer Society [ACS], 2014). African Americans are disproportionately impacted by CRC with greater incidence and mortality rates compared to Whites (ACS, 2013). Early detection of CRC leads to better treatment outcomes and reduces overall mortality (ACS, 2014). The U.S. Preventive Services Task Force (USPSTF), American Cancer Society (ACS), American College of Radiology, and U.S. Multi-Society Task Force on CRC all recommend screening beginning at age 50 for average-risk adults through one of four recommended tests: yearly fecal occult blood test (FOBT), sigmoidoscopy every five years, double contrast barium enema (DCBE) every five years, or colonoscopy every ten years (ACS, 2014; Levin et al., 2008; USPSTF, 2015). The organizations also recommend that screening begin earlier and often more frequently for high-risk individuals (e.g., family history, personal history of polyps; ACS, 2014; Levin et al., 2008; USPSTF, 2015). FOBT, sigmoidoscopy, and DCBE are able to detect CRC while colonoscopy is able to detect CRC and remove precancerous polyps, thereby preventing cancer (ACS, 2014). The American College of Gastroenterology recommends African Americans begin screening at age 45 (Rex et al., 2009) due to an earlier mean age of development in African Americans and the proximal distribution of cancers in the colon (Agrawal et al., 2005). Unlike sigmoidoscopy, which only finds polyps in the distal end of the colon (sigmoid colon) and rectum, colonoscopy examines the entire colon and can detect proximal cancers (Laiyemo et al., 2011). Therefore, the American College of Gastroenterology recommends African Americans undergo colonoscopy for their CRC

Americans are not meeting the recommended CRC screening guidelines (ACS, 2013). Longitudinal data has found similar CRC screening rates between African Americans and Whites in recent years, however screening disparities persist within the African American population (Agency for Healthcare Research and Quality [AHRQ], 2016). For example, poor, low-income, and middle income African Americans (47.6%, 51.5%, and 61.7%, respectively) are screened much less often than high-income African Americans (71.6%; AHRQ, 2016). Screening rates in these populations are below the Healthy People 2020 objective of 71% (U.S. Department of Health and Human Services [DHHS], 2015).

Researchers suggest targeted and culturally appropriate intervention efforts to eliminate health disparities (Gupta et al., 2014). Health services research targeting health disparities in vulnerable populations—groups facing discrimination or bias in health services due to social determinants of health or race/ethnicity—can reduce and eventually eliminate health disparities (Kilbourne, Switzer, Hyman, Crowley-Matoka, & Fine, 2006). Social determinants of health are the "conditions in the environments in which people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks" (DHHS, 2015). Healthy People 2020 has arranged social determinants of health into five domains: (1) economic stability (e.g., employment, poverty); (2) education (e.g., educational attainment including high school graduation); (3) health and health care (e.g., access to health care, health literacy); (4) neighborhood and build environment (e.g., housing quality, environmental conditions); and (5) social and community context (e.g., civic participation, perceptions of discrimination and equity; DHHS, 2015). With a better understanding of how the social determinants of health unique to these

populations lead to health disparities, researchers are better equipped to develop, implement, and evaluate targeted interventions (Kilbourne et al., 2006).

Informed decision making. A patient's individual autonomy is an important value that should be recognized during the medical decision making process, particularly when patients have a choice between various screening or treatment options (van Dam, Kuipers, Steyerberg, van Leerdam, & de Beaufort, 2013). As CRC screening offers a variety of screening choices, researchers suggest an individual should have the sufficient knowledge and ability to make their own screening decision (Marteau, Dormandy, & Michie, 2001). Due to the complexities of decision making in CRC screening, a variety of decision aids have been developed to help individuals with making an informed decision (O'Connor et al., 1998). The Ottawa Decision Support Framework was developed to assist researchers with the development of decision aids (O'Connor, et al., 1998). The framework proposes three aspects to decision making: decisional needs, decision support, and decisional quality (O'Connor, et al., 1998). A comparative effectiveness review for cancer screening and treatment decision aids found insufficient evidence for the effectiveness of decision aids targeting vulnerable populations. (Trikalinos, Wieland, Adam, Zgodic, & Ntzani, 2014). However, this may be a result of insufficient understanding of contextual factors impacting decision making outcomes.

Within the Ottawa Decision Support Framework, a variety of decisional needs for individuals have been identified that must be recognized for health providers to sufficiently help the individual make a choice (O'Connor et al., 1998). While this framework was designed for the development of decision aids, the current published literature investigating the decisional needs of individuals and how their needs may be related to the decision

making process is limited (Manne et al., 2014). For decision aids to be effective, researchers need to better understand the various types of "needs" individuals have and how health providers may be able to support these needs.

Decisional needs. Within the category of decisional needs, three specific needs have been suggested to be related to decision making among African Americans: decisional conflict, decision self-efficacy, and decisional preference. Decisional conflict reflects how uncertain an individual feels about making a decision and may be related to factors such as unclear values and lack of clarity related to the screening options (O'Connor, 2006). The Ottawa Decision Support Framework and other research suggests when individuals' decisional conflict is low, they are better able to make a screening decision (Stacey et al., 2011). Decision aids have been found to reduce decisional conflict for CRC screening in a variety of populations (Lillie et al., 2014). Decision self-efficacy is how much confidence an individual has to make their decision (O'Connor, 2006) and research suggests that high decision self-efficacy is positively related to making a screening decision among individuals. Factors that may help increase an individual's decision self-efficacy include previously completing the decision (e.g., having already completed the screening test; Vijaykumar, Wray, Jupka, Clarke, & Shahid, 2013) and believing they have sufficient information to make a decision (Hoffman et al., 2014).

Decisional preference describes how involved an individual wishes to be in the decision making process (Charles, Gafni, & Whelan, 1999). Until the 1980s, a paternalistic decision making style was dominant among patient-provider communication and decision making. This style relies on the health provider to make the decision that is in the best interest of the individual (Charles et al., 1999). In the 1980s however, a paradigm shift

occurred and two additional decision making styles have become more commonly preferred by individuals: shared and informed. A shared decision making style calls for both the individual and the health provider to decide on a treatment or screening option together. An informed style however allows the individual to make the decision for themselves after receiving all necessary information from their provider (e.g., all available options, benefits, risks; Charles et al., 1999). African American patients have shown greater preference for involvement in the decision making compared to White patients (Messina, Lane, & Grimson, 2005). Additionally, past research has shown African Americans between the ages of 50 and 75 are more likely to prefer a shared decision making style for CRC screening rather than a paternalistic or informed decision making style (Schroy III, Glick, Robinson, & Heeren, 2007). Another study examining decision making among CRC patients found older individuals and women were more likely to prefer a more passive—or shared—decision than younger individuals and men (Salkeld, Solomon, Short, & Butow, 2004).

Colorectal cancer screening test preference. For an individual to make a shared or informed choice to complete CRC screening, the individual must decide which test they wish to complete. As there are a variety of CRC screening tests, the decision to identify which screening test an individual prefers can be complicated and dependent on a variety of factors (Lillie et al., 2014). Studies have investigated the preferred CRC screening test among populations, but results have been mixed: some studies identified FOBT as the most preferred while others found a greater preference for colonoscopy or sigmoidoscopy (Leard, Savides, & Ganitas, 1997; Pignone, Bucholtz, & Harris, 1999; Powell et al., 2009; Ruffin IV, Fetters, & Jimbo, 2007; Sheikh, Kapre, Calof, Ward, & Raina, 2004; Wolf, Basch, Brouse, Shmukler, & Shea, 2006). While researchers have identified CRC screening preference

among African Americans (with mixed findings), little published literature examines screening test preference in relation to social determinants of health such as health literacy. Among a racially and ethnic diverse population, individuals with adequate health literacy were more likely to have heard of colonoscopy (versus other screening tests) than individuals with low health literacy (Arnold et al., 2012). In this same population, providers were more likely to recommended colonoscopy to individuals with adequate health literacy and FOBT to individuals with low health literacy (Arnold et al., 2012). Health literacy may be associated with an individual's ability to comfortably understand all relevant information for each screening test.

Health literacy. Health literacy has many different definitions, however this study uses the clinical approach to health literacy that focuses on the communication between a provider and their patient to reduce limitations in patient-provider communication (Pleasant & Kuruvilla, 2008). Individuals with lower health literacy are less likely to understand written health information (The National Academies of Sciences, Engineering, and Medicine [NAS], 2015; van der Heide, Uiters, Schuit, Rademakers, & Fransen, 2015). Additionally, health providers have low ability to correctly identify health literacy levels in individuals which may directly impact the decision making process (Mazor et al., 2010). Low health literacy is associated with lower CRC screening rates and reduced knowledge of available CRC screening tests (Guerra, Dominguez, & Shea, 2005). Another study found health literacy to be a significant predictor of CRC screening status among adults age 65 and older. However, health literacy was not a significant predictor of CRC screening for adults aged 50 to 64 (White, Chen, & Atchison, 2008). There is limited research investigating the relationship between health literacy and indicators of decision making, particularly decisional

conflict, decision self-efficacy, and decisional preference (van der Heide et al., 2015). As health literacy is associated with reduced knowledge and overall screening rates, health literacy may be associated with the decisional needs of individuals. Additionally, as individuals with low health literacy often have low knowledge of each CRC screening test, their screening test preferences may differ from an individual with greater health literacy.

Theoretical Framework

This research was guided by the Ottawa Decision Support Framework (O'Connor, 1998) and integrates several theories to better understand the relationships between various components of decision making (i.e., decisional preference, decisional conflict, decision selfefficacy, CRC screening test preference), and two models for health literacy. The Ottawa Decision Support Framework is grounded in several theories (O'Connor, 1998), two of which were applied in the proposed research: decisional conflict (Janis & Mann, 1977) and self-efficacy (Bandura, 1977). Decisional conflict is an individual's uncertainty about the best course of action when more than one choice is available, particularly when options involve possible regret, loss, or risk, and challenges individual values (O'Connor, 2006). Self-efficacy is an individual's perceived confidence in performing a task (Bandura, 1977) and was operationalized as decision self-efficacy; how much confidence an individual has to make their decision (O'Connor, 2006). Decisional preference was guided by the work of Charles and colleagues (1999) who propose three decisional preference styles: paternalistic (provider decides for the patient), shared (equal decision making between provider and patient), and informed (patient decides with sufficient information about options from provider or other sources).

This research study was also guided by the definitions for health literacy provided by the Centers for Disease Control (CDC; 2015) and Ad Hoc Committee on Health Literacy (1999), this research study focuses on the relationship between individuals' fundamental literacy skills and indicators of decision making for CRC screening. The field of health literacy has continuously been developed and redefined since the 1980s (Pleasant & Kuruvilla, 2008). The clinical approach to health literacy used in the present study focuses on the communication between a provider and their patient and how to reduce limitations in patient-provider communication (Pleasant & Kuruvilla, 2008). This approach to health literacy measures fundamental literacy skills (e.g., knowledge of clinical terminology, numeracy) and helps to ensure the patient-provider encounter concludes in each party's full comprehension of one another (Pleasant & Kuruvilla, 2008).

Problem Statement

African Americans have greater CRC incidence and mortality rates compared to Whites (ACS, 2013). While early detection of CRC leads to better treatment outcomes and reduces overall mortality (ACS, 2014), CRC screening rates among African Americans are lower than Whites (ACS, 2013). To ensure autonomy for all individuals (van Dam et al., 2013), informed decision making for CRC screening (whether or not they decide to get screened) should be available for everyone (Smith et al., 2015). Individuals make an informed decision through the process of choosing an action (when choice is available) when the individual has sufficient knowledge and can choose an action consistent with their beliefs (Marteau et al., 2001).

The Ottawa Decision Support Framework proposes decisional needs that should be considered when helping individuals make a decision (O'Connor, 2006). Three of these

decisional needs are decisional conflict, decision self-efficacy, and decisional preference (O'Connor, 2006). While research has cited decisional needs as important components of making an informed decision, the published literature is limited in the examination of associations between these components (Manne et al., 2014).

Additionally, health literacy has been associated with lower CRC screening rates (Guerra et al., 2005) and aspects of the decision making process (Mazor et al., 2010). Despite attempts to identify CRC screening test preference (Leard et al., 1997; Pignone et al., 1999; Powell et al., 2009; Ruffin IV et al., 2007; Sheikh et al., 2004; Wolf et al., 2006), research has not conclusively identified a commonly preferred screening test. This may be due to limited published research that has examined factors such as family CRC history, particularly as these factors may be related to individuals' preferred CRC screening test. Additional research may help elucidate the potential relationships between social determinants of health, including health literacy, and their preferred CRC screening test.

Purpose of the Study

The purpose of this study was to examine the relationships between social determinants of health—with a focus on health literacy—and four indicators of decision making (decisional conflict, decision self-efficacy, decisional preference, and CRC test preference). Additionally, age and gender were examined as potential moderators of these relationships. As research has identified differences in the relationship between health literacy and CRC screening for adults aged 50 to 64 versus adults aged 65 and older (White et al., 2008), age may moderate the relationship between health literacy and indicators of decision making. Furthermore, women are often responsible for communicating and maintaining their family's health information (Wiseman, Dancyger, & Michie, 2010) and

previous research has identified greater health literacy among women compared to men (Arnold et al., 2012) and greater preference for shared (versus informed) decision making (Salkeld et al., 2004). Therefore, gender was also assessed as a potential moderator. This research focused on African Americans who have participated in a church-based cancer early detection educational intervention in Prince George's County, Maryland. Rather than compare social determinants of health and decision making indicators across racial/ethnic groups, the research focused on factors within the African American population. Furthermore, this study focused on a unique subgroup of church-going African Americans with the majority of participants having at least some college and only about half were married. Additionally, the majority of participants had health insurance and had previously been screened for CRC. The study also examined a number of indicators of social determinants of health—following the five DHHS domains (2015)—including employment status for 'economic stability,' educational attainment for 'education,' and health insurance for 'health and health care.' As African Americans already experience disproportionately high incidence and mortality from CRC, as well as lower screening rates (ACS, 2014), the proposed study aims to examine the relationship of health literacy and other social determinants of health with indicators of decision making for CRC screening.

Public Health Implications

The research helps inform future research examining social determinants of health and decision making for CRC screening amongst African Americans through a better understanding of factors (e,g., decisional needs, CRC screening test preference, health literacy) associated with decision making. The proposed study is consistent with the Healthy People 2020 objectives to reduce the CRC mortality rate (Objective C-5), increase the CRC

screening rate (Objective C-16), and increase the number of adults counseled by their health providers about CRC screening (Objective C-18.3; U.S. Department of Health and Human Services, 2015).

Research Aims and Hypotheses

<u>Aim 1</u>: To examine the relationship between health literacy and decisional conflict for CRC screening and the potential moderating role of age and gender on this relationship.

H1a: Health literacy will be negatively associated with decisional conflict for African Americans aged 50 to 75.

H1b: The associations between health literacy and decisional conflict will be strengthened for African Americans between the ages of 50 and 64 compared to African Americans between the ages of 65 and 75.

H1c: The associations between health literacy and decisional conflict will be strengthened for African American women compared to African American men.

<u>Aim 2</u>: To examine the relationship between health literacy and decision self-efficacy for CRC screening and the potential moderating role of age and gender on this relationship.

H2a: Health literacy will be positively associated with decision self-efficacy for African Americans aged 50 to 75.

H2b: The associations between health literacy and decision self-efficacy will be strengthened for African Americans between the ages of 65 and 75 compared to African Americans between the ages of 50 and 64.

H2c: The associations between health literacy and decision self-efficacy will be strengthened for African American women compared to African American men.

<u>Aim 3</u>: To examine the relationship between health literacy and decisional preference for CRC screening and the potential moderating role of age and gender on this relationship.

H3a: African Americans between the ages of 50 and 75 with greater health literacy will be more likely to prefer making an informed (versus shared) decision for CRC screening compared to individuals with lower health literacy.

H3b: The associations between health literacy and decisional preference will be strengthened for African Americans between the ages of 50 and 64 compared to African Americans between the ages of 65 and 75.

H3c: The associations between health literacy and decisional preference will be strengthened for African American men compared to African American women.

<u>Aim 4:</u> To examine the relationship between health literacy and CRC screening test preference and the potential moderating role of age and gender on this relationship.

H4a: African Americans between the ages of 50 and 75 with greater health literacy will be more likely to prefer colonoscopy (versus FOBT) for CRC screening compared to individuals with lower health literacy.

H4b: The associations between health literacy and CRC test preference will be strengthened for African Americans between the ages of 65 and 75 compared to African Americans between the ages of 50 and 64.

H4c: The associations between health literacy and decisional preference will be strengthened for African American women compared to African American men.

<u>Aim 5</u>: To identify correlates of decision making indicators (decisional conflict, decision self-efficacy, decisional preference, CRC test preference) among four subgroups of African Americans: individuals aged 50 to 64, individuals aged 65 to 75, men, and women.

Definition of Terms

<u>African American</u>: "A person having origins in any of the Black racial groups of Africa" (U.S. Census Bureau, 2013) or otherwise self-identifies as African American.

<u>Colonoscopy</u>: A CRC screening test that examines "the inside of the colon using a colonoscope, inserted into the rectum" (NCI, 2015). This CRC screening test can detect CRC, as well as prevent CRC through the removal of polyps that may be precancerous and would otherwise become malignant (ACS, 2014).

<u>Colorectal cancer (CRC)</u>: Cancer that has developed in the colon or rectum (National Cancer Institute [NCI], 2015).

<u>Colorectal cancer test preference</u>: If given a choice by their provider, an individual's preferred CRC screening test.

<u>Decisional conflict</u>: The level of uncertainty an individual may have about the best course of action when more than one choice is available, particularly when options involve possible regret, loss, or risk, and challenges individual values (O'Connor, 2006).

<u>Decision self-efficacy</u>: An individual's confidence to make a decision between more than one option (O'Connor, 2006).

<u>Decisional preference</u>: An individual's preference of how involved they wish to be in the decision making process (Charles et al., 1999). For this study, three types of decisional preference were used: paternalistic, shared, and informed (defined below).

<u>Fecal occult blood test (FOBT)</u>: A CRC screening test that checks for blood in the stool using small stool samples on a card. Blood may be a sign of CRC or other health problems, including polyps that may be precancerous (NCI, 2015).

<u>Health literacy</u>: "The degree to which an individual has the capacity to obtain, communicate, process, and understand basic health information and services to make appropriate health decisions" (CDC, 2015).

<u>Informed decision making</u>: The *process* of choosing an action (when choice is available) by an individual when the individual has sufficient knowledge and they are able to choose an action that is consistent with their beliefs (Marteau et al., 2001).

<u>Informed decisional preference</u>: An individual's decision making preference where the patient makes the final decision after the provider gives all necessary information to the patient, and/or the patient obtains information from other sources (e.g., Internet, other media, family; Charles et al., 1999).

<u>Paternalistic decisional preference</u>: An individual's decision making preference that relies on the provider (e.g., physician, nurse) to make medical decisions on behalf of the patient (Charles et al., 1999).

<u>Shared decisional preference</u>: An individual's decision making preference that involves a joint decision between a provider and patient, ideally with the two parties agreeing on one treatment or screening test choice (Charles et al., 1999).

<u>Sigmoidoscopy</u>: A CRC screening test that examines "the lower colon using a sigmoidoscopy, inserted into the rectum" for polyps and removes a small tissue sample for biopsy to detect CRC (NCI, 2015).

<u>Social determinants of health</u>: "Conditions in the environments in which people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks" (DHHS, 2015).

Chapter 2: Literature Review

Informed Decision Making

An informed decision is an outcome of an individual having sufficient knowledge and the ability to choose an action that is consistent with their beliefs (Marteau et al., 2001). The Task Force on Community Preventive Services states that for an individual to have made an informed decision "the patient must (1) understand the risk or seriousness of the disease or condition, (2) understand the preventive service, including the risks, benefits, alternatives, and uncertainties, (3) have weighed his or her values regarding the potential harms and benefits associated with the service, [and] (4) have engaged in decision-making at a level he or she desires and feels comfortable" (Sheridan, Harris, Woolf, & Shared Decision-Making Workgroup of the U.S. Preventive Services Task Force, 2004). There is general agreement among researchers and health providers that, should patients wish to be involved in the decision making process, patients should have the ability to make an informed choice regarding clinical tests, allowing patients to make an informed choice that respects their autonomy (van Dam, Kuipers, Steyerberg, van Leerdam, & de Beaufort, 2013). To maximize an individual's autonomy and preference for making an informed decision, there must be more than one viable choice and individuals need sufficient information about the choices (Entwistle, Carter, Cribb, & McCaffery, 2010).

Informed decision making tools have been developed to assist individuals with the decision making process (O'Connor et al., 1999) for health decisions that may depend on individual preferences and where a general consensus of the best course of action may be lacking (Volk, Cass, & Spann, 1999). When screening options for individuals are complex (e.g., two or more recommended screening tests available, tailored screening based on

individual risk factors, conflicting recommendations) the individuals' decision is "preference-sensitive" (Jimbo et al., 2013). In preference-sensitive situations where more than one screening strategy may exist—such as CRC screening—and patients wish to be involved in the decision making process, informed decision making for patients is vital (O'Conner et al., 2007).

Importance of informed decision making in colorectal cancer screening. The United States Preventive Services Task Force (USPSTF; 2015) and the American Cancer Society (ACS; Smith et al., 2015) recommend patients make a shared or informed decision for CRC screening, particularly as the various CRC screening test options differ in their pros and cons. For example, a colonoscopy can prevent CRC by removing the polyp before it becomes cancerous (Smith et al., 2015) while a fecal occult blood test (FOBT) detects cancer but doesn't require the extensive preparation that a colonoscopy requires (ACS, 2015). When helping individuals identify their preferred screening test and increase their ability in making a decision, any information provided must align with the individuals' values (Lafata, Divine, Moon, & Williams, 2006; Iyengar & Lepper, 2000).

Shared decision making involves a joint decision between a provider and patient, ideally with the two parties agreeing on one treatment or screening test choice (Charles et al., 1999) and has been identified as a strategy to increase CRC screening (Schroy III et al., 2007). Shared decision making has been recommended by various organizations such as the USPSTF (2014) and ACS (Smith et al., 2015) as FOBT, sigmoidoscopy, and colonoscopy were found to have similar cost-effectiveness (Schroy III et al., 2007). While some organizations have recommendations for a more involved decision making process (Smith et al., 2015; USPSTF, 2015), no one decision making style is 'better' than another (Charles et

al., 1999), and providers should assure patient autonomy by respecting the patients' preferred decisional preference (van Dam et al., 2013). Research has found that most patients wish to participate in the selection of their CRC screening test either on their own or in a shared decision with their provider (Dolan & Frisina, 2002). However, one study found only 43% of patients took part in a discussion with their provider about decision making for CRC screening and less than 1% of visits included all elements of shared or informed decision making (e.g., values clarification; Wunderlich et al., 2010). Another study found that only 6% of discussions about CRC screening included an evaluation of the patients' test preferences (Katz et al., 2012).

Ottawa Decision Support Framework

Use of decision aids to assist patients make a decision by helping patients clarify their values and providing several forms of key information (e.g., all available treatment or screening options, risks and benefits of each option) has increased (O'Connor et al., 1998). The Ottawa Decision Support Framework was designed to help researchers develop decision aids that provide sufficient decision support for individuals (O'Connor et al., 1998). The framework is grounded in several theories including the Theory of Reasoned Action (Ajzen & Fishbein, 1980), decisional conflict (Janis & Mann, 1977), decision analysis (Keeney, 1982), social support (Norbeck, 1988), self-efficacy (Bandura, 1982), and values (Fischhoff, Slovic, & Lichtenstein, 1981).

Decision support process. Decision aids using the Ottawa Decision Support Framework are best for decisions that (a) have a new diagnosis or circumstance, (b) have uncertain benefits or risks and require careful deliberation, or (c) require more effort in the decision itself than the behavior to be taken (O'Connor et al., 1998). The Ottawa Decision

Support Framework is organized into a three-step process: (1) assessing the decision support needs of the individual, (2) providing decision support tailored to the individual, and (3) evaluating the individual's satisfaction with their decision making and its outcomes (Murray, Miller, Fiset, O'Connor, & Jacobsen, 2004). This three-step process is designed to provide assurance to health care providers that the quality of individuals' decision making is high.

Decisional needs. The Ottawa Decision Support Framework proposes that the needs of an individual must be identified to successfully help the individual make a decision (O'Connor et al., 1998). This first step of the framework has four categories of decisional needs: perceptions of the decision, perceptions of others, resources to make decision, and characteristics (Murray et al., 2004). Perceptions of the decision include an individual's knowledge and expectations of the resulting behavior (e.g., screening test, treatment option), their values and how they relate to the decision, initial level of decisional conflict, initial stage of decision making, and their predisposition towards choosing an option (Murray et al., 2004).

The individual's *perceptions of others* examines the individual's viewpoint of others' practices and opinions of available choices, support and pressure from others, and the individual's preferred role in the decision making process (Murray et al., 2004). Perceptions of others' practices and opinions is defined as the individual's view of what others in their lives (e.g., family, peers, health provider) think is the appropriate choice for the individual to make. Support is the various forms of support (e.g., tangible, informational) that an individual may receive to help them with their decision making and pressure is the individual's perceptions of persuasion they may receive from important others to choose a particular option (Murray et al., 2004). Lastly, the individual's preferred role in making a

decision is defined as how much an individual wants to be involved in the process, as well as how much they want others to be involved (Murray et al., 2004). There are various resources proposed to influence the decisional support needs of the individual including previous experience with the options, outcomes, or the decision making process. Other resources include their self-confidence (i.e., self-efficacy), motivation, and skill to make a decision. Lastly, external resources that may impact their decisional needs include other resources that may provide various types of support (i.e., informational, instrumental, emotional, appraisal) and the sources of those resources (e.g., social networks, health care services, support groups; Murray et al., 2004). The fourth category is the *characteristics* of both the individual and the provider (Murray et al., 2004). Characteristics applicable to the individual include gender, age, marital status, education, occupation, and health status. Provider characteristics include ethnicity, age, gender, practice location, years of clinical experience, counseling style, and clinical education (Murray et al., 2004). The various components to be assessed help health care providers tailor the decision support to the individual's needs and will ideally lead to a more informed decision that results in a positive evaluation of the decision support (O'Connor et al., 1998). However, while the framework acknowledges that these various components are a vital role in making a decision, the published literature does not have a sufficient understanding of the associations between these components (Manne et al., 2014). Figure 2.1 outlines the theoretical applications of the decisional needs in the proposed study.

Decision support. After assessing the individual's needs, the next step in the Ottawa Decision Support Framework is the provision of tailored decision support from health professionals (O'Connor et al., 1998). When using the framework, the support provided by health providers must match the needs of the individual. The framework outlines four

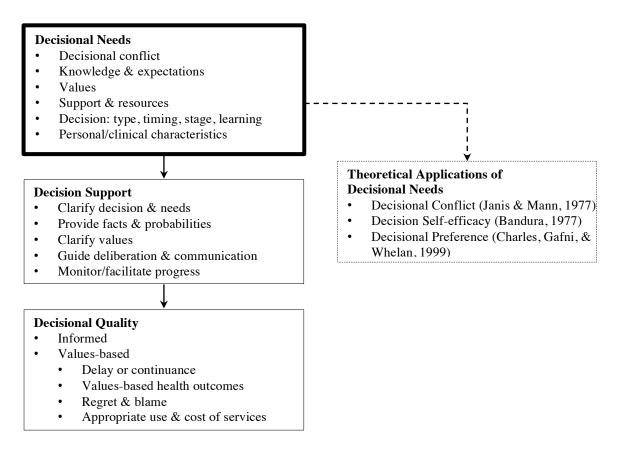


Figure 2.1. Theoretical Application of the Decision Support Framework adapted from the Ottawa Decision Support Framework (O'Connor, 2006)

components to the decision support (Murray et al., 2004). The first component is to *provide* access to information that (a) is specific to the individual's health situation (e.g., screening test, treatment, specific health condition); (b) describes the options they must choose from; (c) identifies the possible outcomes from each option; and (d) gives others' opinions (e.g., family, health care providers; Murray et al., 2004). The second component is to *re-align the individual's expectations of the outcomes*. The individual's outcome expectations are assessed prior to giving decision support and it is important to reassess the individual's expectations after information about their health situation, options, and potential outcomes are provided (Murray et al., 2004). Additionally, clarification of the individual's values is needed to help the individual identify the option that best supports their values (Murray et al.,

2004). Lastly, decision support should provide guidance to the individual for the steps of decision making, how to communicate their options and decision to others, how to handle pressure from others, and how to access resources and support (Murray et al., 2004).

Decisional quality. After receiving decision support, the individual must make their decision (O'Connor et al., 1998). The evaluation does not distinguish between "bad" and "good" decisions (e.g., choosing the "best" treatment option, deciding to not complete a screening test), but rather evaluates the quality and outcomes of the decision making.

Examples of components evaluated related to the individual's decision making includes improved knowledge, reduced decisional conflict, concordance between identified values and the chosen option, and satisfaction with the decision making (Murray et al., 2004).

Components to be evaluated related to the decision outcomes are improved quality of life, continued persistence with the individual's choice, reduced regret and distress, and an informed use of resources (Murray et al., 2004).

Decisional conflict. First proposed by Janis and Mann (1977), decisional conflict is defined as an individuals' "uncertainty about a course of action to take when choice among options involves risk, loss, regret, [and] challenge to personal life values" (p. 3, O'Connor, 2006). Past research has suggested several factors that may contribute to individuals' decisional conflict, including unclear values, lack of information, perceived pressure from others, and skill deficits (O'Connor, 2006). Research has also shown that decision aids help individuals reduce their decisional conflict (Stacey et al., 2011).

Decision aids help to reduce the factors associated with high decisional conflict by providing decisional support to individuals (O'Connor, 1995). These tools assist individuals through three mechanisms: (a) providing information about their options, benefits, risks, and

relevant health information; (b) helping individuals clarify their values; and (c) providing structure to help individuals move through the steps involved in decision making and how to communicate their decision to others (e.g., providers, family; O'Connor, 2006). O'Connor and colleagues (1998) proposes a Decision Support Framework that places decisional conflict in the *client's and practitioner's perceptions of the decision*, alongside knowledge (of the health problem and relevant choices), expectations (i.e., perceived/probable risks and benefits), and values (i.e., individual's importance of risks and benefits). High quality decision making outcomes often includes low decisional conflict for individuals, and other factors such as defined values, sufficient knowledge, and satisfaction with the final decision. This research study uses the definition of decisional conflict as proposed by O'Conner (2006) in the context of the Decision Support Framework.

assessed through the application of decision aids designed to help individuals make sound decisions in medical choices (O'Connor et al., 1998). The current literature has limited application of decisional conflict to CRC screening, however Dolan and Frisina (2002), assessed decisional conflict after the implementation of a patient decision aid for CRC screening and found a reduction in decisional conflict compared to individuals in a control group. The reduced decisional conflict was attributed to increased values clarity, increased knowledge, and greater perceived decision quality. There were no significant differences, however, in CRC screening completion between the two groups (Dolan & Frisina, 2002). Decisional conflict has also been applied to individuals with increased risk for Lynch Syndrome (hereditary nonpolyposis CRC) who are making the decision to complete a microsatellite instability test (diagnostic test for Lynch Syndrome; Hall et al., 2011).

Individuals received either a decision aid or a brief description of the microsatellite instability test. Decisional conflict was significantly reduced for individuals receiving the decision aid through increased knowledge (Hall et al., 2011).

Decisional conflict has also been examined in relation to decision making for breast and prostate cancer screening. Researchers found that women aged 40 to 44 who had low knowledge about mammography had significantly greater levels of decisional conflict compared to women who were more informed about mammography (Nekhlyudov, Li, & Fletcher, 2008). A systematic review of the literature found the use of decision aids to help individuals make a screening decision was associated with decreased decisional conflict for cancer screening (Trikalinos et al., 2014). Another study investigating the effect of a decision aid on decision making among first-degree relatives of prostate cancer survivors found decreases in decisional conflict in both groups (treatment group with decision aid and control group with general decision aid; Davis et al., 2014). Limited research has been published investigating decisional conflict among African Americans—particularly for CRC screening. However, two decision aids targeting prostate cancer informed decision making saw decreases in decisional conflict among African American men in the decision aid treatment groups (K. L. Taylor et al., 2006; Williams et al., 2013).

Decision self-efficacy. Developed by Bandura (1977), self-efficacy is a construct most commonly associated with Social Cognitive Theory (Bandura, 1986). Self-efficacy is defined as an individual's confidence in their ability to influence the events that impact their life (Bandura, 1977). It is proposed that an individual's level of perceived self-efficacy determines if the individual will initiate a behavior, how much effort will be given towards the behavior, and how long the behavior will last (Bandura, 1977). Self-efficacy is shaped by

performance accomplishments (e.g., performance exposure, participant modeling); verbal persuasion (e.g., self-instruction, suggestion); vicarious experience (e.g., live modeling); and physiological states (e.g., attribution, relaxation; Bandura, 1977). For example, under this model an individual who has practiced decision making, viewed others partake in decision making, have verbal feedback from themselves or another individual (e.g., health proivder) as they go through the process, and are relaxed through the process, will have increased self-efficacy to complete the decision making process.

Using the Ottawa Decision Support Framework, clinical trial self-efficacy was a significant predictor of clinical trial preparedness in individuals with a cancer diagnosis (Manne et al., 2014). Further, individuals received an education intervention focused on cancer clinical trial enrollment and those with increased decision self-efficacy were significantly more likely to have reduced decisional conflict (S. M. Miller et al., 2013). Preparation for considering enrollment in a cancer clinical trial mediated the relationship between decision self-efficacy and decisional conflict (S. M. Miller et al., 2013).

Decision self-efficacy in cancer screening. While decision self-efficacy has been evaluated in a variety of cancer screening studies, few have focused on CRC. One study examining perceived risk and self-efficacy found patients who believed they are at average or high risk for CRC and felt they had a high level of information regarding CRC screening reported greater confidence in their screening decision (Hoffman et al., 2014). Due to the inconsistency in screening recommendations and increased attention to informed decision making in prostate cancer (ACS, 2010), many prostate cancer screening studies have examined decision self-efficacy after completion of a decision aid intervention. Researchers evaluating a prostate cancer screening intervention using a computer-based decision aid

found higher decision self-efficacy among men who made an explicit screening decision at baseline compared to men who were undecided in their screening decision (Allen et al., 2011). After the intervention, men completing the decision aid had greater decision self-efficacy compared to men in the comparison group (Allen et al., 2011).

Decision self-efficacy among African Americans. African American men who participated in a prostate cancer screening session presented by a cancer survivor had significantly greater decision self-efficacy compared to men completing a similar session presented by a health educator (Vijaykumar et al., 2013). Additionally African American men had increased decision self-efficacy after completing an educational outreach intervention for prostate cancer in a community setting (Wray, Vijaykumar, Jupka, Zellin, & Shahid, 2011). A church-based prostate cancer screening decision aid intervention developed using the Ottawa Decision Support Framework increased decision self-efficacy among African American men (Drake, Shelton, Gilligan, & Allen, 2010). An additional computer-based decision aid saw increases in decision self-efficacy and decision conflict among African American men in a community setting (Sultan et al., 2014).

Decisional preference. Research has shown that patients traditionally relied on a paternalistic decision-making style with their providers (Charles et al., 1999). A paternalistic decision making style relies on the provider (e.g., physician, nurse) to make medical decisions on behalf of the patient. This dominant decision making style persisted until the 1980s and was grounded by certain assumptions: (a) there was only one single best treatment and physicians were knowledgeable of the best treatment, (b) physicians were consistent in their treatment application across patients, (c) physicians were in the best position to determine tradeoffs between different treatment options, and (d) physicians were concerned

for their patients well being and were invested in treatment decisions (Charles, Gafni, & Whelan, 1997).

This decision making style became less prominent in the 1980s as several developments emerged including increased choice between treatment options, recommendation differences for various populations, concern for increasing health care costs (Charles et al., 1999), and more recently, increased gathering of health information from other sources such as the Internet (Fox & Duggan, 2013). Two other decision making styles have since become more commonly preferred by patients: shared and informed (Charles et al., 1999). The shared decision making style involves both the provider and patient deciding together, ideally with the two parties agreeing on one treatment or screening test choice (Charles et al., 1999). The informed decision making style occurs when the provider gives all necessary information to the patient, and/or the patient obtains information from other sources (e.g., Internet, other media, family), and the patient makes the final decision (Charles et al., 1999).

Decisional preference is a critical part to decision making as individuals need to identify how involved they wish to be in the process, and ideally, they must convey this to their provider. If the patient and the provider are not following the same decision making style (e.g., provider prefers paternalistic while patient prefers shared), conflict may arise (Charles et al., 1997). When two parties are not 'on the same page,' the resulting tension may lead to poor outcomes including a poor evaluation of the decision by the patient (e.g., unclear values, dissatisfaction with the decision making process, increased regret and distress) and increases the likeliness of delayed or no screening (O'Connor et al., 1998). Ideally, if a patient does not convey their preferred decision making style, the provider should take the

steps to assess the preferred decision making and discuss how they will use this preferred style (O'Connor et al., 1998). No one decision making style is 'better' than another (Charles et al., 1999), and providers should assure patient autonomy by respecting the patients' preferred decisional preference (van Dam et al., 2013).

Decisional preference among African Americans. African American patients have shown greater interest in being involved in the decision making process for CRC screening than White patients (Messina et al., 2005). African American patients, however, have overall lower CRC screening knowledge, no past history of shared or informed decision making for cancer screening, and often do not have the same opportunity from their provider to have any control over their decision making outcome compared to White patients (Messina et al., 2005). Among average-risk African Americans between the ages of 50 and 75, slightly more than half (55%) preferred shared decision making with a provider over a patient-dominant decision making model (i.e., individual prefers to make decision primarily on their own; 28%) or provider-dominant decision making model (i.e., individual prefers a provider makes the screening decision; 16%). No statistically significant differences were found when compared to other races/ethnicities (i.e., Black, White, Hispanic, and "other"; Schroy III et al., 2007).

Mistrust towards health professionals has been well documented in the African

American community (Agrawal et al., 2005; Greiner, Born, Nollen, & Ahluwalia, 2005; K.

A. Griffith, Passmore, Smith, & Wenzel, 2012; Lumpkins et al., 2015; Purnell, Katz,

Andersen, & Bennett, 2010) and may be related to decisional preference (Entwistle, 2004).

African Americans with diabetes cited trust as a factor in their decisional preference (Peek et al., 2013). Another study found individuals who had greater trust in their provider were more

likely to prefer a shared decision, while those who had less trust preferred to make their own decisions. Greater levels of mistrust are associated with reduced intention to complete CRC screening (Purnell et al., 2010). African Americans from an urban community health center identified mistrust as a barrier to CRC screening and also expressed (a) they did not want to be 'an experiment' and (b) it is up to the patient to be an advocate for themselves (Greiner et al., 2005). Two studies cited participants' views of their health providers caring more about money than patients (Greiner et al., 2005; Lumpkins et al., 2015). Additionally, individuals with a family history of CRC felt providers do not treat African American patients as well as other patients (K. A. Griffith et al., 2012).

Colorectal cancer test preference. Concordance between provider recommendation and patient test preference for CRC screening can contribute to low rates of screening completion and understanding patient preferences may increase receptivity to CRC screening (Hawley et al., 2012). Researchers have found conflicting preferences for certain CRC screening tests (Leard et al., 1997; Pignone et al., 1999; Powell et al., 2009; Ruffin IV et al, 2007; Sheikh et al., 2004; Wolf et al., 2006). Immediately after participation in an interactive electronic decision tool for CRC screening—compared to a standard, informational CRC website—individuals were more likely to have a CRC screening test preference. This preference, however, did not persist to follow-up 6 months later (Ruffin IV et al., 2007).

Additionally, individuals who completed the interactive electronic decision tool were more likely to be screened for CRC, but an additional analysis found the decision tool may have increased screening test completion, as just having a CRC test preference alone was not significantly predictive of screening test completion (Ruffin IV et al., 2007). Similarly, after reading descriptions of three CRC screening tests (FOBT, sigmoidoscopy, and colonoscopy)

the majority of patients surveyed at a community hospital (82%) preferred to be screened for CRC (Sheikh et al., 2004). Individuals were significantly more likely to prefer to be screened if they had at least a high school education or knew someone with colon polyps or colon cancer (Sheikh et al., 2004).

While some researchers have found colonoscopy to be preferred most often (Powell et al., 2009), others have found FOBT to be more commonly favored (Pignone et al., 1999; Wolf et al., 2006). Additionally, other studies have found only marginal differences between preference for colonoscopy and FOBT (e.g., Leard et al., 1997). Among primary care patients between the ages of 50 and 75, no one CRC screening test was dominantly preferred: colonoscopy was marginally preferred (38%) over FOBT (31%) followed by barium enema (14%) and sigmoidoscopy (13%; Leard et al., 1997). However, another study among U.S. veterans aged 50 to 75 found 37% of respondents preferred colonoscopy, 29% preferred FOBT, and only 5% preferred sigmoidoscopy, while the remaining individuals expressed no preference, preferred a different screening test (i.e., barium enema), or did not want screening (Powell et al., 2009). Additionally, individuals with greater perceived susceptibility, as well as lower educational attainment (i.e., no college education) and lower income, were more likely to prefer colonoscopy compared to other screening options (Powell et al., 2009).

When asked if patients preferred sigmoidoscopy every 5 years with yearly FOBT or colonoscopy every 10 years (consistent with screening procedures available for this patient population in a community hospital) approximately half of respondents preferred sigmoidoscopy with FOBT (55%), 29% preferred colonoscopy, and 16% did not want to be screened. Individuals who previously had a colonoscopy were significantly more likely to prefer colonoscopy. Additionally, while the relationship was not significant, individuals who

previously had sigmoidoscopy were slightly more likely to prefer colonoscopy (Sheikh et al., 2004).

After given information about FOBT, sigmoidoscopy, and colonoscopy and asked for their test preference, individuals between the ages of 50 and 75 mostly preferred FOBT alone (45%), followed by FOBT with sigmoidoscopy (38%) and sigmoidoscopy alone (13%), while only 1% of individuals preferred colonoscopy (Pignone et al., 1999). The percentage of individuals preferring FOBT with sigmoidoscopy increased to 47% when individuals were told they would have no out-of-pocket costs for any of the screening tests. However, the percentage preferring FOBT with sigmoidoscopy decreased to 31% and the percentage preferring FOBT alone increased to 53%. when told they would have out-of-pocket costs. Individuals who had previously been screened for CRC using any testing method were significantly more likely to prefer both FOBT and sigmoidoscopy (Pignone et al., 1999).

Similarly, a majority of CRC screening age-eligible urban adults preferred FOBT after receiving a description of FOBT, sigmoidoscopy, and colonoscopy from a health educator (90%; Wolf et al., 2006). Individuals with household incomes of \$50,000 or less were significantly more likely to prefer FOBT than individuals with household incomes greater than \$50,000 (93% and 79%, respectively). The most cited reason for preferring FOBT among participants was convenience and among the 6% who preferred colonoscopy, did so because they felt it was the most accurate and reliable test. At a six-month follow-up, 59% of participants completed the CRC screening test they initially indicated they preferred, and 41% were screened for CRC but had a different screening test than preferred. The most common reason cited for the change in screening test was due to a provider recommendation that was different from their preferred screening test.

Test preference among African Americans. Research examining CRC screening test preference among African Americans has most commonly been completed in larger analyses of populations with varying races and ethnicities. Additionally, research to date has not examined the association of social determinants of health on CRC screening test preference solely within an African American population. For example, 49% of respondents self-identified as African American in the research completed by Dolan and colleagues (2013), however no statistically significant differences were found between racial/ethnic groups. Similarly, when examining CRC test preferences between race/ethnicities, Shokar and colleagues (2010) did not find any consistent preference differences within subgroups. Studies that focus on an African American population may be able to elucidate variations in CRC screening preferences that may assist future research targeting screening behaviors in this population.

In a sample of US veterans, Black veterans (14% of the study population) were 20% less likely to prefer FOBT and 48% more likely to express no screening test preference than White veterans (Powell et al., 2009). Additionally, Black veterans had overall greater preference for colonoscopy compared to other screening test options. Schroy III and colleagues (2007) found African Americans were three times as likely to prefer colonoscopy and 75% less likely to prefer FOBT compared to Whites. Overall, 70% of African Americans preferred colonoscopy over FOBT (16%) and stool DNA testing (14%).

While the percentage of African Americans was not high enough to allow for a separate analysis, patients at a community hospital who were grouped as race/ethnicities other than White or Hispanic were significantly more likely to prefer colonoscopy (73%) than the combination of sigmoidoscopy and FOBT (26.5%; Sheikh et al., 2004). Conversely,

91% of African Americans in the research conducted by Wolf and colleagues (2006)—70% of the study population—preferred FOBT over colonoscopy or sigmoidoscopy. There were no statistically significant differences in preference for FOBT between African Americans and other racial/ethnic groups.

Focus groups were conducted with African American and White participants about the pros and cons of different CRC screening tests (colonoscopy, FOBT, barium enema, and sigmoidoscopy; Ruffin IV et al., 2007). Following the focus groups, individuals privately identified their preferred CRC screening test. Over half of African Americans (55%) most favored colonoscopy, followed by FOBT (30%), barium enema (12%), and sigmoidoscopy (3%). Additionally, no statistically significant differences between races were found.

Health Literacy

Health literacy is the "degree to which an individual has the capacity to obtain, communicate, process, and understand basic health information and services to make appropriate health decisions" (CDC, 2015). Health literacy has been found to have an impact on the health promotion of populations as decreased health literacy can limit access to health care information and services, as well as participation in health programs (NAS, 2015). While the influence of health literacy has been identified for certain health outcomes, many relationships between health literacy and outcomes have not been identified (NAS, 2015). The U.S. has placed an emphasis on increasing health literacy among the population and Healthy People 2020 has included a health literacy objective with the goal to increase the number of individuals who are able to understand the instructions provided by their health care provider (DHHS, 2015).

The field of health literacy has continuously been developed and redefined since the 1980s (Pleasant & Kuruvilla, 2008). The clinical approach to health literacy used in the present study focuses on the communication between a provider and their patient and how to reduce limitations in patient-provider communication (Pleasant & Kuruvilla, 2008). This approach to health literacy measures fundamental literacy skills (e.g., knowledge of clinical terminology, numeracy) and helps to ensure the patient-provider encounter concludes in each party's full comprehension of one another (Pleasant & Kuruvilla, 2008). The 1999 definition of health literacy from the American Medical Association's (AMA) Ad Hoc Committee on Health Literacy (1999) demonstrates the clinical approach to health literacy: "the constellation of skills, including the ability to perform basic reading and numerical tasks required to function in the health care environment" (p. 553). From this approach, health literacy can be viewed as a risk factor, where low health literacy impacts the patient-provider interaction in a clinical setting (Nutbeam, 2008). Using the definitions provided by the CDC (2015) and Ad Hoc Committee on Health Literacy (1999), this research study focuses on the relationship between individuals' fundamental literacy skills and indicators of decision making for CRC screening.

Health literacy and indicators of decision making. Limitations in adults' retention of messages verbatim were identified through a qualitative study assessing individuals' ability to understand spoken—versus written—cancer messages (Mazor et al., 2010). After hearing the cancer message, however, adults had greater ability to restate the 'gist' of the message. The reduced ability to retain and restate spoken messages highlights the difficulty individuals with low health literacy may have when hearing health-related messages in spoken form. As providers often have low ability to judge their patients' health literacy skills

(Rogers, Wallace, & Weiss, 2006), these findings have potential implications on the difficulty providers have when conveying important health information to their patients (Mazor et al., 2010). In the past, providers have received little, if any, training for communicating important information to patients with low health literacy. In recent years, researchers have begun developing and implementing training interventions aimed at increasing providers' skills and comfort level (Price-Haywood, Harden-Barrios, & Cooper, 2014; Ripath, Greene, & Weise, 2007).

Providers who received an educational session helping them communicate with low-literacy individuals—literacy skills less than a ninth grade level—were able to obtain FOBT completion rates higher than providers who did not receive training (56% and 30%, respectively; Ferreira et al., 2005). However, while an intervention that provided skills training for providers to improve communication to individuals with low health literacy increased communication about cancer risk and shared decision making for CRC screening, providers who received the training did not have significantly higher patient CRC screening rates than providers who did not receive the skills training (Price-Haywood et al., 2014). Unlike the study completed by Ferreira and colleagues (2005), CRC screening tests include FOBT, sigmoidoscopy, colonoscopy, and barium enema (Price-Haywood et al., 2014).

Health literacy and colorectal cancer screening. While limited health literacy can have an impact on an individuals' understanding of general cancer risk and screening information, CRC has its own unique challenges. The current CRC screening test instructions typically provided for patients can be complicated to understand and often requires multiple steps (Vernon & Meissner, 2008). The current literature often focuses on just FOBT

screening tests as this has been widely considered the most feasible method for CRC screening because of insurance and cost concerns (Arnold et al., 2012).

Most participants (96%) surveyed at Federally Qualified Health Centers had heard of CRC, however individuals with low health literacy were significantly less likely to know someone who has been diagnosed with CRC, think finding CRC early is helpful, or have seen/heard an advertisement promoting CRC screening (Arnold et al., 2012). Approximately half of this population had low health literacy—men and those residing in urban areas were significantly more likely to be low literate. When asked about specific CRC screening tests, individuals with low health literacy were significantly less likely to have heard of any CRC screening tests. For those participants who could name specific CRC screening tests, individuals with low health literacy were more likely to name FOBT than individuals with adequate health literacy (Arnold et al., 2012).

Conversely, individuals with adequate health literacy were more likely than individuals with low health literacy to name colonoscopy (Arnold et al., 2012). Individuals with low health literacy were significantly less likely to have high perceived benefits of CRC screening, had lower self-efficacy to obtain an FOBT kit, and had greater perceived barriers to screening. Providers also significantly differed in their CRC screening recommendations to individuals with low and adequate health literacy. Individuals with low health literacy were significantly more likely to receive recommendations for FOBT and significantly less likely to receive recommendations for colonoscopy (Arnold et al., 2012).

Patients surveyed at four community clinics were significantly less likely to have heard of CRC, FOBT, sigmoidoscopy, or colonoscopy if they had low health literacy (Guerra et al., 2005). Individuals with low health literacy were also significantly less likely to identify

the differences between a colonoscopy and sigmoidoscopy, when individuals should begin CRC testing, and how often individuals should be screened using colonoscopy or sigmoidoscopy. Somewhat similarly to the findings of Arnold and colleagues (2012), individuals with low health literacy were significantly less likely to have received encouragement to be screened with any screening test (i.e., FOBT, sigmoidoscopy, or colonoscopy). Arnold and colleagues (2012), however, found individuals with low health literacy were more likely to have received a recommendation for FOBT. Lastly, individuals with low health literacy were significantly less likely to want to know if they have cancer (Guerra et al., 2005). However, there were no significant differences between individuals with low and adequate health literacy in other attitude items (e.g., embarrassment towards CRC screening, perceived harm and pain). Individuals who have never been screened did not significantly differ between health literacy levels in their reporting that a provider recommendation for CRC screening would motivate them to get screened for CRC (Guerra et al., 2005).

Similar findings among male veterans ages 50 and older were identified where individuals with limited health literacy were significantly less likely to have heard of CRC or any type of CRC screening tests (FOBT and sigmoidoscopy specifically; Dolan et al., 2004). Limited health literacy was also a significant predictor of increased perceived susceptibility, increased concerns about FOBT (i.e., worried FOBT is messy or inconvenient). However, unlike Guerra and colleagues (2005), male veterans with limited health literacy were less likely to get an FOBT if recommended by a provider (Dolan et al., 2004). Additionally, participants with less than a high school education were almost four times as likely to have limited health literacy compared to those with a high school diploma or greater.

Adults age 50 and older from a community health clinic in an underserved community were significantly more likely to have limited health literacy if they had Medicaid (versus Medicare or both insurance types) and less than a ninth grade education (Peterson, Dwyer, Mulvaney, Dietrich, & Rothman, 2007). Individuals with limited health literacy were also significantly more likely to have greater reported barriers to FOBT or colonoscopy. There were no significant differences however, in reported completion of CRC screening for individuals either current with CRC screening recommendations or ever having been screened for CRC (Peterson et al., 2007).

Adults aged 40 to 75 were surveyed in the HMO Cancer Research Network for their health literacy and cancer screening behaviors (Morris et al., 2013). Individuals with low health literacy had significantly lower listening, numeracy, and subjective reading skills. Individuals with low health literacy were more likely to avoid visiting health providers and had greater fatalistic views on cancer prevention and cancer overall and reported significantly less control over their health. However, individuals with adequate or high health literacy were significantly less likely to avoid information about illnesses they did not currently have and were significantly more likely to seek information about cancer prevention and screening from sources other than health providers (e.g., Internet, friends, family). Additionally, those with low health literacy were significantly less likely to have heard of colonoscopy—the only CRC screening test assessed—and somewhat, although not significant, less likely to be upto-date with CRC screening (Morris et al., 2013).

Health literacy was not a significant predictor of CRC screening for adults aged 50 to 64 participating in a large national survey (White, Chen, & Atchison, 2008). Adults age 65 and older, however, were significantly less likely to have been screened for CRC if they had

lower health literacy. A smaller study of 42 individuals found no significant differences between low and high health literacy in CRC screening rates (Liu, Fleck, Goldfarb, Green, & Porter, 2011). No significant differences in CRC screening were found between patients at a large university hospital with limited or adequate health literacy (D. P. Miller, Brownlee, McCoy, & Pignone, 2007). Additionally, individuals with less than a high school education were significantly more likely than individuals with a high school education or greater to have limited health literacy. Individuals with limited health literacy and those with less than a high school education were significantly less likely to name or describe a CRC screening test (D. P. Miller et al., 2007).

Health literacy among African Americans. Lower rates of health literacy among

African Americans have been identified across multiple studies (Arnold et al., 2012; Dolan et al., 2004; D. P. Miller et al., 2007; Morris et al., 2013; Peterson et al., 2007). Many of these studies were located in health clinics within underserved communities (Arnold et al., 2012; Dolan et al., 2004; Morris et al., 2013; Peterson et al., 2007), which may limit the generalizability of these studies to more heterogenous African American populations. D. P. Miller and colleagues (2007) research located in a large university hospital found African Americans—who were more likely to have low health literacy—were less likely to name or describe a CRC screening test compared to Whites.

Chapter 3: Methods

Study Overview

While research has begun to identify social determinants of health associated with decision making—and particularly shared decision making between patients and providers—there are still many factors that have not yet been investigated. Within the subfield of CRC research, there is limited research examining predictors of decision making indicators (e.g., decisional conflict, decisional preference) among African Americans. As the field moves towards development of tools designed to increase shared and informed decision making and subsequent screening test completion, a thorough understanding of the social determinants of health impacting decision making in this population is necessary. Therefore, this study examines social determinants that have been identified as related to CRC screening behavior, but not previously examined in the context of decision making for CRC screening. Findings may help inform future research identifying mechanisms for the development tools that may increase CRC screening test completion among African Americans.

Study Design

The study is ancillary to an on-going project using data from participants enrolled in a parent study with an additional seed grant study [known to participants as *A Focus on Colorectal Cancer Early Detection* (Focus on CRC)]. The parent project was Project HEAL (*Health through Early Awareness and Learning*), a church-based cancer early detection implementation trial in African American churches (Holt et al., 2014). The seed grant collected data from a subset of Project HEAL participants, focusing on health literacy and CRC informed decision making.

Conceptual Models

The first four aims of the study examined the relationship between health literacy and four indicators of decision making: decisional conflict, decision self-efficacy, decisional preference, and CRC test preference. Within each aim, the potential moderation of age and gender was also examined. The conceptual models for each aim are displayed in Figure 3.1.

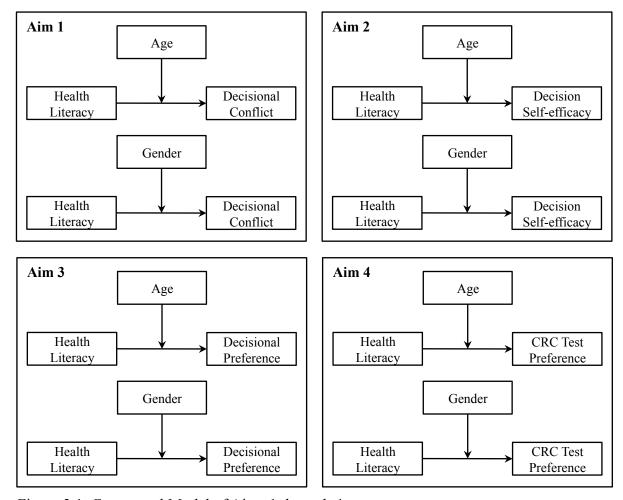


Figure 3.1. Conceptual Model of Aims 1 through 4

As the fifth aim of the study examines correlates to indicators of decision making, a conceptual model would not be appropriate.

Project HEAL. Community Health Advisors (CHAs) from 14 churches in Prince George's County, Maryland were trained to deliver a 3-part workshop series focusing on

breast, prostate, and colorectal cancer to congregants in their own churches. Project HEAL combined three evidence-based interventions into one overarching package to be delivered in three workshops. The first workshop provided an overview of cancer, the second workshop focused on breast and prostate cancer (men and women broke into two different groups), and the third workshop discussed CRC.

As an implementation trial, Project HEAL aimed to compare two methods of training lay peer CHAs who then led the 3-part workshop series. Churches enrolled in the study were randomized into two study conditions: technology-based CHA training versus traditional classroom CHA training. Churches in the technology-based condition had CHAs trained using a web-based CHA training website, while churches in the traditional classroom condition had CHAs trained through in-person classroom sessions (Santos et al., 2014).

Study Site

Churches participating in Project HEAL all self-identified as African American churches and had a mean of 226 adult congregation members (SD = 181), 173 of whom attended weekly (SD = 129). Project HEAL was primarily developed for individuals born in the U.S. who have "origins in any of the Black racial groups of Africa" (U.S. Census Bureau, 2013). Per an in-depth discussion in an advisory panel meeting, it was determined that churches self-identifying as "Black"—versus "African American"—may have a higher percentage of congregation members born in other countries. The term African American was then used instead of Black for church recruitment to differentiate churches with congregation members primarily born in the U.S. Churches were predominately Baptist (n = 4), followed by non-denominational (n = 3) and African Methodist Episcopal (n = 2). Most of the churches had established health ministries before enrollment in Project HEAL (n = 9)

and 12 churches—regardless of health ministry status—had completed a mean of seven health activities within the past two years (SD = 5).

Study Sample

Eligibility. The sample for the study was a convenience sample of Project HEAL participants. Participants were eligible for the Focus on CRC seed grant and the proposed study if they (a) enrolled in Project HEAL, (b) were between the ages of 50 and 75 at time of Project HEAL enrollment, (c) attended one of the 14 churches who completed the Project HEAL 12-month follow-up workshop within the present study's data collection timeline, and (d) completed the Project HEAL baseline and 12-month surveys. Participants were eligible to enroll in Project HEAL if they (a) self-identified as African American, (b) were between the ages of 40 and 75, and (c) had no personal history of breast, prostate, or colorectal cancer.

Recruitment and informed consent. Project HEAL participants were recruited by Project HEAL CHAs in their churches. CHAs used a variety of methods to recruit participants including announcements during Sunday service, ministry meetings, and church bulletins, word-of-mouth, emails, and text messages. While CHAs were encouraged to have participants enroll at workshop one, participants were able to enroll at any of the three Project HEAL workshops. CHAs were responsible for their own reminder methods to maintain participant attendance throughout the three workshops.

Participants were recruited for the Focus on CRC seed grant study through an initial mailing with a recruitment letter asking participants to complete and mail back the enclosed survey using the provided pre-addressed and stamped envelope. The mailing also informed participants to contact study staff via mail, telephone, or email if they prefer to take the survey via telephone or online. If participants did not mail the survey back within two weeks,

research staff called participants up to three times and asked participants (a) to mail back the survey, (b) if they would like us to resend the survey, or (c) to complete the survey over the telephone. After three calls, participants were contacted via email and invited to complete the survey (a) online using Qualtrics or (b) via telephone by calling study staff. Participants received a \$25 Target gift card upon completion of each survey.

The University of Maryland, College Park Institutional Review Board (IRB) approved the proposed study and the Focus on CRC seed grant through an addendum submitted under the parent grant (Project HEAL; Appendices B and C). Participants completed informed consent at time of Project HEAL enrollment (Appendix D) and the recruitment letter (Appendix E) informed participants who by completion of the Focus on CRC survey, they consented to the survey.

Sample description

Project HEAL had 203 participants currently enrolled between the ages of 50 and 75 who were eligible to complete the Focus on CRC seed grant survey. The mean age of these participants was 60.1 (*SD* = 6.97). The majority of the participants were female (65%), married (50%), and employed full-time (45%). Most of the participants had a high school education or greater (93%) with 27% holding a 4-year degree. The median income was \$50,001-\$60,000. Participants were asked about their CRC screening history (FOBT, sigmoidoscopy, and colonoscopy) in the baseline survey. Most had heard of colonoscopy (91%) and FOBT (63%) while only 38% had heard of sigmoidoscopy. Participants were asked about their screening history for each test if they had heard of that particular test (71% have ever had a colonoscopy, 54% have ever had a sigmoidoscopy, and 62% have ever had FOBT). Overall, 24% had never been screened for CRC.

Focus on Colorectal Cancer study sample. The final study sample for Focus on CRC consisted of 111 participants with a mean age of 60.8 (SD = 7.0; Table 3.1). The participants were predominately female (69.3%), married (53.2%), and had at least some college (36.4%) or a college degree (28.2%). Most participants were employed full-time (41.4%) and had private health insurance (41.4%). At Project HEAL baseline, the participants had a mean CRC knowledge score of 7.5 (SD = 1.7; maximum score = 9). The most common CRC screening tests participants had ever completed at Project HEAL baseline was colonoscopy (68.5%) followed by FOBT (40.5%) and then sigmoidoscopy (28.8%). A comparison of responders and nonresponders for eligible Project HEAL participants found significant differences in CRC knowledge and workshop attendance (both overall and at the CRCspecific workshop; ps < .05). The responders had greater CRC knowledge, attended an overall greater number of workshops, and had a higher percentage in attendance at the CRCspecific workshop compared to nonresponders (ps < .05). This suggests that responders of the Focus on CRC survey may have been more engaged in Project HEAL and more knowledgeable about CRC screening than nonresponders.

Data Collection

Background variables and family CRC history were collected in the Project HEAL baseline survey (Appendix F). The survey was completed upon participant enrollment at any of the three workshops. The baseline survey was administered as a paper-and-pencil survey and took approximately 40 minutes for participants to complete. Project HEAL research staff was available to assist participants as needed.

Table 3.1. Demographics Characteristics of Eligible Project HEAL Responders and Nonresponders

Table 3.1. Demographics Characteristics of Eligible Project HEAL Responders and Nonresponders					
		Eligible	Eligible		
	Total	Nonresponders	Responders		
	(n = 203)	(n = 92)	(n = 111)		
Characteristic	n (%) or $M \pm SD$	n (%) or $M \pm SD$	n (%) or $M \pm SD$		
Age	60.1 ± 6.8	59.4 ± 6.6	60.8 ± 7.0		
Gender					
Female	57 (28.1)	26 (28.3)	70 (69.3)		
Male	146 (71.9)	66 (71.7)	31 (30.7)		
Marital status					
Married	97 (48.5)	38 (42.7)	59 (53.2)		
Single	48 (24.0)	20 (22.5)	28 (25.2)		
Other	55 (27.5)	31 (34.8)	24 (21.6)		
Education					
< High school diploma	16 (8.0)	6 (6.7)	10 (9.1)		
High school diploma	59 (29.5)	30 (33.3)	29 (26.4)		
Some college	75 (37.5)	35 (38.9)	40 (36.4)		
College degree	50 (25.0)	19 (21.1)	31 (28.2)		
Employment					
Full-time	84 (41.4)	37 (40.2)	47 (42.3)		
Part-time	18 (8.9)	10 (10.9)	8 (7.2)		
Disabled	15 (7.4)	6 (6.5)	9 (8.1)		
Retired	65 (32.0)	27 (29.3)	38 (34.2)		
Not currently	21 (10.3)	12 (13.0)	9 (8.1)		
Health Insurance ⁺					
Private	100 (49.3)	50 (54.3)	50 (45.0)		
Medicare/Medicaid	32 (15.8)	14 (15.2)	18 (16.2)		
Other	20 (9.9)	8 (8.7)	12 (10.8)		
Multiple	42 (20.7)	15 (16.3)	27 (24.3)		
None	9 (4.4)	5 (5.4)	4 (3.6)		
CRC knowledge (max score = 9)*	7.0 ± 2.2	6.6 ± 2.5	7.5 ± 1.7		
Ever had FOBT ^a	81 (39.9)	36 (39.1)	44 (40.5)		
Ever had sigmoidoscopy ^a	51 (25.1)	19 (20.7)	32 (28.8)		
Ever had colonoscopy ^a	138 (68.0)	62 (67.4)	76 (68.5)		
Attended CRC WS ^{a*}	99 (48.8)	38 (41.3)	61 (55.0)		
WS attendance $(max score = 3)^*$	1.9 ± 0.8	1.8 ± 0.8	2.0 ± 0.8		
First-degree family history of CRC ^{a+}	27 (13.3)	17 (18.5)	10 (9.0)		

Notes: CRC = colorectal cancer, FOBT = fecal occult blood test, WS = workshop. abinary variable with 0 = no and 1 = yes.

Focus on Colorectal Cancer survey protocol. The independent and dependent variables were collected in the Focus on CRC seed grant survey (Appendix G). The survey was administered approximately two months after participants' completion of the Project HEAL 12-month follow-up workshop. This time frame was chosen to minimize participant burden. The survey took approximately 10 minutes to complete via telephone or online. The

 $p^+ < .10, p^* < .05, p^* < .001$

research staff was unable to determine the time needed to complete the survey via paper-andpencil.

Measures

Independent variable

Health literacy was measured using four items modified from the Short Test of Functional Health Literacy (STOFHLA) and the Rapid Estimate of Adult Literacy in Medicine (REALM; Chew, Bradley, & Boyko, 2004) and an additional modified item. These items have been previously used among diverse populations (Halverson et al., 2013) and unlike other health literacy assessments, allows for respondent self-administration—other measures require an interviewer-administered format (Baker, Williams, Parker, Gazmararian, & Nurss, 1999; Davis et al., 1993; Parker, Baker, Williams, & Nurss, 1995) and as a result, were not suitable for the study protocol.

The three items from the STOFHLA asked "how often do you have problems learning about your medical condition because of difficulty understanding written information," "how often do you have someone help you read hospital materials," and "how confident are you filling out medical forms by yourself?" A fourth item was added to this set of items to better fit the participant population as the item asking about hospital materials may not be suitable to a community-based participant population: "How often do you have someone help you read medical information?" The response items for these items was a five-point Likert-type scale: *never* (1), *occasionally* (2), *sometimes* (3), *often* (4), and *always* (5). The last item from the REALM asked "How confident are you filling out medical forms by yourself?" and was also measured on a five-point Likert-type scale from *not at all confident* (1) to *very confident* (5). Three items were reverse coded to indicate a higher score as having

greater health literacy and a total sum was calculated from the five items (maximum score = 25). The scale was assessed for reliability with the newly added item (α = .74).

Moderator variables

Age was assessed through a single item asking for participants' date of birth at enrollment and then transformed into a continuous item by calculating the age of the participant on the date of enrollment. The item was dichotomized into two groups for the moderation analyses and stratified analysis by subgroup: 50-64 (0) and 65-75 (1). The continuous item was used as a covariate in the main analyses when either (a) not analyzed as a moderator or (b) within the stratified analysis for age.

Gender was assessed through a single dichotomous item that was identified by the participant during enrollment and coded *male* (0) or *female* (1).

Dependent variables

Decisional conflict was assessed using a low-literacy ten-item scale (O'Connor, 2010). While a longer 16-item is available, due to the inclusion of a health literacy assessment—and potentially lower health literacy of some participants—and to reduce participant burden (Nunnally & Bernstein, 1994), the shorter low-literacy ten-item scale was used. In addition to fewer items on the low-literacy scale, this scale has only three response options compared to five on the original. Example items include "do you know which options are available to you," "do you know the benefits of each option," and "do you have enough advice to make a choice?" The response options for each item was yes (4), no (0), and unsure (2).

The scale score is calculated by summing the items, dividing by ten and multiplying by 25 and ranges from 0 (no decisional conflict) to 100 (extremely high decisional conflict;

O'Connor, 2010). The low-literacy scale had acceptable reliability ($\alpha > .80$) in a population of 149 men (73.6% Black or African American) in a prostate cancer screening decisional aid intervention (Linder et al., 2011) and good reliability in the current study population ($\alpha = .93$).

Decision self-efficacy was measured using an 11-item Likert-type scale (O'Connor, 2002). Each item was measured on a five-point scale from *not at all confident* (0) to *very confident* (4). Sample items include "I feel confident I can express my concerns about each choice," "ask for advice," and "delay my decision if I feel I need more time." The scale is scored by summing the items, dividing by 11, and multiplying by 25 and scores range from 0 (not at all confident) to 100 (very confident). The decision self-efficacy scale was found to have good reliability (α = .92) in women making medical decisions regarding osteoporosis treatment (Bunn & O'Connor, 1996) and demonstrated good reliability in the study population (α = .94).

Decisional preference was assessed using a single item that asked respondents "Who would you prefer to make decisions about colorectal cancer screening?" The item has previously been used in a community-based sample CRC screening decision making study (Messina et al., 2005). The original item had four response options: (a) I prefer to make decisions about CRC screening after seriously considering my doctor's opinion, (b) I prefer to make decisions about CRC screening, (c) I prefer that my doctor and I share the responsibility for decisions about CRC screening, and (d) I prefer to leave all decisions about CRC screening to my doctor. As the Focus on CRC seed grant study included measures of social support, the item was modified to include three additional items referring to the respondent's family and friends: (a) I prefer that my family and I share the

responsibility for decisions about colorectal cancer screening, (b) I prefer to leave all decisions about colorectal cancer screening to my family, and (c) I prefer that my friends and I share the responsibility for decisions about colorectal cancer screening.

The majority of participants chose *I prefer to make decisions about colorectal cancer screening after seriously considering my doctor's opinion* (48%, n = 47) or *I prefer that my doctor and I share the responsibility for decisions about colorectal cancer screening* (44%, n = 43), while 5.1% chose *I prefer to make decisions about colorectal cancer screening* (n = 5) and 3% chose *I prefer that my family and I share the responsibility for decisions about colorectal cancer screening* (n = 3). As a result, the item was recoded to a dichotomous variable for those responding to either an informed choice (*I prefer to make decisions about colorectal cancer screening after seriously considering my doctor's opinion*, coded as 0) or shared choice (*I prefer that my doctor and I share the responsibility for decisions about colorectal cancer screening*, coded as 1).

Colorectal cancer test preference was assessed using a single item ("Now that you have heard descriptions of all four colon cancer screening tests, which one would you prefer to get, if you had a choice?"). The single item has been used in a previous study identifying CRC screening test preference in a population with a large African American sample size (47%; Hawley et al., 2012). Five categorical response options were adapted to Project HEAL CRC content: FOBT, sigmoidoscopy, colonoscopy, "other," and don't know/not sure.

Following the same protocol used in Project HEAL and a previous church-based CRC screening intervention (Holt et al., 2012), descriptions and pictures of each screening test will be provided to ensure full understanding of each screening test option. The descriptions were based on those provided in the Behavioral Risk Factor Surveillance System (CDC, 2006).

62% of respondents chose colonoscopy (n = 62) and 23% chose FOBT (n = 23), while only 15% chose sigmoidoscopy, other, or don't know/not sure (n = 15). As a result, the variable was recoded to a dichotomous variable with two response options: FOBT (0) and colonoscopy (1).

Covariates included in the analysis are age, gender, marital status, education, employment status, health insurance status, CRC knowledge, and CRC screening status. All items were assessed on the Project HEAL baseline survey.

Marital status was assessed through a single categorical item with five response options: *single, living with partner, married, separated or divorced,* and *widowed*. Marital status was recoded into three categories: *married, single,* and *other*.

Education was assessed using a single ordinal item ("What is the highest grade or year of school you have completed?") with five response options: elementary (1), some high school (2), high school graduate (3), some college or technical school (4), and college graduate (5). The item was recoded collapsing elementary and some high school into one category (less than a high school diploma), while the other three response options remained the same.

Employment status was assessed through a single categorical item ("Do you currently work for pay outside of the home?") with five response options: *full-time, part-time, not currently, I'm retired,* and *I'm receiving disability.*

Health insurance status was assessed through four dichotomous items with yes and no as the two response options for each item and instructions for participants to mark all that apply. Participants were asked "Which, if any, types of health insurance do you have?" and the four items were Medicaid, Medicare, insurance through an employer/work, and any other

form of health insurance. The items were recoded into one categorical item with five response options (*Private, Medicare/Medicaid, Other, Multiple,* and *None*). Categorical variables were dummy coded prior to inclusion in the final regression analyses.

Colorectal cancer knowledge was assessed using a previously validated instrument comprised of nine items. Initially developed by Green and Kelly (2004), the instrument has been used in a similar population of African Americans taking part of a church-based cancer screening education program (Holt et al., 2011; Holt et al., 2012). The instrument was shortened for surveys in Project HEAL to reduce participant burden (Nunnally & Bernstein, 1994), but internal reliability was still acceptable ($\alpha = .73$). Each item has three response options: yes (3), no (1), and not sure (2). Two items will be reverse coded ("colorectal cancer affects only older White men" and "colorectal cancer screening is not necessary if there are no symptoms"). The items are recoded to correct (1) and incorrect (0) and then summed to calculate an index score with higher scores indicating greater CRC knowledge.

Previous colorectal cancer screening status was assessed through a series of items that asked respondents if they had heard of a particular CRC screening test (FOBT, sigmoidoscopy, and colonoscopy) and then if respondents chose a *yes* response, the respondents were asked if they had ever completed that screening test. Both items had three response options: *yes, no,* and *not sure*. These two items were recoded into one dichotomous item for each CRC screening test with two response options: *ever been screened* (1) and *never been screened* (0). Nonresponse (FOBT: n = 4; sigmoidoscopy: n = 3; colonoscopy: n = 3) and *not sure* responses (FOBT: n = 12; sigmoidoscopy: n = 4; colonoscopy: n = 3) were coded as *never* (Holt et al., 2011; Holt et al., 2012).

HEAL workshop attendance was assessed through project tracking by Project HEAL researchers and each workshop (total of three workshops) was coded as *absent* (0) and *attended* (1). A total sum was calculated for participants' overall attendance with a possible range of 1-3. The third workshop was a CRC-specific workshop and attendance at this workshop was included as a separate variable.

First-degree family colorectal cancer history was measured using one item asking participants to identify individuals in their family who have been diagnosed with CRC. The item asked participants "has anybody in your family (first-degree relative) had colorectal cancer" and has eight categorical response options: father, mother, brother, sister, son, daughter, none, and not sure. Each response option was coded 1 for a marked response and 0 for no response. The items' responses were summed (excluding none and not sure responses) for a single continuous item of total number of family members diagnosed with CRC and then recoded to a dichotomous item with two response options: family history of CRC (1) and no family history (0).

Data Analysis

SPSS Version 23.0 was used for all analyses. Univariate and Bivariate analyses were conducted followed by regression analyses. An alpha level of .05 was used for all analyses and an alpha level of .10 was used to identify trends. A confirmatory factor analysis was completed to identify subscales for decisional conflict and decision self-efficacy. Only one factor for both decisional conflict and decision self-efficacy was identified (data not shown).

Univariate and bivariate analysis. All items were analyzed for their distribution using descriptive statistics (e.g., frequencies, means, standard deviations). Chi-square, ANOVA, and correlation analyses were used to assess relationships between all variables.

Chi-square analyses were used for categorical variables (e.g., health insurance, marital status, CRC screening test preference). ANOVA was used to identify significant differences between categorical (with more than two response options) and continuous variables. Posthoc analyses using Tukey were completed for ANOVA models with a p-value of .10 or less. Lastly, correlation analyses were used to identify significant differences between continuous and dichotomous categorical variables (e.g., age, gender, family CRC history, CRC knowledge). Bivariate analyses were also completed to identify significant differences between participants who attended or were absent for the CRC-specific workshop in Project HEAL. Collinearity between covariates was assessed for inclusion in the final data analysis models. If two covariates had a statistically significant relationship (p < .05), only one covariate was kept in the model. Additionally, covariates were retained in the final regression analyses (described below) if they had a p-value below .20 in the bivariate analyses. Inclusion of covariates was also informed by previous literature.

Regression analysis. Regression analyses were used as the primary method to assess the conceptual models for aims one through four. The first and second aims used multivariable linear regression due to continuous dependent variables: decisional conflict and decision self-efficacy. The third and fourth aims used multivariable logistic regression due to dichotomous dependent variables: decisional preference (shared versus informed) and CRC test preference (FOBT versus colonoscopy). Forced entry was used for the regression analyses. Due to the somewhat small sample size, stepwise entry into the regression models was not completed as it can reduce degrees of freedom resulting in a loss of power (Baybak, 2004). The moderation analyses followed the steps provided by Baron and Kenny (1986). For all aims, the first entry block included the covariates while block two had the

independent variable and the proposed moderator (age or gender). The final block entry included the interaction variable (independent variable x moderator). Continuous covariates were standardized into z-scores prior to the regression analyses to allow for plotting the interaction slopes for visualization (Dawson, 2014). Interaction slopes were plotted using Excel 2011 (Dawson, n.d.).

Stratified analyses. Based on previous literature suggesting possible differences by gender and age (50-64 and 65-75) for CRC screening decision making, stratified analyses was also conducted. Due to low power (see power analysis below), only univariate and bivariate analyses were completed and can be found in Appendix A.

Missing data. The missing data for all variables is less than 5% and due to the very small number of cases for each variable with missing data (n < 5), a determination of whether or not data was missing completely at random through statistical tests was not appropriate. Options available for handling missing data of less than 5% include listwise deletion, pairwise deletion, and mean substitution (Roth, 1994). With the small percentage of missing data, mean substitution (or mode for categorical variables) was used for all missing data. While mean substitution may lessen variance estimates, it helped maintain degrees of freedom, thereby maintaining power (Roth, 1994). As the overall sample size is somewhat small, listwise deletion would have reduced the sample size even further and resulted in a loss of power. Pairwise deletion was also not suitable as it results in sample differences for each statistic. Additionally, between these three methods for handling missing data, research has found conflicting results for the most accurate method (Roth, 1994) and due to the small percentage of missing data, mean substitution may be comparable to other methods.

Power analysis. Based on the continuous engagement of Project HEAL participants through retention activities (e.g., newsletters, recent 12-month follow-up meeting), a recruitment rate of 70% (n =153) from the 203 eligible participants was expected. As the Focus on CRC seed grant study included a categorical dependent variable a sample size of 148 was calculated from a power analysis using G*Power (Faul, Erdfelder, Buchner, & Lang, 2009) for logistic regression (A. B. Taylor, West, Aiken, 2006). Due to limited literature examining the proposed research method, a moderate effect size of 2.0 was used for this analysis (Rosenthal, 1996). However, a smaller sample size than desired was obtained (n = 111) and due to recoding for two dependent variables ("decisional preference" and "CRC screening test preference") the sample size dropped even further. A post-hoc analysis was completed using the smallest sample size (n = 96) for the four aims using regression analyses. With the provided sample size of 96 and a moderate effect size of 2.0 using logistic regression data analysis, the (lowest) power reached for the current study was 0.73.

Stratified analysis. The stratified analysis has four subgroup analyses: men, women, ages 50-64, and ages 65-75. The smallest sample size is among men (n = 31) and the power analysis for this group found a power of 0.27. As a result, regression analyses of the subgroups would not have sufficient power. As a result, only univariate and bivariate analyses were completed. Results of these analyses can be found in Appendix A.

Human Subjects Concern

Informed consent. The Focus on CRC seed grant was submitted and approved by the University of Maryland, College Park IRB under the parent study for the completion of the proposed study (see appendices C and D). Each participant completed informed consent during the initial enrollment with Project HEAL. A \$25 gift card was provided for both the

baseline and Focus on CRC seed grant surveys as a token of appreciation for participants' time.

Eligibility and enrollment. Participants were informed at time of enrollment that their participation was voluntary and they were able to drop out of the study at any time. Participants were eligible for the proposed study if they self-identified as African American, were between the ages of 50 and 75 at the time of Project HEAL enrollment, and had no personal history of breast, prostate, and colorectal cancer. Participants must have enrolled in Project HEAL and completed the Project HEAL 12-month survey to be eligible for the Focus on CRC seed grant survey.

Potential risks and benefits. There were no significant potential risks for participants; however, small risks may have included negative feelings or distress while completing the surveys. Participants did not receive any direct benefits from participating in the surveys, but were informed of the potential benefit to other individuals through future research and application of information learned through the present study.

Confidentiality. There were risks to confidentiality as participants completed the Focus on CRC seed grant survey through mail, by phone, or online and interception of the survey with identifiers was possible until time of survey receipt by the research staff. The research staff attempted to minimize breach of confidentiality through several steps. All phone calls to participants were completed in a private room on a university telephone ensuring confidentiality on the end of the research staff during phone interviews. Surveys completed online were completed through a secure, password protected software (Qualtrics) and once downloaded were immediately stripped of all personal identifiers. Similarly, once surveys were received via mail (or completed in-person for the Project HEAL baseline

surveys), all personal identifiers were stripped. All surveys were kept in a locked cabinet in a locked office separate from any identifiers (stored in a different locked cabinet) and all data stored on computers were deidentified and stored in password-protected folders and/or servers.

Chapter 4: Results

Descriptive Statistics

A total of 111 eligible Project HEAL participants completed the ancillary follow-up survey. A comparison of demographic variables between eligible nonresponders and responders found only one significant difference in baseline CRC knowledge with responders having greater baseline CRC knowledge compared to nonresponders (p < .05; Table 4.1). Responders had a mean age of 60.8 (SD = 6.9) and were predominately female (69.3%; Table 4.1). Approximately half of participants were married (53.2%) and had some college (36.4%) or a college degree (28.2%). Most participants were employed full-time (42.3%) or retired (34.2%). Private health insurance was the most common type of health insurance (45.0%) and only 3.6% did not have any health insurance. Most participants have had colonoscopy for CRC screening (68.5%). Participants attended a mean of two workshops (out of a possible three) and 55.0% attended the workshop focusing on CRC. A comparison between those who attended and did not attend the CRC-specific workshop found those who attended the workshop had attended an overall greater number of workshops (p < .05) and had a marginally lower percentage of individuals who had ever been screened using sigmoidoscopy (p < .10). Individuals who attended the CRC-specific workshop were significantly more likely to prefer making a shared decision versus an informed decision compared to individuals who did not attend the CRC-specific workshop (p < .05).

Table 4.2 presents the descriptive statistics for the four decision making indicators in this population. Participants had a mean score of 18.2 for decisional conflict (SD = 25.8). The maximum score of decisional conflict is 100 and a lower score indicates lower conflict. Additionally, participants had a mean score of 85.4 for decision self-efficacy (SD = 17.7)

with a maximum score of 100 and greater scores indicating greater self-efficacy. Participants were split between shared and informed preference (47.1% and 52.9%, respectively). The majority of participants preferred colonoscopy over FOBT for their next CRC screening test (75.0% and 25.0%, respectively).

Table 4.1. Demographic Characteristics of Focus on CRC Participants and Comparison of Participants who Attended and Did Not Attend the Project HEAL CRC Workshop

		Attended CRC	Did Not Attend
	Total	workshop	CRC workshop
	(n = 111)	(n = 61)	(n = 50)
Characteristic	n (%) or $M \pm SD$	n (%) or $M \pm SD$	n (%) or $M \pm SD$
Age	60.8 ± 6.9	61.1 ± 7.3	60.5 ± 6.5
Gender			
Female	70 (69.3)	48 (78.7)	32 (64.0)
Male	31 (30.7)	13 (21.3)	18 (36.0)
Marital status			
Married	59 (53.2)	33 (54.1)	26 (52.0)
Single	28 (25.2)	16 (26.2)	12 (24.0)
Other	24 (21.6)	12 (19.7)	12 (24.0)
Education			
< High school diploma	10 (9.1)	6 (9.8)	4 (8.0)
High school diploma	29 (26.4)	15 (24.6)	14 (28.0)
Some college	40 (36.4)	22 (36.1)	19 (38.0)
College degree	31 (28.2)	18 (29.5)	13 (26.0)
Employment			
Full-time	47 (42.3)	24 (39.3)	23 (46.0)
Part-time	8 (7.2)	3 (4.9)	5 (10.0)
Disabled	9 (8.1)	5 (8.2)	4 (8.0)
Retired	38 (34.2)	23 (37.7)	15 (30.0)
Not currently	9 (8.1)	6 (9.8)	3 (6.0)
Health Insurance			
Private	50 (45.0)	31 (50.8)	19 (38.0)
Medicare/Medicaid	18 (16.2)	7 (11.5)	11 (22.0)
Other	12 (10.8)	4 (6.6)	8 (16.0)
Multiple	27 (24.3)	16 (26.2)	11 (22.0)
None	4 (3.6)	3 (4.9)	1 (2.0)
CRC knowledge (max score = 9)	7.5 ± 1.7	7.5 ± 1.5	7.5 ± 2.0
Ever had FOBT	44 (40.5)	27 (44.3)	18 (36.0)
Ever had sigmoidoscopy ⁺	32 (28.8)	14 (23.0)	18 (36.0)
Ever had colonoscopy	76 (68.5)	42 (68.9)	34 (68.0)
WS attendance $(max score = 3)^*$	2.0 ± 0.8	2.6 ± 0.6	1.4 ± 0.5
First-degree CRC family history ^a	10 (9.0)	7 (11.5)	3 (6.0)
Health literacy (max score = 25)	21.1 ± 3.6	21.4 ± 3.8	20.7 ± 3.3

Notes: CRC = colorectal cancer, FOBT = fecal occult blood test, WS = workshop. ^abinary variable with 0 = no and 1 = yes.

p < .10, p < .05, p < .001

Table 4.2. Descriptive Statistics of Decision Making Indicators of Focus on CRC Participants and Comparison of Participants who Attended and Did Not Attend the Project HEAL CRC Workshop

		Attended CRC	Did Not Attend
	Total	workshop	CRC workshop
	(n = 111)	(n = 61)	(n = 50)
Indicator	n (%) or M (SD)	n (%) or M (SD)	n (%) or M (SD)
Decisional conflict (max score = 100)	18.2 ± 25.8	16.6 ± 25.7	20.1 ± 26.2
Decision self-efficacy (max score = 100)	85.4 ± 17.7	85.8 ± 19.6	85.0 ± 15.1
Decisional preference ^{a*}			
Shared	48 (47.1)	31 (57.4)	17 (35.4)
Informed	54 (52.9)	23 (42.6)	31 (64.6)
CRC test preference ^b			
FOBT	24 (25.0)	15 (30.0)	9 (19.6)
Colonoscopy	72 (75.0)	35 (70.0)	37 (80.4)

Notes: CRC = colorectal cancer, FOBT = fecal occult blood test, WS = workshop. ^aAttended: n = 54, Absent: n = 48. ^bAttended: n = 50, Absent: n = 46. ^{*}p < .10, *p < .05, **p < .001

Bivariate Statistics

Chi-square analyses did not find any significant associations between categorical predictor variables (i.e., health insurance, employment status, marital status) and the two dichotomous dependent variables (i.e., decisional preference, CRC test preference; ps > .10; Table 4.3). The ANOVA analyses identified significant associations between employment status and decisional conflict [F(4,106) = 4.632, p < .05; Table 4.4]. Post-hoc analyses identified a significant difference for decisional conflict between individuals not currently working (M = 42.8, SD = 37.6) and both individuals working full-time (M = 15.4, SD = 20.0) or retired individuals (M = 10.4, SD = 18.0; ps < .05). The difference in decisional conflict between individuals working part-time (M = 35.0, SD = 35.7) and retired individuals approached significance (p < .10). Additionally, decisional conflict varied within marital status [F(2,110) = 2.819, p < .10) with married individuals reporting greater decisional conflict (M = 22.4, SD = 30.9) than single individuals (M = 8.6, SD = 16.2; p < .10). There were no significant differences in mean decisional conflict for health insurance or for decision self-efficacy among marital, employment, or health insurance status (ps > .10).

Table 4.3. Chi-square Analyses for Decisional Preference and CRC Test Preference among Focus on

CRC Participants

	Decisional Preference (n = 102)		CRC Test Preference (n = 96)			
	Shared	Informed	X^2	FOBT	CS	X^2
Marital status			2.534			1.205
Married	24	27		15	36	
Single	16	12		5	18	
Other	8	15		4	18	
Employment			0.664			
Full-time	21	24		10	32	5.079
Part-time	3	5		2	5	
Disabled	3	4		0	7	
Retired	18	17		8	24	
Not currently	3	4		4	4	
Health Insurance			2.399			1.477
Private	18	27		33	13	
Medicare/Medicaid	7	9		11	4	
Other	7	5		8	2	
Multiple	14	11		17	5	
None	2	2		3	0	

Notes: CRC = colorectal cancer, FOBT = fecal occult blood test, CS = colonoscopy.

Table 4.4. ANOVAs for Decisional Conflict and Decision Self-Efficacy among Focus on CRC Participants (N = 111)

	Decisional Conflict		Decision Self-Efficacy	
Variable	$M \pm SD$	F	$M \pm SD$	F
Marital status		2.819 ⁺		0.429
Married	22.4 ± 30.9^{a}		85.6 ± 18.5	
Single	8.6 ± 16.2^{a}		87.4 ± 18.8	
Other	19.2 ± 17.9		82.9 ± 14.3	
Employment		4.632^{*}		0.689
Full-time	15.4 ± 20.0^{b}		86.3 ± 17.0	
Part-time	35.0 ± 35.7^{c}		88.9 ± 13.8	
Disabled	26.1 ± 38.7		77.5 ± 27.0	
Retired	$10.4 \pm 18.0^{c,d}$		86.5 ± 15.8	
Not currently	$42.8 \pm 37.6^{b,d}$		81.6 ± 21.4	
Health Insurance		0.750		1.308
Private	16.4 ± 25.8		88.1 ± 16.5	
Medicare/Medicaid	26.9 ± 34.0		77.4 ± 22.4	
Other	12.9 ± 12.9		87.1 ± 15.2	
Multiple	17.2 ± 23.9		85.6 ± 17.0	
None	23.8 ± 29.3		81.8 ± 15.9	

Notes: CRC = colorectal cancer. Post-hoc using Tukey completed for ANOVAs with p < .10. ^aWithingroup pairwise comparison: p < .10. ^{b-d}Within-group pairwise comparison: p < .05 p < .05, *p < .05, *p < .05, *p < .001

 $p^{+} < .10, p^{*} < .05, p^{**} < .001$

The results of the correlation analyses are shown in Table 4.5. Gender was moderately correlated with decisional conflict and decision self-efficacy with women having lower decisional conflict [r(109) = -.22, p < .05] and greater decision self-efficacy [r(109) =.20, p < .05] compared to men. Education was negatively correlated with decisional conflict [r(109) = -.31, p < .05] and positively correlated with decision self-efficacy [r(109) = .29, p < .05].05]. CRC baseline knowledge was also negatively correlated with decisional conflict [r(109) = -.24, p < .05]. Individuals with a first-degree family history of CRC had significantly lower decision self-efficacy than individuals without a family history [r(109) = -.29, p < .05]. While not significant, greater workshop attendance was positively correlated with decision self-efficacy [r(109) = .16, p < .10]. Health literacy had moderate to strong correlations with decisional conflict [r(109) = -.44, p < .001] and decision self-efficacy [r(109) = .54, p < .001].001]. Decision self-efficacy was negatively associated with decisional conflict [r(109) = -.50, p < .001]. While not statistically significant, women were more likely to prefer having an shared rather than informed decision compared to men [r(109) = .16, p < .10]. Attending the CRC-specific workshop [r(109) = .22, p < .05] and greater overall workshop attendance [r(109) = .26, p < .05] was positively associated with preferring a shared decision (versus informed decision). Lastly, having ever been screened for CRC using sigmoidoscopy [r(109)] = .24, p < .05] and colonoscopy [r(109) = .27, p < .05] were significantly associated with preferring colonoscopy for the next CRC screening test. Conversely, while not significant, having ever been screened for CRC using FOBT was associated with preferring FOBT for the next CRC screening test [r(109) = -.19, p < .10].

Table 4.5. Correlations Matrix for Decision Making Indicators among Focus on CRC Participants (N = 111)

Variable	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
1. Age		11	03	06	.20*	.33**	.37**	.04	.13	.20*	13	14	04	.04	.02
2. Gender	11	_	.09	.03	06	14	12	.16	.05	16	.18*	22*	.20*	.18	.10
3. Education	03	.09	_	.31*	11	04	01	.02	.01	05	.41**	31*	.29*	11	03
4. CRC 4. knowledge	05	.03	.31**	_	01	.09	.04	.01	02	.09	.24*	24*	.15	.10	.05
5. Ever had FOBT	.20*	06	11	01	_	.20*	.13	08	.10	.06	.08	12	06	11	19 ⁺
6. Ever had FS	.33**	14	04	.09	.20*		.22*	14	20*	.22*	01	13	08	07	.24*
7. Ever had CS	37**	12	01	.04	.13	.22*	_	01	.08	.15	.01	07	06	.09	.27*
8. CRC WS	.04	.16	.02	.01	08	14	.01		.72**	.07	.09	07	.03	.22*	12
9. Total WS	.13	.05	.01	02	.10	20*	.08	.72**	_	.06	09	08	.16+	.26*	10
10. Family CRC history	.20*	16	05	.09	.06	.22*	.15	.07	.06	_	13	02	29 [*]	.09	00
Health literacy	13	.18+	.41**	.24*	.08	01	.01	.09	.09	13		44**	.54**	03	.06
12. Decisional conflict	14	22*	31*	24*	12	13	07	07	08	02	44**	_	50**	14	04
13. Decision self-efficacy	04	.20*	.29*	.15	06	08	06	.03	.16+	29*	54**	50**		.07	.02
14. Decisional preference ^a	.04	.18+	11	.10	11	07	.09	.22*	.26*	.09	03	14	.07		.02°
15. CRC test preference ^b	.02	.10	03	.05	19 ⁺	.24*	.27*	12	10	00	.06	04	.02	.02°	_

Notes: CRC = colorectal cancer, FOBT = fecal occult blood test, FS = sigmoidoscopy, CS = colonoscopy, WS = workshop. a n=102. b n=96. c n = 89 $^+$ $p < .10, ^*p < .05, ^{**}p < .001$

Collinearity analysis. Bivariate analyses found collinearity between several of the covariates. Employment was significantly associated with three variables: marital status, health insurance status, and education (ps < .05; data not shown). Additionally, age was significantly associated with five variables: health insurance status, family CRC history, and ever been screened using FOBT, sigmoidoscopy, or colonoscopy (ps < .05). Gender and marital status were significantly associated with each other, as were education and CRC knowledge (ps < .05). Lastly, attendance at the CRC-specific workshop was positively associated with overall workshop attendance (p < .001). After identifying variables with pvalues less than .2 (data not shown) and removing covariates significantly associated with one another, the following covariates were retained for the regression analyses: age, gender, employment, CRC knowledge, overall workshop attendance, and family CRC history. Despite significant associations with other variables, age, employment, health insurance status, and family CRC history were retained in the regression analyses to gain a better understanding of their relationship with decision making (see Arnold et al., 2012; Chatterjee, Chattopadhyay, & Levine, 2015; White et al., 2008; Zlot, Silvey, Newell, Coates, & Leman, 2012). Additionally, the three variables for "ever been screened" using FOBT, sigmoidoscopy, or colonoscopy were included in the regression model for CRC test preference due to near-significant or significant bivariate associations with CRC test preference (FOBT: p < .10; sigmoidoscopy and colonoscopy: ps < .05).

Regression Analyses

Decisional conflict. Table 4.6 shows the linear regression analyses of decisional conflict with age as a moderator. Covariates included in the analyses were gender, health insurance status, employment, CRC knowledge, workshop attendance, and family CRC

history. The first model only includes the covariates and was statistically significant [F(12,110) = 2.670, p < .05]. While not significant, women had lower decisional conflict compared to men ($\beta = -.163$, p < .10). Individuals who were not currently working had significantly greater levels of decisional conflict than individuals working full-time ($\beta = .277$, p < .05). Individuals working part-time also had greater decisional conflict compared to individuals working full-time, although this relationship was not significant ($\beta = .163, p < .163$) .10). Additionally, CRC knowledge at Project HEAL baseline was negatively associated with decisional conflict ($\beta = -.221$, p < .05). Model two was statistically significant and included covariates, the independent variable (health literacy), and the moderator [age; F(14,110) =4.229, p < .001]. A significant difference between both individuals not currently working (β = .207, p < .05) and working part-time ($\beta = .187, p < .05$) with individuals employed fulltime persisted in the second model. Health literacy was negatively associated with decisional conflict ($\beta = -.431$, p < .001). Individuals aged 65 to 75 had lower decisional conflict compared to individuals aged 50 to 64 (β = -.203, p < .10). The third model was statistically significant and included the interaction [health literacy x age; F(15,110) = 3.971, p < .001]. The significant associations between individuals working not currently working or working part-time persisted in the third model (β = .224 and β = .195, respectively; ps < .05). Health literacy was also significant ($\beta = -.369$, p < .05), however neither the moderator (age), nor the interaction were significant. Figure 4.1 displays the interaction plot for decisional conflict x age and illustrates lower decisional conflict among individuals aged 65 to 75 compared to 50 to 64 and the overall lower decisional conflict for individuals with greater health literacy.

Table 4.7 shows the linear regression analyses of decisional conflict with gender as a moderator. The same covariates were used in these analyses. The first model only includes

the covariates and was statistically significant [F(12,110) = 2.373, p < .05]. Individuals who were not currently working had significantly greater levels of decisional conflict than individuals working full-time ($\beta = .270, p < .05$). Individuals working part-time also had greater decisional conflict compared to individuals working full-time ($\beta = .196$, p < .05). Additionally, CRC knowledge at Project HEAL baseline was negatively associated with decisional conflict ($\beta = -.231$, p < .05). Model two was statistically significant and included covariates, the independent variable, and the moderator [gender; F(14,110) = 4.149, p <.001]. A significant difference between both individuals not currently working ($\beta = .200, p < .001$). .05) and working part-time (β = .184, p < .05) with individuals employed full-time persisted in the second model. CRC knowledge was no longer significant, but was still negatively associated with decisional conflict ($\beta = -.155$, p < .10). Health literacy was negatively associated with decisional conflict ($\beta = -.432$, p < .001). Gender was not significantly associated with decisional conflict. The third model was statistically significant and included the interaction [health literacy x gender; F(15,110) = 3.832, p < .001]. The significant associations between individuals working, not currently working, or working part-time persisted in the third model ($\beta = .200$ and $\beta = .184$, respectively; ps < .05). The negative association between CRC knowledge and decisional conflict was approaching significance in this model ($\beta = -.155$, p < .10). Health literacy was also significant ($\beta = -.428$, p < .05), however neither the moderator (gender), nor the interaction were significant. Figure 4.1 displays the interaction plot for decisional conflict x gender and shows the overall lower decisional conflict for individuals with greater health literacy and lower decisional conflict among women compared to men (although this relationship is not significant).

Table 4.6. Hierarchical Linear Regression Analyses for Decisional Conflict with Age as a Moderator (N = 111)

		Model 1			Model 2			Model 3	
	B	SE	eta	B	SE	$oldsymbol{eta}$	B	SE	β
Gender									
Men	Ref			Ref			Ref		
Women	-9.351	5.226	163 ⁺	-7.736	4.868	135	-7.448	4.892	130
Insurance									
Private	Ref			Ref			Ref		
Medicare/Medicaid	2.944	8.327	.042	-7.791	8.222	112	-8.656	8.314	124
Other	-4.805	7.725	058	-7.573	7.097	091	-7.345	7.117	089
Multiple	4.007	6.150	.067	8.437	6.500	.141	9.037	6.559	.151
None	4.288	12.626	.031	8.110	11.588	.059	7.020	11.696	.051
Employment									
Full-time	Ref			Ref			Ref		
Part-time	16.228	9.459	.163+	18.529	8.871	$.187^{*}$	19.418	8.953	.195*
Disabled	4.635	10.616	.049	4.481	9.720	.048	5.852	9.898	.062
Retired	-7.028	5.965	130	-3.487	5.974	064	-3.622	5.989	067
Not currently working	26.135	9.230	.277*	19.557	8.617	$.207^{*}$	21.116	8.865	.224*
CRC knowledge	-5.721	2.350	221*	-3.482	2.207	135	-3.578	2.215	138
Workshop attendance	-2.227	2.460	086	-1.759	2.256	068	-1.758	2.261	068
Family CRC history									
No	Ref			Ref			Ref		
Yes	-3.235	8.310	036	-5.614	7.676	062	-6.095	7.717	068
Main Effects									
Health literacy				-3.080	.693	431**	-2.636	.899	369 [*]
Age									
50-64				Ref			Ref		
65-75				-11.076	6.518	203 ⁺	9.251	26.971	.169
Interaction									
Health Literacy x Age							-0.971	1.250	376
R^2			.246			.381			.385
ΔR^2			-			.135			.004
F			2.670^{*}			4.229**			3.971**

p < .10, p < .05, p < .001

Table 4.7. Hierarchical Linear Regression Analyses for Decisional Conflict with Gender as a Moderator (N = 111)

$ \begin{array}{c ccccccccccccccccccccccccccccccccccc$	β
-2.140 3.434 003 -4.07 3.173 101 -4.000 3.173	181
Insurance	
Private Ref Ref Ref	
Medicare/Medicaid 5.421 8.482 .078 -8.528 8.217122 -8.513 8.274	122
Other -4.265 7.833051 -7.044 7.120085 -7.056 7.168	085
Multiple 7.572 6.830 .126 6.817 6.240 .114 6.807 6.282	.113
None 1.644 12.807 .012 6.313 11.660 .046 6.340 11.754	.046
Employment	
Full-time Ref Ref Ref	
Part-time 19.505 9.805 .196* 18.328 8.927 .184* 18.308 8.998	.184*
Disabled 3.822 10.797 .041 3.683 9.783 .039 3.674 9.838	.039
Retired -5.761 6.800106 -3.373 6.187062 -3.362 9.838	.039
Not currently working 25.407 9.574 .270* 18.861 8.782 .200* 18.817 8.949	.200*
CRC knowledge -5.963 2.389231* -3.996 2.206155 ⁺ -3.999 2.221	155 ⁺
Workshop attendance -2.281 2.499088 -1.729 2.268067 -1.725 2.283	067
Family CRC history	
No Ref Ref	
Yes520 8.441006 -5.300 7.736059 -5.288 7.788	059
Main Effects	
Health literacy -3.083 0.697432** -3.056 1.138	428*
Gender	
Men Ref Ref	
Women -7.205 4.870126 -6.407 27.057	112
Interaction	
Health Literacy x Gender -0.039 1.305	015
$R^2 .225 .377$.377
ΔR^2 .152	.000
F 2.373* 4.149**	3.832**

p < .10, p < .05, p < .001

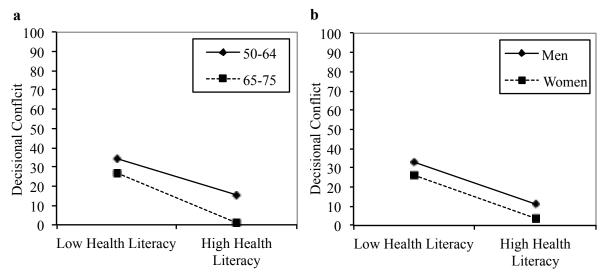


Figure 4.1. Interaction plots for health literacy and decisional conflict with moderators (a) age and (b) gender for Focus on CRC participants.

Decision self-efficacy. Table 4.8 shows the linear regression analyses of decision self-efficacy with age as a moderator. The first model only includes the covariates and was statistically significant [F(12,110) = 2.281, p < .05]. Covariates included in the analyses were gender, health insurance status, employment, CRC knowledge, workshop attendance, and family CRC history. CRC knowledge at Project HEAL baseline ($\beta = .172$, p < .10) and overall attendance at Project HEAL workshops ($\beta = .162$, p < .10) were positively associated with decision self efficacy, but not significant. Individuals with a family CRC history had significantly lower decision self-efficacy compared to individuals without a family history ($\beta = .334$, p < .05). Model two was statistically significant and included covariates, the independent variable (health literacy), and the moderator [age; F(14,110) = 5.200, p < .001]. The positive association between workshop attendance and decision self-efficacy was still approaching significance in this model ($\beta = .142$, p < .10). The third model was statistically significant and included the interaction [health literacy x age; F(15,110) = 4.850, p < .001]. Workshop attendance was positively associated with decision self-efficacy but was not

significant (β = .142, p < .10). Family CRC history was still significant in this model (β = .291, p < .05), as was health literacy (β = .503, p < .001), however neither the moderator (age), nor the interaction were significant. Figure 4.2 displays the interaction plot for decision self-efficacy x age and shows greater decision self-efficacy among individuals aged 65 to 75 compared to 50 to 64 and the overall greater decision self-efficacy for individuals with greater health literacy.

Table 4.9 shows the linear regression analyses of decision self-efficacy with age as a moderator. The first model only includes the covariates and was statistically significant [F(12,110) = 2.079, p < .05]. The same covariates used in the previous analyses were used in this set of analyses. CRC knowledge at Project HEAL baseline ($\beta = .171, p < .10$) and overall attendance at Project HEAL workshops ($\beta = .172, p < .10$) were positively associated with decisional conflict, but not significant. Individuals with a family CRC history had significantly lower decision self-efficacy compared to individuals without a family history (β = -345, p < .001). Model two was statistically significant and included covariates, the independent variable (health literacy), and the moderator [gender; F(14,110) = 4.881, p <.001]. The positive association between workshop attendance and decision self-efficacy was approaching significance in this model ($\beta = .149$, p < .10). Family CRC also had a significant relationship with decision self-efficacy ($\beta = -.287$, p < .05). Health literacy was positively associated with decision self-efficacy ($\beta = .535$, p < .001). Gender was not a significant predictor of decision self-efficacy. The third model was statistically significant and included the interaction [health literacy x gender; F(15,110) = 4.509, p < .001]. Workshop attendance was positively associated with decision self-efficacy but was not significant (β = .148, p < .10) and family CRC history was still significant in this model ($\beta = -.287$, p < .05). Health

Table 4.8. Hierarchical Linear Regression Analyses for Decision Self-efficacy with Age as a Moderator (N = 111)

Table 4.8. Hierarchical Linear	Kegression Ai	Model 1	ccision scii	-cificacy with	Model 2	oucrator (IV -	- 111)	Model 3	
	B	SE	β	B	SE	β	B	SE	β
Gender			,			,			,
Men	Ref			Ref			Ref		
Women	5.577	3.665	.142	3.964	3.190	.101	3.810	3.209	.097
Insurance									
Private	Ref			Ref			Ref		
Medicare/Medicaid	-3.214	5.795	067	6.754	5.387	.142	7.216	5.453	.151
Other	-2.373	5.376	042	-0.011	4.650	.000	-0.133	4.668	002
Multiple	-2.614	4.280	064	-5.144	4.259	126	-5.465	4.302	133
None	-8.335	8.787	088	-11.606	7.529	123	-11.022	7.672	117
Employment									
Full-time	Ref			Ref			Ref		
Part-time	7.968	6.582	.117	6.701	5.812	.099	6.260	5.872	.092
Disabled	-6.793	7.388	105	-6.741	6.368	105	-7.474	6.492	116
Retired	1.860	4.151	.050	-0.236	3.914	006	-0.164	3.928	004
Not currently working	-3.052	6.423	047	2.198	5.646	.034	1.364	5.815	.021
CRC knowledge	3.029	1.636	$.172^{+}$	1.135	1.446	.064	1.186	1.453	.067
Workshop attendance	2.865	1.712	.162+	2.511	1.478	.142+	2.511	1.483	.142+
Family CRC history									
No	Ref			Ref			Ref		
Yes	-20.520	5.783	334*	-18.131	5.030	298**	-17.874	5.062	291*
Main Effects									
Health literacy				2.695	0.454	.552**	2.457	0.590	.503**
Age									
50-64				Ref			Ref		
65-75				7.013	4.271	.188	-3.864	17.690	104
Interaction									
Health Literacy x Age							0.520	0.820	.295
R^2			.218			.431			.434
ΔR^2						.213			.003
F			2.281*			5.200**			4.850**
$^{+}n < 10 * n < 05 * n < 001$									

p < .10, p < .05, p < .001

Table 4.9. Hierarchical Linear Regression Analyses for Decision Self-efficacy with Gender as a Moderator (N = 111)
--

		Model 1		-	Model 2			Model 3	
	B	SE	$oldsymbol{eta}$	B	SE	β	B	SE	β
Age	-1.468	2.394	083	0.612	2.110	.035	0.621	2.114	.035
Insurance									
Private	Ref			Ref			Ref		
Medicare/Medicaid	-3.688	5.879	077	7.694	5.437	.161	7.670	5.474	.161
Other	-2.519	5.428	044	-0.270	4.711	005	-0.250	4.743	004
Multiple	-2.391	4.733	058	-2.168	4.129	053	-2.151	4.157	052
None	-7.674	8.876	081	-11.125	7.715	118	-11.169	7.777	118
Employment									
Full-time	Ref			Ref			Ref		
Part-time	7.840	6.796	.115	8.375	5.907	.123	8.408	5.953	.124
Disabled	-6.984	7.483	108	-6.804	6.473	106	-6.790	6.509	105
Retired	3.592	4.712	.097	1.814	4.094	.049	1.795	4.123	.048
Not currently working	-4.241	6.636	066	1.119	5.811	.017	1.193	5.921	.019
CRC knowledge	3.025	1.656	$.171^{+}$	1.389	1.460	.079	1.395	1.469	.079
Workshop attendance	3.046	1.732	$.172^{+}$	2.628	1.500	$.149^{+}$	2.622	1.510	.148+
Family CRC history									
No	Ref			Ref			Ref		
Yes	-21.169	5.850	345**	-17.630	5.119	287*	-17.651	5.153	287*
Main Effects									
Health literacy				2.612	0.461	.535**	2.567	0.753	.526*
Gender									
Men				Ref			Ref		
Women				3.545	3.222	.090	2.203	17.902	.056
Interaction									
Health Literacy x Gender							0.066	0.864	.038
R^2			.203			.416			.416
ΔR^2						.213			.000
F			2.079^{*}			4.881**			4.509**
$+n < 10^{-8} n < 05^{-88} n < 001$									

p < .10, p < .05, p < .001

literacy was significant (β = .526, p < .05), however neither the moderator (gender), nor the interaction were significant. Figure 4.2 displays the interaction plot for decision self-efficacy x gender and shows greater decision self-efficacy among women compared to men and the overall greater decision self-efficacy for individuals with greater health literacy.

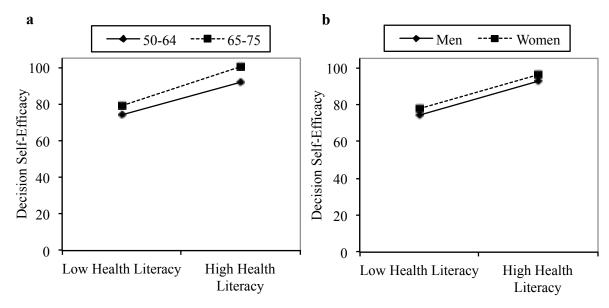


Figure 4.2. Interaction plots for health literacy and decision self-efficacy with moderators (a) age and (b) gender for Focus on CRC participants.

Decisional preference. Table 4.10 shows the logistic regression analyses of decisional preference with age as a moderator. The first model only includes the covariates and was not statistically significant $[X^2 (12, N = 102) = 17.791, p > .10]$. Covariates included in the analyses were gender, health insurance status, employment, CRC knowledge, workshop attendance, and family CRC history. Women were 3.23 times as likely to prefer making a shared decision compared to men (p < .05). Additionally, participants who attended a greater number of workshops were significantly more likely to prefer making a shared decision (OR = 2.370, 95% CI: 1.29,4.35; p < .05). Model two included covariates, the independent variable (health literacy), and the moderator [age; $X^2 (14, N = 102) = 18.254, p > .10$]. The third model was also not statistically significant and included the interaction

(decisional preference x age; X^2 (15, N = 102) = 18.431, p > .10). In the second and third models women were still 3.40 times as likely to prefer making a shared decision compared to men (p < .05). Additionally, individuals who attended a greater number of workshops were significantly more likely to prefer a shared decision (OR = 2.378, 95% CI: 1.29,4.39; p < .05). Health literacy, age, and the interaction (health literacy x age) were not significant in the models. Figure 4.3 illustrates the probability of preferring a shared decision for those ages 50 to 64 and 65 to 75. No visual difference in probability can be seen in the plot.

Table 4.11 shows the logistic regression analyses of decisional preference with gender as a moderator. Similar to the previous regression analyses for decisional preference, none of the three models were significant. The same covariates were used in these models. Workshop attendance was significant for all three models and in the final model individuals who attended a greater number of workshops were 2.419 times as likely to prefer making a shared decision as individuals attending fewer workshops (p < .05). Gender (moderator) was significant in the second model, but not the third model once the interaction term was included. In the second model women were 3.37 times as likely to prefer making a shared decision compared to men (p < .05). Neither health literacy nor the interaction term was significant. Figure 4.3 shows the interaction plot for health literacy x gender and the probability of preferring a shared decision.

Table 4.10. Hierarchical Logistic Regression Analyses for Decisional Preference with Age as a Moderator (N = 102)

	N	Model 1	N	Iodel 2	N	Model 3
	OR	95% CI	OR	95% CI	OR	95% CI
Gender						
Men	1.00		1.00		1.00	
Women	3.233	$[1.107, 9.444]^*$	3.374	[1.139, 9.990]*	3.396	$[1.146, 10.061]^*$
Insurance						
Private	1.00		1.00		1.00	
Medicare/Medicaid	3.598	[0.634, 20.411]	2.976	[0.480, 18.439]	2.859	[0.452, 18.086]
Other	3.199	[0.727, 14.083]	3.064	[0.686, 13.672]	3.127	[0.702, 13.929]
Multiple	2.864	$[0.868, 9.455]^{+}$	2.662	[0.678, 10.454	2.729	[0.692, 10.770]
None	1.326	[0.156, 11.257]	1.399	[0.162, 12.057]	1.331	[0.153, 11.563]
Employment						
Full-time	1.00		1.00		1.00	
Part-time	0.691	[0.126, 3.786]	0.660	[0.116, 12.057]	0.687	[0.120, 3.946]
Disabled	0.471	[0.055, 4.021]	0.465	[0.054, 3.972]	0.496	[0.056, 4.373]
Retired	0.686	[0.220, 2.142]	0.658	[0.194, 2.239]	0.660	[0.194, 2.238]
Not currently working	0.329	[0.048, 2.270]	0.305	[0.041, 2.250]	0.332	[0.044, 2.531]
CRC knowledge	1.147	[0.876, 1.503]	1.171	[0.885, 1.549]	1.171	[0.884, 1.552]
Workshop attendance	2.370	$[1.291, 4.352]^*$	2.378	$[1.287, 4.394]^*$	2.378	$[1.288, 4.393]^*$
Family CRC history						
No	1.00		1.00		1.00	
Yes	2.001	[0.373, 10.740]	1.901	[0.356, 10.162]	1.910	[0.354, 10.298]
Main Effects						
Health literacy			0.952	[0.822, 1.103]	0.975	[0.810, 1.173]
Age						
50-64			1.00		1.00	
65-75			1.084	[0.298, 3.937]	3.448	[0.011, 1047.65]
Interaction						
Health Literacy x Age					0.946	[0.725, 1.235]
X^2		17.791		18.254		18.431

Notes: Informed decision coded as reference group for decisional preference. p < .10, p < .05, p < .05, p < .001

Table 4.11. Hierarchical Logistic Regression Analyses for Decisional Preference with Gender as a Moderator (N = 102)

		Iodel 1		Iodel 2		Model 3
	OR	95% CI	OR	95% CI	OR	95% CI
Age	0.978	[0.893, 1.070]	0.972	[0.884, 1.068]	0.973	[0.885, 1.070]
Insurance						
Private	1.00		1.00		1.00	
Medicare/Medicaid	2.694	[0.518, 14.015]	3.128	[0.501, 19.543]	3.133	[0.502, 19.562]
Other	2.760	[0.675, 11.278]	3.059	[0.683, 13.700]	3.076	[0.685, 13.817]
Multiple	2.312	[0.683, 7.823]	3.269	[0.872, 12.259]	3.278	[0.873, 12.316]
None	1.447	[0.171, 12.247]	1.331	[0.151, 11.701]	1.308	[0.148, 11.527]
Employment						
Full-time	1.00		1.00		1.00	
Part-time	0.551	[0.095, 3.192]	0.753	[0.131, 4.343]	0.763	[0.132, 4.418]
Disabled	0.471	[0.054, 4.081]	0.464	[0.054, 3.984]	0.458	[0.053, 3.953]
Retired	0.890	[0.260, 3.040]	0.809	[0.255, 2.910]	0.800	[0.221, 2.892]
Not currently working	0.382	[0.059, 4.081]	0.263	[0.035, 2.006]	0.276	[0.034, 2.208]
CRC knowledge	1.128	[0.872, 1.461]	1.171	[0.886, 1.549]	1.175	[0.887, 1.555]
Workshop attendance	2.284	$[1.267, 4.115]^*$	2.428	$[1.307, 4.510]^*$	2.419	$[1.301, 4.497]^*$
Family CRC history						
No	1.00		1.00		1.00	
Yes	1.952	[0.369, 10.312]	2.106	[0.380, 11.664]	2.126	[0.382, 11.825]
Main Effects						
Health literacy			0.943	[0.812, 1.095]		
Gender					0.922	[0.718, 1.185]
Men			1.00		1.00	
Women			3.370	$[1.136, 9.997]^*$	1.752	[0.004, 747.253]
Interaction					1.032	[0.772, 1.381]
Health Literacy x Gender						
X^2		13.044		18.610		18.656

Notes: Informed decision coded as reference group for decisional preference. p < .10, p < .05, p < .001

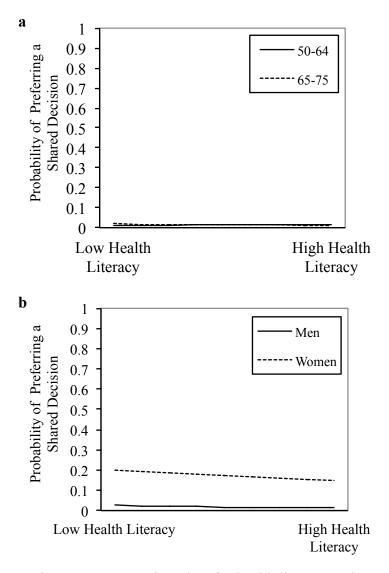


Figure 4.3. Interaction plots for health literacy and decisional preference with moderators (a) age and (b) gender for Focus on CRC participants.

Colorectal cancer test preference. Table 4.12 shows the logistic regression analyses of CRC test preference with age as a moderator. Covariates included in the analyses were gender, health insurance status, employment, CRC knowledge, ever been screened using FOBT, sigmoidoscopy, or colonoscopy, workshop attendance, and family CRC history. The first model included only the covariates and was statistically significant $[X^2 (15, N = 96) = 33.405, p < .05]$. Women were 3.88 times as likely to prefer colonoscopy (over FOBT)

compared to men, although this relationship was not significant (p < .10). Individuals who have ever had FOBT were 79% less likely to prefer colonoscopy than individuals who have never had FOBT (p < .05). Additionally, individuals who have ever had sigmoidoscopy were 15.33 times as likely to prefer colonoscopy than individuals never having sigmoidoscopy (p < .05). Similarly, individuals ever having colonoscopy were 7.613 times as likely to prefer colonoscopy than individuals never having previously completed colonoscopy (p < .05). The second model included the independent variable and moderator and was also significant $[X^2(17, N = 96) = 36.835, p < .05]$. The relationship between ever having FOBT and preferring colonoscopy less than FOBT was still significant (OR = 0.16, 95% CI: 0.04, 0.63; p < .05). Similarly, individuals previously having sigmoidoscopy (OR = 17.118, 95% CI: 2.03, 114.12) or colonoscopy (OR = 9.00, 95% CI: 1.86, 43.63) were still significantly more likely to prefer colonoscopy over FOBT (ps < .05). Also, age was approaching significance in this model. Individuals aged 65 to 75 were 82% less likely to prefer colonoscopy than individuals aged 50 to 64 (p < .10). The third model included the interaction term and was significant [X^2 (16, N = 96) = 39.090, p < .05]. Previous FOBT, sigmoidoscopy, or colonoscopy screening behavior were significant in this final model. Individuals who have ever had FOBT were 81% less likely to prefer colonoscopy than individuals who have never had FOBT (p < .05). Individuals ever having sigmoidoscopy were 20.20 times as likely to prefer colonoscopy than individuals never having sigmoidoscopy (p < .05). Individuals ever having colonoscopy were 9.18 times as likely to prefer colonoscopy than individuals never previously having colonoscopy (p < .05). None of the main effects (health literacy, age) or the interaction term were significant in this model. Figure 4.4 displays the interaction plot for health literacy x age and the probability of preferring colonoscopy.

Table 4.13 shows the logistic regression analyses of CRC test preference with gender as a moderator. All three models were statistically significant [Model 3: X^2 (16, N = 96) = 35.332, p < .05] and had the same covariates as the previous set of analyses. Previous CRC screening was the only significant association with CRC test preference in these models. In the final model, individuals who have ever had FOBT were significantly more likely to prefer FOBT (over colonoscopy) compared to individuals never having FOBT (OR = 0.23, 95% CI: 0.06,0.86; p < .05). Additionally, individuals ever having sigmoidoscopy were 18.26 times as likely to prefer colonoscopy than individuals never having sigmoidoscopy (p < .05). Lastly, individuals ever having colonoscopy were 9.14 times as likely to prefer colonoscopy (p < .05). None of the main effects or interaction term were significant. Figure 4.4 illustrates the interaction plot for health literacy x gender for the probability of preferring colonoscopy.

Table 4.12. Hierarchical Logistic Regression Analyses for CRC Test Preference with Age as a Moderator (N = 96)

	N	Model 1	N	Model 2	N	Model 3
	OR	95% CI	OR	95% CI	OR	95% CI
Gender						
Men	1.00		1.00		1.00	
Women	3.881	$[0.873, 16.630]^{+}$	2.707	[0.583, 12.563]	3.356	[0.684, 16.461]
Insurance ^a		2				
Private	1.00		1.00		1.00	
Medicare/Medicaid	0.907	[0.144, 7.240]	1.440	[0.161, 12.904]	1.322	[0.144, 12.100]
Other	5.654	[0.636, 50.290]	5.453	[0.590, 50.362]	5.923	[0.627, 55.906]
Multiple	1.119	[0.239, 5.236]	2.403	[0.380, 15.183]	3.011	[0.436, 20.794]
Employment		. , ,		, ,		. , ,
Full-time	1.00		1.00		1.00	
Part-time	0.241	[0.025, 2.296]	0.429	[0.040, 4.649]	0.522	[0.047, 5.823]
Retired	0.517	[0.100, 2.684]	0.974	[0.152, 6.251]	0.851	[0.129, 5.618]
Not currently working	0.376	[0.049, 2.895]	0.258	[0.030, 2.234]	0.372	[0.038, 3.625]
CRC knowledge	1.041	[0.729, 1.487]	1.060	[0.733, 1.532]	1.053	[0.724, 1.532]
Ever had FOBT						
No	1.00		1.00		1.00	
Yes	0.206	$[0.056, 0.751]^*$	0.160	$[0.041, 0.633]^*$	0.189	$[0.047, 0.755]^*$
Ever had sigmoidoscopy						
No	1.00		1.00		1.00	
Yes	15.329	[1.904, 123.411]*	17.118	[2.033, 144.122]*	20.201	[2.244, 181.861]*
Ever had colonoscopy		, ,				. , ,
No	1.00		1.00		1.00	
Yes	7.613	[1.684, 34.406]*	9.004	[1.858, 43.631]*	9.184	[1.821, 46.327]*
Workshop attendance	0.759	[0.323, 1.783]	0.781	[0.322, 1.894]	0.722	[0.381, 1.876]
Family CRC history						
No	1.00		1.00		1.00	
Yes	1.415	[0.179, 11.157]	1.371	[0.163, 11.553]	1.383	[0.158, 12.117]
Main Effects		, ,				
Health literacy			1.046	[0.880, 1.244]	1.175	[0.928, 1.488]
Age						
50-64			1.00		1.00	
65-75			0.182	$[0.025, 1.309]^{+}$	42.808	[0.023, 81382.8]
Interaction						
Health Literacy x Age					0.771	[0.545, 1.091]
X^2		33.405*		36.835 [*]		39.090^*

Notes: "No health insurance" under health insurance and "disabled" under employment excluded from analyses due to low sample size. FOBT coded as reference group for CRC test preference. $^+p < .10, ^{**}p < .05, ^{***}p < .001$

Table 4.13. Hierarchical Logistic Regression Analyses for CRC Test Preference with Gender as a Moderator (N = 96)

	N	Iodel 1	N	Model 2	N	Model 3
	OR	95% CI	OR	95% CI	OR	95% CI
Age	0.926	[0.808, 1.063]	0.935	[0.812, 1.075]	0.931	[0.808, 1.072]
Insurance						
Private	1.00		1.00		1.00	
Medicare/Medicaid	1.051	[0.129, 8.580]	1.184	[0.139, 10.054]	1.198	[0.135, 10.614]
Other	3.909	[0.554, 27.588]	5.552	[0.620, 49.684]	4.840	[0.532, 44.027]
Multiple	1.287	[0.253, 6.547]	1.544	[0.288, 8.269]	1.414	[0.253, 7.895]
Employment						
Full-time	1.00		1.00		1.00	
Part-time	0.402	[0.040, 4.006]	0.353	[0.033, 3.775]	0.349	[0.032, 3.803]
Retired	1.085	[0.179, 6.594]	0.785	[0.120, 5.129]	0.831	[0.126, 5.481]
Not currently working	0.242	[0.030, 1.970]	0.315	[0.037, 2.670]	0.254	[0.027, 2.364]
CRC knowledge	1.070	[0.764, 1.499]	1.027	[0.723, 1.461]	1.036	[0.731, 1.466]
Ever had FOBT						
No	1.00		1.00		1.00	
Yes	0.215	$[0.061, 0.761]^*$	0.208	$[0.056, 0.769]^*$	0.229	$[0.061, 0.860]^*$
Ever had sigmoidoscopy						
No	1.00		1.00		1.00	
Yes	10.869	$[1.671, 70.672]^*$	19.355	$[2.183, 171.630]^*$	18.260	$[2.051, 162.579]^*$
Ever had colonoscopy						
No	1.00		1.00		1.00	
Yes	7.113	$[1.621, 31.217]^*$	9.112	[1.913, 43.399]*	9.142	[1.919, 43.553]*
Workshop attendance	0.783	[0.337, 1.820]	0.755	[0.316, 1.806]	0.721	[0.296, 1.756]
Family CRC history						
No	1.00		1.00		1.00	
Yes	1.020	[0.134, 7.766]	1.395	[0.173, 11.238]	1.527	[0.185, 12.635]
Main Effects						
Health literacy			1.035	[0.867, 1.234]	1.156	[0.836, 1.599]
Gender						
Men			1.00		1.00	
Women					91.179	[0.033, 253930.8]
Interaction						
Health Literacy x Gender					0.851	[0.580, 1.250]
X^2		31.282*		34.638*		35.332 [*]

Notes: "No health insurance" under health insurance and "disabled" under employment excluded from analyses due to low sample size. FOBT coded as reference group for CRC test preference. p < .10, p < .05, p < .001

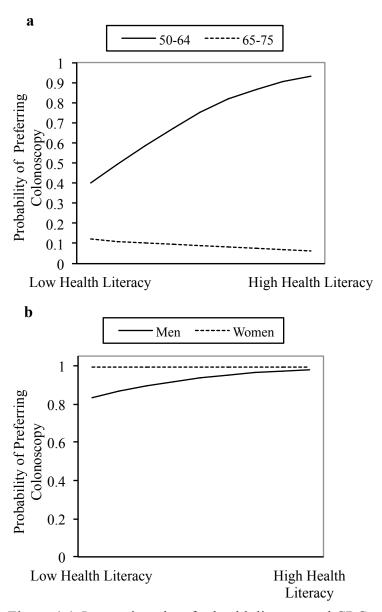


Figure 4.4. Interaction plots for health literacy and CRC test preference with moderators (a) age and (b) gender for Focus on CRC participants.

Chapter 5: Discussion

The purpose of this study was to examine the relationship of health literacy and other social determinants of health related with indicators of decision making for CRC screening among African Americans. As this population experiences disparities relating to CRC screening, incidence, and mortality (ACS, 2014), a better understanding of the social determinants of health related to low CRC screening is required to develop targeted and effective interventions (Kilbourne et al., 2006). The research was guided by the Ottawa Decision Support Framework focusing on the "decisional needs" of an individual who are suggested to impact decision making outcomes (O'Conner et al., 1998). The research recruited participants from Project HEAL who were engaged in a cancer early detection program in African American churches (Holt et al., 2014). The study population was a fairly heterogeneous population regarding sociodemographic factors such as education, employment, and marital status and provided a first step to understanding the complexities of decision making for CRC screening among African Americans.

Moderation Analyses

The moderation analyses of both age and gender across the first four aims were not significant (ps > .10), demonstrating no significant interactions between age or gender with health literacy for any of the four dependent variables (i.e., decisional conflict, decision self-efficacy, decisional preference, CRC test preference). Therefore, the second and third hypotheses for the first four aims were not supported. However due to the low sample sizes—particularly among men (n = 31) and older individuals (aged 65 to 75; n = 37) in the study population—the lack of significance may be related to insufficient power. The interaction plot for age and CRC test preference (Figure 4.4a, p = .143) suggests a difference

in CRC test preference based on both health literacy and age, particularly for the younger age group. Younger individuals aged 50 to 64 with greater health literacy had greater odds for preferring colonoscopy than younger individuals with lower health literacy. This pattern did not appear for the older age group. Previous research has identified variations in the relationship between health literacy and CRC screening between these two age groups (White et al., 2008). However while the current findings suggest there may be differences in the younger population, previous research found health literacy to be a significant predictor of CRC screening status among adults age 65 and older (White et al., 2008). It should be noted that the previous study used CRC screening behavior as the dependent variable while the present study had CRC test preference as the dependent variable, which may account for differences in study findings. Future research should reexamine the possible moderation effects of age and gender on these decision making indicators among a larger population sample.

Decisional Conflict

Several of the findings suggest certain social determinants of health are related to decisional conflict. CRC knowledge and health literacy has previously been associated with decision making (Messina et al., 2005) and health literacy has been identified as a predictor of knowledge (see Arnold et al., 2012; Dolan et al., 2004; Morris et al., 2013). These two factors had a significant association with one another in the current study and were both negatively associated with decisional conflict (ps < .05) and these findings support the first hypothesis for Aim 1 (H1a). Previous research has similarly found that women with low levels of knowledge about mammography had significantly greater levels of decisional conflict (Nekhlyudov et al., 2008). This was consistent with the findings of the present study

as both CRC knowledge and health literacy were negatively associated with decisional conflict. Bivariate analyses also found educational attainment to be significantly related to decisional conflict—individuals with greater educational attainment had lower decisional conflict (p < .05). Previous research has found a significant association between education and preference for completing CRC screening (Sheikh et al., 2004). Education has also been associated with CRC screening test knowledge and preference (D. P. Miller et al., 2007; Powell et al., 2009). Future research should seek to further identify the relationships between health literacy, CRC knowledge, education, and decisional conflict in this population.

Gender was also significantly associated with decision making in the bivariate analyses (p < .05) and women had significantly lower decisional conflict compared to men. However, this relationship was not statistically significant in the regression analyses (p >.10). Research has shown women are often responsible for communicating and maintaining their family's health information (Wiseman, Dancyger, & Michie, 2010) and may be related to reduced decisional conflict in this population. Additionally, other predictors of CRC decision making (e.g., family support, CRC beliefs) have been found to vary between men and women (Brittain, Loveland-Cherry, Northouse, Caldwell, & Taylor, 2012). Future research should investigate the association between gender and decision making indicators to identify possible targets for interventions to ensure quality decision making outcomes among both men and women. Additionally, single individuals had slightly lower decisional conflict than married individuals (p < .10). Decisional conflict was significantly lower for single individuals than married individuals among individuals aged 50 to 64 (p < .05; Table A.4) and this relationship was not found among individuals aged 65 to 75 (p > .10). These results suggest married individuals may have different considerations when making decisions for

CRC screening than single individuals. The current published literature has not examined the relationship between marital status and indicators of decision making and these findings raise questions about the differences in decision making for married versus unmarried individuals.

Employment was another factor that was significant in both studies; individuals who were not currently working or only working part-time had greater decisional conflict than retired individuals or individuals working full-time (ps < .05). This relationship held for individuals aged 50 to 64 (ps < .05; Table A.4), but not for the older population (aged 65 to 75; ps > .10). However, the older population in the current study was significantly more likely to be retired (p < .001; Table A.1) and employment may only be a concern for younger individuals not yet at retirement age. Furthermore, this relationship was significant among women (ps < .05; Table A.10), but not men (ps > .10). It should be noted that there was no significant difference in employment status between men and women (p > .10; Table A.7). Research has not identified employment as a factor significantly associated with decisional conflict for CRC screening, however unemployment was significantly associated with lower odds of CRC screening completion in a predominantly African American population (Chatterjee, Chattopadhyay, & Levine, 2015). These findings suggest a stable income through steady employment or retirement may reduce the decisional conflict an individual may have when making a medical decision. Previous research has found increased preference for sigmoidoscopy or colonoscopy (versus FOBT) when individuals were told they would have no out-of-pocket costs for any CRC screening test (Pignone et al., 1999) and CRC screening rates among low- and middle-income individuals increased after the elimination of cost-sharing from the Affordable Care Act (Fedewa et al., 2015). A high percentage of the current study population had health insurance and there may have been insufficient power to

identify statistically significant differences in individuals without any health insurance. Future research should further investigate the relationship between socioeconomic factors and decision making outcomes in African Americans, particularly as CRC screening rates are lower in poor to middle-income African Americans compared to high-income African Americans (AHRQ, 2016).

Decision Self-Efficacy

The results for the regression analyses with decision self-efficacy supported the first hypothesis for Aim 2 (H2a) as individuals with greater health literacy had significantly greater decision self-efficacy (p < .05). These findings also support previous research that found individuals with high health literacy were significantly more likely to receive encouragement for CRC screening, have greater self-efficacy to complete screening, lower perceived barriers and greater perceived benefits to screening (Arnold et al., 2012). Educational attainment was positively correlated with decision self-efficacy in the bivariate analyses (p < .05). Again, education has been significantly associated with CRC screening preference and knowledge (D. P. Miller et al., 2007; Powell et al., 2009; Sheikh et al., 2004). Additionally, women had significantly greater decision self-efficacy compared to men in the bivariate analyses (p < .05), however this was no longer significant in the regression analyses (p > .10). The role of women as 'health historians' in their families (Wiseman et al., 2010) may be related to their increased decision self-efficacy and this relationship should be investigated to identify potential mechanisms for interventions in this population.

Research investigating family history and cancer screening behaviors is inconclusive (see K. A. Griffith, McGuire, Royak-Schaler, Plowden, & Steinberger, 2008). However, the present study found individuals with a first-degree family history of CRC had significantly

lower decision self-efficacy compared to individuals without a family history. Approximately 20% of CRC cases are associated with a family history (Ahsan et al., 1998; Fuchs et al., 1994) and screening recommendations for CRC change when an individual has a first-degree family history of CRC with recommendations to use colonoscopy at earlier ages and varying—often greater—frequency (ACS, 2014). While these individuals may not have significantly greater conflict in making the decision, the knowledge of having a family history and perhaps a shift in a provider's CRC screening recommendations may reduce the overall confidence in making a decision. The findings suggest the relationship between decision self-efficacy and family history may need to be further investigated as they may indicate another significant relationship that may prompt tailored decision aids for individuals with a family history.

Decisional Preference

The first hypothesis for Aim 3 (H3a; individuals with greater health literacy will be more likely to prefer making an informed decision) was not supported by the findings as health literacy was not significantly related to decisional preference (p > .10). The current study found women preferred a shared decision making style compared to men (p < .05) and is consistent with previous research among CRC patients that found women were more likely to prefer shared decision making (Salkeld et al., 2004). The gender stratified analyses (Table A.12) found women with a family history of CRC were significantly more likely to prefer a shared decision (p < .05) and no significant relationships were identified for men (ps > .10). However due to the low sample size future research should reexamine social determinants of health and their relation to decisional preference by gender in a larger population.

Study participants were enrolled in a cancer early detection program that included three workshops covering breast, prostate, and colorectal cancer. These messages were primarily delivered by CHAs with the addition of an educational booklet (given to all participant regardless of overall attendance). Individuals who attended a greater number of Project HEAL workshops and those who attended the CRC-specific workshop were significantly more likely to prefer making a shared decision for CRC screening than an informed decision (ps < .05). This is consistent with previous research that found slightly more than half of a population of average-risk African Americans between the ages of 50 and 75 preferred making a shared decision with their providers for CRC screening while approximately 25% preferred making an informed decision primarily on their own after receiving a short educational module on CRC screening (Schroy III et al., 2007). Future research should identify the causal relationship between workshop attendance and decisional preference. Specifically, did the workshop attendance increase decisional preference for a shared decision or were individuals who attended more workshops already prefer shared decision making?

Colorectal Cancer Test Preference

While just having a CRC test preference alone may not always be predictive of screening test completion (Ruffin IV et al., 2007), concordance between provider recommendation and patient test preference for CRC screening can contribute to low rates of screening completion (Hawley et al., 2012). A better understanding of patient preferences for CRC screening may increase receptivity to CRC screening and subsequently, CRC screening rates (Hawley et al., 2012). Previous research has found that individuals previously receiving colonoscopy were significantly more likely to prefer colonoscopy (Sheikh et al., 2004). This

was consistent with the study findings as previous screening behavior was the only significant association with CRC test preference (ps < .05). This may have been a result of familiarity and experience with those particular CRC screening tests. The first hypothesis for Aim 4 (H4a; individuals with greater health literacy will be more likely to prefer colonoscopy) was not supported by the findings as health literacy was not significantly related to CRC test preference (p > .10). Additionally, as previously discussed, the older population (65-75) were more likely to prefer FOBT over colonoscopy than the younger population (p < .10). There is no known published research investigating decision making factors between an older and younger cohort of adults eligible for CRC screening, however these findings suggest future research may be warranted to identify the differences between these two age groups.

Limitations

There are several limitations to the proposed study including possible selection bias from participants' enrollment in the study. Certain demographic items (e.g., individuals without any health insurance) had low sample sizes and may not have had sufficient power to detect statistical significance. Furthermore, eligible participants were recruited by the CHAs within each church and participants may have self-selected into the study. Additionally, the study focuses on individuals between the ages of 50 and 75 as the Focus on CRC seed grant only recruited individuals in this age range following USPSTF screening guidelines (2015). While these ages meet many of the screening recommendations, the American College of Gastroenterology define African Americans as a high risk group and recommends screening beginning at age 45 (Rex et al., 2009). While some screening recommendations may start at age 50, individuals might begin considering their CRC test preference prior to turning 50.

Had the Focus on CRC seed grant recruited individuals aged 45 through 49, an additional 70 individuals would have been eligible for the survey. Future research may consider extending eligibility to individuals age 40 or 45.

Another limitation of this study is the lack of analysis of potential associations between decision making and cancer screening behavior. Due to the timing of the Focus on CRC seed grant and the Project HEAL parent grant, variables collected on the seed grant survey were obtained after the Project HEAL 12-month follow-up survey that reported cancer screening behaviors. Additionally, while a 24-month survey is currently being collected for Project HEAL that will ask for participants' cancer screening behaviors, the data collection is ongoing and would not have concluded in a timeframe suitable for inclusion in this study.

Barriers to CRC screening may be a potential confounder to decision making but had much greater missing data (up to 26% missing) compared to other variables in the baseline survey due to skip patterns. As the data was missing at random—missing due to another variable, in this case the items causing skip pattern—the recommended steps would be to remove the cases that have missing data. Imputation or another technique to handle the missing data is not suggested as the data is providing insufficient information to properly impute data (Gelman & Hill, 2006). Due to the already low sample size, removing additional cases would lower the power even further and as a result, barriers to CRC screening were excluded from the present study.

As the independent and dependent variables were collected at the same time point, the study is unable to assess any potential causal relationships between variables. Rather, the findings can only suggest possible associations between variables that should be further

examined with future studies. Additionally, there may be other possible explanations for decision making in CRC screening that were not included in the study.

Participants' interpretation of "shared" and "informed" decision may not be consistent with the definitions used in the proposed study. As the surveys were completed with close-ended items without the ability for further elaboration from participants on item responses, it is unknown how participants may have interpreted the items. The scales used for certain items (i.e., decisional conflict, decision self-efficacy) also may not have been well-suited for a community-based sample. The items were developed for clinical settings and patients actively completing a decision aid. Therefore, constructs such as "conflict" may not be viewed similarly in a community-based sample as they are in a clinic-based sample. Future research should revisit the decision-related items used in the Focus on CRC survey to confirm the items are appropriately developed for a community-based sample.

Strengths

Strengths to the research include the targeted focus on a population who has already been identified as impacted by health disparities. Research has established that African Americans are screened less often for CRC and experience greater rates of incidence and mortality (ACS, 2014). Additional research examining differences in screening rates and behaviors between population groups (e.g., African Americans and Whites) may not necessarily be sufficient to identify solutions to increase screening rates within one specific population. Therefore, by focusing within the African American population, research may begin to identify factors that are specific to this population for CRC screening. Additionally, the population group was community-based and already engaged in a health promotion program. By focusing on a community-based sample who was enrolled in a health promotion

program, the research provides a unique perspective on African Americans who are actively engaged in their own health.

Implications for Public Health

While the screening gap between African Americans and Whites may be beginning to close, gaps persist within the African American population (e.g., high-income African Americans are screened more often than lower income individuals; AHRQ, 2016). These findings highlight areas that may be incorporated into decision aids targeted for African Americans considering CRC screening, particularly subgroups within the African American population who may experience disparate access to health services. To effectively reduce and eventually eliminate health disparities, researchers need to understand the social determinants of health that are driving the disparities (Kilbourne et al., 2006). These findings demonstrate that within this population, certain social determinants of health may be associated with decision making.

The demographics of this study population are unique from other published literature examining decision making—particularly concerning CRC—among African Americans.

While other studies may have demographics similar to the current study (see K. L. Taylor et al., 2006), these studies are focusing on cancers other than CRC. Additionally, many other studies focus on low-income or low-literacy African Americans in settings such as Federally Qualified Health Centers (see Arnold et al., 2012). Studies have shown that the African American middle class is growing, and a proportion of these individuals are single and living alone (Marsh, Darity Jr., Cohen, Casper, & Salters, 2007). As martial status was significantly associated with decisional conflict in the present study, it is important to understand what constitutes middle class African Americans, especially as it relates to marital status. Past

research has suggested the majority of middle class African Americans are married, however 25% have never married and live alone (Marsh et al., 2007). This is consistent with the demographics of the current study where only 53% were married and 25% had never been married. Research has found that single African Americans living alone live in neighborhoods that are more racially segregated and have lower income than married African Americans or white Americans of any marital status (Marsh & Iceland, 2010). As screening disparities persist within the African American population based on income level (AHRQ, 2016) and the current study findings suggest additional differences in decision making for CRC screening based on marital status, it is vital that researchers understand how individuals in this growing population make important medical decisions. Future research should further examine decision making among middle class African Americans to clarify how this group approaches decision making for CRC screening.

In addition to demographic factors such as marital status, the study population consisted of church-going individuals—a characteristic that may influence their decision making and overall screening habits for CRC. Past research has found positive associations between religiosity and health behaviors, including cancer screening (see Leyva, Nguyen, Allen, Taplin, & Moser, 2015). Additionally, spiritually-based messages have been effective tools to increase cancer screening among church-going African Americans (see Holt et al., 2012). Research has suggested social support as a mechanism linking religious behavior and cancer screening (Berkman & Glass, 2000) and has been found to partially mediate the relationship between religiosity and CRC screening behavior (Leyva et al., 2015). Churchgoing individuals may be able to draw support from fellow congregation members such as emotional support to reduce anxiety (Kinney, Bloor, Martin, & Sandler, 2005). Additional

research is needed to clarify the relationship between religiosity and decision making for CRC screening among African Americans, including the potential mediating effect of social support.

A first-degree family history of CRC was negatively associated with decision self-efficacy, suggesting knowledge of a family history may alter the decision making process for CRC screening. Previous research has found individuals with a family history were more likely to discuss their risk for developing CRC as well as CRC screening with their health providers (Zlot et al., 2012). Additionally, while research has found associations between perceived risk, fatalism, and social support with CRC screening (Boonyasiriwat et al., 2014), other research has found African Americans with a family history of CRC are screened less often than Whites with a family history (K. A. Griffith et al., 2008). Furthermore, African Americans with a family history are screened less often than African Americans without a family history (K. A. Griffith et al., 2008). Further research is needed to understand predictors of decision making and screening for African Americans with a family history of CRC. Additional research is also suggested to identify differences in decision making for individuals with a family history of CRC and a family history of any cancer to identify how these individuals approach CRC screening.

The current study findings suggest there may differences between men and women in indicators of decision making. For example, women had significantly lower decisional conflict and preferred a different decision making style than men (p < .05). As previously mentioned, women are often the 'health historians' for their families (Wiseman et al., 2010). This may have increased their self-efficacy for making complex health decisions. However, research has identified normative expectations for African American men where they avoid

regular visits with their health provider, and when they do visit, are often dissatisfied with the quality of patient-provider communication (D. M. Griffith, Allen, & Gunter, 2011). This may have been reflected in the findings of the current study and suggests future research is needed to further examine the differences identified between men and women in this study to help inform gender-specific CRC screening interventions. Gender-specific CRC screening interventions have been developed to increase CRC screening behaviors among African American men and women (see Babikian & Chang, 2015; Dietrich et al., 2007; Phillips, Hendren, Humiston, Winters, & Fiscella, 2015; Powe, 2002; Ravenell et al., 2013). African American men have expressed interest in programs that bring men together in fellowship to discuss cancer screening (Langford, Griffith, Beasley, & Braxton, 2014) and interventions in settings such as barbershops have demonstrated high receptivity among men in this population (Ravenell et al., 2013). CRC screening interventions developed specifically for women have found success when also including breast and/or cervical cancer screening (Dietrich et al., 2007; Phillips et al., 2015).

Differences found between adults aged 50 to 64 and 65 to 75 highlight the need for further investigation of social determinants of health within these two groups. Previous research has identified differences in CRC screening adherence after a screening intervention among these two groups; participants aged 65 and older had significantly higher screening rates at follow-up compared to participants aged 50 to 64 (Denberg, et al., 2006). There are no known interventions targeting adults specifically in either age group, however an intervention located in senior centers that had a primarily African American population with a mean age of 74 years found increased CRC knowledge at follow-up (Powe, Ntekop, & Barron, 2004). A more detailed examination of the differences in decision making between

adults aged 50 to 64 and adults aged 65 to 75 may help identify potential mechanisms for interventions tailored to a specific age group.

The current study only examined one component (i.e., decisional needs) of the Ottawa Decision Support Framework that is a small part of the total decision making process (O'Connor et al., 1998). As CRC screening is a behavior that must be repeated every one, five, or ten years (USPSTF, 2015), researchers should understand the full decision making process, including decision support and decisional quality. Particularly as the current study found previous CRC screening behavior was predictive of CRC test preference, researchers need to understand the predictors of decisional quality. Overall satisfaction with the decision making process and concordance between an individual's values and the chosen option is associated with reduced distress and decisional regret, improved quality of life, and continued persistence with one's choice (e.g., continued colonoscopy every ten years; Murray et al., 2004). Future research is suggested to examine the decision making process through decisional quality to identify any significant predictors of decisional quality among African Americans to help further inform future development of decision aids.

While the current study examined decisional preference, it did not investigate concordance between decisional preference and the actual decision making style used for CRC screening. The Focus on CRC survey had an additional item for who 'usually makes' the decision (e.g., provider, patient, shared) and it is suggested that a future study examining the concordance between preferred and usual decision making is completed. The study also had a high percentage of individuals who had been previously screened for CRC and study findings found a significant relationship between previous CRC screening behavior and CRC test preference. Additional research is suggested to identify factors associated with decision

making for individuals who have never been screened for CRC as their lack of experience with the CRC screening tests may change how they approach decision making for CRC screening.

Overall, the study findings suggest further research is needed to better understand the associations identified between health literacy and other social determinants of health with indicators of decision making among African Americans. While the study population had some heterogeneity in indicators of social determinants of health (e.g., employment, educational attainment), a larger sample with a greater percentage of individuals without health insurance may help elucidate the impact of financial constraints on decision making. Additionally, qualitative interviews or focus groups may be another method to understand the social determinants of health impacting decision making. Once researchers more fully understand the relationship of social determinants of health with decision making, findings can be used to develop, implement, and evaluate targeted interventions (Kilbourne et al., 2006). The setting (e.g., clinical, community-based) should be determined by future exploratory research and should be sensitive to resources—both for the individual and health services. Overall, these findings are a step towards a better understanding of how social determinants of health are related to decision making for CRC screening among African Americans.

Appendix A – Stratified Analyses: Age and Gender

Age Stratified Analyses

Table A.1. Demographic Characteristics of Focus on CRC Participants aged 50-64 and 65-75

Table A.1. Demographic Characteristics of	Focus on CRC Partic	ipants aged 50-64 an	d 65-75
	Age 50-64	Age 65-75	
	$n (\%)$ or $M \pm SD$	$n (\%)$ or $M \pm SD$	
Characteristic	n = 74	n = 37	<i>p</i> -value
Gender			.079
Male	17 (23.0)	14 (37.8)	
Female	57 (77.0)	23 (62.2)	
Marital status			.008
Married	32 (43.2)	27 (73.0)	
Single	21 (28.4)	7 (18.9)	
Other	21 (28.4)	3 (8.1)	
Education			< .001
< High school diploma	6 (8.1)	4 (10.8)	
High school diploma	22 (29.7)	7 (18.9)	
Some college	24 (32.4)	17 (45.8)	
College degree	22 (29.7)	9 (24.3)	
Employment	, ,	, ,	< .001
Full-time	42 (56.8)	5 (13.5)	
Part-time	4 (5.4)	4 (10.8)	
Disabled	7 (9.5)	2 (5.4)	
Retired	12 (16.2)	26 (70.3)	
Not currently	9 (12.2)	0(0.0)	
Health Insurance			< .001
Private	42 (56.8)	8 (21.6)	
Medicare/Medicaid	12 (16.2)	6 (16.2)	
Other	11 (14.9)	1(2.7)	
Multiple	5 (6.8)	22 (59.5)	
None	4 (5.4)	0 (0.0)	
CRC knowledge (max score = 9)	7.4 ± 1.9	7.6 ± 1.5	.674
Ever had FOBT ^a	28 (37.8)	17 (45.9)	.268
Ever had sigmoidoscopy ^a	16 (21.6)	16 (43.2)	.017
Ever had colonoscopy ^a	44 (59.5)	32 (86.5)	.003
Attended CRC WS ^a	41 (55.4)	20 (54.1)	.526
WS attendance (max score = 3)	2.0 ± 0.8	2.2 ± 0.8	.247
First-degree family history of CRC ^a	4 (5.4)	6 (16.2)	.067
Health literacy (max score = 25)	21.4 ± 3.2	20.5 ± 4.3	.226

Notes: CRC = colorectal cancer, FOBT = fecal occult blood test, WS = workshop. a binary variable with 0 = no and 1 = yes.

Table A.2. Descriptive Statistics of Decision Making Indicators for Focus on CRC Participants aged 50-64 and 65-75

	Age 50-64	Age 65-75	
	n (%) or $M \pm SD$	n (%) or $M \pm SD$	
Indicator	n = 74	n = 37	<i>p</i> -value
Decisional conflict (max score = 100)	20.5 ± 27.1	13.5 ± 22.8	.178
Decision self-efficacy (max score = 100)	85.1 ± 18.2	86.1 ± 16.7	.797
Decisional preference ^a			.264
Shared	30 (44.1)	18 (52.9)	
Informed	38 (55.9)	16 (47.1)	
CRC test preference ^b			.348
FOBT	15 (23.1)	9 (29.0)	
Colonoscopy	50 (76.9)	22 (71.0)	

Notes: CRC = colorectal cancer, FOBT = fecal occult blood test, WS = workshop. a Age 50-64: n = 68, Age 65-75: n = 34. b Age 50-64: n = 65, Age 65-75: n = 31.

Table A.3. Chi-square Analyses for Decisional Preference and CRC Test Preference among Focus on CRC Participants Aged 50-64 and 65-75

		D	ecisional	Preference					CRC Test	Preference		
	Age	50-64 (n = 6)	8)	Age	65-75 (n = 3)	4)	Age	50-64 (n =	= 65)	Age	65-75 (n =	= 31)
	Shared	Informed	X^2	Shared	Informed	X^2	FOBT	CS	X^2	FOBT	CS	X^2
Marital status			1.460			3.827			0.110			1.794
Married	13	13		11	14		7	21		8	15	
Single	10	11		6	1		4	14		1	4	
Other	7	14		1	1		4	15		0	3	
Employment			0.137			1.479			5.823			1.705
Full-time	18	22		3	2		9	29		1	3	
Part-time	2	2		1	3		0	3		2	2	
Disabled	2	3		1	1		0	5		0	2	
Retired	5	7		13	10		2	9		6	15	
Not currently	3	4		0	0		4	4		0	0	
Health Insurance			0.855			3.896			1.208			2.564
Private	21	16		6	2		9	29		4	4	
Medicare/Medicaid	7	4		2	3		3	7		1	4	
Other	5	6		0	1		2	7		0	1	
Multiple	3	2		8	12		1	4		4	13	
None	2	2		0	0		0	3		0	0	

Notes: CRC = colorectal cancer, FOBT = fecal occult blood test, CS = colonoscopy. p < .10, p < .05, p < .001

Table A.4. ANOVAs for Decisional Conflict and Decision Self-Efficacy among Focus on CRC Participants Aged 50-64 and 65-75 (N = 111)

		Decisional	Conflict			Decision Se	lf-Efficacy	
-	Age 50-64 (n	= 74)	Age 65-75 (n	= 37)	Age 50-64 (n	= 74)	Age 65-75 (n	= 37)
Variable	$M \pm SD$	F	$M \pm SD$	F	$M \pm SD$	F	$M \pm SD$	F
Marital status		5.382*		1.048		0.441		0.897
Married	30.9 ± 34.4^{b}		12.2 ± 22.8		83.7 ± 19.9		87.7 ± 16.8	
Single	7.9 ± 15.8^{b}		10.7 ± 18.4		88.3 ± 20.6		84.7 ± 12.8	
Other	17.4 ± 15.3		31.7 ± 32.5		84.1 ± 16.7		74.2 ± 25.0	
Employment		6.285^{**}		0.374		1.171		0.236
Full-time	$14.9 \pm 18.5^{b,c,e}$		20.0 ± 32.6		86.1 ± 17.6		87.2 ± 13.1	
Part-time	$53.8 \pm 31.2^{b,d}$		16.3 ± 32.5		88.1 ± 11.6		89.8 ± 17.6	
Disabled	33.6 ± 41.3^{a}		0.0 ± 0.0		73.1 ± 29.5		93.2 ± 0.0	
Retired	$5.0 \pm 8.3^{a,d,f}$		12.9 ± 20.7		90.3 ± 8.2		84.7 ± 18.2	
Not currently	$42.8 \pm 37.6^{c,e,f}$		_		81.6 ± 21.4			
Health Insurance		1.227		0.083		0.550		2.741^{+}
Private	17.1 ± 25.8		12.5 ± 26.7		87.3 ± 17.4		92.3 ± 9.9	
Medicare/Medicaid	32.1 ± 39.1		16.7 ± 19.7		80.9 ± 24.2		70.5 ± 18.3	
Other	13.6 ± 13.2		5.0 ± 0.0		86.0 ± 15.4		100.0 ± 0.0	
Multiple	34.0 ± 19.2		13.4 ± 23.6		77.7 ± 19.0		87.4 ± 16.5	
None	23.8 ± 29.3		13.5 ± 22.8		81.8 ± 15.9		86.1 ± 16.7	

Notes: CRC = colorectal cancer. Post-hoc using Tukey completed for ANOVAs with p < .10. Within-group pairwise comparison: p < .10. b-fWithin-group pairwise comparison: p < .05. No individuals in 65-75 age group were "not currently working." p < .10, p < .05, p < .05, p < .05

Table A.5. Correlations Matrix for Decision Making Indicators among Focus on CRC Participants ages 50-64 (N = 74)

Variable	1	2	3	4	5	6	7	8	9	10	11	12	13	14
1. Gender	_	.21*	.10	10	03	12	.09	.06	01	.13	16	.12	.19	.09
2. Education	.21*		.27*	25*	08	03	.02	06	02	.37*	29*	.28*	03	.03
3. CRC knowledge	.10	.27*	_	10	09	.04	.10	.04	.07	.24*	21 ⁺	.15	.22+	.01
4. Ever had FOBT	10	25*	10		.20+	.08	.03	01	.06	.02	05	17	12	19
5. Ever had FS	03	08	09	.20+		.30*	06	14	.17	.03	03	11	07	.29*
6. Ever had CS	12	03	.04	.08	.30*		02	.04	.20+	.08	06	14	.12	.28*
7. CRC WS	.09	.02	.10	.03	06	02		.70**	.21+	.11	09	04	.24*	07
8. Total WS	.06	06	.04	01	14	.04	.70**		.08	.04	11	.17	.30*	.00
9. Family CRC history	01	02	.07	.06	.17	.20+	.21+	.08		01	.03	28*	.24*	05
10. Health literacy	.13	.37*	.24*	.02	.03	.08	.11	.04	01		41**	.41**	.01	.20
11. Decisional conflict	16	29*	21+	05	03	06	09	11	.03	41**		48**	15	03
12. Decision self-efficacy	.12	.28*	.15	17	11	14	04	.17	28*	.41**	48**		.05	.10
13. Decisional preference ^a	.19	03	.22+	12	07	.12	.24*	.30*	.24*	.01	15	.05		.02°
14. CRC test preference ^b	.09	.03	.01	19	.29*	.28*	07	.00	05	.20	03	.10	$.02^{c}$	_

Notes: CRC = colorectal cancer, FOBT = fecal occult blood test, FS = sigmoidoscopy, CS = colonoscopy, WS = workshop. a n = 68. b n = 65. c n = 60. $^{+}$ p < .10, * p < .05, ** p < .051

Table A.6. Correlations Matrix for Decision Making Indicators among Focus on CRC Participants ages 65-75 (N = 37)

Variable	1	2	3	4	5	6	7	8	9	10	11	12	13	14
1. Gender	_	14	10	.05	22	.02	.29+	.09	26	.22	41*	.38*	.23	.08
2. Education	14	_	.41*	.16	.04	.02	.01	.06	08	.49*	35*	.31+	27	14
3. CRC knowledge	10	.41*		.18	.46*	001	22	21	.12	.29+	33*	.13	20	.18
4. Ever had FOBT	.05	.16	.18		.18	.21	.20	.31+	.04	.19	25	.17	12	18
5. Ever had FS	22	.04	.46*	.18	_	13	29 ⁺	41*	.21	.01	26	06	11	.22
6. Ever had CS	.02	.02	001	.21	13		.11	.09	04	02	.01	.16	06	.39*
7. CRC WS	.29+	.01	22	.20	29 ⁺	.11		.77**	04	.06	01	18	.17	23
8. Total WS	.09	.06	21	.31+	41*	.09	.77**		.003	.22	.07	.13	.14	29
9. Family CRC history	26	08	.12	.04	.21	04	04	.003		17	02	37*	11	.09
10. Health literacy	.22	.49*	.29+	.19	.01	02	.06	.22	17		57**	.78**	06	16
11. Decisional conflict	41*	35*	33*	25	26	.01	01	.07	02	57**		56**	10	08
12. Decision self-efficacy	.38*	.31+	.13	.17	06	.16	18	.13	37*	.78**	56**		.11	12
13. Decisional preference ^a	.23	27	20	12	11	06	.17	.14	11	06	10	.11		05 ^c
14. CRC test preference ^b	.08	14	.18	18	.22	.39*	23	29	.09	16	08	12	05°	

Notes: CRC = colorectal cancer, FOBT = fecal occult blood test, FS = sigmoidoscopy, CS = colonoscopy, WS = workshop. a n = 34. b n = 31. c n = 29. $^{+}$ p < .10, * p < .05, ** p < .001

Gender Stratified Analyses

Table A.7. Demographic Characteristics of Male and Female Focus on CRC Participants

	Men	Women	
	$n (\%) \text{ or } M \pm SD$	n (%) or $M \pm SD$	
Characteristic	n = 31	n = 80	<i>p</i> -value
Age	62.0 ± 6.8	60.3 ± 7.0	.255
Marital status			.021
Married	23 (74.2)	36 (45.0)	
Single	4 (12.9)	24 (30.0)	
Other	4 (12.9)	20 (25.0)	
Education			.373
< High school diploma	5 (16.1)	5 (6.3)	
High school diploma	6 (19.4)	23 (28.7)	
Some college	13 (41.9)	28 (35.0)	
College degree	7 (22.6)	24 (30.0)	
Employment			.605
Full-time	11 (35.5)	36 (45.0)	
Part-time	4 (12.9)	4 (5.0)	
Disabled	3 (9.7)	6 (7.5)	
Retired	10 (32.3)	28 (35.0)	
Not currently	3 (9.7)	6 (7.5)	
Health Insurance			.324
Private	11 (35.5)	39 (48.8)	
Medicare/Medicaid	7 (22.6)	11 (13.8)	
Other	3 (9.7)	9 (11.3)	
Multiple	10 (32.3)	17 (21.3)	
None	0(0.0)	4 (5.0)	
CRC knowledge (max score = 9)	7.4 ± 2.1	7.5 ± 1.6	.776
Ever had FOBT ^a	14 (45.2)	31 (38.8)	.342
Ever had sigmoidoscopy ^a	12 (38.7)	20 (25.0)	.117
Ever had colonoscopy ^a	24 (77.4)	52 (65.0)	.150
Attended CRC WS ^a	13 (41.9)	48 (40.0)	.066
WS attendance (max score $= 3$)	2.0 ± 0.8	2.1 ± 0.8	.582
First-degree family history of CRC ^a	5 (16.1)	5 (6.3)	.107
Health literacy (max score = 25)	20.0 ± 3.9	$21.5 \pm 3.5^{+}$.055

Notes: CRC = colorectal cancer, FOBT = fecal occult blood test, WS = workshop. ^abinary variable with 0 = no and 1 = yes.

Table A.8. Descriptive Statistics of Decision Making Indicators for Male and Female Focus

on CRC Participants

on erre runnipunts			-
	Men	Women	
	n (%) or $M \pm SD$	n (%) or $M \pm SD$	
Indicator	n = 31	n = 80	<i>p</i> -value
Decisional conflict (max score = 100)	27.1 ± 29.5	14.8 ± 23.6	.043
Decision self-efficacy (max score = 100)	79.8 ± 17.5	87.6 ± 17.3	.034
Decisional preference ^a			.050
Shared	9 (32.1)	39 (52.7)	
Informed	19 (67.9)	35 (47.3)	
CRC test preference ^b	, ,	, ,	.247
FOBT	8 (32.0)	35 (22.5)	
Colonoscopy	17 (68.0)	39 (77.5)	

Notes: CRC = colorectal cancer, FOBT = fecal occult blood test, WS = workshop. ^aMen: n = 28, Women: n = 74. ^bMen: n = 25, Women: n = 71.

Table A.9. Chi-square Analyses for Decisional Preference and CRC Test Preference among Male and Female Focus on CRC Participants

	•	D	ecisional l	Preference					CRC Test	Preference		
	N	Men (n = 28)		W	omen $(n = 74)$)	N.	fen (n = 2)	5)	Wo	men (n =	71)
	Shared	Informed	X^2	Shared	Informed	X^2	FOBT	CS	X^2	FOBT	CS	X^2
Marital status			5.305 ⁺			1.234			0.006			1.142
Married	6	14		18	13		6	13		9	23	
Single	3	1		13	11		1	2		4	16	
Other	0	4		8	11		1	2		3	16	
Employment			2.703			2.175			3.107			2.437
Full-time	4	7		17	17		2	7		8	25	
Part-time	1	3		2	2		1	2		1	3	
Disabled	2	1		1	3		0	2		0	5	
Retired	2	7		16	10		3	5		5	19	
Not currently	0	1		3	3		2	1		2	3	
Health Insurance			6.604^{+}			1.789			1.797			2.013
Private	0	9		18	18		4	5		9	28	
Medicare/Medicaid	3	3		4	6		1	5		3	6	
Other	1	2		6	3		1	1		1	7	
Multiple	5	5		9	6		2	6		3	11	
None	0	0		2	2		0	0		0	3	

Notes: CRC = colorectal cancer, FOBT = fecal occult blood test, CS = colonoscopy. p < .10, p < .05, p < .001

Table A.10. ANOVAs for Decisional Conflict and Decision Self-Efficacy for Male and Female Focus on CRC Participants (N = 111)

		Decisional	l Conflict			Decision Sel	f-Efficacy	
_	Men $(n = 3)$	31)	Women (n =	= 80)	Men $(n = 3)$	31)	Women (n	= 80)
Variable	$M \pm SD$	F	$M \pm SD$	F	$M \pm SD$	F	$M \pm SD$	F
Marital status		0.299		2.839+		0.077		0.712
Married	28.9 ± 31.8		18.2 ± 30.1^{a}		80.4 ± 18.3		88.8 ± 18.1	
Single	27.5 ± 32.0		5.4 ± 10.0^{a}		76.7 ± 17.0		89.2 ± 18.8	
Other	16.3 ± 10.3		19.8 ± 19.2		79.0 ± 17.7		83.6 ± 17.3	
Employment		0.389		6.246^{**}		0.189		1.483
Full-time	28.6 ± 26.4		11.4 ± 16.0^{b}		78.9 ± 14.8		88.5 ± 17.2	
Part-time	41.3 ± 49.7		28.8 ± 19.7		83.0 ± 17.6		94.9 ± 6.5	
Disabled	20.0 ± 34.6		29.2 ± 43.4		82.6 ± 15.1		75.0 ± 32.5	
Retired	20.5 ± 24.4		6.8 ± 13.9^{c}		76.8 ± 21.5		90.0 ± 11.9	
Not currently	31.7 ± 35.5		$48.3 \pm 40.6^{b,c}$		85.6 ± 24.9		79.5 ± 21.6	
Health Insurance		0.702		0.643		2.079^{+}		0.749
Private	37.3 ± 36.6		10.5 ± 18.5^{a}		82.2 ± 16.4		89.8 ± 16.3	
Medicare/Medicaid	19.3 ± 25.2		31.8 ± 39.0^{a}		72.1 ± 18.4		80.8 ± 24.9	
Other	18.3 ± 16.1		11.1 ± 12.2		77.3 ± 21.7		90.4 ± 12.4	
Multiple	24.0 ± 27.0		13.2 ± 21.8		83.2 ± 18.1		87.0 ± 16.7	
None	_		23.8 ± 29.3		_		81.8 ± 15.9	

Notes: CRC = colorectal cancer. Post-hoc using Tukey completed for ANOVAs with p < .10. ^aWithin-group pairwise comparison: p < .10. ^bWithin-group pairwise comparison: p < .05. ^cWithin-group pairwise comparisons: p < .001. All men in sample had health insurance. p < .10, p < .05, p < .05

Table A.11. Correlations Matrix for Decision Making Indicators among Male Focus on CRC Participants (N = 31)

Variable	1	2	3	4	5	6	7	8	9	10	11	12	13	14
1. Age	_	.25	01	.12	47*	.09	12	.03	.29	12	10	23	05	.04
2. Education	.25		.33+	13	.30	.15	.05	.11	.13	.20	27	.13	26	.10
3. CRC knowledge	01	.33+		06	.19	.07	14	12	.04	.30+	38*	.37*	.02	.06
4. Ever had FOBT	.12	13	06		.21	.03	.15	.04	22	.06	16	.16	18	14
5. Ever had FS	.47*	.30	.19	.21		05	27	29	.19	.08	25	.02	24	.21
6. Ever had CS	.09	.15	.07	.03	05		01	12	.03	.11	.23	.08	.04	05
7. CRC WS	12	.05	14	.15	27	01	_	.75**	02	.13	.03	.20	.23	32
8. Total WS	.03	.11	12	.04	29	12	.75**	_	.12	.05	.11	.18	.22	28
9. Family CRC history	.29	.13	.04	22	.19	.03	02	.12	_	12	001	42*	24	09
10. Health literacy	12	.20	.30+	.06	.08	.11	.13	.05	12	_	31 ⁺	.57*	09	.12
11. Decisional conflict	10	27	38*	16	25	.23	.03	.11	011	31	_	35 ⁺	09	19
12. Decision self-efficacy	23	.13	.37*	.16	.02	.08	.20	18	42*	.57*	35+	_	.19	.06
13. Decisional preference ^a	05	26	.02	18	24	.04	.23	.22	24	09	09	.19		24 ^c
14. CRC test preference ^b	.04	.10	.06	14	.21	05	32	28	09	.12	19	.06	24 ^c	_

Notes: CRC = colorectal cancer, FOBT = fecal occult blood test, FS = sigmoidoscopy, CS = colonoscopy, WS = workshop. a n = 28. b n = 25. c n = 22. $^+$ $p < .10, ^*p < .05, ^{**}p < .001$

Table A.12. Correlations Matrix for Decision Making Indicators among Female Focus on CRC Participants (N = 80)

Variable Variable	1	2	3	4	5	6	7	8	9	10	11	12	13	14
1. Age	_	13	08	.23*	.27*	.44**	.13	.17	.13	11	19 ⁺	.06	.11	.02
2. Education	13	_	.29*	10	18	06	02	04	14	.49**	13*	34*	08	10
3. CRC knowledge	08	.29*		.01	.05	.03	.08	.03	.14	.21+	15	.03	.13	.04
4. Ever had FOBT	.23*	10	.01		.19	.15	.07	.13	.22+	.10	12	13	07	20 ⁺
5. Ever had FS	.27*	18	.05	.19		.30*	06	15	.21+	01	12	09	.03	.29*
6. Ever had CS	.44**	06	.03	.15	.30*		.04	.16	.19+	.01	24*	08	.13	.40*
7. CRC WS	.13	02	.08	.07	06	.04		.71**	.21+	.03	06	09	.18	07
8. Total WS	.17	04	.03	.13	15	.16	.71**		.05	.10	15	.14	.27*	04
9. Family CRC history	.13	14	.14	.22+	.21+	.19+	.21+	.05		07	09	19 ⁺	.26*	.11
10. Health literacy	11	.49**	.21+	.10	01	.01	.03	.10	07		47**	.50**	05	003
11. Decisional conflict	19 ⁺	13*	15	12	12	24*	06	15	09	47**		55**	10	.06
12. Decision self-efficacy	.06	34*	.03	13	09	08	09	.14	19 ⁺	.50**	55**	_	03	05
13. Decisional preference ^a	.11	08	.13	07	.03	.13	.18	.27*	.26*	05	10	03	_	.10°
14. CRC test preference ^b	.02	10	.04	20+	.29*	.40*	07	04	.11	003	.06	05	.10°	_

Notes: CRC = colorectal cancer, FOBT = fecal occult blood test, FS = sigmoidoscopy, CS = colonoscopy, WS = workshop. a n = 74. b n = 71. c n = 67. $^+$ p < .10, * p < .05, ** p < .001

Appendix B – IRB Addendum for Focus on Colorectal Cancer

UNIVERSITY OF MARYLAND COLLEGE PARK

Institutional Review Board

Amendment Application

To ensure an accurate and streamlined review of your Amendment Application, please provide the following information:

- 1) State what is being proposed and where in the protocol and/or consent what was changed.
- We are submitting revised and new materials for use in our study:
 - 1. Revised 12-month Follow-up Shortened Survey Letter
 - 2. 12-month Shortened Survey (male and female versions)
 - 3. "A Focus on Colorectal Cancer Early Detection" (CRC) survey to be administered to a subpopulation of currently enrolled participants (paper-and-pencil version).
 - 4. CRC Recruitment Letter Mail Version
 - 5. CRC Gift Card Thank You Letter

[additional information redacted that is irrelevant to proposed study and specific to parent grant]

- 2) Provide the rationale/justification for the change.
 - 1. In line with the principle of reciprocity, we will be mailing the \$25 gift card along with the shortened survey to be completed by the participant.
 - 2. The 12-month Shortened Survey will be mailed to participants who have still not completed the full-length 12-month survey.
 - 3. The CRC survey will be an additional data collection tool to collect items among a subpopulation of participants (those aged 50-75 at enrollment). This survey will be the primary data collection tool for Erin Tagai's dissertation and falls within the context of our overall research aims.
 - 4. The recruitment letter will accompany the mailed CRC survey to invite participants to complete the survey.
 - 5. The CRC gift card thank you letter will be mailed along with a \$25 Target gift card to participants who complete the CRC survey via mail, phone, or web.

All study forms submitted in this addendum have been reviewed by community partners and the research team.

3) State what impact the change has on risks to participants. Please state the number of currently enrolled participants and if the changes will require re-consent. If the changes will not require re-consent, please state why.

No change to risk or re-consent needed for the shortened survey letter or shortened survey.

However, the newly added CRC survey was not in the initial consent form signed by participants requiring re-consent. A waiver for re-consent is sought as (1) the research involves no more than minimal risk to participants, (2) the waiver will not adversely affect the rights and welfare of the participants, and (3) the research cannot be carried out without

the waiver. Participants were initially consented in-person at enrollment and it will not be possible to re-consent participants in-person for completion of the newly added survey. Additionally, the newly added survey will not change the risk to participants, as the survey falls within the context of our overall research aims, and survey administration will follow current study protocol.

The number of currently enrolled participants is 481. The number of participants meeting eligibility for the new survey is 214.

4) State whether the change has an impact on the scientific integrity of the study, (i.e. decreases, increases, no impact).

No impact in scientific integrity to the study

5) List the documents included with the application that have been modified (consent forms, flyers, data collection forms, surveys). State what has been changed in each modified document.

We are submitting revised and new materials for use in our study:

- 1. Revised 12-month Follow-up Shortened Survey Letter
- 2. 12-month Shortened Survey (male and female versions)
- 3. "A Focus on Colorectal Cancer Early Detection" (CRC) survey to be administered to a subpopulation of currently enrolled participants (paper-and-pencil version).
- 4. CRC Recruitment Letter Mail Version
- 5. CRC Gift Card Thank You Letter

[additional information redacted that is irrelevant to proposed study and specific to parent grant]

6) If adding a student and their project (in the domain of the currently approved project), please request addition of their name to the Approval Letter.

The added CRC survey and related materials are associated with a student project for Erin Tagai who has worked on the parent grant since 2012 as a graduate research assistant. She is familiar with the currently established parent grant protocol. This project is for the completion of her dissertation and will use data from the CRC survey as well as previously collected surveys (baseline, postsession, and 12-month surveys).

Appendix C – IRB Addendum Approval Letter



1204 Marie Mount Hall College Park, MD 20742-5125 TEL 301.405.4212 FAX 301.314.1475 irb@umd.edu www.umresearch.umd.edu/IRB

DATE: August 29, 2014

TO: Cheryl L. Holt, PhD

FROM: University of Maryland College Park (UMCP) IRB

PROJECT TITLE: [341256-27] Implementation of evidence-based cancer early detection in

Black churches

REFERENCE #: 10-0691

SUBMISSION TYPE: Amendment/Modification

ACTION: APPROVED
APPROVAL DATE: August 29, 2014
EXPIRATION DATE: November 16, 2014
REVIEW TYPE: Expedited Review

REVIEW CATEGORY: Expedited review category # 7

Thank you for your submission of Amendment/Modification materials for this project. The University of Maryland College Park (UMCP) IRB has APPROVED your submission. This approval is based on an appropriate risk/benefit ratio and a project design wherein the risks have been minimized. All research must be conducted in accordance with this approved submission.

This submission has received Expedited Review based on the applicable federal regulation.

Please remember that informed consent is a process beginning with a description of the project and insurance of participant understanding followed by a signed consent form. Informed consent must continue throughout the project via a dialogue between the researcher and research participant. Federal regulations require each participant receive a copy of the signed consent document.

Please note that any revision to previously approved materials must be approved by this committee prior to initiation. Please use the appropriate revision forms for this procedure which are found on the IRBNet Forms and Templates Page.

All UNANTICIPATED PROBLEMS involving risks to subjects or others (UPIRSOs) and SERIOUS and UNEXPECTED adverse events must be reported promptly to this office. Please use the appropriate reporting forms for this procedure. All FDA and sponsor reporting requirements should also be followed.

All NON-COMPLIANCE issues or COMPLAINTS regarding this project must be reported promptly to this office.

This project has been determined to be a Minimal Risk project. Based on the risks, this project requires continuing review by this committee on an annual basis. Please use the appropriate forms for this procedure. Your documentation for continuing review must be received with sufficient time for review and continued approval before the expiration date of November 16, 2014.

Please note that all research records must be retained for a minimum of three years after the completion of the project.

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Generated on IRBNet

Current IRB expiration: 11/16/16

Appendix D – Project HEAL Consent Form

Project Title	Implementation of evidence-based cancer early detection in Black
Why is this research being done?	churches This is a research project being conducted by Cheryl L. Holt, PhD at the University of Maryland, College Park. We are inviting you to participate in this research project because you are a church-attending African American woman or man age 40-75, who has not had breast, prostate, or
	colorectal cancer. The purpose of this research project is to find the best way to share information on breast, prostate, and colorectal cancer early detection, through African American churches.
What will I be asked to do?	We created an educational workshop series, that will be conducted in African American churches, and we would like to see how well we can do in getting it out to reach those in the African American faith community. If eligible, you will complete an initial questionnaire and attend a series of 3 workshops at the church. The workshops may be photographed and/or video recorded. You will complete an initial survey, another 12 months from now, and a final survey 24 months from now. You will be one of 420 men and women chosen for this program. Your total involvement on the project should be 8 hours, which includes 6 hours in 3, 2-hour workshops, and two follow-up surveys. You will receive a \$25 gift card for each of three program surveys you complete, for a possible total of \$75. You will receive gift cards based on your completed surveys. If you complete 1 survey = \$25 total, 2 surveys = \$50 total, 3 surveys = \$75 total.
What about confidentiality?	We will do our best to keep your personal information confidential. To help protect your confidentiality, your name will not appear on your survey. Information from your participation will be used for the purposes of instruction and scientific publication only. Your identity as a participant will not be revealed in any way by the investigators. Although we will not disclose your identity, we cannot guarantee that others in your group will maintain confidentiality. Information will be made public only in the form of summaries, which make it impossible to tell who the participants were. If you like, you can receive a copy of the results of this investigation and/or discuss the study with a staff person. Just call one of the numbers at the end of this form and we will be happy to answer all of your questions and furnish you with a copy of the results.
	All project data that contains names or identifiers will remain in secured storage such as a locked filing cabinet. If we write a report or article about this research project, your identity will be protected to the maximum extent possible. Your information may be shared with representatives of the University of Maryland, College Park or governmental authorities if you or someone else is in danger or if we are required to do so by law. For some forms, we will use a unique numeric code for your survey instead of your name. Your name will not be

	included on the surveys and other coplaced on the survey and other collection identification key, we will be able to Only Dr. Holt will have access to the report or article about this research protected to the maximum extent possibared with representatives of the Ur or governmental authorities if you or are required to do so by law.	eted data. Through the use of an link your survey to your identity. If we write a roject, your identity will be ssible. Your information may be niversity of Maryland, College Park			
What are the	There may be some risks from partic	ipating in this research study. You			
risks of this	may feel some stress or anxiety from				
research?	this risk is not considered serious. W information gathered may be used in publications relating to this project. property of the study staff.	orkshops will be video recorded and scientific presentations and The recordings will remain the			
What are the	You may benefit from learning more				
benefits of this	through the workshops. In addition,	, , , , , ,			
research?	valuable information on the best way				
	faith community on the importance of				
Do I have to be	Your participation in this research is				
in this research?	choose not to take part at all. If you				
May I stop		ne. If you decide not to participate in			
participating at	this study or if you stop participating				
any time?	penalized or lose any benefits to whi				
What if I have	This research is being conducted by				
questions?	Behavioral and Community Health, a				
	College Park. If you have any questi				
	please contact Dr. Cheryl L. Holt, U				
		College Park, MD 20742; 301-405-			
	6659; <u>cholt14@umd.edu</u> . If you have questions about your right.	hts as a rosparch subject or wish to			
	report a research-related injury, please contact: Institutional Review Board Office, University of Maryland, College Park, Maryland,				
	20742; (e-mail) <u>irb@umd.edu</u> ; (te				
	This research has been reviewed according to the control of the co				
	Maryland, College Park IRB procedu				
	subjects.				
Signature and	NAME OF SUBJECT				
Date	SIGNATURE OF SUBJECT				
	DATE				

Appendix E – Focus on Colorectal Cancer Recruitment Letter

PAX CRC Survey



«Today's_Date »

Dear «First_Name» «Last_Name»,

On behalf of the Project HEAL team, I wish to thank you for your continued participation. At this time, I am in the process of completing my dissertation that will focus on colorectal cancer early detection. As an enrolled Project HEAL participant between the ages of 50 and 75 I am asking for your help in filling out an additional survey that will help me complete my dissertation.

By completing this survey, you will receive an additional \$25 gift card. This survey is in addition to the Project HEAL baseline, 12-month, and 24-month surveys.

Please complete the enclosed survey and return the survey in the included pre-stamped envelope by [date 2 weeks from mailing date]. If we have not received your returned survey by this time, you may receive a reminder phone call from us. Alternatively, you may complete this survey at [web address].

This survey has been added to Project HEAL and has been approved by the University of Maryland Institutional Review Board. By responding to the survey questions and returning a completed survey, you consent to participating in the research. We will mail your \$25 gift card after we have received your completed survey.

If you have any questions or concerns, please feel free to contact me at 301-405-2521 or ekelly 7@ umd.edu.

Thank you for your time, and we look forward to seeing you again at our two-year follow-up with «Church». God Bless.

Sincerely,

Erin K. Tagai, MPH Graduate Research Assistant

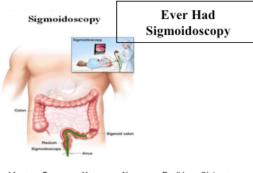
/Enclosure

Appendix F – Measures from Project HEAL Baseline Survey

Only survey measures included in the proposed study have been included. Additional measures were collected on the original survey.

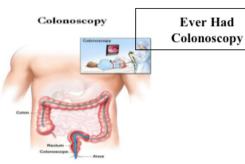
omen ZB		ID#		CH ID#	
	Family CRC History				
as anybody in your fami	ly (first degree relative) had colorectal cance	r? (Mar	k all that ap	ply)	
	Mother Sister				
	_ Sister Daughter				
None	Not sure				
e any other family men	ber had colorectal cancer? (Mark all that app	NA)			
Grandfather	Grandmother	, iy)			
Uncle	Aunt				
Cousin	Other:				
None	Not sure				
	CDC IV I . I				
Vomen ZB	CRC Knowledge	ID#_		CH ID#_	
These next few question	s are about colorectal cancer:				
o you agree or disagre	e with the following statements?		Disagree	Agree	Not Sure
Colorectal cancer is cancer	er of the colon or rectum.				Juic
Colorectal cancer affects	only older White men.				
Risk of colorectal cancer b	pecomes greater as a person gets older.				
oth men and women are	at risk for colorectal cancer.				
Colorectal cancer begins a	as a growth in the colon or rectum.				
Bleeding is a symptom to	report to your doctor.				
	ng is not necessary if there are no symptoms.				
Finding colorectal cancer	· · · · · · · · · · · · · · · · · · ·				
he treatment for colorect	al cancer may not be as bad if the cancer is four	nd early			
Vomen ZB		ID#			
he doctor's office to be te	Ever Ha	d FO	BT	1	
	270.11.				
Poge Assauling Kin	3				
lave you ever <u>heard of</u> t	this test? Yes	_ No	Don't	know/No	t sure
f yes, please go to the n	ext page (page <mark>8</mark>) of the survey.				
f no, please skip to pag	e <mark>10</mark> of the survey.				
Vomen ZB If you have never heard of	a Fecal Occult Blood test (stool test), please SKIP to	ID# page <mark>1</mark>		_ CH ID#_	
lave you ever used a ho	ome kit to do this test? Yes No		Don't know/l	Not Sure	
Vhen did you do your la	st FOBT? Month Ye	ar			
In the past yea	nce you did your last blood stool test using a ar (12 months ago or less) d 2 years ago (more than 12 months but less the ears ago (More than 24 months ago)				

We would like to ask you about a test called Sigmoidoscopy:
Sigmoidoscopy is an exam in which a tube is inserted in the rectum to examine the bowel for signs of cancer or other health problems. During the sigmoidoscopy, you are awake.



Signardosage Anna		
Have you ever heard of a flexible sigmoidoscopy?Yes	No Don	't know/Not sure
If yes, please go to the next page (page 11) of the survey.		
If no, please skip to page 12 of the survey.		
Women ZB [If you have never heard of a Sigmoidoscopy, please SKIP to page 12 of		CH ID #
Have you ever had a flexible sigmoidoscopy? Yes	_ No Don't kno	w/Not sure
If yes, when did you have your last flexible sigmoidoscopy?	Month	Year
If yes, how long has it been since you had your last sigmoidos. Within the past year (12 months ago or less) Between 1 and 2 years ago (more than 12 months but le Between 2 and 3 years ago (more than 24 months but le Between 3 and 5 years ago (more than 36 months but le Between 5 and 10 years ago More than 10 years ago Never Don't know/Not sure	ess than 24 months ago ess than 36 months ago ess than 60 months ago)
Women ZB	ID#	CH ID #
We would like to ask you about a test called Colonoscopy: A colonoscopy is an exam in which a tube is inserted in the rectum other health problems. During the colonoscopy you are given media		

Colonoscopy Ever Had



	Resture Coleroscope Artes
Have you	ever heard of a colonoscopy? Yes No Don't know/Not sure
If yes, ple	ease go to the next page (page <mark>13</mark>) of the survey.
If no, plea	ase skip to page <mark>15</mark> of the survey.
Have you	ve never heard of a Colonoscopy, please SKIP to page 15 of the survey.] ever had a colonoscopy? Yes No Don't know/Not sure
	en did you have your last colonoscopy? Month Year
if yes, no	w long has it been since you had your last colonoscopy? Within the past year (12 months ago or less) Between 1 and 2 years ago (more than 12 months but less than 24 months ago) Between 2 and 3 years ago (more than 24 months but less than 36 months ago) Between 3 and 5 years ago (more than 36 months but less than 60 months ago) Between 5 and 10 years ago More than 10 years ago Never Don't know/Not sure

Wollkii ZD		10#	OH ID #
La	stly, please tell us a little abo	out yourself:	
What is your date of birth?		Age	
Are you Single			
Living with partner	Marital Status		
Widowed			
Which, if any, types of health insur	rance do you have?	Mark all that apply Yes No	Health
Medicaid Medicare Insurance through an employer/work	(ex. Blue Cross or HMO)		Insurance
Any other form of health insurance			
What is the highest grade or year of Grades 1 through 8 (Elementary	y)	d?	
Grades 9 through 11 (Some Hig Grade 12 or GED (High School College 1 year to 3 years (Some	Graduate) e college or technical school)	Education	
College 4 years or more (College	ge graduate)		
Do you currently work for pay outs Full time	side of the home?		
Part-time Not currently I'm retired	Employment		
I'm receiving disability			

Appendix G – Measures from Focus on Colorectal Cancer Survey

Decisional Conflict

Only survey measures included in the proposed study have been included. Additional measures were collected on the original survey.

, , , , , , , , , , , , , , , , , , , ,	ing optio	ns:	, cc1310.	iiai C	mine
			Yes	No	Unsur
Do you know which options are available to you?					
Do you know the benefits of each option?					
Do you know the risks and side effects of each option?					
Are you clear about which benefits matter most to you?					
Are you clear about which risks and side effects matter most	to you?				
Do you have enough support from others to make a choice?					
Are you choosing without pressure from others?					
Do you have enough advice to make a choice?					
Are you clear about the best choice for you?					
Do you feel sure about what to choose?					
se next few questions are about understanding medical inform			Healt		
w often do you have problems learning about your	Occas	sionally	Sometin	nes Ofte	en Alv
dical condition because of difficulty understanding tten information?]
w often do you have someone help you read spital materials?]
w often do you have someone help you read dical information?] [
w often can you fill out medical forms by yourself?] [
	1	2	3	4	5
ow confident are you filling out medical forms by yourself?					
					-
et the facts about the medication choices available to me					
of the facts about the medication choices available to me of the facts about the benefits of each choice					
et the facts about the medication choices available to me et the facts about the benefits of each choice et the facts about the risks and side effects of each choice					
at the facts about the medication choices available to me at the facts about the benefits of each choice at the facts about the risks and side effects of each choice aderstand the information enough to be able to make a choice	0	0			
et the facts about the medication choices available to me et the facts about the benefits of each choice et the facts about the risks and side effects of each choice inderstand the information enough to be able to make a choice sk questions without feeling dumb					
It the facts about the medication choices available to me It the facts about the benefits of each choice It the facts about the risks and side effects of each choice It the facts about the risks and side effects of each choice It desired the information enough to be able to make a choice It questions without feeling dumb It press my concerns about each choice					
et the facts about the medication choices available to me at the facts about the benefits of each choice et the facts about the risks and side effects of each choice aderstand the information enough to be able to make a choice sk questions without feeling dumb spress my concerns about each choice					
It the facts about the medication choices available to me at the facts about the benefits of each choice at the facts about the risks and side effects of each choice derstand the information enough to be able to make a choice k questions without feeling dumb press my concerns about each choice k for advice					
et the facts about the medication choices available to me et the facts about the benefits of each choice et the facts about the risks and side effects of each choice inderstand the information enough to be able to make a choice					
et the facts about the medication choices available to me et the facts about the benefits of each choice et the facts about the risks and side effects of each choice inderstand the information enough to be able to make a choice sk questions without feeling dumb express my concerns about each choice sk for advice gure out the choice that best suits me					
It the facts about the medication choices available to me It the facts about the benefits of each choice It the facts about the risks and side effects of each choice It the facts about the risks and side effects of each choice It derivations without feeling dumb It derivations without feeling dumb It derivatives It deri					
It the facts about the medication choices available to me It the facts about the benefits of each choice It the facts about the risks and side effects of each choice It the facts about the risks and side effects of each choice Idensity of each choice in the facts about the risks and side effects of each choice Idensity of each choice in the facts about each choice Idensity of each choice In the choice that best suits me Indie unwanted pressure from others in making my choice In the clinic team know what's best for me	c c c c c c c c c c c c c c c c c c c		Deci	sional	Pref

CRC Screening Test Preference

Now that you have heard descriptions of colorectal cancer screening tests in the Project HEAL workshops and educational booklets, which one would you prefer to get, if you have a choice? (choose only one)

☐ Fecal Occult Blood Test



This test is done to check for colon cancer. It is done at home, using a set of 3 cards, to check if your stools have blood. To do this test, you need to take some of the stool and smear it on the card. Then, you return the card to the doctor's office to be tested.

☐ Flexible Sigmoidoscopy



Sigmoidoscopy is an exam in which a tube is inserted in the rectum to examine the bowel for signs of cancer or other health problems. During the sigmoidoscopy, **you** are awake

□ Colonoscopy



A colonoscopy is an exam in which a tube is inserted in the rectum to examine the bowel for signs of cancer or other health problems. During the colonoscopy you are given medicine to put you to sleep.

Other:

□ Don't know/Not sure

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