

# COLORECTAL CANCER SCREENING: A NON-INVASIVE APPROACH

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This thesis is dedicated to all those who have suffered from colorectal cancer and their loved ones. One patient in particular, who will remain nameless, lost his life at age 27 to colorectal cancer. His battle inspired this author to pursue this research.

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## COLORECTAL CANCER SCREENING: A NON-INVASIVE APPROACH

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Colorectal cancer (CRC) is the third most common malignant neoplasm worldwide and is expected to affect six percent of Americans within their lifetime (National Cancer Institute, 2003). Clinicians worldwide struggle with selecting the most accurate, cost-effective CRC screening tool. Could a noninvasive screening tool be the answer or part of the answer to the dilemmas surrounding CRC screening?

The purpose of this correlational, replication study was to determine whether symptoms such as rectal bleeding, change in bowel habit, and weight loss are associated with symptomatic colorectal cancer using a sample of individuals scheduled for a routine colonoscopy. This study can be considered a pilot study since it has never been replicated in the United States (U.S).

Data obtained from 47 Bowel Symptom Assessment Questionnaires (BSAQs) given to patients undergoing routine colonoscopy at Greenview Regional Hospital in Bowling Green, Kentucky were analyzed to address the research objectives of the study. None of the patients had colorectal cancer, but 15 of the 47 patients had polyps. None of the symptoms showed a significant correlation with polyps according to chi-square analysis. T-tests of the means of the polyp group versus the no polyp group showed no difference between the population means for each of the examined variables. Selva scores generated from the BSAQ did not show a

significant relationship with the presence or absence of polyps. Additional findings, limitations, and implications for future research are discussed.



## CHAPTER 1

### Introduction

#### *Background and Significance*

Colorectal cancer (CRC) is the third most common malignant neoplasm worldwide and is expected to affect six percent of Americans within their lifetime (National Cancer Institute, 2003). Some individuals are at a higher risk of developing CRC. Known CRC risk factors include: a genetic condition such as familial adenomatous polyposis or hereditary nonpolyposis colorectal cancer, a personal history of colorectal cancer or adenomas, first degree relative with colorectal cancer, first degree relative with adenomas diagnosed before age 60, a personal history of breast, endometrial, or ovarian cancer, or a personal history of chronic ulcerative colitis or Crohn's colitis (National Cancer Institute). Interestingly, these high risk individuals account for only 25 percent of all colorectal cancers. Thus, screening low-risk individuals is necessary to identify the remaining 75 percent of CRC cases (National Cancer Institute).

Screening for colorectal cancer involves looking for the disease before it has symptoms (American Cancer Society, 2003). The importance of CRC screening is evident when analyzing the survival rates of this disease. Bennett (2002) states that the five-year survival rate for patients diagnosed with CRC in its earliest stages is about 90%. If the disease has spread to adjacent organs or lymph nodes, the five-year survival rate drops to 50%. Once the disease has metastasized to distant sites, this rate drops to only 5% (Bennett). The average patient dying of colorectal cancer will lose 13 years of life (U.S. Preventative Services Task Force, 2002). Estimates suggest that implementation of currently available cancer prevention and screening strategies at the population level could reduce cancer mortality in the United States by approximately 60% (Emmons, 2001).

### *Research Problem*

Screening for CRC can detect colorectal malignancy in its earliest stages, thus offering patients a better prognosis after diagnosis. Unfortunately, most CRC screening methods are invasive and expensive. While some research suggests colonoscopy to be the epitome of CRC screening (Swaroop & Larson, 2002), there are risks involved with this procedure. Barium enema studies and flexible sigmoidoscopies are also invasive and may be inconclusive (Swaroop & Larson). Fecal occult blood testing, stool DNA analysis, and stool minichromosome protein analysis are non-invasive yet require further testing if results are positive (Swaroop & Larson).

In fact, clinicians worldwide struggle with selecting the most accurate, cost-effective CRC screening tool. Researchers in England (Selvachandran, Hodder, Ballal, Jones, and Cade, 2002) decided to test a new CRC screening tool after studying the histories and clinical presentations of patients with symptomatic CRC. These researchers designed a questionnaire based upon common clinical symptoms found among CRC patients. After comparing the questionnaire score for CRC risk with the malignancy score assigned by a senior colorectal surgeon, the questionnaire was predictive of CRC (Selvachandran et al). Could this noninvasive screening tool be the answer or part of the answer to the dilemmas surrounding CRC screening?

### *Purpose Statement*

The purpose of this correlational, replication study was to determine whether symptoms such as rectal bleeding, change in bowel habit, and weight loss were associated with symptomatic colorectal cancer using a sample of individuals scheduled for a routine colonoscopy. This study can be considered a pilot study since it had never been replicated in the United States (U.S).

### *Development of the Framework*

### *The Need for Screening*

Screening is included in the ideals of health promotion. Nola Pender's Health Promotion Model (Pender, 2001) has been used to guide research involving the screening aspects of health promotion. Pender's model (see Appendix A) has been used in areas such as adolescent health promotion (Montgomery, 2002), construction workers' use of hearing protection (Lusk et al., 1999), and health promotion behaviors in cardiac rehabilitation patients (Sakraida, 2002).

According to the World Health Organization (2003), any cancer screening is justified if four criteria are met:

- 1) The disease is common and associated with serious morbidity or mortality.
- 2) Screening tests are accurate in detecting early stage disease.
- 3) Treatment after the detection of the disease via screening can improve prognosis when compared to prognosis if treatment is received after usual diagnosis.
- 4) Studies show that the potential benefits outweigh the potential harms and costs of screening.

Colorectal cancer meets all four criteria and is thus justified for screening. In fact, if all adults age 50 and older had routine colorectal cancer screening, more than one third of CRC deaths could be avoided (Centers for Disease Control, 2002).

Screening has also been shown to reduce CRC-related morbidity and mortality (Stoffel & Syngal, 2002). Colorectal cancer screening has also been shown to be as cost-effective as screening mammography (Winawer & Zauber, 2000). The U.S. Preventative Services Task Force (2002) indicates that CRC screening is likely to be cost-effective regardless of the strategy chosen; this means it will cost less than \$30,000 per additional year of life gained.

Individuals with known risk factors for CRC account for only 25 percent of all colorectal cancers (National Cancer Institute, 2003). Thus, screening low-risk individuals is necessary to identify the remaining 75 percent of CRC cases. The good news for those individuals with no known risk factors is that CRC has a detectable, curable preclinical stage (adenoma) of about 8 to 12 years before it advances and becomes more fatal (Huether, 2002). Thus, CRC is ideal for screening and early detection.

Studies show that there is room for improvement in current CRC screening campaigns. Despite an increase in public awareness of colorectal cancer and Medicare reimbursement for screening, colorectal cancer screening rates remain low (Barclay, 2003). In 1999, only 25.6-38.6% of Kentucky adults over the age of 50 had a CRC screening test within the recommended time interval (Centers for Disease Control, 2002). Bliss and Sawchuk (2000) note that participation in early cancer screening is effective in decreasing mortality, but fear of diagnosis may exist as a barrier.

Almost 50% of Americans who should be screened for colorectal cancer are not doing so at the recommended intervals (American Cancer Society, 2003). A survey of nearly 88,000 people aged 50 or older identified the screening tools being used in the U.S. (American Cancer Society). Approximately 45% of respondents stated they had used a home fecal occult blood test and 47% reported having sigmoidoscopy or colonoscopy at least once (American Cancer Society). These figures do not reflect the American Cancer Society recommendations that every adult over age 50 should have a fecal occult blood test every year and a sigmoidoscopy every five years. A colonoscopy every 10 years is an alternative to the sigmoidoscopy every five years (American Cancer Society).

*The Family Nurse Practitioner's Role in Screening*

Nurses have been successful in developing, implementing, and evaluating screening tools in various areas of healthcare. For example, Janssen, Holt, and Sugg (2002) developed and implemented a protocol for domestic violence assessment in an obstetrical setting. Their efforts resulted in a screening rate increase of 18%, from 42% to 60%, which has been sustained for the first 18 months of the program. Marshall, McConkey, and Moore (2003) organized obesity health screenings for individuals with intellectual disabilities and found that a sedentary lifestyle seemed to be the most consistent risk factor for obesity in the intellectually disabled.

Loftus and Weston (2001) reviewed the role of the nurse practitioner in nurse-led cancer care clinics. The nurse practitioner's skills and knowledge were evident in the care of colorectal cancer patients (Loftus and Weston). Miller (1999) also examined the role of the nurse practitioner (NP) in the correctional health setting. Theory-based health promotion interventions were discussed for this setting in an effort to improve correctional facility NP practice (Miller).

As previously stated, CRC will likely affect six percent of Americans in their lifetime (National Cancer Institute, 2003). Since family nurse practitioners are sometimes the only primary health care provider for patients, nurse practitioners may diagnose dozens of patients with CRC in their careers. Rakowski, DeDecker, and Westendorp (2001) estimate that 70-90% of colon cancers could be indemnified and removed through CRC screening before they become invasive. Emmons (2000) adds that a substantial number of clinical trials have shown that brief counseling by a primary care provider is effective in changing the health behaviors of many patients.

Because health promotion is one of the cornerstones of nursing practice, screening for malignancies is an essential responsibility of the nurse practitioner. While some specialized

nurse practitioners are able to perform flexible sigmoidoscopy (Rakowski et al ., 2001), others must be able to recognize the symptoms of CRC and expedite gastroenterology referral when indicated. If nurse practitioners know which questions to ask patients in order to predict the malignancy risk for that patient, gastroenterologists may view certain cases as more urgent than others. This may eventually lead to earlier referral, earlier diagnosis, and earlier treatment.

Rakowski et al. (2001) measure successful nursing care by how well informed clients are and how well prepared they are to make decisions that will keep them in a state of health. Emmons (2000) notes that strong relationships exist between health behaviors and risk for leading causes of adult morbidity and mortality. Thus, informing the public about these risk factors in the guise of health promotion may in turn reduce adult morbidity and mortality. Based on CRC screening rates, nurses have not been providing adequate care to their clients in terms of patient education (Rakowski et al .).

As nurse practitioners pioneer the non-invasive approach to CRC screening, patients and community members may begin to recognize the early warning signs of CRC. This increased awareness and knowledge of risk factors could lead to earlier reporting of symptoms to primary care providers as well as lifestyle modifications. Nurse practitioners could also encourage other members of the medical community to follow CRC screening guidelines and to stress the importance of colorectal health to their patients (Rakowski et al ., 2001) .

### *Research Objectives*

The objectives of this study were to:

1. identify variables associated with colorectal cancer using a questionnaire administered to patients with distal colonic symptoms

2. determine a patient's malignancy risk score (Selva score) using the data obtained in the questionnaire
3. evaluate the relationship between the Selva score and the presence or absence of colorectal cancer based on pathology results from a colonoscopy.

### *Hypotheses*

The research hypothesis for this study was that the questionnaire will show a significant level of predictiveness for symptomatic colorectal cancer (based on the results of the point biserial correlation coefficient). The null hypothesis for this study was that there will be no relationship between the Selva score generated by the BSAQ and the incidence of colorectal cancer in patients scheduled for a routine colonoscopy (also based on the results of the point biserial correlation coefficient).

### *Definitions of major variables or concepts*

#### *Appraisal Tools*

*Questionnaire score.* Data from the questionnaires was entered into the computer database where each factor was given a numerical score. The score weights were higher with high-risk symptoms such as rectal bleeding or more frequent, loose stools. The computer program (MAABS) automatically generated the malignancy score (Selva score) from the values entered for each symptom (Selvachandran et al ., 2002).

*Bowel symptoms.* The specific symptoms included on the patient consultation questionnaire (see Appendix B) were: age and sex, blood per rectum (several factors), change in bowel habits (several factors), urgency, and incomplete emptying, perianal symptoms, abdominal symptoms, weight loss, loss of appetite, tiredness, family history, and relevant medical history (Selvachandran et al ., 2002). The Statistical Package for the Social Sciences

(SPSS) software was used to analyze the nominal data, such as abdominal pain, change in bowel habit, and rectal bleeding.

*Colorectal cancer classification.* Colorectal cancers were classified as the absence or presence of cancer. Adenocarcinoma, scirrhous tumors, or neuroendocrine tumors (National Cancer Institute, n.d.) on the pathology report met the criteria for the presence of cancer.

#### *Assumptions*

There were many assumptions associated with this research proposal.

1. Primary care providers want early CRC detection for their patients.
2. Patients want early detection of CRC.
3. Patients with altered health status will seek health care.
4. Advanced practice nurses are responsible for recognizing an altered state of health.
5. Patients are open to education.

Nola Pender's Health Promotion Model also has several assumptions that can be linked to this research (Pender, Murdaugh, & Parsons, 2002):

1. Persons seek to create conditions of living through which they can express their unique health potential.
2. Health professionals constitute a part of the interpersonal environment, which exerts influence on persons throughout their lifespan.
3. Prior behavior and inherited and acquired characteristics influence beliefs, affect, and enactment of health-promoting behavior.
4. Persons commit to engaging in behaviors from which they anticipate deriving personally valued benefits.



5. Persons are more likely to commit to and engage in health-promoting behaviors when significant others model the behavior, expect the behavior to occur, and provide assistance and support to enable the behavior.

*Relevance to FNP practice*

Family nurse practitioners are often the only primary health care provider for patients. As previously stated, CRC will likely affect six percent of Americans (National Cancer Institute, 2003). This translates into dozens of patients that a nurse practitioner may treat in his or her career. Because health promotion is one of the cornerstones of nursing practice, screening for malignancies is essential to the nurse practitioner. The nurse practitioner must be able to recognize the symptoms of CRC and expedite gastroenterology referral when indicated. If nurse practitioners knew which questions to ask patients in order to predict the malignancy risk for that patient, gastroenterologists may view certain cases as more urgent than others. This may eventually lead to earlier referral, earlier diagnosis, and earlier treatment.

Saunders (2002) challenges nurse practitioners (NPs) to offer patient education to all patients who are candidates for CRC screening. She encourages NPs to inform patients of the risks, benefits, and supporting evidence for each of the 4 CRC screening techniques and then allow the patient to make an informed choice as to which method they prefer. Saunders believes that screening rates are low simply because patients are not aware of their options. She also urges NPs to convince insurers to pay for colonoscopy citing the following reasons: effectiveness, patient adherence, and it only needs to be performed every 10 years.

As nurse practitioners pioneer the non-invasive approach to CRC screening, patients and community members may begin to recognize the early warning signs of CRC. This increased awareness and knowledge of risk factors could lead to earlier reporting of symptoms to primary

care providers as well as lifestyle modifications. Nurse practitioners could also encourage other members of the medical community to follow CRC screening guidelines and to stress the importance of colorectal health to their patients.

### *Significance*

The future of CRC screening is in the hands of the primary care community. The cornerstones of nursing practice include health promotion, health education, and disease prevention. By using research-based methods to screen for CRC, perhaps mortality from the disease can be reduced. Increased awareness in the nursing community may be all that is necessary to begin a new trend in the early detection and more widespread screening and prevention of colorectal cancer in this country. The BSAQ tool may offer a valuable supplement to current protocols for colorectal cancer.

Screening can only reach its fullest potential when there is adherence by health care providers to the proven regimens (Rakowski, DeDecker, & Westendorp, 2001). Other ways to reduce mortality and morbidity involve timely and appropriate diagnostic evaluation of any screening abnormalities. Primary care providers must educate all adult clients about CRC prevention and screening and must also follow-up on any positive screening results.

## CHAPTER 2

### Literature Review

Colorectal cancer is the second leading cause of cancer deaths in the United States and the third most common cancer in the U.S. If colon cancer is found in its early stages, it is often curable. Studies show that approximately 50% of all deaths from colorectal cancer can be prevented through lifestyle modification and implementation of widespread screening (Winawer & Zauber, 2000). With the wide variety of CRC screening tools, intense debate over the efficacy, cost-effectiveness, and patient compliance has led to vast amounts of research.

#### *Relevant Theoretical Literature*

Nola Pender's Health Promotion Model (HPM) is relevant to this research (see Appendix A). Pender believes that prior related behavior, personal factors, perceived benefits of action, perceived barriers to action, perceived self-efficacy, activity-related effect, interpersonal influences, and situational influences all have a direct or indirect effect on the likelihood of engaging in health-promoting behaviors (Sakraida, 2002). Each of these factors must be considered when designing, implementing, and evaluating a CRC screening tool.

Pender's HPM is unique when applied to CRC screening behaviors. Prior related behaviors may include the frequency with which an individual visits their primary care provider. Personal factors may include an individual's family member dying from CRC. Perceived benefits of action might be early detection of CRC. Perceived barriers to action might revolve around the sensitive nature of CRC screening. Interpersonal influences might be that an individual is married to a gastroenterologist who strongly believes in CRC screening.

Nola Pender believes the opportunities for advanced practice nurses in health promotion are astounding. She believes that NPs must incorporate research findings about health promotion

into clinical practice, community partnerships, and health promotion programs. She encourages NPs to understand the dynamics of behavior in order to build effective interventions. (University of Michigan School of Nursing, 2001)

Health promotion can be carried out on an individual level or a population perspective (Emmons, 2000). While individually-based interventions may be more effective for high-risk individuals, population-based efforts are better for health promotion as it relates to widespread diseases or conditions. Emmons notes that even small changes at the population level can lead to large effects on disease risk.

### *Relevant Research Literature*

#### *Unmodifiable Risk Factors for Colorectal Cancer*

Some individuals are at a higher risk of developing CRC if they have the following risk factors: a genetic condition such as familial adenomatous polyposis (FAP) or hereditary nonpolyposis colorectal cancer (HNPCC), a personal history of colorectal cancer or adenomas, first degree relative with colorectal cancer, first degree relative with adenomas diagnosed before age 60, a personal history of breast, endometrial, or ovarian cancer, or a personal history of chronic ulcerative colitis or Crohn's colitis (National Cancer Institute, 2003). Age is another unmodifiable CRC risk factor, with 93% of cases occurring in people age 50 and older (Centers for Disease Control, 2002). Persons in high-risk categories must be referred to a gastrointestinal specialist for development of an individualized surveillance plan (Radowski, DeDecker, & Westendorp, 2001).

#### *Modifiable Risk Factors for Colorectal Cancer*

Slattery et al. (1999) note that the prevalence of CRC is highest in populations of high socioeconomic status, possibly as a result of dietary and lifestyle customs. Alberts (2002) adds

that dietary risk factors for CRC have been identified including eating red meat or any broiled meat. There are conflicting reports on whether high amounts of dietary fiber reduce the risk of CRC. Studies show an increased incidence of CRC associated with a diet high in total fat, protein, calories, alcohol, and meat and low in calcium and folate (Robinson, 2002).

Evidence suggests that 60 minutes of daily vigorous activity may reduce CRC risk by 30% (Slattery et al., 1997). Obesity with excess fat in the waist area is also associated with an increased incidence of CRC (Robinson, 2002). Cigarette smoking and high alcohol consumption, particularly beer consumption linked with rectal cancer, have been linked to increased risk of CRC (Robinson). Rex (2002) elaborates that previous studies suggest as much as 20% of colorectal cancer can be attributed to cigarette smoking and that smokers have an equivalent increased risk to those with a positive family history.

#### *Three Levels of Colorectal Cancer Risk*

During the 2001 annual conference of the American Society of Colon and Rectal Surgeons (ASCRS), three categories of colorectal cancer risk were identified (Simmang et al., 2002).

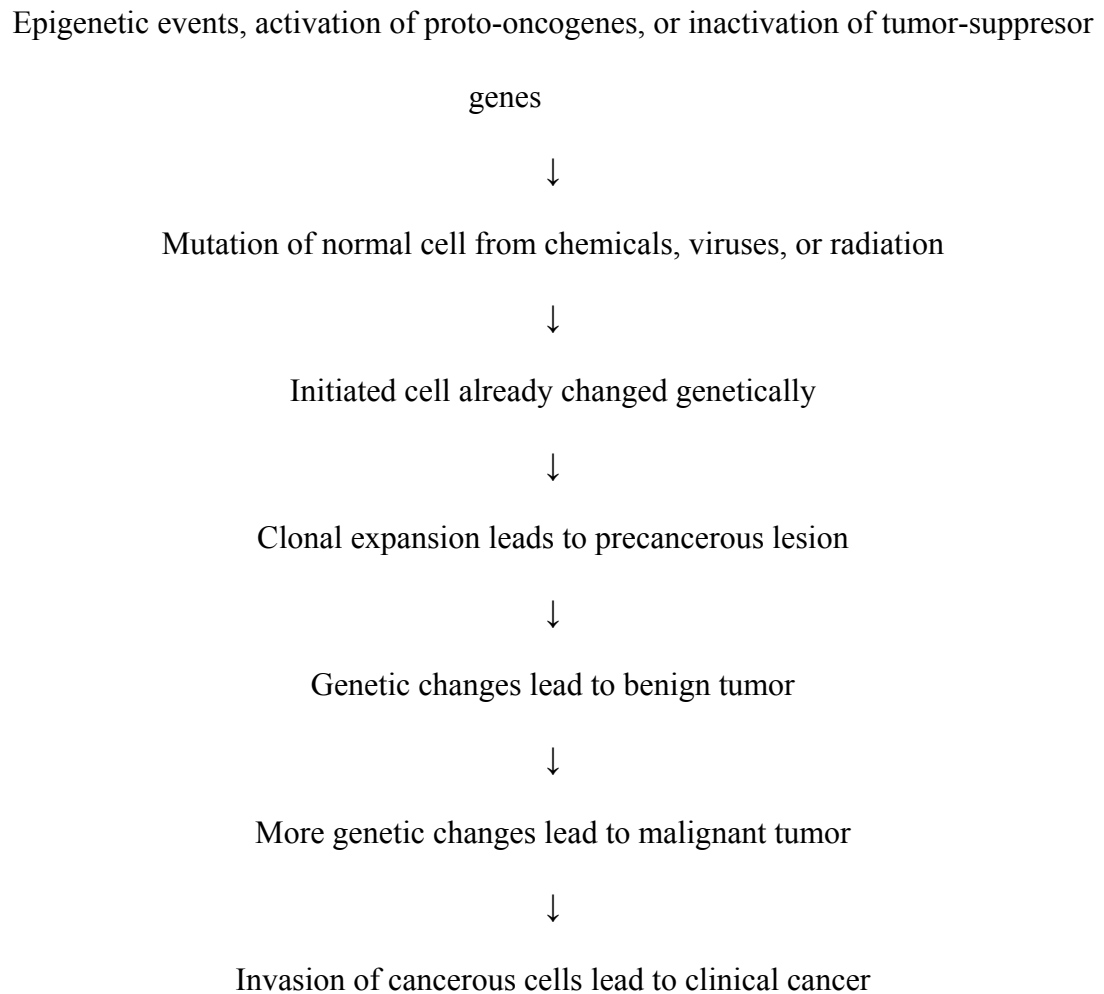
- *Low / average risk:* Individuals without symptoms or risk factors and without a first-degree relative diagnosed with colorectal cancer belong in this group. This group represents 65% to 75% of the population.
- *Moderate risk:* Individuals with a family or personal history of colorectal cancer are in this group, which comprises 20% to 30% of the population.
- *High risk:* Individuals with a history of FAP, HNPCC, or ulcerative colitis are in this group.

### *Pathophysiology of Colorectal Cancer*

Colorectal cancer follows a multistage development pathway as shown in Figure 1. This pathway begins with epigenetic events, activation of proto-oncogenes, or inactivation of tumor-suppressor genes (Huether, 2002). Normal colorectal cells are then mutated as a result of chemicals, viruses, or radiation. This mutation process genetically alters the cell. The altered cell experiences clonal expansion and becomes a group of cells called a preneoplastic lesion. More cellular genetic change leads to a benign tumor, a malignant tumor, and finally clinical cancer (Huether). The gene most closely linked with CRC is the p53 gene. Altered p53 genes are present in 85% of CRC cases (Huether).

Adenomatous polyps are the precursor to most colorectal cancers. These polyps are a direct result of a chromosome five mutation (Huether, 2002). While most polyps are benign, some are neoplastic and become highly malignant after the mucosa is penetrated. Fortunately, colorectal adenomas can be detected early since the mucosa may not be penetrated for several years. Huether notes that the larger the polyp, the higher the risk of colorectal malignancy.

Most colorectal cancers are deemed moderately differentiated adenocarcinomas (Huether, 2002). Colorectal tumors often have a long preinvasive phase and continue to grow slowly after invasion. CRC tumors must traverse the muscularis mucosae into the lymphatic channels before metastasis can occur (Huether). When metastasis does occur, the liver is often affected because the portal vein carries the venous blood flow from the colorectal tumor to the liver (Bliss & Sawchuk, 2000).



*Figure 1.* Conceptual map of the multistage development of colorectal cancer (Huether, 2002).

### *Clinical Manifestations of Colorectal Cancer*

Clinical manifestations of CRC vary depending on which section of the colon is affected. Symptoms can be nonspecific and may not appear until the disease is advanced (Bliss & Sawchuk, 2000). Symptoms may include: abdominal pain, anemia resulting in weakness and fatigue, dark red or mahogany-colored blood mixed with the stool or bright red blood on the surface of the stool, progressive abdominal distention, and change in bowel habits (Huether, 2002). A change in bowel habit consistent with CRC is a stool that is narrower than usual (Centers for Disease Control, 2002). Late signs of CRC may include: pallor, cachexia, lymphadenopathy, ascites, and hepatomegaly if the liver is involved (Bliss & Sawchuk).

Rectal bleeding is often under-reported as many patients attribute any presence of blood to hemorrhoids (Rakowski, DeDecker, & Westendorp, 2001). The American Cancer Society (ACS) also mentions a feeling that you need to have a bowel movement that is not relieved after the bowel movement (2003). The ACS adds that the narrow stools must last more than a few days to be considered a possible symptom of CRC.

### *Screening Guidelines*

There are currently four recommended screening strategies for CRC in average-risk individuals according to the Agency for Healthcare Research and Quality (Swaroop & Larson, 2002). These strategies are: annual fecal occult blood test (FOBT), flexible sigmoidoscopy (FS) every 5 years, double-contrast barium enema every 5 to 10 years, and colonoscopy every 10 years (Swaroop & Larson, 2002). The American Cancer Society (2003) recommends that all people over age 50 have a FOBT every year and a sigmoidoscopy every five years or a colonoscopy every 10 years. Ideally, the patient and physician choose a test that together meets



their expectations. However, a patient's preferred screening option may differ from the preferred choice of the physician.

New guidelines from the U.S. Multisociety Task Force on Colorectal Cancer recommend that patients with one or two tubular adenomas less than one centimeter (cm) should have their first follow-up colonoscopy at five years (Barclay, 2003). Patients with advanced or multiple adenomas (three or more) should have their first follow-up colonoscopy at three years (Barclay, 2003). The new guidelines also address those with a family history of FAP and encourage genetic testing and consideration of colectomy. Genetic testing in children can be delayed until 10 years of age. Those with HNPCC should have a colonoscopy every six months to a year beginning at age 20 to 25 years or 10 years before the youngest cancer diagnosis in the family (Barclay, 2003).

U.S. Preventive Services Task Force (2002) recommends that patients discontinue CRC screening when age or comorbid conditions limit life expectancy. Benefits of screening individuals over the age of 80 may be limited as a result of competing causes of death.

*Fecal occult blood testing.* The newest guidelines from the U.S. Multisociety Task Force on Colorectal Cancer encourage annual fecal occult blood testing for people over the age of 50 who fall into the average risk category for CRC (Barclay, 2003). FOBT has shown mortality reduction and CRC incidence reduction. Each of the screening tools mentioned do have limitations. One drawback of this test is the different kits used to test stool for occult blood. Research has shown large variations in results from the Hemocult test kit versus the HemoQuant test kit (Barclay).

Medications and food may also affect the FOBT. The American Cancer Society (2003) suggests that patients follow these guidelines: avoid all non-steroidal anti-inflammatory drugs

for seven days before testing, avoid vitamin C in excess of 250 milligrams from either supplements or citrus juices three days before testing, and avoid red meats for three days before testing. The American Cancer Society adds that a test of a stool sample from a digital rectal exam is not an adequate substitute. The take-home multiple sample method should be used for FOBT.

Another drawback with FOBT is compliance. Most patients whose family members have CRC never seek FOBT screening from their own physicians. Physicians have also found lack of follow-up from patients whose FOBT tests positive. Even after being notified of the positive results, patients decide not to come back for further testing. A final drawback with FOBT is that if the test is positive, further testing (most often colonoscopy) is required to confirm a diagnosis of CRC (Swaroop & Larson, 2002).

*Barium enema examination.* Barium enema examinations have not been shown to decrease CRC mortality or incidence (Swaroop & Larson, 2002). Screening with barium enema is generally reserved for persons in whom colonoscopy is technically impossible (Radowski, DeDecker, & Westendorp, 2001). Research has shown that double-contrast barium enemas are only 48% effective at detecting adenomas greater than 1 cm. Again, further testing (most often colonoscopy) is required after barium enema examination to confirm a diagnosis of CRC (Swaroop & Larson).

*Flexible sigmoidoscopy.* Use of flexible sigmoidoscopy (FS) resulted in a slight decrease in CRC mortality (Swaroop & Larson, 2002). FS, like the other screening methods, does have its disadvantages. First, a patient has to cleanse the colon in preparation for FS. Patients do not always do this properly; this results in inadequate examination. Second, no sedation is given for FS as this procedure is performed in the physician's office. This leads to patient discomfort and

thus poor patient compliance. Third, FS can only detect distal adenomas; proximal adenomas can not be visualized using FS. Bliss and Sawchuk (2000) state that approximately 50% of colorectal cancers are out of reach of the sigmoidoscope. Finally, most physicians do not perform FS routinely. This again leads to inadequate examination and greater risk of missing a neoplasm (Swaroop & Larson).

*Colonoscopy.* Colonoscopy as a primary screening strategy for CRC has several advantages. It has shown a significant decrease in CRC mortality and incidence. It also allows the physician to visualize the entire length of the colon. There are no further examinations after colonoscopy; one either has an adenoma or CRC or not. It may be more cost-effective due to its ability to diagnose with a single exam and thus only one visit. It only needs to be performed every 10 years in average-risk individuals, whereas other tests such as FOBT are recommended annually. Patients prefer colonoscopy because a sedative is administered; this increases patient comfort and thus patient compliance and satisfaction. Colonoscopy, as with any invasive procedure, does have a risk for complications. Bleeding occurs in approximately 0.2% of cases and perforation of the colon occurs in approximately 0.1% of cases (Swaroop & Larson, 2002).

Swaroop and Larson (2002) make a strong case for colonoscopy as the primary screening strategy for CRC. It has been shown to be an effective diagnostic tool. Colonoscopy may be performed in a hospital outpatient department, in a clinic, or in a doctor's office. It usually takes 15-30 minutes unless polypectomy is required (American Cancer Society, 2003). It is also cost-effective, and patients prefer it. Rakowski, DeDecker, & Westendorp (2001) state that the colonoscopy may decrease the incidence of CRC by 76 to 90 percent.

*Virtual colonoscopy.* Virtual colonoscopy is actually a special computerized tomography (CT) scan of the colon. The preparation for this exam is the same as for barium enema or

colonoscopy. Air is pumped into the colon to distend it before it is scanned. While this exam may be more accurate than the barium enema, it is not as thorough as a colonoscopy (American Cancer Society, 2003). Its advantages are that it can be done quickly, without sedation, at a lower cost than colonoscopy (American Cancer Society). However, if a polyp or growth is found, a colonoscopy will be required to remove those growths. ACS does not currently recommend virtual colonoscopy for early detection of CRC.

*Swallowable camera.* In August 2001, the United States Food and Drug Administration approved a swallowable camera that detects polyps and cancers in the small intestine. This device allows for examination by taking pictures every 30 seconds of the gastrointestinal tract. As it exists now, this pill is not useful in detecting colorectal cancer. One reason is that its battery only lasts eight hours, which is not enough time to photograph the entire gastrointestinal tract. Another reason is that the colon is so large in relation to the pill that parts of the colon would be missed during its photographic journey. (Cancer Research and Prevention Foundation, 2003)

*Analysis of minichromosome maintenance proteins in stool.* Davies et al. (2002) conducted a clinical evaluation study in which minichromosome maintenance protein 2 (MCM2) was analyzed in stool specimens from patients with symptomatic colorectal cancer and from healthy control patients. Thirty-seven of 40 patients with CRC had MCM2 cells in their stool specimens, while none of the healthy 25 control subjects had MCM2 cells in their stool. These results are promising for future research on detecting CRC from a non-invasive approach, the stool specimen (Davies et al., 2002).

*DNA stool test.* There are ongoing trials for a new DNA stool test which shows greater sensitivity than FOBT but less than that of colonoscopy (Barclay, 2003). One such trial is

intended for use in average-risk individuals who decline colonoscopy. Early results confirm that this test will be superior to FOBT but inferior to colonoscopy as predicted (Rex, 2002).

*Bowel symptoms assessment questionnaire (BSAQ).* Selvachandran et al. (2002) describe a practical scoring method to predict colorectal cancers. This score (the Selva score) was developed in early 1999 by S. N. Selvachandran and derived subjectively based on clinical experience. These researchers administered a questionnaire, the BSAQ, to 2268 patients who were referred to surgeons by their general practitioners for distal colonic symptoms. Referrals were prioritized with a malignancy risk score (different from the Selva score) by a senior colorectal surgeon separately from the risk score of the questionnaire. The two scoring systems (Selva score versus surgeon's priority score) were then compared after colonoscopy revealed cancer rates in these patients. Results showed that the two systems in conjunction could be used as an accurate system for prediction of symptomatic colorectal cancer.

*Other colorectal screening programs.* Burke et al. (2002) conducted a study to evaluate the long-term effects of a colorectal screening program. Burke et al. targeted women's interest in CRC screening, since women often direct the health care of the family and the community. Burke et al. recognized that most women already participate in routine breast and cervical cancer screenings. Results of the study suggest that individuals involved in a CRC screening program are more likely to continue with future screenings, even in average-risk populations.

Harris, Byles, Cockburn, and D'Este (2000) evaluated a general practice-based recruitment strategy for colorectal screening. Thirty general practitioners (GPs) volunteered to be part of a CRC screening trial in New South Wales. The GPs had a total of 303 patients who reported a family history of CRC; 158 were placed in the intervention group and 145 were placed in the control group. The intervention consisted of those patients being given a pamphlet

detailing CRC risk factors and screening tests; the pamphlet had a tear-off page requesting FOBT be given to the patient. Results showed that 18% of patients in the intervention group requested the FOBT screening while only 6% of patients in the control group requested FOBT screening. Harris et al. concluded that a pamphlet by itself was a weak intervention.

### *Prevention of colorectal cancer*

*Chemoprevention of colorectal cancer.* In addition to surveillance, chemoprevention is another option for reducing the incidence of colorectal cancer. Alberts (2002) identifies the aim of chemoprevention as using noncytotoxic nutrients and/or drugs to circumvent the development or progression of precancerous cells. Promising agents being studied in clinical trials include nonsteroidal anti-inflammatory drugs (NSAIDs) such as Aspirin and Sulindac, non-NSAIDs (Folic acid, Selenium, Curcumin, Calcium carbonate, and Difluoromethylornithine), and NSAID-related drugs (Celecoxib, Rofecoxib, and Exisulind). Studies show that regular ingestion of aspirin and NSAIDs can produce a 30% to 50% reduction in incidence and mortality of CRC after at least five years of continuous use (Roy, 2002).

*Lifestyle changes.* Bennett (2002) discusses some lifestyle changes that may reduce the risk of developing CRC. These include taking a multivitamin containing folic acid every day, exercising for at least 30 minutes daily, eating less red meat, avoiding smoking, and reducing or eliminating alcohol consumption.

### *The Future of Colorectal Cancer Screening*

The Center for Disease Control (2003) developed a comprehensive CRC initiative designed to increase public awareness of CRC, increase PCP awareness of CRC screening guidelines, promote improved patient-provider communication about CRC screening, support CRC research, and provide funding to state programs to implement CRC priorities. The CDC is

using these efforts to reach a goal of the national health objectives for 2010: to reduce the CRC death rate.

### *Gaps in the Knowledge*

Despite an increase in public awareness of colorectal cancer and Medicare reimbursement for screening, colorectal cancer screening rates remain low (Barclay, 2003). Bliss and Sawchuk (2000) note that although participation in early cancer screening is effective in decreasing mortality, fear of diagnosis may exist as a barrier.

## CHAPTER 3

### Methods and Procedures

#### *Introduction*

This section describes the research design, sample, setting, instrument and measurement methods, data collection procedures, and ethical considerations for this study. Rationale for chosen methodologies are included from the literature.

#### *Research Design*

A correlational, replication research design was used in this study. Correlational research is designed to determine a relationship between two variables; if a correlation is found, an outcome can be predicted (University of Georgia, 2002). For this study, a Selva score computed from the Bowel Symptoms Assessment Questionnaire (BSAQ) was compared to the colonoscopy results (presence or absence of CRC) of participants (Selvachandran et al ., 2002). A point biserial correlation coefficient was calculated to determine the strength of the relationship between the Selva score and the presence of colorectal cancer (CRC). Even though this study was completed in England, predictive studies must be repeated to apply results to different groups (California State University Fullerton, 2001). Furthermore, statistical predictions based on correlations have been shown to be superior to predictions formed from clinical experience (Shaughnessy & Zechmeister, 2002).

#### *Sample*

A purposive convenience sample of patients scheduled for routine colonoscopies was used. Only individuals under the age of 18 and emergent colonoscopy patients were excluded from this study.



Based on a power analysis, the sample size for this study needed to be 392. A power level of 0.80, and alpha level of 0.05, and a moderate effect size were used in the power analysis formulas developed by Cohen (Polit & Hungler, 1999). Selvachandran et al. (2002) used a sample size of 2268 patients over a two-year study period.

### *Setting*

This study was conducted in the endoscopy area of the outpatient department of a 211-bed for-profit hospital (see Appendix B for letter of permission). Selvachandran et al. (2002) used a similar setting in England and had no subjects refuse or withdraw. Since the hospital's endoscopy suite performs only 1000-1500 routine colonoscopies a year (G. Easton, personal communication, April 7, 2003), this setting did not provide access to the appropriate number for this study's sample.

### *Instruments*

#### *Description of the Instrument*

The BSAQ is a questionnaire developed by Selvachandran et al. in 1999 (see Appendix C). The questionnaire was tested in a two-year study involving 2268 patients with distal colonic symptoms in England. The BSAQ consists of 33 items that are measured using a weighted numerical score. This score (the Selva score) was developed in early 1999 by S. N. Selvachandran and derived subjectively based on clinical experience. The questionnaire examines topics such as age, sex, rectal bleeding, changes in bowel habits, perianal symptoms, abdominal symptoms, weight loss, loss of appetite, fatigue, family history, and relevant medical history (Selvachandran et al., 2002). Selvachandran et al. reported high levels of reliability (specific reliability measures were not discussed) with their 1999-2001 study.

The BSAQ is written at the sixth-grade reading level. Instructions for use are clearly written at the top of the BSAQ. Scoring occurred using a software program, the Medical Adaptable Audit Base Systems (MAABS), also developed by Selvachandran. Permission to use the BSAQ was obtained via electronic mail with David Cade (see Appendix C). The level of measurement obtained from each item on the BSAQ was be nominal. The Selva score itself was be ratio level data.

#### *Administration and Scoring*

All six of the endoscopy nurses met with the researcher for about thirty minutes to discuss the research project, administration of the questionnaires, and informed consent before any data collection began. A paper and pencil questionnaire was administered to patients in the endoscopy area of the hospital. After obtaining informed consent (see Appendix D), the patient was asked to complete the questionnaire (see Appendix E). A nurse was available for assistance if the patient had questions or was functionally illiterate. Each nurse received prior training by the researcher in ways to avoid leading the patient to a certain answer. The completed BSAQs were stored in a locked filing cabinet in the endoscopy unit and given to the researcher weekly during the duration of the study. The collaborating researchers in England entered the answers from the BSAQs into the MAABS software provided. A paper copy of the data was kept as well as a computer disc back-up of all data. Results were shared with Selvachandran et al. at the completion of the study.

Burns and Grove (2001) defines measurement error as the difference in what exists in reality and what the research instrument measured. Strategies to decrease measurement error in this study included training of endoscopy nurses before data collection begins, providing a comfortable room and adequate time for participants to complete the BSAQ, using only one

researcher to enter data into the MAABS, consistently and routinely checking for errors in administration and scoring, and consulting a statistician to make suggestions before data collection begins.

#### *Data Collection Procedures*

The researcher met with staff of the endoscopy area before beginning data collection. All endoscopy nurses were trained on administering the questionnaire and storing the completed BSAQs. Endoscopy nurses approached patients in the endoscopy area, obtained consent, and administered the questionnaire to patients waiting for their colonoscopy exam. The collaborating researchers in England entered all data into the MAABS software. A flow chart of the data collection process was used (Appendix F). The data was kept in a faculty sponsor's office under a double-lock system. Only initials and medical record numbers were used to identify participants in order to maintain confidentiality.

The researcher needed and received full cooperation from Greenview Regional Hospital to meet the goals of this study. Staff, physician, and agency cooperation were essential to the success of this project. The researcher made herself available to those who were involved in this study via telephone, electronic mail, and personal visits to the endoscopy unit.

#### *Data Analysis*

Descriptive statistics and chi-square analysis was performed on data such as rectal bleeding, abdominal pain, change in bowel habit, and age using SPSS software. These calculations addressed research objective one.

Welkowitz, Ewen, and Cohen (2000) suggest using the point biserial correlation coefficient ( $r_{pb}$ ) when exploring the relationship between a continuous variable (Selva score) and a dichotomous variable (presence or absence of colorectal cancer). The point biserial correlation

coefficient tests for statistical significance in the same manner as the Pearson  $r$ . These calculations addressed the second and third research objectives.

### *Ethical Considerations*

Following approval from the thesis committee, the Western Kentucky University Human Subjects Review Board (HSRB) was asked to grant approval of this study before data collection began (see Appendix G). The endoscopy nurses asked each participant to sign an informed consent form as well as a medical record release form from the hospital to allow access to colonoscopy results of the participants.

The only risks the subjects may have endured were the inconvenience or the time involved in answering the questionnaire and possibly mild discomfort due to the sensitive nature of the questions. If a patient appeared to be extremely nervous about the colonoscopy, the endoscopy staff chose not to approach that patient. There was no criteria for anxiety level; this was according to the endoscopy nurse's instincts. This researcher did not intend to increase the subject's level of anxiety about their medical procedure.

Although there were no known direct benefits to participants, the indirect benefits were potentially notable. This research may eventually lead to earlier referral, earlier diagnosis, and earlier treatment of CRC. Individuals involved in a CRC screening program are more likely to continue with future screenings, even in average-risk populations (Burke et al., 2002). Screening has been shown to reduce CRC-related morbidity and mortality (Stoffel & Syngal, 2002). Colorectal cancer screening has also been shown to be as cost-effective as screening mammography (Winawer & Zauber, 2000).

As this non-invasive approach to CRC screening receives more attention from the media and medical community, patients and community members may begin to recognize the early

warning signs of CRC. This increased awareness and knowledge of risk factors could lead to earlier reporting of symptoms to primary care providers as well as lifestyle modifications. Nurse practitioners could also encourage other members of the medical community to follow CRC screening guidelines and to stress the importance of colorectal health to their patients.

#### *Dissemination*

A formal presentation of the results of this study was given by the researcher on April 29, 2004 for all faculty of Western Kentucky University College of Health and Human Services. Results will be presented at Annual Research Day of the Kappa Theta chapter of Sigma Theta Tau, International in Bowling Green, Kentucky in November 2004.

## CHAPTER 4

### Results

#### *Introduction*

The purpose of this correlational, replication study was to determine whether symptoms such as rectal bleeding, change in bowel habit, and abdominal pain are associated with symptomatic colorectal cancer using a sample of individuals scheduled for a routine colonoscopy. Data obtained from 47 BSAQs given to subjects undergoing routine colonoscopy at Greenview Regional Hospital in Bowling Green, Kentucky were analyzed to address the research objectives of the study. Additional findings, limitations, and implications for future research are discussed in conjunction with the results of the data analysis.

#### *Sample Demographics*

A sample of 47 patients waiting for their routine colonoscopy was obtained during the months of August, September, October, and November 2003. There were 25 males and 22 females. Ages ranged from 27 to 76, with a mean age of 56.13 and a standard deviation of 11.34.

#### *Objective One*

The first objective of this study was to identify variables associated with colorectal cancer using a questionnaire administered to patients with distal colonic symptoms. Based on an extensive literature review, variables such as rectal bleeding, change in bowel habit, and abdominal pain are all symptoms of CRC. None of the patients had CRC, but 15 had polyps. Since polyps are a precursor to CRC, variables were linked to the presence of polyps (see Tables 1, 2, and 3).

Table 1

*Change in Bowel Habit and Polyps*

	Yes Polyps	No Polyps	Total
Change in BM	4	10	14
No Change in BM	10	22	32
Total	14	32	46

Table 2

*Rectal Bleeding in Polyps*

	Yes Polyps	No Polyps	Total
Yes Bleeding	4	12	16
No Bleeding	11	20	31
Total	15	32	47

Table 3

*Abdominal Pain and Polyps*

	Yes Polyps	No Polyps	Total
Yes Pain	7	14	21
No Pain	7	17	24
Total	14	31	45

The ages of patients with polyps ranged from 42 to 72 with a mean age of 54.87; 4 of the 15 patients with polyps were under the age of 50. This is interesting since the American Cancer Society (2003) does not recommend routine screening to low-risk individuals until the age of 50. Of those four patients, two had a family history of colon cancer, but two did not.

Chi-square ( $\chi^2$ ) analysis was performed on the variables: rectal bleeding, change in bowel habit, and abdominal pain as they related to the presence or absence of polyps. Chi-square analysis was attempted on the relationship of polyps to the following variables: age, rectal bleeding, change in bowel habit, and abdominal pain. Chi-square could not be performed on bowel habit or rectal bleeding due to a cell frequency of 4 (no less than 5 is expected in a 2x2 table). Chi-square for abdominal pain and polyps was 0.09. For significance at the .05 level, this distribution was not significant.

A t-test was performed on the following means of the two groups (polyps versus no polyps): Selva score, age, rectal bleeding, change in bowel habit, and abdominal pain. T-tests of the means of the polyp group versus the no polyp group showed no difference between the population means for each of these variables.

#### *Objective Two*

The second objective of this study was to determine a patient's malignancy risk score (Selva score) using the data obtained in the questionnaire. The mean Selva score for the 32 patients without polyps was 25.44. The mean Selva score for the 15 patients with polyps was 26.13. Selva scores ranged from 4 to 60.

#### *Objective Three*

The third objective of this study was to evaluate the relationship between the Selva score and the presence or absence of colorectal cancer based on pathology results from a colonoscopy.



This was originally going to be analyzed using the point biserial correlation coefficient ( $r_{pb}$ ) by exploring the relationship between a continuous variable (Selva score) and a dichotomous variable (presence or absence of colorectal cancer). The point biserial correlation coefficient tests for statistical significance in the same manner as the Pearson  $r$ . Since there were no subjects with CRC in this study, the Selva score was related to the presence or absence of polyps.

The point biserial correlation ( $r_{pb}$ ) coefficient for Selva scores in relation to the presence or absence of polyps was +0.02. This means approximately 2% of variability in polyps is predicted by Selva score. Thus, there was no relationship between the Selva score and the presence or absence of polyps.

### *Hypotheses*

The research hypothesis for this study was that the questionnaire will show a significant level of predictiveness for symptomatic colorectal cancer (based on the results of the point biserial correlation coefficient). The null hypothesis for this study was that there will be no relationship between the Selva score generated by the BSAQ and the incidence of colorectal cancer in patients scheduled for a routine colonoscopy (also based on the results of the point biserial correlation coefficient). Since none of the patients in the study had colorectal cancer, the researcher could not evaluate either hypothesis.

### *Summary*

None of the 47 patients in this study had colorectal cancer, however nearly 1/3 of the patients had one or more polyps. According to chi-square analysis, rectal bleeding, abdominal pain, and change in bowel habit did not have a significant relationship to polyps. T-tests of the means of the polyp group versus the no polyp group showed no difference between the

population means for each of the above variables. The patients' Selva scores ranged from 4 to 60. Selva scores did not have a significant relationship to the presence of polyps.

## CHAPTER 5

### Discussion

#### *Introduction*

Notable findings and conclusions are discussed in regard to the study's research objectives. Strengths and limitations of the research are identified as well as implications for future research.

#### *Discussion of Findings*

While none of the patients had CRC, 15 of the 47 patients (32%) had polyps. Polyps are a known precursor to CRC, so relationships between polyps and CRC symptoms were examined. Selva scores were also compared to the presence or absence of polyps. The mean Selva score for the 32 patients without polyps was 25.44. The mean Selva score for the 15 patients with polyps was 26.13. While the polyp group had a slightly higher mean Selva score, there was no statistical difference between groups. Selva scores ranged from 4 to 60.

Selvachandran et al. (2002) had 95 patients with CRC out of a sample of 2268 patients. Patients with CRC had a mean Selva score of 76.5, while patients without CRC had a mean Selva score of 44.5. Selvachandran et al. noted that patients with colitis or large polyps had higher Selva scores than most patients who did not have CRC. Based on these results, Selvachandran et al. determined that a Selva score above 70 shows a cancer risk of one in five, while a Selva score under 40 has a cancer risk of one in 967. These Selva score guidelines hold true for the results in this study since no patients had a Selva score above 60 and no patients had CRC.

### *Framework*

Nola Pender's Health Promotion Model (HPM) was used as the framework for this research. Prior related behavior, personal factors, perceived benefits of action, perceived barriers to action, perceived self-efficacy, activity-related effect, interpersonal influences, and situational influences all have a direct or indirect effect on the likelihood of engaging in health-promoting behaviors such as CRC screening.

It is interesting to note the differences in Selva scores between the England study and this study in the United States. Patients in the U.S. who did not have CRC had a mean Selva score of 25.44 (without polyps) or 26.13 (with polyps), while patients in England who did not have CRC had a mean Selva score of 44.5. This could be due to the small sample size in the American study, or it may be linked to health-promotion behaviors of Americans. Perhaps Americans are being screened for CRC when they have much fewer symptoms and risk factors than English patients.

### *Strengths*

#### *Instrumentation*

Since this is a replication study, the instrument (BSAQ) has been used in previous studies. Reliability and validity for the BSAQ has been established and documented, although specific values were not discussed (Selvachandran et al., 2002). The BSAQ also allows the researcher to analyze relationships among a large number of variables in a single study.

LaMar (2002) explains one problem with the interpretation of correlational research. This problem relates to a large number of variables being measured and analyzed without justifiable rationale for their inclusion. Lamar (2002) goes on to say that preliminary research to establish that the variables in a study are relevant to its purpose may help researchers avoid this problem.

The literature review for this study supports that the variables are relevant to the purpose of the study.

Swaroop and Larson (2002) identified several risk factors for CRC. Age (above 50), family history of CRC or adenomas, adenomatous polyposis coli, personal history of adenomas or CRC, and inflammatory bowel disease are all risk factors for CRC. Selvachandran et al. (2002) found that rectal bleeding and change in bowel habits to looser, more frequent stools had the highest relative-risk ratios for CRC. Each of these variables is included in the BSAQ (Selvachandran et al ., 2002).

#### *Data Collection*

Reliable data collection methods were enhanced through intrarater reliability. Intrarater reliability, or unitizing reliability, refers to the ability of the researcher to code similar events the same way every time they are observed (Burns & Grove, 2001). Again, this was not an issue since this was not an observational study and answers from the BSAQ were simply entered into the MAABS software. Even though there were several nurses distributing the BSAQ, the patients were able to complete the form with minimal to no assistance. As previously mentioned, all six endoscopy nurses received the same verbal training on administering the BSAQ by the primary researcher.

#### *Medical Records*

One strength of this study was the completeness of the medical record. Thanks to the cooperative staff at Greenview's Medical Records Department, the researcher was able to obtain 100% of the operative and pathology reports needed for this study.

## *Limitations*

### *Sampling Method*

Correlational research runs the risk of not being able to eliminate confounding variables (University of Georgia, 2002). For example, a patient with Crohn's disease may score a high Selva score from the BSAQ but have no evidence of colorectal cancer. However, a Crohn's disease sufferer will often be scheduled for a routine colonoscopy. Such results may skew the findings of this study. There was one patient who had a diagnosis of Crohn's disease.

Another weakness revolves around purposive sampling. There is no guarantee that every individual in the population has an equal chance of being included in the sample when purposive sampling is employed (Shaughnessy & Zechmeister, 2002).

### *Sample size*

Also, another limitation of this study was the small sample size. Based on the power analysis, 392 subjects were needed for this study. Only 47 subjects were recruited during the three-month data collection period. Since the primary researcher was unable to personally collect the data, she entrusted the data collection to six registered nurses at the data collection site. Although the nurses reported to the researcher each week when completed questionnaires were picked up from the data collection site, the researcher questioned why such a small sample was obtained. The nurses reported that certain weeks were busier than others, which limited their time to obtain informed consent and allow the patients to complete the questionnaires. The nurses also reported that some patients were too anxious about the procedure to participate in the study.

### *Instrumentation*

As previously discussed in Chapter 3, the instrument (BSAQ) includes questions that are subjective in nature, which may threaten internal validity. What one individual considers to be a “small amount” of blood may be considered a “large amount” of blood by another individual. It was noted that a few BSAQs were not entirely completed. This missing data may have been due to lack of understanding of the questions or the sensitive nature of the questions. It did not appear that any of the subjects ran out of time to complete the BSAQ, because the questions left blank were not on the last page of the questionnaire.

Although Selvachandran et al. reported high levels of reliability (specific reliability measures were not discussed) with their 1999-2001 study (Selvachandran et al., 2002), this does not guarantee satisfactory reliability in samples of a different population (Burns & Grove, 2001). California State University Fullerton (2001) gives reasons why accuracy may be decreased in a predictive study. A few reasons mentioned are unreliable variables, length of time between data collection of predictor and criterion variables, and the broadness of the criterion. Unreliable demographic variables may have existed in this study such as those individuals who had no distal colonic symptoms but decided to undergo colonoscopy because their neighbor just passed away as a result of CRC.

### *Data Analysis*

Since the primary researcher was collaborating with researchers in England, the data analysis that addressed research objectives two and three involved the Selva score. This score can only be calculated through the MAABS software provided by Selvachandran et al (2002). During the data collection process, the primary researcher was informed by her partners in England that they preferred to enter the data into their software and provide Selva scores to the

researcher instead of sending the researcher the MAABS software. Once data collection was complete, the primary researcher made copies of the completed BSAQs, operative reports, and pathology reports and mailed them to England as allowed in the informed consent. This left part of the data analysis out of the researcher's control.

#### *Implications for Future Research*

This study provides several implications for future research. First, this study could be replicated and include a much larger sample size. A larger sample size would increase the likelihood of subjects having colorectal cancer, thus allowing the study's original intent to be carried out. The Selva score could then be compared with the presence or absence of CRC, instead of with the presence or absence of polyps.

Second, the BSAQ could be used in the primary care setting. If primary care providers administered the BSAQ to all patients with CRC risk factors or over the age of 50, symptoms of CRC might be recognized earlier. This might lead to earlier referral, diagnosis, and treatment.

#### *Implications for Advanced Nursing Practice*

Advanced registered nurses such as nurse practitioners and nurse educators can gain knowledge from this study. First, knowing the background and significance of CRC might encourage NPs and nurse educators to discuss CRC with their patients, students, and colleagues. Second, understanding the strengths and weaknesses of various screening options as well as the American Cancer Society screening recommendations will help them provide better patient care, patient education, and nursing education. Finally, recognizing the sometimes vague symptoms associated with CRC may lead to earlier screening, diagnosis, and treatment.

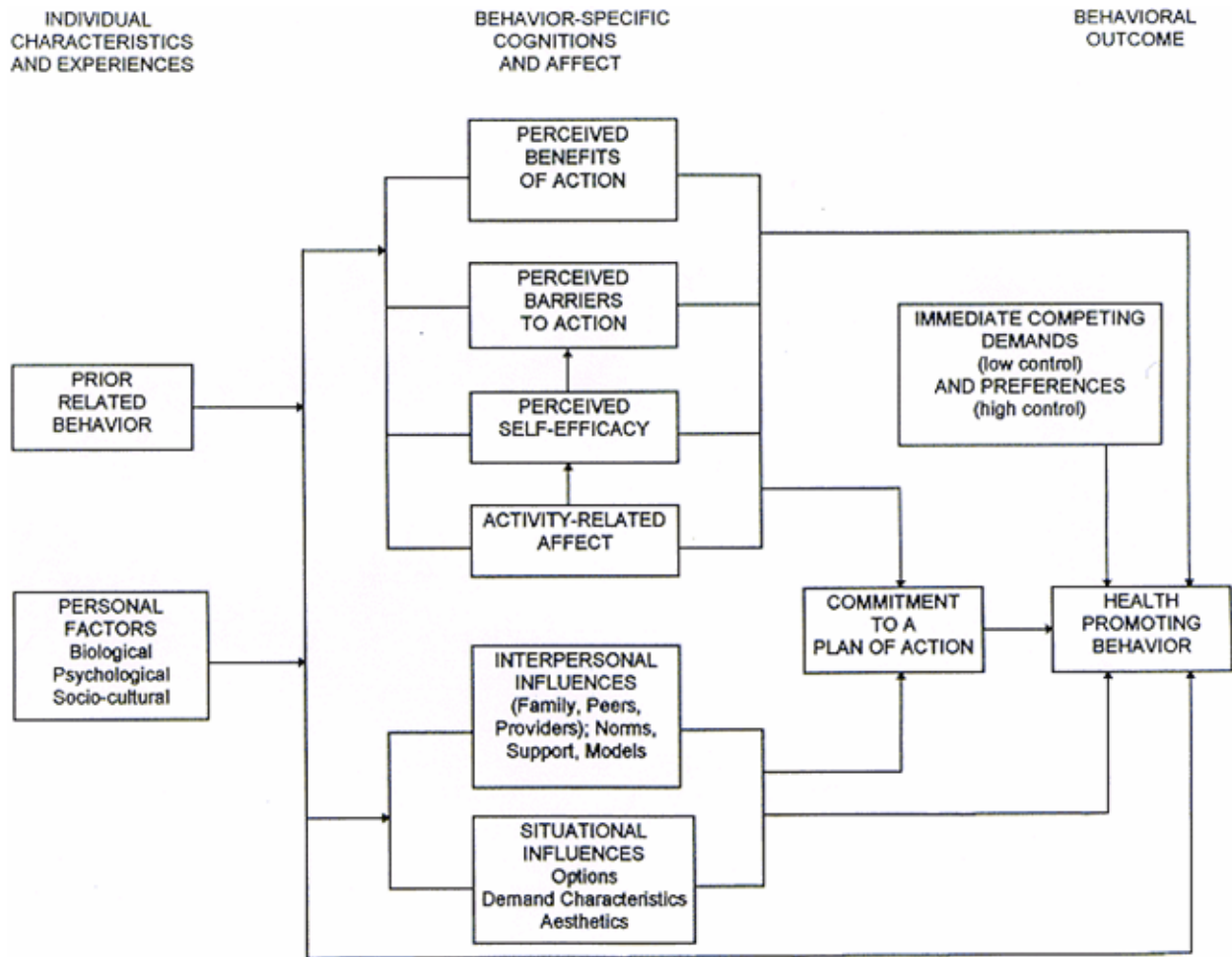


### *Conclusions*

This study explored the controversial topic of colorectal cancer screening, utilizing a non-invasive self-report screening tool. Symptoms of CRC were identified and evaluated with the BSAQ. Results of the BSAQ were then compared with results of the colonoscopy on the 47 subjects involved in this study. Although no subjects had CRC, 15 subjects had polyps. Despite a lack of significant findings, this research has implications for advanced practice nursing as well as for future research. If the nursing community can embrace and continue this research, perhaps CRC will no longer be the second leading cause of cancer deaths in the United States.

APPENDIX A

Nola Pender's Health Promotion Model



Revised Health Promotion Model

## APPENDIX B

Copy of Electronic Mail from Sharon Moore received on July 14, 2003

Dear Amy,

>

> Your request to have Greenview participate in your research study has been  
> approved. We'll send you an official letter tomorrow authorizing you to ask  
> endoscopy patients to participate in your study providing necessary medical  
> records release forms and consent forms are documented.

>

> Would you be so kind as to email me back with your correct mailing address  
> or shall we send the letter to WKU?

>

> Thank you.

> Sharon J. Moore

> Administrative Assistant

> for Sherry McDonald, RN Chief Nursing Officer

> Greenview Regional Hospital

> 270-793-5105 phone

> 270-793-5205 fax

> <http://www.GreenviewHospital.com>

## APPENDIX C

Copy of Electronic Mail from David Cade received on February 17, 2003

Dear Amy,

Thanks for your email. As yet we do not have studies ongoing in the USA. We would be very happy for you to be involved. Would the study be in Primary or Secondary care? How many clinicians are likely to be involved? You would need to send details of sites and clinicians to customise the program. We have a number of sites in the UK using the system and many more who are interested. Eventually it will need to be linked to a commercial outfit as the requests are outstripping our ability to cope, and we have many other interrelated projects on the go.

David

## APPENDIX D

Informed Consent Document (Western Kentucky University, 2002)

Project Title: Colorectal Cancer Screening: A Noninvasive Approach

Investigator: Amy Frazier, Department of Nursing, (270) 542-4409  
136 Landrum Road, Auburn, KY, 42206

You are being invited to participate in a project conducted through Western Kentucky University and Greenview Regional Hospital. The University and Greenview Regional Hospital require that you give your signed agreement to participate in this project.

A nurse will explain to you in detail the purpose of the project, the procedures to be used, and the potential benefits and possible risks of participation. You may ask him/her any questions you have to help you understand the project. A basic explanation of the project is written below. Please read this explanation and discuss with the nurse any questions you may have.

If you then decide to participate in the project, please sign on the last page of this form in the presence of the person who explained the project to you. You should be given a copy of this form to keep.

1. **Nature and Purpose of the Project:**

The purpose of this study is to determine whether a questionnaire is predictive of colorectal cancer.

2. **Explanation of Procedures:**

The research procedure involves answering questions about your symptoms. This process should only take about five minutes of your time. If you choose not to participate in the study, there will be no effect on your services here at Greenview Regional Hospital or any current or future endeavors with Western Kentucky University.

3. **Discomfort and Risks:**

There should not be any discomfort associated with this questionnaire process. The only identified risk is that it will take about five minutes of your time.

4. **Benefits:**

The benefits of this research project apply to the future of colorectal screening and prevention. Earlier referral, diagnosis, and treatment of colorectal cancer are the ultimate goals of this project. You may not have any direct benefit.

5. **Confidentiality:**

Your initials and your medical record number will be linked to these data your

colonoscopy results for identification purposes only. After they are matched, your initials and medical record number will be removed and replaced with a numerical code. The data will then be entered into a computer, identified only by the numerical code. When the data are analyzed, there will be no names on the data. This identifying data will not be used when this report is published or discussed. Only the persons involved in data collection and analysis will see these results. The data will be stored in a locked file cabinet behind a locked door after it is obtained. This data may be shared with researchers in England who created the questionnaire.

**6. Refusal/Withdrawal:**

Refusal to participate in this study will have no effect on any future services you may be entitled to from the University or Greenview Regional Hospital. Anyone who agrees to participate in this study is free to withdraw from the study at any time with no penalty.

*If you have any questions about this research study, please contact Amy Frazier, home phone (270) 542-4409, work phone (270) 796-6298. You may also contact the faculty sponsor for this research study: Donna Blackburn, Ph.D., office phone 745-3579. For further information regarding this project, please contact Dr. Phil Meyers, Human Protections Administrator at (270) 745-4652 or Ms. Steva Kaufman, Compliance Specialist at (270) 745-4652.*

*You understand also that it is not possible to identify all potential risks in an experimental procedure, and you believe that reasonable safeguards have been taken to minimize both the known and potential but unknown risks.*

\_\_\_\_\_  
Signature of Participant

\_\_\_\_\_  
Date

\_\_\_\_\_  
Witness

\_\_\_\_\_  
Date

THE DATED APPROVAL ON THIS CONSENT FORM INDICATES THAT  
THIS PROJECT HAS BEEN REVIEWED AND APPROVED BY  
THE WESTERN KENTUCKY UNIVERSITY HUMAN SUBJECTS REVIEW BOARD  
Dr. Phillip E. Myers, Human Protections Administrator  
TELEPHONE: (270) 745-4652

## APPENDIX E

Bowel Symptoms Assessment Questionnaire  
(used with permission from David Cade of Mid Cheshire Hospitals in England)

Patient's Sticker

**Please place an "x" in the most appropriate answer box.**

1. HAVE YOU HAD ANY RECTAL BLEEDING? Yes  No   
 If "YES", continue below. If "NO", go to question 2.
- A. State whether the blood is
- |  |                  |                          |
|--|------------------|--------------------------|
|  | Fresh or Bright  | <input type="checkbox"/> |
|  | Old or Dark      | <input type="checkbox"/> |
|  | Both Fresh & Old | <input type="checkbox"/> |
- B. Is the blood
- |  |                             |                          |
|--|-----------------------------|--------------------------|
|  | Seen on tissue only         | <input type="checkbox"/> |
|  | Separate from stool         | <input type="checkbox"/> |
|  | Mixed with stool            | <input type="checkbox"/> |
|  | Separate and Mixed in stool | <input type="checkbox"/> |
|  | Uncertain separate or mixed | <input type="checkbox"/> |
- C. When you see blood in stool, is it
- |  |              |                          |
|--|--------------|--------------------------|
|  | Small amount | <input type="checkbox"/> |
|  | Large amount | <input type="checkbox"/> |
- D. How often have you seen blood when having a bowel movement?
- |  |                          |                  |                          |
|--|--------------------------|------------------|--------------------------|
| Everyday   | <input type="checkbox"/> | Every few days   | <input type="checkbox"/> |
| Every week   | <input type="checkbox"/> | Every few weeks  | <input type="checkbox"/> |
| Every month  | <input type="checkbox"/> | Every few months | <input type="checkbox"/> |
| Only once or twice in the past year <input type="checkbox"/> |                          |                  |                          |
- E. How long have you been noticing blood with your bowel movements?
- |                      |                          |              |                          |
|----------------------|--------------------------|--------------|--------------------------|
| Less than four weeks | <input type="checkbox"/> | 1-3 months   | <input type="checkbox"/> |
| 4-6 months           | <input type="checkbox"/> | 6-12 months  | <input type="checkbox"/> |
| 1-2 years            | <input type="checkbox"/> | Over 2 years | <input type="checkbox"/> |
- F. Since you were referred to the hospital, has the bleeding
- |                   |                          |                    |                          |
|-------------------|--------------------------|--------------------|--------------------------|
| Gotten worse      | <input type="checkbox"/> | Improved           | <input type="checkbox"/> |
| Remained the same | <input type="checkbox"/> | Completely stopped | <input type="checkbox"/> |
2. WHAT HAS BEEN YOUR NORMAL BOWEL HABIT? (prior to any recent change)
- |  |                          |          |                          |
|--|--------------------------|----------|--------------------------|
| Normal bowel movement                          | <input type="checkbox"/> | Diarrhea | <input type="checkbox"/> |
| Constipation (less frequent and harder stools) | <input type="checkbox"/> |          |                          |
| Alternating diarrhea and constipation          | <input type="checkbox"/> |          |                          |
- How often do you normally have a bowel movement?
- |                   |                          |                  |                          |
|-------------------|--------------------------|------------------|--------------------------|
| Once a day        | <input type="checkbox"/> | Once in few days | <input type="checkbox"/> |
| 2-3 times per day | <input type="checkbox"/> | Once a week      | <input type="checkbox"/> |

Varies few times a day to every few days

3. DO YOU HAVE ANY CHANGES IN YOUR BOWEL HABIT? Yes  No

If "YES" continue below. If "NO", go to question 4.

A. If you have change in your bowel habit...

Diarrhea

Constipation (less frequent and harder stools)

Alternating diarrhea and constipation

Normal motion or stools

B. Do you have bowel movements more frequently than normal to you?

Yes  No

2-4 times more per day

5-6 times more per day

7-10 times more per day

C. Is the increase in bowel movements worse at any particular time of day?

Yes  No  Morning  Night

D. Do you have to "rush" to have a bowel movement? Yes  No

E. How long have you had these symptoms?

Less than four weeks  1-3 months

4-6 months  6-12 months

1-2 years  Over 2 years

F. Since you were referred for a colonoscopy, has the change in bowel habits

Gotten worse  Improved

Remained the same  Completely stopped

4. Do you see

Slime (jelly-like fluid) in your stools Yes  No

Slime and blood in your stools Yes  No

5. After a bowel movement, do you feel that you have NOT emptied your bowels satisfactorily? Yes  No

6. Do you have pain in your tummy (abdomen)? Yes  No

If "YES", continue below. If "NO" go to question 7.

Lower tummy pain  Spasms of tummy pain

Left sided tummy pain or discomfort  Right sided tummy pain / discomfort

Pain all over the tummy

7. Do you have symptoms around your rectum? Yes  No

If "YES" continue below. If "NO" go to question 8.

Pain during a bowel movemet  Lump or swelling at the rectum



Irritation and itching  Leakage or soiling from the rectum

8. Have you lost weight recently? Yes  No   
 Over 10 pounds in three months without trying   
 Weight loss does not concern you   
 Due to dieting

9. Have you had a decrease in appetite? Yes  No

10. Have you been excessively tired recently? Yes  No

11. Do you take regular medications? Yes  No

If "YES" continue below. If "NO" go to question 12.

Iron tablets  Steroids / Prednisone tablets   
 Medication for diabetes  Blood thinners / Coumadin   
 Any other medications (please list) \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

12. Have you had any of these illnesses in the past? Yes  No

If "YES" continue below. If "NO" go to question 13.

Bowel / Colon polyps   
 Colitis (inflammation of the bowel)   
 Cancer

If you have had cancer, in which part of the body? \_\_\_\_\_

13. Have any of your close blood relatives had cancer? Yes  No

If "YES" continue below. If "NO" go to question 14.

\*When stating grandparents, aunts, or uncles, please indicate father's or mother's side.\*

Relation *	Age when cancer was found	Part of the body

14. Please give us any other information that you think may be relevant.

\_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

Signature \_\_\_\_\_ Date \_\_\_\_\_

## APPENDIX F

## Flow Chart of Data Collection Process

Patient scheduled for routine colonoscopy enters endoscopy area of the outpatient department at Greenview Regional Hospital



Endoscopy nurse approaches patient about study, receives informed consent, and gives patient the BSAQ



Patient completes the BSAQ (with assistance of nurse if necessary) and returns BSAQ to nurse



Nurse files BSAQ into researcher's locked box through the small opening on the top of the box in the endoscopy area



Researcher retrieves completed BSAQs once a week



Researcher enters BSAQ responses into MAABS weekly



Researcher takes BSAQs to faculty sponsor's office weekly after coding them into the MAABS software

\*Colonoscopy results of participants are reviewed and recorded into researcher's computer database as available and placed in faculty sponsor's office as available \*

## APPENDIX G

## Human Subjects Review Board Letter of Approval

## WESTERN KENTUCKY UNIVERSITY

Human Subjects Review Board

Office of Sponsored Programs

104 Foundation Building

270-745-4652; Fax 270-745-4211

E-mail: [Phillip.Myers@Wku.Edu](mailto:Phillip.Myers@Wku.Edu)

In future correspondence please refer to HS04-004, July 18, 2003

Amy Frazier  
136 Landrum Road  
Auburn, KY 42206

Dear Amy:

Your research project, "Colorectal Cancer Screening: A Noninvasive Approach," was reviewed by the HSRB and it has been determined that risks to subjects are: (1) minimized and reasonable; and that (2) research procedures are consistent with a sound research design and do not expose the subjects to unnecessary risk. Reviewers determined that: (1) benefits to subjects are considered along with the importance of the topic and that outcomes are reasonable; (2) selection of subjects is equitable; and (3) the purposes of the research and the research setting is amenable to subjects' welfare and producing desired outcomes; that indications of coercion or prejudice are absent, and that participation is clearly voluntary.

1. In addition, the IRB found that: (1) **signed informed consent will be obtained from all subjects.** (2) Provision is made for collecting, using and storing data in a manner that protects the safety and privacy of the subjects and the confidentiality of the data. (3) Appropriate safeguards are included to protect the rights and welfare of the subjects.

a. Your research therefore meets the criteria of **Expedited Review** and is **Approved**.

2. Please note that the institution is not responsible for any actions regarding this protocol before approval. If you expand the project at a later date to use other instruments please re-apply. Copies of your request for human subjects review, your application, and this approval, are maintained in the Office of Sponsored Programs at the above address. Please report any changes to this approved protocol to this office. **A Continuing Review protocol will be sent to you in the future to determine the status of the project.**

Sincerely,

Phillip E. Myers, Ph.D.  
Director, OSP and  
Human Protections Administrator  
cc: Human Subjects File HS04-004  
cc: Dr. Donna Blackburn

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