2015

Efforts to Improve Colorectal Cancer Screening Rates

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Dr. Sharon Lock, Advisor

DNP Practice Inquiry Project Report

Efforts to Improve Colorectal Cancer Screening Rates

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Spring 2015

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Dedication

This Capstone Project is dedicated to my mom (Do Soo Kim) who passed away in January 2015. She gave the greatest love and everything to her children. Without her love and sacrifice, I could not have come this far. To my sons, Kent and Benton, who are the strongest pillars in my life. Because of you, I am becoming a better and stronger person. To Carolyn and Don Hawkins, who provide their love and support to my boys and I. Because of you, I could stand my feet on the ground when my life turned up-side down.

Acknowledgements

I would like to thank the following people for their commitment, help, guidance, and supports for my DNP Practice Inquiry Project.

Dr. Sharon Lock (my faculty advisor and committee chair) - You guided me through the whole process of the DNP Capstone Project. Your guidance and help were critical to my success in completion of the project.

Dr. Henrietta Bada (my committee member) -You taught me how to utilize Redcap and analyze Data. Your intelligence and experience helped me to overcome my shortcomings in data analysis and interpretation. I was so honored working with you for my project.

Dr. Kathy Wheeler (my committee member) -You spent your time in reading, reviewing, and providing advices which strengthened my manuscripts.

All Professors (who taught me in the College of Nursing) - Your encouragement and support led me to this success.

My classmates - We went together through this journey. You inspired me.

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Introduction to DNP Practice Inquiry Project

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Introduction

Colorectal cancer (CRC) is the second leading cause of cancer deaths in both men and women in the United States (U.S. Cancer Statistics Working Group, 2013). In 2011, 51,783 people died from CRC (Centers for Disease Control and Prevention [CDC], 2014a). CRC can be prevented by utilizing routine screening recommended by U.S. Preventive Service Task Force (USPSTF, 2008). USPSTF (2008) recommends people with average-risk be screened for CRC at age 50 years and older. Current low CRC screening rate at 64.5% in 2010 (CDC, 2013a) indicates that many more Americans will be diagnosed with CRC in the future. Researchers studying the causes of low participation in CRC screening have recognized that there are barriers related to use of invasive test methods (flexible sigmoidoscopy and colonoscopy) such as uninsured status, and lack of providers' recommendation. Fecal occult blood test (FOBT) such as high-sensitivity FOBT or fecal immunochemical test (FIT) is one of the recommended tests by USPSTF. A low sensitivity of gFOBT for detecting polyps and CRC is considered to be a major barrier in its utilization which is low at 10.4% as a screening modality (CDC, 2013b).

In an effort to increase CRC screening rates, to improve utilization of FOBT may be worth investigating. The initial focus of this DNP practice inquiry project was to examine the efficacy of FOBT and if utilization of FOBT will be a reliable test methods in detecting polyps or CRC. The first manuscript is a literature review of studies published between 2008 and 2015 that focused on the efficacy of FOBTs in people aged 50 years and older. During this review, FOBT was recognized as optimal alternative tests for those who are reluctant to undergo an invasive method for CRC screening although the efficacy of FIT is not as high as the efficacy of colonoscopy. With the findings from the literature review, the next step of this project was to identify a strategy that can promote increasing the utilization of FOBT. The second manuscript

evaluates an innovative program known as FluFOBT program to examine the potential impacts on improving CRC screening rates among low-income eligible adults. Findings from conducting an evaluation of the program showed its effectiveness in increasing CRC screening rates and having significant cost benefits. These findings led to curiosity about what advanced practice registered nurses (APRN) know of the current CRC screening recommendation guidelines and their attitude toward making a referral for CRC screening. The final manuscript focuses on examining the relationship between the APRN knowledge level of the current CRC screening recommendation guidelines and their self-reported referral rates of CRC screening by conducting online survey via Kentucky Coalition of Nurse Practitioners and Nurse Midwives listserv.

Manuscript # 1:

Efficacy of Fecal Occult Blood Test: A Literature Review

Abstract

Colorectal Cancer (CRC) is the second leading cause of cancer deaths in both men and women in the United States. In 2011, 51,783 people including 26,804 men and 24,979 women died in 2011. Evidence-based CRC screening guidelines by U.S. Preventive Service Task Force (USPSTF, 2008) recommend a high-sensitivity fecal occult blood test (guaiac FOBT) and fecal immunochemical test (FIT) annually, but the utilization of both tests is low at 10.4%. Offering non-invasive methods to those who are reluctant to participate in CRC screening may be worth investigating. The purpose of this review of literature is to describe the efficacy of FOBT (guaiac-based FOBT [gFOBT] & fecal immunochemical test [FIT]) in screening CRC. Findings showed that FIT compared with gFOBT is superior in detecting CRC and advanced neoplasia and participating rates.

Keywords: colorectal cancer screening, screening modalities, fecal occult blood test, fecal immunochemical test, efficacy, fecal occult blood test randomized controlled trial, and fecal occult blood test systemic review.

Efficacy Fecal Occult Blood Test:

A Literature Review

Introduction

Colorectal cancer (CRC) is the second leading cause of cancer deaths in both men and women in the United States (U.S. Cancer Statistics Working Group, 2013). Although CRC deaths have been declining over the past two decades, 51,783 people including 26,804 men and 24,979 women died in 2011(Centers for Disease Control and Prevention [CDC], 2014) and nearly 50,310 were projected to die from it in 2014 (American Cancer Society [ACS], 2014a; Siegel, DeSantis, & Jemal, 2014). The incidence rates of CRC also have been decreasing by an average of 3.4% yearly over the past 10 years (Siegel et al., 2014). Regardless, 135,260 people were diagnosed with CRC in 2011 (CDC, 2014) and nearly136, 000 were expected to be diagnosed with CRC in 2014(Siegel et al., 2014). Incidence and death of CRC can be substantially reduced when recommended screening tests by U.S. Preventative Service Task Force (USPSTF, 2008) are properly utilized for eligible adults. Regrettably, the low CRC screening rate at 64.5% in 2010 (CDC, 2013a) indicates that many more American will be diagnosed with CRC in the future.

Research suggests that one barrier for CRC screening may be use of invasive methods such as sigmoidoscopy and colonoscopy. Offering non-invasive methods to those who are reluctant to participate in CRC screening may be worth investigating. The purpose of this review of literature is to describe efficacy of FOBT in screening CRC.

Background

Detecting polyps or CRC at an early stage can be challenging as, generally, there are no apparent signs and symptoms. Even when CRC advances, the nonspecific nature of gastrointestinal symptoms makes it difficult to recognize CRC without appropriate tests. These nonspecific gastrointestinal symptoms include abdominal pain, rectal bleeding, anemia, unintended weight loss, and alteration in bowel habits (Jednak & Nostrant, 1998; Tomlinson, Wong, Au, & Schiller, 2012). CRC screening guidelines from USPSTF (2008) recommends people with average-risk (i.e. those who have no family history of colorectal neoplasia) be screened for CRC at age 50 years and older. Currently, there are several tests detecting CRC including sigmoidoscopy, standard colonoscopy, virtual (CT) colonoscopy, double contrast barium enema, fecal occult blood tests (FOBT) and stool DNA, (ACS, 2014b; National Cancer Institute[NCI], 2014a). The USPSTF CRC screening guidelines recommend utilization of the following three tests; high-sensitivity fecal occult blood test (FOBT) including fecal immunochemical test (FIT), sigmoidoscopy with FOBT, and colonoscopy (USPSTF, 2008). According to USPSTF CRC screening recommendations guidelines, high sensitivity FOBT or FIT (annually), sigmoidoscopy with FOBT (every 5 years with every 3 years), and colonoscopy (every 10 years) are recommended for adults with average risk (USPSTF, 2008). A colonoscopy is recommended as a follow-up test for people with abnormal findings as it is considered the gold standard procedure for making a diagnosis and preventing CRC by many expert medical groups.

Although effectiveness of these modalities in detecting polyps or CRC has been demonstrated in numerous studies, current low CRC screening rates indicate an under-utilization of these tests. Willingness to undergo a CRC screening test may be an important step for the eligible adults. Researchers studying the causes of low participation in CRC screening have

recognized that there are barriers related to the tests that use invasive methods. In an effort to increase CRC screening rates, offering non-invasive methods to those who are reluctant to participate in CRC screening may be worth investigating. FOBT and FIT are both non-invasive methods recommended as screening tests by USPSTF, but the utilization of them are low at 10.4% (CDC, 2013b). Both high- sensitivity FOBT and FIT examine feces to detect occult blood and can be done at a user's convenience at his or her home. This may be an applicable choice for those who are unwilling to undergo colonoscopy or sigmoidoscopy.

FOBT was introduced around 1970 and has been evolving since then (Schapiro, 2007). FOBT detects hidden blood products in stool by using chemical guaiac. The concept of detecting occult blood in stool by using guaiac gum was credited to Van Deen in 1864 (Simon, 1985). This principle is based on the idea that the fragile blood vessels at the surface of enlarged polyps and CRC are easily damaged by the passing feces (ACS, 2014b). FOBT is divided into two groups; guaiac-based (gFOBT) and immunochemical (iFOBT or FIT). The earlier method known as gFOBT relies on detecting heme, the pigment-producing component of hemoglobin (Young, St. John, Rose, & Blake, 1990; Young, 2004). A reaction between heme and a 3-6% hydrogen peroxide developer in ethanol or methanol results in oxidation of guaiac causing the appearance of a blue color (Carroll, Seaman, & Halloran, 2014). GFOBT requires moderate amount of heme in order to produce the appearance of blue color, (Young et al., 2014). However, consumption of certain foods such as meat products, peroxide-rich fruits, and vegetables can influence the test result (Sinatra, St. John, & Young, 1999). Plant peroxides that are hemoproteins and bloods from meat products react with the hydrogen peroxide developer and produce oxidation of guaiac that may lead to a false positive test result (Sinatra et al., 1999; Young et al., 2014). Since heme from animal blood is similar to heme from human blood,

gFOBT cannot distinguish them apart (Young et al., 2014). Antioxidants also disrupt the chemical reaction between heme and the hydrogen peroxide developer, and can lead to a false negative test result (Young, 2004).

FIT also examines blood in feces by utilizing antibodies rising against the globin portion of human hemoglobin. Globin is specific to species, thus the test result is less likely affected by the influence of hemoglobin from dietary resources and diet restriction prior to the FIT is unnecessary (Carroll et al., 2014). Human hemoglobin in stool binds to antibodies when it is mixed with the reaction mixture and gathers the complexes form of globin (Carroll et al., 2014). As a result, the fecal sample becomes turbid that can be measured by a turbidimeter (Carroll et al., 2014). A higher rate of the turbidity indicates higher human hemoglobin concentration in feces (Carroll et al., 2014). Globin in feces suggests bleeding from lower gastrointestinal (GI) tract such as the colon or rectum because globin from the upper GI tract including mouth, pharynx, esophagus, stomach, and duodenum are rapidly degraded while passing through the path of upper GI tract (Enterix Inc, 2013; Smith, Young, Cole, & Bampton, 2006).

The earlier gFOBT demonstrated a low sensitivity for detecting CRC (Imperiale, Ransohoff, Itzkowitz, Turnbull, & Ross, 2004), and thus was problematic as a modality for CRC screening. Rehydrating the stool samples has improved sensitivity, and newer gFOBT such as Hemoccult II Sensa were developed to improve sensitivity (Smith et al., 2006). Commonly used gFOBT tests require three stool samples ideally taken at three different times (Washington State Department of Health, 2010). GFOBT cards have three sections with two windows on each section. Patients are instructed to smear stool from two different parts of the sample in each window for three separate stool samples. After completion of all three sections, the gFOBT card needs to be sent to a laboratory or health care facility for analysis. Although most FITs continue

to use a similar sampling technique with gFOBT, sampling methods have been evolving with FIT. A brush-based sampling method is a new- comer that requires for a user to swish the brush at the surface of the toilet bowel water after the stool is immersed (Young, 2004). InSure®FIT™, one of the new-comers using the brush technique, has two flaps where the swished brush will be dabbed (Enterix Inc, 2013). Two flaps require separate stool samples in order to improve detection of blood (Enterix Inc, 2013). After completion, the test is sent to designated laboratory for analysis.

Convenience and acceptability combined with ease and simplicity in stool sampling are characteristics for the ideal FOBT (Young, 2004). Researchers conducted a randomized cohort trial among urban residents aged between 50 and 69 years in Adelaide, Australia comparing participation rates among three groups; the Hemoccult SENSA (gFOBT) requiring three stool samplings using a spatula and the restriction of certain foods and drugs; FlexSure OBT (FIT) requiring three stool samplings using a spatula and no food and drug restriction; and InSure®FIT™ (FIT) requiring two samplings using a brush (Cole, Young, Esterman, Cadd, & Morcom, 2003). Cole et al. (2003) identified the highest participation in the group using InSure®FIT™ with 39.6% while the group using FlexSure had a participation rate of 30.5%. The group using the Hemoccult SENSA was the lowest at 23.4% in participation. This study demonstrated that convenience and acceptability play a vital role for people in determining whether or not to participate in CRC screening.

Large randomized controlled trials in Europe have also validated that FOBT can reduce CRC mortality (Bosetti et al., 2011; Hardcastle et al., 1996; Mandel et al., 2000). In order to be successful, a screening test must have several characteristic, including eligible individual's willingness to participate, convenience to the test, and the essential sensitivity/specificity of the

test (Young et al., 2014). Sensitivity and specificity of FOBT also must be compatible compared with other modalities such as colonoscopy and sigmoidoscopy.

Methods

Electronic databases including the Cumulative Index to Nursing and Allied Health Literature (CINAHL), EBSCOhost, Pubmed, ScienceDirect, Cochrane Systematic Review, and Google Scholar were searched using the keywords colorectal cancer screening, screening modalities, fecal occult blood test, fecal immunochemical test, efficacy, fecal occult blood test randomized controlled trial, and fecal occult blood test systemic review. Inclusion criteria consisted of articles published between 2008 and 2015 that focused on the efficacy of FOBTs (gFOBT and FIT) in people aged 50 years and older. In order to assess the applicability of articles to the study, article titles and abstracts were initially reviewed. If titles and abstracts were not sufficient in providing eligibility, the entire article was reviewed.

Search Results

Twelve studies met the inclusion criteria. Three studies were randomized controlled trials (RCT) including Hol et al. (2009), Lindholm, Brevinge, and Haglind (2008), and Quintero et al. (2012). Cochrane Systematic Review included one study by Hewitson, Glasziou, Watson, Towler, and Irwig (2008). The remaining eight studies consisted of observational studies; Grazzini et al. (2009), Parra-Blanco et al. (2010), Kershenbaum, Flugelman, Lejbkowicz, Arad, and Rennert (2012), Ou et al. (2013), Shin et al. (2012), Parente et al. (2014), Quintero et al. (2014), and Turenhout et al. (2014). The sample size for three RCT studies ranged from 15,011 to 68,308. The Cochrane Systematic Review examined nine articles describing four RCTs consisting of more than 320,000 participants in a period of 8 to 18 years. Sample size for nine

observational studies ranged from 1,918 to 325, 881. Shin et al. (2012) did not specify the number of participants but described the total number of tests performed.

Researchers studied the effects of utilizing FOBTs as a CRC screening modality on the outcomes of performances in CRC detection rates and/or participation in CRC screening (Grazzini et al., 2009; Hol et al., 2009; Kershenbaum et al., 2012; Ou et al., 2013; Parra-Blanco et al., 2010; Quintero et al., 2012; Quintero et al., 2014; Shin et al., 2013; Turenhout et al., 2014) and reduction in CRC incidence and/or mortality (Hewitson et al., 2008; Lindholm et al., 2008; Parente et al., 2014). Other outcomes included cost effectiveness (Parente et al., 2014) and occurrence of major complications (Quintero et al., 2012).

Key Findings

CRC & Advanced Neoplasia Detection

Most studies focused on FOBTs efficacy in detecting CRC and advanced neoplasia, including an adenoma ≥ 10.0mm, villous adenoma, and early stage cancer based on the NCI definition (NCI, 2014b). When discussing the efficacy of a screening test, sensitivity, specificity, positive predictive values (PPV), and negative predictive values (NPV) are commonly used values. Sensitivity refers to the ability of a test to detect diseased individuals correctly, while specificity is defined as an ability of the test to identify disease-free individuals correctly (Parikh, Mathai, Parikh, Sekhar, & Thomas, 2008). The probability of having a disease with a positive result is known as PPV, while NPV is probability of not having a disease with a negative test result (Parikh et al., 2008).

The majority of studies reviewed agreed on the superior efficacy of FIT compared with the efficacy of gFOBT in detecting advanced neoplasia and CRC (Hewitson et al., 2008; Grazzini et al., 2009; Ou et al., 2013; Parra-Blanco et al., 2009; Shin et al., 2013). Sensitivities

of FIT and gFOBT were 61% versus 23.8% respectively in detecting significant neoplasia with food intake restrictions including red meats, vegetables, and vitamin C for three days prior to stool sampling (Parra-Blanco et al., 2009). Hewitson et al. (2008) found the sensitivity of gFOBT as ranging from 55% to 57% compared with the sensitivity of high-sensitive gFOBT ranging from 82% to 92%. Screening with high sensitivity gFOBT annually also demonstrated achieving high rates of cancer detection (Kershenbaum et al., 2012; Parra-Blanco et al., 2010). For example, Kershenbaum et al. (2012) found that annual Hemoccult Sensa (gFOBT) was achieving high success in detecting CRC by about 84-93% of expected CRC occurrence in Jewish populations aged 50-64 years and 90-99% for Jewish populations aged 65-74 years.

Interestingly, Shin et al. (2013) and Turenhout et al. (2014) recognized a difference in sensitivity of the FIT between in men and women. For instance, males had higher sensitivity by13% to 23% than females at all cut-off values; 50ng/ml, 75ng/ml, 100ng/ml, and 200ng/ml (Turenhout et al., 2014). Shin et al. (2013) reported smaller difference (5.87%) of sensitivity between men and women. Two studies (Castiglione, et al., 2007; Malila, Oivanen, Malminiemi, & Hakama, 2008) in Europe also reported similar findings of higher sensitivity of FIT in men than in women.

Parra-Blanco et al. (2009) found that PPV of FIT was 43.4% while PPV of gFOBT was 39.0%. Parra-Blanco et al., (2009) also learned that NPV of FIT was 97.5% and NPV of FOBT was 95.4%. Hol et al. (2010) reported similar results with findings from Parra-Blanco et al., (2009).

Reducing CRC Incidence and Mortality

Large RCTs (Bosetti et al., 2011; Hardcastle et al., 1996; Mandel et al., 2000) in Europe have demonstrated the effectiveness of gFOBT in reducing CRC mortality. Several studies

showed similar results (Hewitson et al., 2008; Lindholm et al., 2008; Parente et al., 2014). Hewitson et al. (2008) concluded that combining the annual and biennial screening with FOBT reduced CRC mortality by 16% from conducting Cochrane systemic review of four RCTs. A study in Sweden for Goteborg citizens aged 60 to 64 years with high-sensitivity gFOBT following restrictions on foods (red meats, peroxidase-rich fruits and vegetables) and medicines (iron supplements and vitamin C) for two days prior to collecting stool samples, also showed a similar reduction rate of 16% in CRC mortality (Lindholm et al., 2008). However, the incidence of CRC or overall mortality rate of CRC after 19 years from the start of the trial showed no difference between the screened and controlled groups (Lindholm et al., 2008). Utilizing rehydrated gFOBT (high sensitivity FOBT) two to three times for CRC screening appears to facilitate reducing CRC mortality. Parente et al. (2014) also demonstrated 5-years mortality considerably reduced (19%) in screening group (19%) with a single FIT compared with non-screening group (37%) or pre-screening group (41%).

Participation Rate

Utilization of FOBT seems to facilitate improved CRC screening rates among eligible adults who are reluctant to undergo invasive screening tests (i.e. flexible sigmoidoscopy & colonoscopy). FIT (61.5%) showed higher participation rates than gFOBT (49.5%) or flexible sigmoidoscopy (32.5%) (Hol et al., 2010). Quintero et al., (2012) also found similar results with a participation rate 34.2% for FOBT and 24.6% for colonoscopy (Quintero et al., 2012). Parente et al. (2014) found overall acceptance of FIT was 50%. However, some have found that women have higher participation rates in screening with gFOBT or FIT compared with men (Hol et al., 2010; Parra-Blanco et al., 2009).

Strategies and Cut-Off Values

Two types of FOBT were evaluated in the studies reviewed; gFOBT and FIT. FIT consisted of two types; qualitative testing for positive or negative for blood in feces (qlFIT) and quantitative measuring hemoglobin content in feces (qnFIT). GFOBT was studied by Hol et al. (2009), Kershenbaum et al. (2012), Lindholm et al. (2008), Ou et al. (2013), and Parra-Blanco et al. (2010). Quantitative FIT was studied by Grazzini et al. (2009), Hol et al. (2009), Parente et al. (2014), Parra-Blanco et al. (2010), Quintero et al. (2012), Quintero et al. (2014), and Turenhout et al. (2014). Both quantitative and qualitative FIT was studied by Ou et al. (2013) and Shin et al. (2013) while FIT and gFOBT were examined by Ou et al. (2013) and Parra-Blanco et al. (2010).

Ou et al. (2013) argued that FIT performance was determined by the cut-off values of hemoglobin in feces ranging from 25 to150 ng/mL. Three studies by Grazzini et al. (2009), Ou et al. (2013), and Turenhout et al. (2014) evaluated FOBT performances at different cut-off values of hemoglobin levels in feces. One study found that males had a higher sensitivity for CRC than females at all cut-off values, including 50ng/ml, 75ng/ml, 100ng/ml, and 200ng/ml (Turenhout et al., 2014). For example, the sensitivity of FIT for CRC at 75ng/ml was considerably higher (93%) in males compared with females (71%). On the other hand, FIT sensitivity for advanced adenomas demonstrated no significant difference for males and females. A study identified that biennial one-time FIT with a cut-off value of 100ng/ml had a higher detection rate for CRC and advanced adenoma than gFOBT (Grazzini et al., 2009), while another study reported that hemoglobin concentration in feces was increased in participants who had polyps bigger than 10mm or advanced adenomas (Ou et al., 2013). Repeated FIT screening with a cut-off value at 50ng/ml annually for three consecutive years demonstrated its compatibility to colonoscopy in CRC screening (Quintero et al., 2014). Repeated FIT has been found to

substantially decrease the need for follow-up screening with colonoscopy by 2-4 folds (Parra-Blanco et al., 2009; Quintero et al., 2014).

Utilizing different strategies of FOBTs seems to influence their performances. Strategies can involve sampling frequency, cut-off values of hemoglobin level I feces, and restriction of diet and medicines. Employing an annual high sensitivity gFOBT (Kershenbaum et al., 2012; Parra-Blanco et al., 2010), a single fecal sample with FIT (Hol et al., 2009; Shin et al., 2013) one time, every two years (Grazzini et al., 2009; Parente et al., 2014; Quintero et al., 2012), or every year for 3 consecutive years (Quintero et al., 2014) were examined in studies. Some researchers asked participants receiving gFOBT to follow restriction of diet and medicines two to three days prior to stool sampling (Lindholm et al., 2008; Parra-Blanco et al., 2010; Kershenbaum et al., 2012). In addition, cut-off values of hemoglobin in feces were used at different levels; 50ng/ml (Ou et al., 2013; Parra-Blanco et al., 2010; Quintero et al., 2014; Turenhout et al., 2014;), 75-79ng/ml (Grazzini et al., 2009; Quintero et al., 2012; Turenhout et al., 2014), and 100ng/ml (Hol et al., 2010; Parente et al., 2014).

Staging Distribution and Location

Stage distribution of a cancer is considered a strong predictor for the 5-year survival rates commonly used in determining cancer outcomes (ACS, 2014b). In other words, detecting CRC at early stages significantly increases 5-year survival rate. Parente et al. (2014) found that overall 5-year survival rate was increased to 81.1 percent in screening group compared with non-screening group (63%) or pre-screening groups (58.9%). CRC detection at stage 1 was 54.7% in the screening group while only 10% for the non-screening group and 15.8% for the pre-screening group. Stage distribution also markedly differed between the screening group and non-screening group (Parente et al., 2014). Kershenbaum et al. (2012) also identified that 70% of the cancer

detected among the Jewish population was at stages Duke's B and lower, meaning that the cancer invades only through the muscle layer (NCI, 2014c).

FIT and gFOBT exhibited differences in detecting advanced neoplasia depending on location. According to the study by Parra-Blanco et al. (2010), advanced neoplasia at proximal location was often found by FIT. Comparing the stage distribution of left and right-sided colon cancer, right-sided colon cancers were detected lower and in relatively advanced stages (Kershenbaum et al., 2012). Findings by Shin et al. (2013) also indicated that the FIT showed the highest sensitivity for the left and sigmoid colon at 87.9%, with the above finding by Kershenbaum et al. (2012). In addition, Shin et al. (2013) found that the sensitivity of FIT was highest for distal colon cancer at 65.9% and rectal cancer at 58.4% compared with proximal colon cancer. However, Quintero et al. (2012) reported that there was no significant difference between FIT and colonoscopy in detecting CRC based on location.

Cost effectiveness

CRC screening appears to be cost effective. FOBT reduced CRC incidence by detecting polyps or CRC at early stage which cost considerably less in treatment compared with the cost of advanced CRC. A study in the Lecco province of Italy by Parente et al. (2014) found the mean total cost for first year diagnosis were €16,435 ($18,571 based on the current money value), €20,862 ($23,574), €29,845($33,725), and €37,288($42,135) for stage I, II, III, and IV respectively.

Complications

One study by Quintero et al. (2012) described 0.5% of participants experienced some form of complication from undergoing a colonoscopy. These complications included bleeding in 12 participants, hypotension or bradycardia in 10 participants, desaturation in 1 participant, and

bowel perforation in 1 participant. On the other hand, only 0.1% of participants in FIT group experienced bleeding, hypotension, or bradycardia. However, the complications in FIT group were related to colonoscopy as a follow up test after the participants had a positive result with FIT.

Discussion

Critique of Studies

Employing FIT compared with gFOBT was associated with a higher participation rate and superior efficacy in detecting advanced neoplasia and CRC, particularly in men. FIT was compatible with a colonoscopy in CRC screening when a cut-off value of 50ng/ml annually was repeatedly used for three consecutive years. FOBT has two types; gFOBT and FIT, which is also divided into qualitative test and quantitative test. Quantitative tests reviewed were measured with several cut-off values of hemoglobin in feces which influenced the performance of FIT. FOBT was also cost effective with few complications. Other interesting findings include the followings; higher FIT sensitivity for CRC in males than in females with all cut-off values, differences between gFOBT and FIT in detecting advanced neoplasia depending on the location of the CRC, and differences in finding CRC at stage distribution with FOBT between screening and non-screening groups.

Limitations

Eight of twelve studies were observational. A limitation related to an observational study is its inability to show causal relationships between interventions and outcomes (Polit & Beck, 2010). Thus, the effect of employing FOBT for the reduction in CRC incidence and mortality rate cannot be fully established. Another limitation of an observational study is related to its strength of evidence, which is inferior compared with RCTs. This results in weakening the

strength of the findings from these studies. Other limitations are related to inconsistency in utilization of FOBT. For instance, reviewed studies used different cut-off values of hemoglobin in feces (25ng/ml, 50ng/ml, 75ng/ml, 100ng/ml, 125ng/ml, and 200ng/ml), different types (high sensitivity gFOBT, qualitative FIT, and quantitative FIT), and different frequency (annual versus biennial). These differences limit reasonable comparison of outcomes.

Implications for Practice

Improving CRC screening rates among eligible adults is critical. Findings from reviewed studies support the utilization of annual FIT for CRC screening as currently recommended by USPSTF. Although the efficacy of FIT is not as high as the efficacy of colonoscopy, providers must understand that FIT has demonstrated significant improvement in its ability to detect advanced neoplasia and CRC recently. As a result, they should offer FIT for those who are hesitant to undergo colonoscopy or unable to be screened with colonoscopy due to their low socioeconomic status.

Conclusion

A low sensitivity of gFOBT for detecting polyps and CRC is considered to be a major barrier in its utilization as a recommended screening modality by USPSTF. FIT compared with gFOBT demonstrated superiority in detecting CRC and advanced neoplasia and participation to screening. In consequence, FIT may be a reasonable test that can be accepted by a broad range of populations. Further research needs to be conducted to determine the most effective cut-off value of hemoglobin that is most effective in detecting polys and CRC. The USPSTF recommendations guidelines for CRC screening in 2008 will be up-dated in the near future. The research findings provided vital evidences that should be considered in up-dating recommended screening modalities for CRC screening.

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Manuscript #2:

Evaluation and Cost Benefits of a FluFOBT Program

Abstract

The purposes: To explore, provide a framework for implementing the Influenza Shot and Home Testing Kit for FOBT program (FluFOBT), and conduct a cost benefit analysis of the program.

Methods: A cost benefit analysis of the FluFOBT program was conducted to estimate the cost of implementing this innovation based on the information provided in implementing the same program at the China town Public Health Center.

Results: A cost-benefit analysis showed a cost-savings per person of $11,810 for men and $12,445 for women. With those cost savings, the 1-4 FluFOBT programs can be implemented. Each program is capable of screening 75-100 eligible adults.

Conclusion: The FluFOBT program appears to be effective not only in improving CRC screening rates but also in saving costs. Implementing the FluFOBT program seems to be a promising way to reach both those of low socioeconomic status and racial/ethnic minorities. The FluFOBT program should be used as an optional program that serves for many eligible adults with inexpensive costs.

Introduction

Colorectal Cancer (CRC) can be a prevented disease by utilizing routine screening recommended by U.S. Preventive Service Task Force (USPSTF, 2008). In 2011, 51,783 people died from CRC (Centers for Disease Control and Prevention [CDC], 2014a). For adults aged 50-75 years with average- risk, the USPSTF CRC screening guidelines recommend using any of the following modalities; fecal occult blood test (FOBT) such as high-sensitivity FOBT or fecal immunochemical test (FIT) annually, sigmoidoscopy every 5 years with FOBT every 3 years, and colonoscopy every 10 years (USPSTF, 2008). Although these tests are effective not only in reducing CRC incidence rate but also in decreasing CRC mortality rate, only 64.5% of eligible adults aged 50 between 75 old with average risk participated to CRC screening in the United States in 2008 (CDC, 2013). Factors that contribute to the low CRC screening rate may vary, but lack of access to health care services among low socioeconomic groups and minority groups may be one of major contributors. The purposes of this paper are to explore, provide a framework for implementing, and conduct a cost benefit analysis of the Influenza Shot and Home Testing Kit for FOBT program (FluFOBT) that targets low-income populations aged 50 to 80 years.

The Institute of Medicine (IOM, 2003) pointed out the existence of disparities in health care in a comprehensive review of racial and ethnic disparities in health care in 2003. Additionally, according to a report by the Kaiser Family Foundation Commission on Medicaid and the uninsured, racial/ethnic minorities are more likely to lack insurance coverage and to live in low income households compared with non-Latino Whites (Garfield, Damico, Stephens, & Rouhani, 2014). The report also indicated that uninsured adults are less likely to receive preventive care and services that focus on disease prevention and heath maintenance, including screening for cancer (Garfield et al., 2014). Ward et al. (2004) also highlighted inequalities in

cancer incidence, mortality, and survival related to poverty. The incidence rates and advanced stage of diagnosis of CRC are likely higher among minority populations (Grubbs et al., 2013). Wong, Gildengorin, Nguyen, and Mock (2007) found that the CRC screening rate was low among Asian-American groups in California compared with non-Latino Whites. Morbidity and Mortality Weekly Report (U. S. Department of Health and Human Services, 2011) provided similar findings on CRC incidence and screening in United States in 2008 and 2010; considerably lower overall CRC screening rate among Asian/Pacific Islander (CDC, 2013). Regrettably, Berry et al. (2009) showed that African Americans are disproportionally burdened with CRC, having the highest CRC incidence rate across all races (CDC, 2013; Lawsin, DuHamel, Weiss, Rakowski, & Jandorf, 2006).

CRC can be costly for both patients and the healthcare system (Howard, Tangka, Seeff, Richardson, & Ekwueme, 2009). The cost for caring for cancer in 2010 was projected to be $124.57 billion nationally (Mariotto, Yabroff, Shao, Feuer, & Brown, 2011). Of that, the cost of caring for patients with CRC was predicted to be $14.14 billion, the second highest cost in 2010 after caring for breast cancer, and the highest cost of initial care (Mariotto et al., 2011). In a study estimating the cost attributable to colon cancer by cancer stage, comorbidity, and patient characteristics, it was found that the mean total cost for colon cancer one year after diagnosis was $29,196 (Luo, Bradley, Dahman, & Gardiner, 2009). Luo et al. (2009) also demonstrated that the cost for caring for a patient with CRC in situ, or local stage, was $27,551, while the cost for a patient with distant stage CRC was $29,933. They found that patient comorbidities influenced costs. For example, one, two, three, or more of comorbidities increased the cost by $2,762, $3,095, and $7, 717, respectively (Luo et al., 2009).

CRC screening has been shown to be cost-effective compared to no screening. In a systematic review for USPSTF, Telford, Levy, Sambrook, Zou, and Enns (2010) showed that the cost savings for CRC screening when compared with no screening was less than $50,000 per life-year-gain (LYG). A similar review of 32 published articles regarding to the cost-effectiveness of CRC screening by Lansdorp-Vogelaar, Knudson, and Brenner (2011) found that cost-savings per LYG were more than $56,000 and $3,400 to $16,000 respectively by employing annual gFOBT and biennial gFOBT when compared with no screening in the U.S. On the other hand, the cost-savings per LYG for colonoscopy was up to $34,000 (Lansdorp-Vogelaar et al., 2009). Additionally, lost productivity per CRC death was estimated at $288,468 in 2006 (CDC, 2011). Evidence clearly suggests that the healthcare system needs new innovations to improve CRC screening rates.

Frazier, Colditz, Fuchs, and Kuntz (2000) demonstrated that CRC screening compared with no screening substantially decreases CRC mortality by 80 percent and prevents CRC incidence by 60 percent at costs similar to other cancer screening tests. Telford et al. (2010) found that a reduction in CRC incidence and mortality by 44 percent and 81 respectively by performing FOBT annually. Other researchers also showed similar results. Hewitson, Glasziou, Watson, Towler, and Irwig (2008) conducted a Cochrane systemic review of four RCTs and concluded that annual and biennial screening with FOBT reduced CRC mortality by 16 percent. Lindholm, Brevinge, and Haglind (2008) found that employing FOBT reduced CRC mortality by 16 percent. Clearly, utilizing FOBT may be an effective way to increase CRC screening rates, and one innovation, the "FluFOBT program," appears to be a promising strategy in promoting CRC screening.

The FluFOBT program offers an influenza shot and a home FOBT Kit if eligible patients are due for CRC screening when they come in for a primary care visit during the flu season. This innovative program could be implemented in public health centers and primary care clinic settings to increase CRC screening rates among low-income, uninsured or underinsured eligible adults. The purposes of this paper are to explore, provide a framework for implementing, and conduct a cost benefit analysis of the influenza Shot and Home Testing Kit for FOBT program (FluFOBT) that targets low-income population age 50 to 75 years.

Description of the Innovation

It is critical to find a solution that will promote CRC screening for low-income, uninsured/underinsured population. A hopeful solution for accomplishing this goal may be utilizing a program known as the FluFOBT. The FluFOBT was developed by Dr. Michael Potter, a physician at University of California San Francisco Department of Family and Community Medicine, and his research team. Development, implementation, and evaluation of the program were funded by CDC and American Cancer Society (ACS), the HMO Cancer Research Network, and the Alexander and Margaret Stewart Trust. In 2013, the Prevent Cancer Foundation awarded the program a "Cancer Prevention Laurel for Innovative Programs," given to the innovators and leaders who made a significant contribution to cancer prevention.

The strength of evidence for this program was graded as moderate, meaning that "the available evidence is sufficient to determine the effects of the preventive service on health outcomes" based on the grading definition by USPSTF Grading Definition (2013).

A pilot test of the program was launched during the flu season at the Chinatown Public Health Center (CPHC) in San Francisco in 2008. Eight primary care clinicians at the CPHC in San Francisco provide care mostly monolingual Cantonese-speaking Chinese immigrants who

live in the Chinatown neighborhood. The clinic handles roughly 14,000 visits each year. The target population for this program was low-income patients aged 50 to 80 years who had not received a recommendation for CRC screening in the previous year. A nurse fluent in Cantonese screened eligibility for CRC screening by reviewing electronic health records (EHR) prior to a patient seeing a healthcare provider. The nurse asked patients if they were interested in getting a flu shot and administered the shot to those who desired it. During this time, the nurse evaluated eligible patients by asking if they were interested in learning about CRC screening.

The nurse provided a brief introduction to CRC screening and showed a 4-minute video in Cantonese that explained CRC screening in detail to those who were interested. The nurse then offered answers to any questions the patients may have had and provided a home FOBT kit and a pre-paid envelope with written return address to those who desired to be screened. The nurse entered the patients' responses about receiving an influenza shot and the FOBT kit to the EHR. Patients who were given a home FOBT kit were provided with instructions in Cantonese on its use and given a pre-paid return envelope. The patients returned the completed kit using the pre-paid envelope to the program's participating laboratory. Patients received negative results by a mail, but those returning positive results were contacted to schedule a follow-up diagnostic evaluation.

Cost Benefits Analysis

Currently, no formal cost-benefit analyses of the program is available in the literature except for the studies performed by the researchers involved in Dr. Potter's program. The cost-effective analysis on CRC screening using FOBT by Lejeune, DanCourt, Arveux, Bonithon-Kopp, and Faivre (2010) demonstrated that the price of FOBT kits strongly influenced the cost-effectiveness results. A large study in the Netherlands by Rossume et al. (2010) reported that a

single FIT screening compared with no screening resulted 13,400 life-years gained and €320 million (≈ $361.6 million) saved over a period of 10 years. In addition, CRC screening saves $10,000 to $25,000 per year of life, according to Pignone, Saha, Hoerger, and Mandelblatt (2002). A study in the Lecco province of Italy by Parente et al. (2014), showed mean total cost for the first year of diagnosis were €16,435 ($18,571 based on the current money value) vs. €20,862 ($23,574) vs. €29,845($33,725) vs. €37,288($42,135) for stage I vs. II vs. III vs. IV, respectively.

Cost

The cost of this innovation will be estimated based on the information provided in the evaluation of the program at the CPHC in San Francisco by Dr. Potter and his colleagues. The program does not require new staff members or additional building space because it utilizes the current nursing staff at the existing clinic settings. However, the program does involve costs for training the nursing staff (a 1-hour session), purchasing program materials, and supplementary FOBT kits. Educational materials, including a multilingual educational video for patients, can be downloaded from htt://flufit.org site at no cost. Screening costs per person vary by test; however, the estimated cost for FOBT kits range from $5 (Lansdorp-Vogelaar et al., 2011), $10 (Singhal et al., 2014) to $30 (Taber, Aspinwall, Heichman, & Kinney, 2014). Singhal et al. (2014) used a median estimated standardized worldwide cost for FOBT and colonoscopy at $10 and $1,000 respectively (rounded to closest whole numbers). The price for FOBT in the U.S. is higher than those in Europe based on the findings by Lejeune et al. (2010). The prices for FIT were ranged from $17.25 to $95 (Lansdorp-Vogelaar, et al., 2009; Mayo Clinic Medical Laboratories, 2013).

In order to estimate the cost for training nursing staff, hourly wages of registered nurses (RN), licensed practical nurses (LPN), and nursing assistants were obtained from Bureau of

Labor Statistics at the U.S. Department of Labor (2014). The average hourly wage for RNs, LPNs, and nursing assistants in Kentucky in 2013 were estimated as $27.65, $18.21, and $11.20 respectively (U.S. Department of Labor, 2014). According to Mayo Clinic Medical Laboratories (2013), the cost for running tests of guaiac based FOBT and FIT were $24 and $95 and were reimbursed by Medicare at the flat rate of $22. With two licensed practical nurses (LPNs) and six nursing assistants (NAs), the cost for training nursing the staff would be $103.62 ($36.42 for two LPNs, and $67.20 for six nursing assistants). The cost for program leaders responsible for organizing and implementing the program will be covered as part of their regular job salaries. As a result, there would be no extra cost spending.

Six providers (4 physicians & 2 advanced practice registered nurse [APRN]) see an average of 500 patients per month. Reflecting to current American population demographics, about 165 patients out of every 500 would be older than 50 years. Of those, approximately 60 patients, based on the current CRC screening rate of 64.5%, may be eligible for CRC screening. The months were counted based on 4 months of the flu months (October through January). Nearly 240 FOBT kits (60 patients for 4months) will be needed. Demand for FOBT/FIT kit may vary. Based on the demand for 240 FOBT/FIT kits, the costs for gFOBT will be $2,400 - $7,200/$4,140 - $22,800 (removing two extreme costs of $5 and $59).

The cost for making postcards for advertising the program are $50 for 1 box (400 postcards) at Vistaprint® (about 33% of 1,200 patients per month) and the postcards can be sent for $0.34 each ($136). The posters can be downloaded and do not cost extra. The cost for making postcards and sending them out is about $190. The total cost for implementing FluFOBT program ranged from (to the nearest dollar) $1,873 to $3,873 vs. $9,348 to $17,123

based on using gFOBT vs. FIT (see Tables 1.2 & 1.2). The large discrepancy between the low limit and the high limit resulted from the difference in the reported FOBT pricing.

On the other hand, a colonoscopy costs are considerably high compared to the cost of gFOBT or FIT. The costs for a colonoscopy vary and are largely determined by service fees. Services necessary for a colonoscopy without a biopsy include facility services, physician services, and anesthesia services (Healthcare BlueBook, 2015). According to a report by the Healthcare BlueBook (2015), the fees for facility services, physician services, and anesthesia services were $692, $421, and $524, respectively, based on performance as outpatient procedure with average surgery time of 45 minutes. Thus the total costs of necessary services for a colonoscopy sums up to about $1,637. However, the actual costs charged for a colonoscopy differs immensely: $533 to $1,570 (Lansdorp-Vogelaar et al., 2009); $1,397 (DeBarros & Steele , 2013); and $1,000 using the median estimated standardized worldwide cost reported by Singhal et al. (2014). Thus, based on the estimated average cost for a colonoscopy reported by the sources above, it may be expected that costs range per person between $1,000- $1,650 (removing the extreme outlier $533 from this estimation). A possible cause of the variance in the above-quoted costs may be a result of the procedure being performed with or without anesthesia.

Benefits

Pignone et al. (2002) and Lansdorp-Vogelaar et al. (2009) demonstrated savings of $10,000 to $25,000 per year of life and nearly $26,000 per LYG in the program with annual FOBT screening. On the other hand, a study by Parente et al. (2014) in Italy showed the cost for first year diagnosis ranged from €16,435 ($18,571) to €37,288 ($42,135). The FluFOBT program can screen for 75 to 100 patients at a cost of $3,196.82- $7,996.82 or $21,996.82 to $40,636.82 (See Tables 1.1 & 1.2). The average total annual costs for caring for patients with

CRC were estimated at between $12,231 to $18,359, based on the Surveillance Epidemiology and End Results (SEER) Medicare approach, considered to be the most accurate in identifying CRC patients (Yabroff et al., 2009). However, the annual medical expenditure costs using Medical Expenditure Panel Survey (MEPS) were significantly less with $8,091 for males and $8,412 for females compared with those who were without cancer (CDC, 2014b). In addition, the annual productivity losses were estimated at $3,719 for males and $4,033 for females due largely to employment disability of 75% (CDC, 2014b). Patients with CRC also experience intangible losses that were not included in the cost-benefit analysis and that cannot be expressed in monetary values, including limited physical activities, interference with physical and mental tasks by cancer treatments (CDC, 2014b), and quality of life.

Conclusion of Cost-Benefit Analysis

The FluFOBT program has proven its effectiveness in increasing CRC screening rates. Evaluation of the piolet program launched in 2008 demonstrated a significant increase of CRC screening rates to 75.3% from 57.3% compared with an increase of 1.7% among eligible patients who did not participate in the program during the program's first influenza season (Walsh, Gildengorin, Green, Jenkins, & Potter, 2012). A cost-benefit analysis shows a cost-savings per person of $11,810 for men and $12,445 for women (see Table 2), which are similar to the cost savings of $10,000 to $25,000 per year of life demonstrated by Pignone et al. (2002). The cost of implementing a FluFOBT program were estimated at between $3,196.82- $7,996.82 when using gFOBT and $21,996.82- $40, 636.82 when using FIT (Tables 1.1& 1.2). Nearly 1-4 programs can be implemented with a cost savings of $11,810 -$12,445. One FluFOBT program can be implemented with a cost saving from 2-3 persons by using FIT. When a FluFOBT

program is capable of providing 75-100 adults with CRC screening at a cost-savings per person of $11,810 -$12,445, the cost benefits are significant.

Implementation of the Innovation

The FluFOBT program may be implemented in primary care clinics by utilizing "the Three Steps of Change" by Kurt Lewin who is recognized as "the founder of the modern social psychology" (Greathouse, 1997). The change model can be implemented in three steps, detailed below: the unfreeze step, the move (transition) step, and the refreeze step. The first step in implementing a new program is to gain supports from top-level administrators and directors by providing contextual information of the innovation, its goal, and a comprehensive plan. Once approval for implementing the innovation is obtained, the change model can be applied to implement the project. The unfreeze step involves building with in a whole group a mood necessity for change. Understanding group dynamics in regards to driving and restraining forces may provide valuable information in terms of recognizing individual goals, needs, and fears (Šuc, Prokosch, & Ganslandt, 2009). Identifying the principle promoters and opponents of the project can be accomplished during workshops and by performing informal interviews. Designating a program leader who can make plans for the program is essential. During this phase, feedback, ideas, and suggestions should be collected and evaluated to minimize conflicts during program implementation.

The move (transition) step involves processing all changes required to be made. The first step should involve promoting the program's launch with patients by creating posters and sending out postcards. In regards to the FluFOBT program, standard steps include: identifying eligible patients aged 50 to 75 years for CRC screening who visit the clinic during flu season; asking if they are interested in getting a flu shot and providing a flu shot if interested; asking if

they are interested in learning more about the FOBT; providing a brief introduction to CRC and FOBT; ask if they are interested in taking a home FOBT kit; providing a home kit along with a pre-paid return envelope and one-page instruction sheet and answering, if asked, any questions about the test; and documenting the procedure in the patients' charts. Individuals need to learn new behaviors related to the implementation of the project through training, education, and communication. In order to ensure the program runs efficiently, nursing staffs need to attend a 1-hour group session, which includes the standard procedures of the program, 1-2 weeks prior to program launch. To try and assess the program's impact on day-to-day operations, a small scale test should be conducted 1-2 days per week before the program is fully operational. The program's participating laboratory also needs to ensure it can manage the increased volume of the FOBT test. Additionally, in order to maintain the effectiveness of the program it is crucial that gastrointestinal specialists be available to perform colonoscopies in an appropriate time frame for those who have positive results with the FOBT test. This can be the most stressful period for individuals who have to learn or adjust to the changes.

The last step involves building reinforcements for sustaining the program after it has been implemented, in particular, monitoring the ongoing process and outcomes. For example, program leaders might conduct feedback meetings after auditing patients' charts. This ongoing process may lead to recognition that refinements or adjustments to the project have become necessary, particularly if compliance with the change is less than expected. Program leaders and top management must provide supports to frontline members who are responsible for running the program during this time in order to prevent them from relapsing back to old patterns of practice. Also, if the participation rate is lower than established goals within a specified time frame, it is

necessary to take extra measures to encourage the remaining patients to return completed tests by contacting them directly through e-mail, text message, or telephone call.

The effect of the program on its recipients can be determined by performing an evaluation (Issel, 2009). However, it can become a distraction from the essence of the program if too many outcomes are considered in an evaluation by producing higher evaluation costs and producing a vast volume of data to analyze (Issel, 2009). Focusing on the key outcome will reduce such distractions (Issel, 2009). The program outcome should monitor the completion rate of CRC screening among FluFOBT program participants versus those who did not participate in the program while visiting the clinic during flu season.

Conclusion

Because of the significant gaps in CRC screening rates among Americans (CDC, 2013; Wong et al., 2007), it is important to make efforts not only to improve CRC screening rates among eligible adults of a low socioeconomic status and racial/ethnic minorities, but also to be cost effective in achieving that goal. Despite the effectiveness of screening tests in reducing the incidence and mortality of CRC, the current CRC screening rate is unsatisfactory. Implementing the FluFOBT program appears to be effective not only in improving CRC screening rates but also in cost saving. Implementing the FluFOBT program appears to be a promising way to reach both those of low socioeconomic status and racial/ethnic minorities. The FluFOBT program should be encouraged to be used as an optional program that is effective for many eligible adults with inexpensive costs.

Table 1.1 The Cost for Implementing FluFOBT Program

	COST	NUMBER	TOTAL
gFOBT kit	$10 - $30	240	$2,400-$7,200
Cost for testing	$24 - $22 (reimburse by Medicare) =$2	240	$480
Nursing assistant	$11.20	6	$67.20
LPN	$18.21	2	$36.42
Stamps for return Kit	$0.34	240	$81.60
Postcards	$50	1box	$50
Stamps for postcards	$0.34	240	$81.60
Total			$3,196.82- $7,996.82

Table 1.2 The Cost for Implementing FluFOBT Program

	COST	NUMBER	TOTAL
FIT kit	$17. 25- $95	240	$4,140- $22,800
Cost for testing	$95-$22 (reimburse by Medicare)=$73	240	$17,520
Nursing assistant	$11.20	6	$67.20
LPN	$18.21	2	$36.42
Stamps for return Kit	$0.34	240	$81.60
Postcards	$50	1box	$50
Stamps for postcards	$0.34	240	$81.60
Total			$21,976.82-$40.636.82

Table 2 **Cost per Colorectal Cancer**

	Male	Female
Annual Medical expenditure	**$8,091**	**$8,412**
Annual Productivity Loss	**$3,719**	**$4,033**
Total	**$11,810**	**$12,445**

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Manuscript #3:

A Descriptive Study to Examine the Relationship between Advanced Practice Registered Nurse Knowledge and Self-Reported Referral Rates for Colorectal Cancer Screening.

Abstract

Purpose: The purpose of this project was to examine the relationship between advanced practice registered nurse (APRN) knowledge about the U.S. Preventive Service Task Force (USPSTF) colorectal cancer (CRC) screening recommendations guideline and self-reported referral rates for CRC screening among APRNs.

Methods: A descriptive internet survey was conducted to examine APRN knowledge about the USPSTF CRC screening recommendation guidelines and their self-reported referral rates for CRC screening by administering the Modified Test Your Knowledge Survey to APRNs.

Results: APRNs self-reported CRC screening referral rates were not associated with their knowledge levels. In addition, APRNs lacked knowledge not only in categorizing risk level of individuals, but also in utilizing the FOBT appropriately.

Conclusions: Although there was no relationship between APRNs knowledge level of USPSTF CRC screening recommendations guidelines and their self-reported CRC screening referral rates, adequate knowledge of the current guidelines are essential for APRNs in order to provide evidence-based safe care. Thus, efforts must be made to improve APRNs risk assessment skills and proper utilizations of FOBT.

Introduction

Colorectal cancer (CRC) is the third most common cancer in the U.S., with a lifetime risk of 5.7 % for men and 5.1 % for women in the U.S. (U.S. Preventive Service Task Force [USPSTF], 2008). Despite the fact individuals can choose among a number of preferred CRC screening tests recommended by the latest USPSTF, unless significant improvement is made in screening rates, CRC prevalence may continue to grow among the aging American population (USPSTF, 2008). Roughly 93% of diagnoses were made among adults older than 50 years of age (Weinberg, 2008). Although CRC incidence rates have been declining annually by 3.4% and mortality rates by 3.0% in recent years (Centers for Disease Control and Prevention [CDC], 2013a), participation in CRC screening reached only 64.5% of eligible adults in 2008 (CDC, 2013a). The Healthy People 2020 cancer objective aims to increase the CRC screening rate to 70.5% (U.S. Department of Health and Human Services [HHS], 2015).

CRC is one of the most highly preventable cancers if individuals participate in screening. The risk for incidence and death of CRC caused by late detection and late intervention can be significantly reduced by adhering to the most recent USPSTF (2008) recommendation guidelines for CRC screening, published in 2008. The USPSTF recommendations are (a) to routinely screen adults aged 50 to 75; (b) to not routinely screen adults aged 76 to 85; and (c) to not screen adults older than 85 (USPSTF, 2008). Understanding barriers to CRC screening is critical in encouraging eligible adults to participate in screening.

Barriers to CRC screening result from multiple factors. Jones, Devers, Kuzel, and Woolf (2010) identified bowel preparation and fear as the most widespread barrier to screening in their study. Green et al., (2008) also described the fear of pain related to the colonoscopy procedure and a diagnosis of CRC as perceived barriers by patients. Jones et al., (2010) also identified

barriers including financial and language difficulties. Lack of a provider's recommendation for CRC screening also was a common theme in discussing barriers to CRC screening. Lasser, Ayanian, Fletcher, and Good (2008) identified "no doctor's recommendation" as one of barriers in their study, and Kelly et al., (2007) and Jones et al., (2010) found that lack of physician recommendation was a barrier to CRC screening. Not surprisingly, other researchers identified a provider recommendation as the most powerful influence on patient decision to undergo CRC screening (Davis et al., 2013; Haverkamp, Perdue, Espey, & Cobb, 2011; Klaunde, Vernon, Nadel, Breen, Seeff, & Brown, 2005; Sarfaty, 2008).

Primary care providers (PCPs) usually initiate CRC screening by making a referral for one of the recommended screening tests (Katz et al., 2012; Ornstein, Nemeth, Jenkins, & Nietert, 2010). Thus, insufficient knowledge of CRC and USPSTF CRC screening guidelines may result in eligible adults being overlooked for CRC screening (USPSTF, 2008). In a survey of internal medicine resident knowledge (n=81), Barrison, Smith, Oviedo, Heeren, and Schroy (2003) concluded that the residents lacked necessary risk assessment skills and knowledge about CRC screening recommendations. Gennarelli et al. (2005) arrived at similar results regarding low physician knowledge of CRC screening guidelines for average-risk patients. Additionally, O'Farrell, Green, Reid, Bowen, and Baldwin (2012) found that CRC screening rates were higher among patients who received a physician's recommendation compared with those patients who did not. Based on these findings, insufficient knowledge regarding screening guidelines among PCPs may negatively affect their ability to offer appropriate screening recommendations to eligible adults.

Advanced practice registered nurses (APRNs) make up nearly 25% of primary care providers in the U. S. (Institution of Medicine [IOM], 2011). Growth in the number of APRNs is

gradually rising while medical students and residents entering primary care are declining (IOM, 2011). Understanding APRNs knowledge of CRC screening recommendation guidelines is essential. It is also important to recognize the relationship between their knowledge level and their referral rates in order to improve CRC screening rates. Nevertheless, there are no published studies on APRN knowledge about the USPSTF CRC screening recommendation guidelines. In an effort to determine how CRC screening rates could be increased, two questions arose. What do APRNs know about the USPSTF CRC recommendation guidelines? Is there a relationship between APRN knowledge regarding the USPSTF CRC recommendations and their self-reported referral rate for CRC screening?

Purpose

The purpose of this project was to examine the relationship between APRN knowledge about the USPSTF CRC screening recommendation guidelines and self-reported referral rates for CRC screening among APRNs.

The aims of this project were to determine; (1) demographic characteristics of APRNs; (2) APRNs knowledge levels about the USPSTF CRC screening recommendation guidelines; (3) the referral rate of APRNs by collecting participant self-reported screening rates; (4) whether educational background is associated with the self-reported referral rates; and (5) the relationship between an APRNs knowledge level about the USPSTF CRC screening recommendation guidelines and the self-reported referral rates for CRC screening.

Methods

Study Design and Sample

A descriptive internet survey was conducted to examine APRN knowledge about the 2008 USPSTF CRC screening recommendations and self-reported referral rates for CRC

screening. The Test Your Knowledge Survey (Sarfaty, 2008, Appendix A) was modified and administered to APRNs through the Kentucky Coalition of Nurse Practitioners and Nurse Midwives listserv (KCNPNM) from January 5 through March 5, 2015.

Currently, 5,321APRNs are registered in Kentucky, with each role broken down as follows; nurse anesthetist (1,215), nurse specialist (178), nurse midwives (100), and nurse practitioner (3,828) (Kentucky Board of Nursing, 2014). Inclusion criteria for this study were (a) APRNs over 18 years old who are subscribers to the KCNPNM listserv; (b) are currently practicing in Kentucky 12 hours or more each week in general practice, family practice, internal medicine, gastroenterology practice, and obstetrics/ gynecology. Exclusion criteria for this study were APRN nursing students who were subscribers to the KCNPNM listserv.

Subject Recruitment

The initial contact with potential eligible participants was made by sending an e-mail via the KCNPNM listserv to all 1,526 subscribing member of KCNPNM on January 5th, 2015 after obtaining permission from the University of Kentucky Medical Institutional Review Board and the Executive Director of KCNPNM (Appendix B). The e-mail included an invitation to participate in the study, information about the study, and a link to access the survey. Follow up e-mails were sent as a reminder to complete the survey to all 1,526 subscribing members of KCNPNM four more times during January and February after the initial e-mail.

Informed Consent Process

The e-mail explained the purpose of this project, anticipated benefits and risks, limitation of confidentiality due to the nature of an online survey, contact information, and statements describing type of participation, and no penalties or loss of benefits for not participating or

withdrawing from the study if they should desire. Participation was voluntary. Completion of the survey constituted consent.

Research Procedures

The Test Your Knowledge Survey was developed as a part of a toolbox to guide primary care providers in promotion of CRC screening (Sarfaty, 2008). The Test Your Knowledge survey was modified to include items related to demographics and referral rates. The survey consists of twenty questions. The first ten questions are related to improving screening rates in practice, and the remaining ten questions focused on the current screening recommendation guidelines. The modified survey is organized into the following four sections; (a) practice and other demographic characteristics; (b) attitude toward improving CRC screening rates in practice; (c) knowledge of CRC screening modalities and recommendation guidelines; and (d) self-reported CRC screening recommendation rate.

Items inquiring about APRN attitudes toward improving CRC screening rates focused on evidence-based essential elements that are effective in improving CRC screening rates (Sarfaty, 2008). These elements include provider recommendation, an office policy about assessing individual risk and insurance coverage, identifying local medical resources and considering patient preference, an office reminder system, and an effective communication system between a provider and patients.

Items assessing APRN knowledge about CRC recommendation guidelines focused on categorizing the risk level of individual patients and applying appropriate CRC screening tests. The item evaluating APRNs' self-reported referral rate was measured by using a four-point Likert scale that contains "*very often*"(90-100%), "*often*" (75-90%), "*average*"(50-75%), "*not often*"(less than 50%) after reviewing the USPSTF CRC screening recommendation guidelines

(Appendix C). Each question was coded 1 for correct response and 0 for incorrect response and a total survey score was calculated for each participant. Question 21 was added to evaluate self-reported APRN referral rates. Questions 22 -31 were added to examine the participant demographics. Thus, the participants were asked about their age, gender, level of nursing education, years of practice as an APRN, the type of APRN license held, type of the clinical setting and county in which they practiced, working hours each week, and average number of patients they see each week. REDCap was used to collect and store data. REDCap is a secure web-based application that supports and manages data capture for small/medium-sized research studies (Harris et al., 2009). Data were securely kept on Biomedical Informatics servers ran by the Institute for Pharmaceutical Outcomes and Policy (IPOP) physically located in the new Biological and Pharmaceutical Complex building at the University of Kentucky.

Data Analysis

Statistical analysis was performed using SPSS. Descriptive statistics were utilized to describe the sample. Frequencies were calculated for each variable. A McNemar Chi-square test (2x2) was used to examine the relationship between APRN knowledge and self-reported referral rates for CRC. If McNemar Chi-square statistic value is > 3.84 and p value is < 0.05, the null hypothesis will be rejected. A p value <0.05 is considered statistically significant.

Results

Demographic characteristics

Ninety-seven participants were recruited from January 5 to March 5, 2015. Of those, 34 participants were excluded based on the incompletion of survey, inability to provide self-reported referral rates for CRC screening due to their practice backgrounds (a thoracic unit, an acute care unit, a retail clinic, & cardiology), practice out of Kentucky, working less than 12

hours per week, retired, or student. Of the remaining 63 participants, a majority (n=59; 93.7%) were female, which reflects the national average (≈92%) of female nurses in nursing fields (U.S. Census Bureau, 2013). Master's prepared APRNs (nearly 75%) dominated the sample while 20.7% were doctorally prepared APRNs. APRNs had been in practice for an average of 11.6 years and an average of 49.8 years old. APRNs from 30 counties participated with the highest participation rate coming from Jefferson County. Demographic characteristics are provided in Table 3.

Regarding attitudes toward improving CRC screening rates in practice, only 44.4% (n=28) of APRNs recognized "*a recommendation*" as the most effective tool for encouraging patients to be screened. One hundred percent (n=63) of APRNs acknowledged that "*postcard reminders*", "*reminder letters*", "*prescription reminders*", and "*telephone calls*" would be effective in improving CRC screening rate, but only 53% of these responded that all four have been demonstrated to be effective. Only 57.1% (n=36) responded to the effectiveness of all four of the chart prompts including "*problem lists*", "*screening schedules*", "*electronic medical record reminders*", and "*chart stickers*". On the other hand, nearly 96.8% (n=61) of APRNs identified "*provider feedback*" as an effective way to improve CRC screening. Over 90% (n=57) of APRNs also acknowledged involving office staffs in the screening process can facilitate improving CRC screening. Table 4 illustrates the results on APRNs attitude toward improving CRC screening rates in practice.

Overall test scores for knowledge level of USPSTF CRC screening recommendation guidelines were 77.9%. The first six questions which were focused on assessing attitudes toward improving CRC screening rates in practice were not included in the overall test scores because they were not related in the evaluation of APRNs knowledge of CRC screening recommendation

guidelines by USPSTF (see Figure 1). Answers were coded either 1 point for a correct response or 0 point for incorrect response. The maximum score was 14 points. A total survey score was calculated for each participant. The distribution of scores is exhibited in Figure 1. Three APRNs answered all questions correctly, while one APRN scored 6, the lowest score. The mean score ± standard deviation was 10.9 ± 2.06 and median of 11.

The majority of APRNs (n=40, 63.5%) answered "*false*" (correct answer) when asked if the digital rectal examination is an acceptable CRC screening practice. Regarding whether a clinician should perform a stool blood test in the office to make sure that at least one CRC screening test was completed, 60.3% (n=38) of APRNs answered "*true*" (incorrect answer). Only 52.4% (n=33) of APRNs answered "*false*" (correct answer) when asked if a stool blood test should be repeated when it is returned with only one positive window. 71.4% (n=45) of APRNs answered "*true*" (incorrect answer) when asked if a positive stool blood test without following the diet restrictions should be repeated. APRNs knowledge level regarding rectal examination and stool blood test are displayed in Table 5.1.

Participants also showed a lack of knowledge when asked to categorize the risk level of patients as average, increased, or high based on the current screening guidelines. For example, 74.6% (n=47) of APRNs answered "*high*" (incorrect answer) when asked them to categorize the risk level of a 20 year-old woman whose mother died of colorectal at age 47. More than half of the APRNs (n=32) also provided incorrect answers to the question that asked to categorize the risk level of a 30 year old male whose older brother was diagnosed with an adenomatous polyp at age 59. The average APRNs correct response on categorizing the risk level for four individual patients was only 40.5%. Table 5.2 illustrates the results on APRNs knowledge of categorizing the risk levels of individual patients.

APRNs demonstrated their knowledge regarding CRC screening ages for "*average-risk*" patients. Nearly 90% of participants knew individuals with average risk for CRC should screen at age 50. The majority of participants also knew colonoscopy has the highest sensitivity and specificity among the recommended modalities and should be used as a follow-up screening test. Table 5.3 shows the APRNs performance on choosing appropriate modalities for individual patients.

When APRNs were asked to rate their referral for CRC screening using a four-point Likert scale that contains "*very often*"(90-100%), "*often*" (75-90%), "*average*"(50-75%), "*not often*"(less than 50%), 51% (n=32) of them reported that they made referrals for CRC screening "*very often*", while 33.3% (n=21) reported making referrals "*often*". Only 15.9% (n=10) of APRNs reported that they made referral for CRC screening "*average*" or "*not often*". Participants who answered "*N/A*" were excluded from this study. Those responses were compared with test scores (n=24 who scored ≥ 11 and n=39 who score <11) to determine if there was a relationship. McNemar's Chi-square test value was $\chi 2 = 6.21$ and p-value = 0.01. Given the assumption that APRNs who scored higher on the test will have higher referral rates (null hypothesis), the McNemar statistic value $\chi 2 = 6.21$ and p-value = 0.01 rejected this assumption. As a result, APRNs knowledge level of CRC screening recommendations guideline and their referral rates were not related. APRNs test scores and their self-reported referral rates for CRC screening is displayed in Table 6.

There was no difference in test scores and very little difference in self-reported referral rates by education levels. The majority of APRNs (83%) with MSN degrees reported their referral rates as "*very often*" or "*often*", 84.6% of APRNs with doctoral degrees reported their

referral rates as "*very often*" or "*often*" while only 63.8% of APRNs with MSN and 62.5% of APRNs with DNP and PhD scored ≥ 11.

Discussion

Provider's recommendation for CRC screening has been identified as the most effective in convincing patients to undergo screening procedures (Davis et al., 2013; Haverkamp et al., 2011; Klaunde et al., 2005; Sarfaty, 2008). All APRNs in this present study agreed with the effectiveness of reminder methods such as postcards, letters, and phone calls in increasing CRC screening rates although not all of them agreed on those reminders as being equally effective.

Other researchers have recognized "*no recommendation*" as one of the barriers to CRC screening (Jones et al., 2010; Kelly et al., 2007; Lesser et al., 2008). Less than 50% of APRNs in this study agreed with the above findings. Green et al. (2013) conducted a study on examining an automated intervention to increase uptake of CRC screening, including EHR-linked mailings, telephone assistance, automated assistance plus nurse navigation. Green et al. (2013) found groups with those interventions, compared with groups with no intervention, were more likely to be current for CRC screening.

Findings from the present study on APRNs were consistent with studies on physicians (Barrison et al., 2003; Gennarelli et al., 2005; Nadel et al., 2010). The average APRNs correct response on categorizing the risk level for four individual patients was only 40.5%. Perhaps those findings may be explained by inadequate explanation of how to categorize the risk level, and the complexity of the risk assessment for developing CRC provided by USPSTF CRC screening recommendation guidelines.

Providers' knowledge of CRC screening recommendation guidelines is a critical component in improving CRC screening among eligible adults. A previous study on internal

medicine residents by Barrison et al. (2003) demonstrated that risk assessment skills on an individual for developing CRC and knowledge about CRC screening recommendations are insufficient. Gennarelli et al. (2005) also found physicians lacked knowledge of CRC screening guidelines for average-risk patients.

Although utilization of FOBT has been decreasing in recent years, FOBT is one of the recommended modalities for CRC screening by USPSTF. Over 60% of participants considered the one-time FOBT administration in the office as being an acceptable practice. Additionally, over 70% of APRNs lacked an understanding that colonoscopy was recommended when a FOBT showed a positive result regardless of the diet restrictions not being followed. One potential cause for APRNs poor knowledge level regarding FOBT may be a declining utilization of FOBT at only 10.4% in recent years (CDC, 2013b).

Many studies have validated that FOBT can reduce CRC incidence and mortality (Bosetti et al., 2011; Hardcastle et al., 1996; Hewitson et al., 2008; Lindholm et al., 2008; Mandel et al., 2000; Parente et al., 2014). For example, conducting Cochrane Systemic Review of four RCTs showed that FOBT reduced CRC mortality by 16% (Hewitson et al., 2008). APRNs demonstrated insufficient knowledge of utilization of the FOBT. A single digital rectal examination with FOBT cannot be recommended as the only test due to its poor sensitivity (4.9%) for detecting CRC (Collins, Lieberman, Durbin, Weiss, & the Veteran Affairs Cooperative Study # 380 group, 2005). Nadel et al. (2010) described the one-time FOBT given by PCPs in the office may be worse than no screening because it fails not only in detecting 95% of cases of advanced neoplasia but also provides a false sense of reassurance.

On the other hand, APRNs were knowledgeable about application of other modalities. Almost all APRNS knew colonoscopy should be used as the follow-up test. Interestingly, the

present study found that APRNs knowledge level was not correlated to their self-reported CRC screening referral rates. Of those (n=24) who scored less than 11, 87.5% indicated that they made referrals very often or often. In addition, analysis found that no statistically significant association in self-reported referral rates between APRNs with MSN and APRNS with DNP or PhD.

Limitations

This study has several limitations. First, an unvalidated instrument was used to measure APRNs knowledge level. However, validity and reliability for this instrument have not been tested. Second, the small sample size is a limitation. Sixty-three participants in the present study represent only 1.2% of total APRNs in Kentucky. Thus, the findings from this study cannot be generalized to the whole APRN population. Lastly, a self-reported referral rate for CRC screening method was utilized. This method may potentially lead to bias since true referral rates could not be determined. A patient's chart audit by using EHR may help to minimize the bias.

Implications for Practice and Research

Findings from this study indicated APRNs knowledge of utilization of FOBT (one of the recommended CRC screening tests) and risk assessment skills were lacking. Suggestions to improve APRNs knowledge in these areas include providing education programs related to utilization of FOBT and risk assessment skills by employing pre-test and post-test. Offering continuous educational unit (CEU) credit hours for the educational program may encourage APRNs to participate in these programs. It may be necessary to produce a simple algorithm of assessing the risk level for developing CRC of individuals for APRNs to use it as a quick reference. In addition, it is essential to create a better instrument to measure APRNs level of CRC screening recommendation guidelines.

Conclusions

The present study aimed to determine if there was a relationship between APRNs knowledge level of CRC screening recommendation guidelines and APRNs self-reported CRC screening referral rates. Findings from this study indicated that APRNs lacked knowledge not only in categorizing the risk level of individuals, but also in utilizing FOBT appropriately. Thus, needs for improvement in APRNs knowledge related to risk assessment skills and utilization of FOBT were identified. APRNs should keep in mind that FOBTs, especially the high-sensitivity FOBT and FIT, have made significant improvements in their sensitivity. Because of improved sensitivity of FOBT or FIT, these tests can be a reasonable alternative that can reach to a broad-range of eligible adults. Although APRNs self-reported CRC screening referral rates were not associated with their knowledge level, sufficient knowledge of the current guidelines are essential for APRNs in order to provide evidence-based safe care. Efforts must be made to improve APRNs risk assessment skills and proper utilizations of the FOBT.

Tables and Figure

Table 3 Demographic Characteristics of APRN

		Frequency	Percent
Gender	Male	3	4.8%
	Female	59	93.7%
	Non-specified	1	1.5%
Education	MSN	47	74.6%
	DNP	10	15.9%
	PhD	3	4.8%
	Others/missing	3	4.8%
Years in Practice	1-5 years	22	34.9%
	6-10 years	12	19%
	11-15 years	6	9.5%
	16-20 years	12	19%
	21-25 years	0	0%
	30 and over years	5	7.9%
APRN Designation	Nurse Practitioners	54	85.7%
	Nurse Midwives	5	7.9%
	Clinical Nurse Specialist	3	4.8%
	Nurse Anesthetist	0	0%
Population Focused	Family Practice	36	57.1%
	Adult (Adult-Gero)	13	20.6%
	Women's Health	11	17.5%
	Acute Care	2	3.2%
	Psychiatric Care	1	1.6%
County	Jefferson	14	22.2%
	Fayette	9	14.3%
	Hardin	3	4.8%
	Breckinridge	2	3.2%
	Caldwell	2	3.2%
	Daviess	2	3.2%
	Franklin	2	3.2%
	Pulaski	2	3.2%
	22 more counties with an APRN	1	35.2%

Table 4 APRNs Attitudes toward Improving Screening Rates in Practice

		Frequency	Percent
Q 1. The most effective tool at an APRN's disposal fir encouraging patients to be screened is	A recommendation (correct answer)	28	44.4%
	An educational pamphlet	7	11.1%
	An educational video	1	1.6%
	None of the above	26	41.3%
	All of the above	1	1.6%
Q 2. Which of the following have been demonstrated to be effective in raising cancer screening rates	Postcard reminders	6	9.5%
	Reminder letters	9	14.3%
	Prescription reminders	3	4.6%
	Telephone calls	9	14.3%
	All of the above (correct answer)	36	57.1%
Q 3. Effective chart prompts include	Problem lists	0	0%
	Screening schedules	12	19%
	Electronic medical record reminders	14	22.2%
	Chart stickers	1	1.6%
	All of the above (correct answer)	36	57.1%
Q 4. A theory-based communication strategy is more effective than generic education	True (correct answer)	48	76.2%
	False	13	27.1%
Q 5. Provider feedback is an effective way to improve office screening rates	True (correct answer)	61	96.8%
	False	2	3.2%
Q 6. Reassignment of office staff to involve them in the screening process can facilitate improved screening rates	True (correct answer)	57	90.5%
	False	4	6.4%

Table 5.1 APRN Knowledge Level about the USPSTF CRC Screening Recommendation Guidelines

		Frequency	Percent
Q 7. The digital rectal exam in an accepted colorectal cancer screening practice.	True False (correct answer)	23 40	36.5% 63.5%
Q 8. Clinician should do a stool blood test in the office to make sure that at least one CRC screening test is completed.	True False (correct answer)	38 25	60.3% 39.7%
Q 9. If a stool blood test kit is returned and only one window is positive, the test should be repeated.	True False (correct answer)	30 33	47.6% 52.4%
Q 10. A positive stool blood test should be repeated if the diet restriction were not followed,	True False (correct answer)	45 18	71.4% 28.6%

Table 5.2 APRN Knowledge Level about the USPSTF CRC Screening Recommendation Guidelines

		Frequency	Percent
Q 11. A 45 year old woman whose father was diagnosed with colorectal cancer at age 70?	Average (correct answer) Increased High	24 33 5	38.1% 52.4% 7.9%
		Missing =1	
Q 12. A 30 year old male whose older brother was diagnosed with an adenomatous polyp at age 59.	Average Increased (correct answer) High	14 30 18	22.2% 47.6% 28.6%
		Missing =1	
Q 13. A 50 year old female whose uncle was diagnosed with adenomatous polyps at age 55.	Average (correct answer) Increased High	33 24 6	52.4% 38.1% 9.5%
Q 14. A 20 year old woman whose mother died of colorectal at age 47	Average Increased (correct answer) High	0 15 47	0% 23.8% 74.6%
		Missing =1	

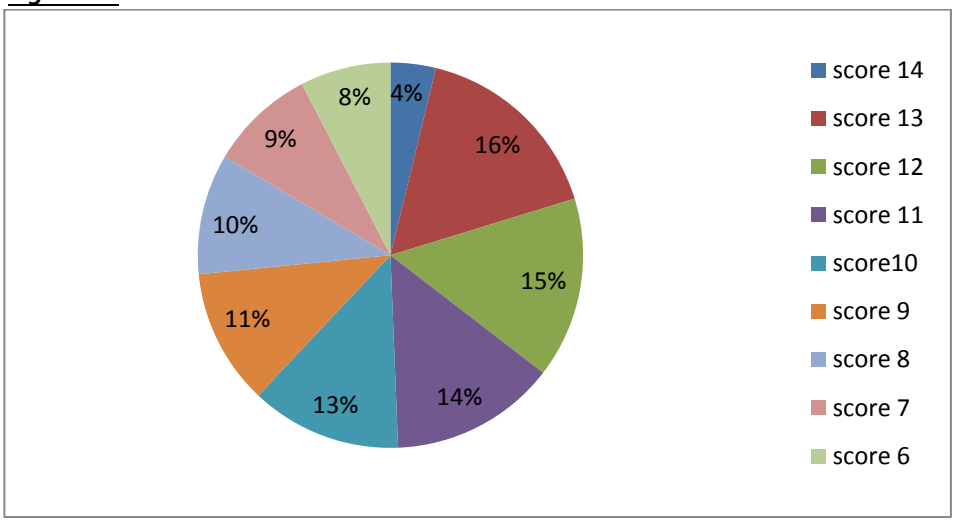
Table 5.3 APRN Knowledge Level about the USPSTF CRC Screening Recommendation Guidelines

		Frequency	Percent
Q 15. At what age should "average-risk" patient begin colorectal cancer screening?	Puberty	0	0%
	Age 25	2	3.2%
	Age 40	5	7.9%
	Age 50 (correct answer)	56	88.9%
	Age 60	0	0%
		Missing=0	
Q 16. At what age should a patient with family history of colorectal cancer or adenomatous polyps affecting one first-degree relative diagnosed at age 55 begin screening?	Puberty	1	1.6%
	Age 25	8	12.7%
	Age 40 (correct answer)	46	73.0%
	Age 50	8	12.7%
	Age 60	0	0%
		Missing=0	
Q 17. What screening modality offers the greatest sensitivity and specificity and should be recommended to those at increased risk?	Stool blood test	1	1.6%
	Stool blood test/Flexible Sig.	5	7.9%
		4	6.3%
	Flexible sigmoidoscopy	53	84.1%
	Colonoscopy (correct answer)	0	0%
	Double–contrast barium enema	0	0%
		Missing=0	
Q 18. What screening modality might be best to recommend to a patient who is distrustful of physicians or very uncomfortable with invasive procedures?	Stool blood test (correct ans.)	51	81%
	Stool blood test/Flexible Sig.	5	7.9%
		0	0%
	Flexible sigmoidoscopy	3	4.8%
	Colonoscopy	4	6.3%
	Double–contrast barium enema	0	0%
		Missing=0	
Q 20. Which of the following screening test(s) are recommended by one or more authoritative groups for patient at risk of hereditary non-polyposis colon cancer or familial adenomatous polyposis?	Stool blood test	1	1.6%
	Flexible Sigmoidoscopy	3	4.8%
	Stool DNA testing	4	6.3%
	Colonoscopy (correct answer)	52	82.5%
		1	1.6%
	Double–contrast barium enema	0	0%
	All of the above	0	0%
		Missing=2	

Table 6 Test Scores and Self-Reported Referral Rates for CRC Screening

	Referral Rate ≥ 75%	Referral Rate < 75%	Total
Test Score ≥ 11	32 (82.1%)	7 (17.9%)	39
Test Score <11	21 (87.5%)	3 (12.5%)	24
Total	53	10	63

Figure 1 Distribution of Test Scores



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Capstone Practice Inquire Project Conclusion

Yong Seon Girdler, RN

University of Kentucky

Colorectal cancer (CRC) is the second leading cause of cancer deaths in both men and women in the United States. The Centers for Disease Control reports that 51,783 people died from CRC in 2011. CRC can be prevented by participating in recommended screening tests including fecal occult blood test (FOBT) such as high-sensitivity FOBT or fecal immunochemical test (FIT) annually. However, only 64.5% of eligible adults were screened for CRC in 2008. Factors contributing to the low CRC screening may vary, but several barriers including invasive screening methods (fear, bowel preparation, and unwillingness to undergo), lack of access to health care services, and lack of provider's recommendation due to insufficient knowledge related to the current CRC screening recommendation guidelines have been identified. It is critical to overcome these barriers for improving CRC screening rates among eligible adults in the United States.

Efforts must be made to improve CRC screening rates among eligible adults. Several strategies for overcoming these barriers were identified from conducting the DNP practice inquiry project. To increase utilization of high-sensitivity FOBT or FIT annually for those who are reluctant to undergo the invasive screening tests or for low-income adults who have lack of access to health care services may help to overcome barriers related to the invasive screening tests. Although the sensitivity of FOBT is not as high as of colonoscopy, employing FOBT has demonstrated its effectiveness not only in reducing CRC mortality and incidence rates but also in increasing participation rates to CRC screening. The current low utilization of FOBT at 10.4% in recent years should be increasing.

Even though the present study found that there was no relationship between APRNs knowledge level about the USPSTF CRC screening recommendation guidelines and their self-reported CRC screening rates, providers' sufficient knowledge of the current guideline is critical

in providing evidence-based safe care. To provide educational programs to APRNs about the current CRC screening recommendation guidelines would improve their knowledge. Developing a simple algorithm of assessing risk level of individual patients by USPSTF may be necessary for providers to use as a quick guide in determining risk level for an individual. As a result, this may lead to more referrals for CRC screening. On the other hands, a better instrument that can measure APRNs knowledge level appropriately should be developed in future research.

Implementing the FluFOBT program may be a strategy in improving CRC screening rates. Evaluation of the pilot program at the Chinatown Public Health Center (CPHC) in San Francisco launched in 2008 demonstrated a significant increase of CRC screening rates to 75.3% from 57.3% among those who were participated in the program. Overcoming the above barriers appears to support efforts for increasing CRC screening rates.

Appendix A

Improving Screening Rates in Practice

1. The most effective tool at an APRN's disposal for encouraging patients to be screened is:
    a. A recommendation
    b. An education pamphlet
    c. An educational video
    d. None of the above
    e. All of the above

2. Which of the following have been demonstrated to be effective in raising cancer screening rates?
    a. Postcard reminders
    b. Reminder letters
    c. Prescription reminders
    d. Telephone calls
    e. All of the above

3. Effective chart prompts include:
    a. Problem lists
    b. Screening schedules
    c. Electronic medical record reminders
    d. Chart stickers
    e. All of the above

Choose whether the statements are true or false. (True/ False)

4. A theory-based communication strategy is more effective than generic education. (T/ F)
5. Provider feedback is an effective way to improve office screening rates. (T/ F)
6. Reassignment of office staff to involve them in the screening process can facilitate improved screening rates. (T/ F)
7. The digital rectal exam is an accepted colorectal cancer screening practice. (T / F)
8. Clinicians should do a stool blood test in the office to make sure that at least one CRC screening test is completed. (T / F)
9. If a stool blood test kit is returned and only one window is positive, the test should be repeated. (T / F)
10. A positive stool blood test should be repeated if the diet restrictions were not followed. (T /F)

The Current Screening Guidelines Categorize the risk level of the following patients as average, increased, or high.

11. A 45-year-old woman whose father was diagnosed with a colorectal cancer at age 70
    ____ Average ____ Increased _____ High

12. A 30-year-old male whose older brother was diagnosed with an adenomatous polyp at age 59.
    ____ Average ____ Increased _____ High
13. A 50-year-old female whose uncle was diagnosed with an adenomatous polyp at age 55.
    ____ Average ____ Increased ____ High
14. A 20-year-old woman whose mother died of colorectal at age 47.
    _____Average ____ Increased _____ High
15. At what age should "average-risk" patients begin colorectal cancer screening?
    ____ Puberty ____ Age 25 ____ Age 40 ____ Age 50 ____ Age 60

16. At what age should a patient with a family history of colorectal cancer or adenomatous polyps affecting one first-degree relative diagnosed at age 55 begin screening?
    ____ Puberty Age 25 Age 40 Age 50 ____ Age 60
17. What screening modality offers the greatest sensitivity and specificity and should be recommended to those at increased risk?
    ___ Stool blood test ___ Stool blood test/Flexible sigmoidoscopy
    ____ Flexible sigmoidoscopy ____ Colonoscopy
    ____ Double-contrast barium enema
18. What screening modality might be best to recommend to a patient who is distrustful of physicians or very uncomfortable with invasive procedures?
    ____ Stool blood test ____ Stool blood test/Flexible sigmoidoscopy
    ____ Flexible sigmoidoscopy ____ Colonoscopy
    Double-contrast barium enema
19. Which of the following screening test(s) are recommended for a 40-year-old patient whose 65-year-old father had colorectal cancer or an adenomatous polyp?
    _____ Stool blood test _____ Flexible Sigmoidoscopy
    _____ Stool DNA testing (sDNA) _____ Colonoscopy
    _____ Double-contrast barium enema (DCBE)
    _____ All of the above

20. Which of the following screening test(s) are recommended by one or more authoritative groups for patients at risk of hereditary non-polyposis colon cancer (HNPCC) or familial adenomatous polyposis (FAP)? (Choose one.)
    _____ Stool blood test _____ Flexible Sigmoidoscopy
    _____ CT colonography (CTC) _____ Colonoscopy
    _____ Double-contrast barium enema (DCBE)
21. How often do you make colorectal cancer screening referral for eligible patients in best your knowledge?
    ____ Very often (4) ___ Often (3) ___ Average (2) ___ Not often (1) ___ N/A (please explain why)

The following questions are for demographic purposes:

22. What is your age?
23. What is your gender?
    ____ Female ____ Male ____ Others

23. What is the highest level of nursing education you have completed?
    ___ MSN ___ DNP ___ PhD ___ Other
24. How many years have you practiced as an APRN?

25. What is your APRN designation?
    _____ Nurse Practitioner ____ Nurse Anesthetist _____ Nurse Midwife
    _____ Clinical Nurse Specialist
26. What is your population focus?
    _____ Family ____ Adult (or Adult-Gero) _____ Acute Care
    _____ Pediatrics _____ Neonatology _____ Women's Health
    _____ Psychiatric Mental Health
27. Please provide the type of clinical setting in which you practice.
    _____ General Practice ____ Family Practice ____ Internal Medicine
    _____ Obstetrics/ Gynecology _____ Gastroenterology Practice
    _____ Other (Please provide the type of your clinical setting)
28. Please indicate the State in which your practice.
    ____ Kentucky _____ Other
29. If in Kentucky, which county do you practice in?
30. How many hours each week do you see patients?
31. About how many patients do you see each week?

Appendix B

Letter of Approval from Kentucky Coalition of Nurse Practitioner and Nurse Midwives

Kentucky Coalition of Nurse Practitioners & Nurse Midwives

To whom it may concern:
The Kentucky Coalition of Nurse Practitioners and Nurse Midwives is in support of Yong Seon Girdler, RN, BSN using our listserv to post a link to her survey regarding A Descriptive Study to Examine the Relationship between APRN Knowledge and Self-Reported Referral Rates for Colorectal Cancer Screening. As a member she has access to over 2000 members via our listserv and internal blogs and messaging systems. We fully support her project.

Sincerely,

Leila Faucette

Executive Director

Appendix C

SCREENING FOR COLORECTAL CANCER
CLINICAL SUMMARY OF U.S. PREVENTIVE TASK FORCE RECOMMENDATION (2008)

POPULATION	ADULTS AGE 50 TO 75*	ADULTS AGE 76 TO 85 YEARS*	ADULTS OLDER THAN 85*
RECOMMENDATION	Screen with high sensitivity fecal occult blood testing (FOBT), sigmoidoscopy, or colonoscopy. **Grade: A**	Do not screen routinely. **Grade: C**	Do not screen. **Grade: D**
	For all populations, evidence is insufficient to assess the benefits and harms of screening with computerized tomography colonography (CTC) and fecal DNA testing. **Grade: I (insufficient evidence)**		

SCREENING TESTS	High sensitivity FOBT, sigmoidoscopy with FOBT, and colonoscopy are effective in decreasing colorectal cancer mortality. The risks and benefits of these screening methods vary. Colonoscopy and flexible sigmoidoscopy (to a lesser degree) entail possible serious complications	
SCREENING TEST INTERVALS	Intervals for recommended screening strategies. Annual screening with high-sensitivity fecal occult blood testing. Sigmoidoscopy every 5 years, with high-sensitivity fecal occult blood testing every 3 years. Screening colonoscopy every 10 years.	
BALANCE OF HARMS AND BENEFITS	The benefits of screening outweigh the potential harms for 50 to 75 year olds.	The likelihood that detection and early intervention will yield a mortality benefit declines after age 75 because of the long average time between adenoma development and cancer diagnosis.
IMPLEMENTATION	Focus on strategies that maximize the number of individuals who get screened. Practice shared decision-making; discussions with patients should incorporate information on test quality and availability. Individuals with a personal history of cancer or adenomatous polyps are followed by a surveillance regimen, and screening guidelines are not applicable.	
RELEVANT USPSTF RECOMMENDATIONS	The USPSTF recommends against the use of aspirin or nonsteroidal anti-inflammatory drugs for the primary prevention of colorectal cancer. This recommendation is available at www.preventiveservices.ahrq.gov	

For a summary of the evidence systematically reviewed in making these recommendations, the full recommendation statement, and supporting documents please go to http://www.preventiveservices.ahrq.gov.

*These recommendations do not apply to individuals with specific inherited syndromes (Lynch Syndrome or Familial Adenomatous Polyposis) or those with inflammatory bowel disease.

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